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# Appendix A

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U.S. EPA. 1984. Assessment of Testing Needs: Oleylamine (9-Octadecenylamine). Support Document, Proposed Health Effects Test Rule, TSCA Section 4. U.S. EPA Document I.D. No. 40-8484001..... A-51

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Boutonnet, J.C. 1994. NORAM SH Détermination de la biodégradabilité facile, essai de dégagement de $CO_2$. Report No. 4656/92/A. ELF Atochem. ..... A-68

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van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN M2C. Report No. CRL F91068. Akzo Research Laboratories Arnhem, The Netherlands..... A-112

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Oleyldimethylamine, distilled (CAS RN 28061-69-0; Octadecen-1-amine, N,N-dimethyl).
van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN DMOD. Report No. CRL F92007. Akzo Research Laboratories Arnhem, The Netherlands. ..... A-120

Dicocomethylamine (CAS RN 61788-62-3; Amines, dicoco alkylmethyl).
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Boutonnet, M. 1991. Evaluation en milieu aqueux de la biodegradatbilite aerobie "ultime" du Noram M2SH DNS; Methode par analyse du dioxide de carbone degage.. Report No. 34028. Atochem D.R.D.I. ..... A-124

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Voelskow, H. and K. Demming. 1996. Study on the Ready Biodegradability of Genamin SH 200. Study Number 95-0060-45. Hoechst AG. ..... A-129

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Voelskow, H. 1990. Study of the Biodegradability in the Zahn-Wellens-Test. Report Number 90-0093-W-1. Hoechst Aktiengesellschaft, Frankfurt, Germany. ..... A-133

Ethomeen C/12 (CAS RN 61791-31-9; Ethanol, 2,2'-iminobis-, N-coco alkyl derivs.).
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van Ginkel, C.G. 1990. Biodegradability of ETHOMEEN T/12. Report/Study No. CRL F90192. Akzo Research Laboratories Arnhem, The Netherlands. ..... A-138

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Armeen HT (CAS RN 61788-45-2; Amines, hydrogenated tallow alkyl).
Mark, U. and I. Arends. 1991. Acute Toxicity of ARMEEN HT to *Brachydanio rerio*. Report/Study No. CRL F91082. Akzo Research Laboratories Arnhem, The Netherlands. ..... A-142

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Handley, J.W. and P.M. Wetton. 1991. The acute toxicity of Amine KK to Rainbow trout (Onchorhynchus mykiss). Project No 116/69. Berol Nobel Nacka AB, Safepharm Laboratories. ..... A-145

Genamin CC 100D (CAS RN 61788-46-3; Amines, coco alkyl).
Markert, M. and R. Jung. 1988. Genaminox CC 100 D Pruefung der akuten Toxizitaet am Fisch Zebraaerbling (Brachydanio rerio). Study No 88.0558/88.0093. Hoechst AG, Hoechst AG. ..... A-147

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Springborn Bionomics, Inc. 1986. Acute Toxicity of Adogen 170D to Bluegill (*Lepomis macrochirus*) in River Water. Toxicity test report submitted to Sherex Chemical Company, Dublin, Ohio. Bionomics Report No. BW-86-3-1955; Study No. 11,187-0585-6101-100. ..... A-149

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Mark, U.E., I.C.M. Garttener, M.G.J. Geurts, M.W.F. Nielen, C.A. Stroo and A.G.M. Kroon. 1995. Acute Toxicity of Oleylamine to *Pimephales promelas*. Report No. RGL F95031. Akzo Nobel Central Research, Arnhem, The Netherlands. ..... A-153

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Jenkins, C.A. 1996. FARMIN DM20: Acute Toxicity to Rainbow Trout. Report No. 96/KAS163/0891. Huntingdon Life Sciences Ltd. Eye, Suffolk, UK.

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FARMIN DM40 (CAS RN 112-75-4; 1-Tetradecanamine, N,N-dimethyl).
Jenkins, C.A. 1996. FARMIN DM40: Acute Toxicity to Rainbow Trout. Report No. 96/KAS177/0230. Huntingdon Life Sciences Ltd. Eye, Suffolk, UK.

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Jung, R. 1988. Short Report: Acute Fish Toxicity. Report Number 88.0057. Pharma Forschung Toxikologie, Germany. ..... A-160

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Jung, R. 1988. Short report: Acute Fish Toxicity – Zebra Fish, 96 Hours, Static. Report Number 88.0115. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany. ..... A-162

Genamin 14 R 302 D (CAS RN 112-75-4; 1-Tetradecanamine, N,N-dimethyl).
Bauer, S. and U. Noack. 1992. Acute Toxicity Test on Fish (Zebra Fish) of Genamin 14 R 302 D. Project Number 920703HK. Study no. FAZ29691. Dr. U. Noack-Laboratories for Applied Biology, Hildesheim, Germany. ..... A-164

FARMIN DM60 (CAS RN 112-69-6; 1-Hexadecanamine, N,N-dimethyl).
Jenkins, C.A. (1996) FARMIN DM60: Acute Toxicity to Rainbow Trout. Report No. 96/KAS177/0231. Huntingdon Life Sciences Ltd. Eye, Suffolk, UK.

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Jenkins, C.A. 1996. FARMIN DM80: Acute Toxicity to Rainbow Trout. Report No. 96/KAS184/0232. Huntingdon Life Sciences Ltd. Eye, Suffolk, UK.

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Genamin 18 R 302 D (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl).
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Calandra, J.C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA. ..... A-350

**5.4 REPEATED DOSE TOXICITY**

Octadecylamine (CAS RN 124-30-1).
Deichmann, W.B. 1957. The Chronic Toxicity of Octadecylamine. Department of Pharmacology, School of Medicine, University of Miami, Coral Gables, FL, USA.

Deichmann, W.B., J.L. Radomski, W.E. MacDonald, R.L. Kascht and R.L. Erdmann. 1957. The Chronic Toxicity of Octadecylamine. Arch. Ind. Health 18:483-487. ..... A-352

Octadecylamine (CAS RN 124-30-1).
W.E. MacDonald, W.B. Deichmann, J.L. Radomski and B.S. Ausin. 1962. The Chronic Toxicity of Octadecylamine in the Rat – A Supplemental Report. Toxicol Appl. Pharmacol. 4:610-612. ..... A-355

Octadecylamine (CAS RN 124-30-1).
Deichmann, W.B. 1957. The Chronic Toxicity of Octadecylamine. Department of Pharmacology, School of Medicine, University of Miami, Coral Gables, FL, USA. ..... A-357

Genamin TA 100 D (CAS RN 61790-33-8; Amines, tallow alkyl).
Oberto, G. 2000. Genamin TA100 "4-Week Toxicity Study in Rats by Oral Route". APAG, Instituto di Ricerche Biomediche "Antoine Marxer" RBM S.p.A. ..... A-360

Oleylamine (9-octadecenylamine, (Z)-; (CAS RN 112-90-3; Cis-9-Octadecenylamine).
Chem MFGS Assn. 1985. 14-Day Dermal Toxicity Range-Finding Study of Oleylamine in Rats (Final Report) with cover letter dated 041185. EPA Doc. No. 40-8584196, Microfiche No. OTS0525400..... A-365

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Amine fluorides 335/242 [Hetaflur; CAS RN 3151-59-5; and 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6].
Killeen, J.C. and W.R. Rapp. 1975. A Two Year Oral Toxicity Study of Amine Fluorides 335/242 in Rats. Project No. 72R-816. Bio/dynamics Inc. ..... A-368

Amine fluorides 335/242 [Hetaflur; CAS RN 3151-59-5; and 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6].
Killeen, J.C. and W.R. Rapp. 1975. A Chronic Oral Toxicity Study of Amine Fluorides 335/242 in Dogs. Project No. 72R-815. Bio/dynamics Inc. ..... A-372

N-methyl-N-octadecyl-1-octadecanamine (CAS RN 4088-22-6; 1-Octadecanamine, N-methyl-N-octadecyl).
Procter & Gamble Co. 1981. Initial Submission: 13 Week Oral (Dietary Administration) Toxicity Study of N-methyl-n-octadecyl-1-octadecanamine in Rats with cover letter dated 081292. EPA Doc. No. 88-9200007039, Microfiche No. OTS0537649. ..... A-375

Ethomeen T/12 (CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.).
Goater, T.O., D. Griffiths and T.F. McElligott. 1965. Ninety-Day Oral Toxicity of Ethomeen T/12 - Albino Rats. Report No. IHR/173. Industrial Hygiene Research Laboratories, Macclesfield, Cheshire..... A-379

Ethomeen T/12 (Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.; CAS RN 61791-44-4).
Goater, T.O., D. Griffiths and T.F. McElligott. 1965. Ninety-Day Oral Toxicity of Ethomeen T/12 – Beagle Dogs. Report No. IHR/175. Industrial Hygiene Research Laboratories, Macclesfield, Cheshire..... A-382

**5.5 GENETIC TOXICITY *IN VITRO***

PA-17 (CAS RN 68511-40-0; 1-Propanamine, 3-(tridecyloxy)-, branched).
San, R.H.C. and M.L. Klug. 1994. *Salmonella* Plate Incorporation Mutagenicity Assay (Ames Test). Report No. G94AV84.501. Microbiological Associates, Inc., USA. ..... A-385

Hexadecylamine (CAS RN 143-27-1).
Akzo Chemie America. 1984. Letter from Akzo Chemie America to US EPA regarding Oleylamine test results with attachment. EPA Doc. No. 40-8484007, Microfiche No. OTS0526846. ..... A-387

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Zeiger, E., B. Anderson, S. Haworth, T. Lawlor and K. Mortelmans. 1988. *Salmonella* Mutagenicity Tests: IV. Results from the Testing of 300 Chemicals. Supplement 12. Environ. Mol. Mutagen. 11:1-158. As cited in German Chemical Society. 1994. Primary Fatty Amines. GDCh-Advisory Committee on Existing Chemicals of Environmental Relevance (BUA). BUA Report 177; December. S. Hirzel, Wissenschaftliche Verlagsgesellschaft Stuttga. ..... A-389

1-Octadecyl amine (CAS RN 124-30-1).
Zeiger, E., B. Anderson, S. Haworth, T. Lawlor and K. Mortelmans. 1988. *Salmonella* Mutagenicity Tests: IV. Results from the Testing of 300 Chemicals. Supplement 12. Environ. Mol. Mutagen. 11:1-158. ..... A-391

1-Octadecyl amine (CAS RN 124-30-1).
Müller, W. 1988. Genamin 18 R 100 D, Study of the Mutagenic Potential in Strains of *Salmonella typhimurium* (Ames test) and *Escherichia coli*. Report No. 88.0407. 01, Hoechst AG, ATA, TH-TVS. ..... A-393

Octadecylamine (CAS RN 124-30-1).
Akzo Chemie America. 1984. Letter from Akzo Chemie America to US EPA Regarding Oleylamine Test Results with Attachment. EPA Doc. No. 40-8484007, Microfiche No. OTS0526846. ..... A-395

Genamin C 100 D (CAS RN 61788-46-3; Coco alkyl amine).
Müller, W. 1988. Genamin CC 100 D. Study of the Mutagenic Potential in Strains of *Salmonella typhimurium* (Ames Test) and *Escherichia coli*. Report No. 88.0193. Hoechst AG, Pharma Research Toxicology and Pathology, Frankfurt/Main, 30 S. ..... A-397

Tallow alkyl amine (CAS RN 61790-33-8).
Hoechst AG. 1988. Genamin TA 100 D, Study of the Mutagenic Potential in Strains of *Salmonella typhimurium* (Ames Test) and *Escherichia coli*. (Unveröffentlichte Untersuchung, Bericht Nr. 88.0411). Hoechst AG, Pharma Research Toxicology and Pathology, Frankfurt/Main, 30 S. ..... A-399

ODA-FG-11-27-87 (CAS RN 112-90-3; Cis-9-Octadecenylamine).
Haworth, S.R. 1985. *Salmonella*/Mammalian-Microsome Plate Incorporation Mutagenicity Assay (Ames Test.). Report No. T2693.501. Microbiological Associates, Inc., Bethesda, MD, USA. Submitted to EPA by Chem. Manuf. Assoc. as EPA Doc. No. 40-8584197. ..... A-401

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(Z)-9-Octadecenylamine (CAS RN 112-90-3).
Yang, L.L. 1985. CHO/HGPRT Mutation Assay in the Presence and Absence of Exogenous Metabolic Activation. Study No. T2693.332001. Microbiological Associates Inc., Bethesda, MD, USA. ..... A-403

Oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine).
Harbell, J.W. 1989. L5178Y TK +/- Mouse Lymphoma Mutagenesis Assay with Confirmation. Study No. T8461.701020. Microbiological Associates Inc., Bethesda, MD, USA. ..... A-406

ODA-FG-11-27-84 (CAS RN 112-90-3; Cis-9-Octadecenylamine).
Putman, D.L. 1985. Chromosome Aberration Assay in Chinese Hamster Ovary (CHO) Cells. Study No. T2693.337010. Microbiological Associates Inc., Bethesda, MD, USA..... A-409

Farmin DM 40 (CAS RN 112-75-4 1-Tetradecanamine, N,N-dimethyl).
May, K. 1996. Farmin DM40: Preliminary Toxicity Screen: Assessment of Mutagenic Potential in Histidine Auxotrophs of *Salmonella typhimurium* (the Ames test). Report No. 96/KAS182/0143. Huntingdon Life Sciences Ltd., Eye, Suffolk England..... A-412

Farmin DM 60 (CAS RN 112-69-6 1-Hexadecanamine, N,N-dimethyl).
May, K. 1996. Farmin DM60: Preliminary Toxicity Screen: Assessment of Mutagenic Potential in Histidine Auxotrophs of *Salmonella typhimurium* (the Ames test). Report No. 96/KAS182/0143. Huntingdon Life Sciences Ltd., Eye, Suffolk England..... A-414

Farmin DM 80 (CAS RN 124-28-7 1-Octadecanamine, N,N-dimethyl).
May, K. 1996. Farmin DM80: Preliminary Toxicity Screen: Assessment of Mutagenic Potential in Histidine Auxotrophs of *Salmonella typhimurium* (the Ames test). Report No. 96/KAS182/0143. Huntingdon Life Sciences Ltd., Eye, Suffolk England..... A-416

Genamin SH 301 (CAS RN 4088-22-6; 1-Octadecanamine, N-methyl-N-octadecyl).
Müller, W. 1988. Genamin SH 301 – Study of the Mutagenic Potential in Strains of *Salmonella typhimurium* (Ames Test) and *Escheria coli*. Report No. 88.0293. Pharma Research Toxicology and Pathology, Frankfurt, Germany..... A-418

DA-1618 [CAS RN 52898-18-7; 1,3-Propanediamine, N-(3-(dodecyloxy)propyl)-].
Lawlor, T.E. 1999. (Draft report) Mutagenicity Test with DA-1618 in the *Salmonella-Escherichia coli*/Mammalian/Microsome Reverse Mutation Assay with a Confirmatory Assay. Study No. 20557-Q-409OECD. Covance Laboratories Inc. ..... A-420

**5.6 GENETIC TOXICITY *IN VIVO***

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Tallow alkyl amine (CAS RN 61790-33-8).
Fassio, F. 2000. Micronucleus Test in Rat Bone Marrow Cells Treated by Oral Route. APAG, Instituto di Richerche Biomediche, "Antoine Marxer" RBM S.p.A. ..... A-422

Oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine,).
Microbiological Associates, Inc. 1989. Oleylamine: Acute *in vivo* Cytogenetics Assay in Mice (Final Report) with cover letter dated 112789. EPA Doc. No. 40-8984323, Microfiche No. OTS0525407..... A-424

Genamin LA 302 D (CAS RN 112-18-5; N,N-Dimethyl-1-dodecanamine).
Stammberger, I. 1999. Genamin LA 302 D. Mammalian Erythrocyte Micronucleus Test in Male and Female NMRI Mice. Report No. 99.0074. Hoechst Marion Roussel Deutschland GmbH, Drug Innovation & Approval, Department of Toxicology/Pathology, Frankfurt, Germany. ..... A-427

**5.8 TOXICITY TO REPRODUCTION**

Genamin TA 100 (CAS RN 61790-33-8; Amines, tallow alkyl).
Bussi, R. 2000. Genamin TA100: Reproduction/Developmental Toxicity Screening Test in Rats by Oral Route. APAG, Instituto di Ricerche Biomediche "Antoine Marxer" RBM S.p.A. ..... A-430

Amine fluorides 335/242 [Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6].
Smith, J.M. 1973. A Segment I Rat Fertility Study of Amine Fluoride 335/242. Project Number 72R-817. Bio/dynamics Inc., East Millstone, NJ, USA..... A-433

**5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY**

Oleylamine (9-Octadecenylamine, (Z)-; (CAS RN 112-90-3; Cis-9-Octadecenylamine).
Mercieca, M.D. 1989. Teratology Study in Rats with Oleylamine. Study No. 3205.9. Springborn Laboratories Inc., Spencerville, OH, USA.

Mercieca, M.D. 1989. Range-Finding Teratology Study in Rats with Oleylamine. Study No. 3205.8. Springborn Laboratories Inc., Spencerville, OH, USA. ..... A-437

Oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine).
Mercieca, M.D. 1989. Teratology Study in Rabbits with Oleylamine. Study No. 3205.11. Springborn Life Sciences, Inc., USA.

Mercieca, M.D. 1989. Range-Finding Teratology Study in Rabbits with Oleylamine. Study No. 3205.10. Springborn Life Sciences, Inc., USA. ..... A-441

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Amine fluorides 335/242 [Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6].
Smith, J.M. 1973. A Segment II Rat Teratology Study of Amine Fluoride 335/242. Project Number 72R-820. Bio/dynamics Inc., East Millstone, NJ, USA. ..... A-445

Amine fluorides 335/242 [Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6].
Smith, J.M. 1973. Segment II Rat Teratology Study of Amine Fluoride 335/242. Project Number 73R-880. Bio/dynamics Inc., East Millstone, NJ, USA. ..... A-448

Amine fluorides 335/242 [Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6].
Smith, J.M. 1973. Amine Fluoride 335/242 Segment II Rabbit Teratology Study. Project Number 72R-818. Bio/dynamics Inc., East Millstone, NJ, USA. ..... A-451

Amine fluorides 335/242 [Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6].
Smith, J.M. 1973. A Segment III Perinatal and Postnatal Study of Amine Fluoride 335/242 in Rats. Project Number 72R-819. Bio/dynamics Inc., East Millstone, NJ, USA. ..... A-454

## 2.1 MELTING POINT

**Test Substance**

| | |
|---|---|
| Identity: | 1-Dodecanamine (CAS RN 124-22-1; Dodecylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | 1996 |
| Remarks: | |

**Results**

| | |
|---|---|
| Melting Point: | 28.3° C |
| Decomposition: | Not stated |
| Sublimation: | Not stated |
| Remarks: | |

**Conclusions** Melting point was provided in a reliable reference text. The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; information provided in a reliable reference text. |

**References**

Lide, D.R. and H.P.R. Frederikse. 1996. CRC Handbook of Chemistry and Physics, 76th edition. CRC Press, Inc.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 3, 2002 |
| Order Number for Sorting: | 30 |
| Remarks: | |

## 2.1 MELTING POINT

**Test Substance**

| | |
|---|---|
| Identity: | NORAM SH (CAS RN 61788-45-2; Amines, hydrogenated tallow alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | N/A |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Melting Point: | 52.9° C |
| Decomposition: | Not stated |
| Sublimation: | Not stated |
| Remarks: | |

**Conclusions** Melting point was provided in a reliable reference text. The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; information provided in a reliable reference text. |

**References**

Weast, R.C. 1988. CRC Handbook of Chemistry and Physics, 69th edition, C-380.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 26, 2002 |
| Order Number for Sorting: | 78d |
| Remarks: | |

## 2.1 MELTING POINT

**Test Substance**

| | |
|---|---|
| Identity: | Octadecylamine (CAS RN 124-30-1) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | NA |
| Year: | 1996 |
| Remarks: | |

**Results**

| | |
|---|---|
| Melting Point: | 52.9° C |
| Decomposition: | Not stated |
| Sublimation: | Not stated |
| Remarks: | |

**Conclusions** Melting point was provided in a reliable reference text. The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; information provided in a reliable reference text. |

**References**

Lide, D.R. and H.P.R. Frederikse. 1996. CRC Handbook of Chemistry and Physics, 76th edition. CRC Press, Inc.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 3, 2002 |
| Order Number for Sorting: | 41 |
| Remarks: | |

## 2.1 MELTING POINT

**Test Substance**

| | |
|---|---|
| Identity: | Armeen® T (CAS No. 61790-33-8; Amines, tallow alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Melting Point: | 34 to 40°C |
| Decomposition: | Not stated |
| Sublimation: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was been adequately characterized in a product data bulletin from the manufacturer. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; the endpoint was provided in a product data bulletin from the manufacturer. |

**References**

Armak Industries. 1978. Physical and Chemical Characteristics of Armeen Aliphatic Amines. Product Data Bulletin 78-5. Armak Industries, Chicago, IL, USA.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 26, 2002 |
| Order Number for Sorting: | 205 |
| Remarks: | |

## 2.1 MELTING POINT

**Test Substance**

| | |
|---|---|
| Identity: | Genamin TA 100, Genamin TA 100 D Armeen T (CAS RN 61790-33-8; Amines, tallow alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | DIN/ISO 3016 |
| GLP: | NA |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Melting Point: | 25 – 30° C |
| Decomposition: | Not stated |
| Sublimation: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was from a reliable European ICCA IUCLID Data Set (2001) that cited a reliable report. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 1C |
| Remarks: | Reliable without restrictions; study according to national standards. |

**References**

Hoechst, A.G. 1996. EG-Sicherheitsdatenblatt Genamin TA 100. 02/08/1996.
As referenced in European ICCA IUCLID Data Set (2001).
Hoechst, A.G. 1997. EG-Sicherheitsdatenblatt Genamin TA 100 D. 17/01/97.
As referenced in European ICCA IUCLID Data Set (2001).

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 24, 2002 |
| Order Number for Sorting: | 201a, 201b |
| Remarks: | |

## 2.1 MELTING POINT

**Test Substance**

| | |
|---|---|
| Identity: | (Z)-9-Octadecenylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | 67% octacecenylamine, 14% octadecylamine and 3% octadecadienylamine |
| Remarks: | Purity based on commercial product Armeen O® or Armeen OD® |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | NA |
| Year: | 1983 |
| Remarks: | |

**Results**

| | |
|---|---|
| Melting Point: | Approximately 70°F (21°C) |
| Decomposition: | NA |
| Sublimation: | NA |
| Remarks: | |

**Conclusions** The endpoint has been adequately characterized by a reputable source. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; information provided by manufacturer's product information. |

**References**

CRCS, Inc. 1983. Information Review: (Z)-9-Octadecenylamine. Prepared under EPA Contract No. 68-01-6650 for TSCA Interagency Testing Committee. [*product chemistry data provided in Armak, 1982. Physical Characteristics of Armeen Aliphatic Amines. Armak Product Data Bull. 78(5)1-25*.]

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 4, 2002 |
| Order Number for Sorting: | 7 |
| Remarks: | |

## 2.1 MELTING POINT

**Test Substance**

| | |
|---|---|
| Identity: | 9-Octadecenylamine, (Z)- (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Melting Point: | 21°C |
| Decomposition: | Not stated |
| Sublimation: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was adequately characterized in a reliable review article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; the results were provided in a reliable TSCA Section 4 Test Rule summary. |

**References**

Malshet, V.G. 1991. Risk Management Document for Oleylamine (CAS RN 112-90-3). In Memorandum from E. Bisinger, Akzo Chemical Co., Chicago, IL, USA. September 12, 1991.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 4, 2002 |
| Order Number for Sorting: | 7a |
| Remarks: | |

## 2.1 MELTING POINT

**Test Substance**

| | |
|---|---|
| Identity: | Armeen® DM12D (CAS RN 112-18-5; N,N-Dimethyl-1-dodecanamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Melting Point: | -20 to -15°C |
| Decomposition: | Not stated |
| Sublimation: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was been adequately characterized in a product data bulletin from the manufacturer. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; the endpoint was provided in a product data bulletin from the manufacturer. |

**References**

Armak Industries. 1978. Physical and Chemical Characteristics of Armeen Aliphatic Amines. Product Data Bulletin 78-5. Armak Industries, Chicago, IL, USA.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 6, 2002 |
| Order Number for Sorting: | 122a |
| Remarks: | |

## 2.1 MELTING POINT

**Test Substance**

| | |
|---|---|
| Identity: | Octadecylamine, N,N-dimethyl- (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | NA |
| Year: | NA |
| Remarks: | |

**Results**

| | |
|---|---|
| Melting Point: | 22.9° |
| Decomposition: | Not stated |
| Sublimation: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was provided in a reliable reference text. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; information provided in a reliable reference text. |

**References** Merck & Co., Inc. Page 545 in: The Merck Index, 11th edition. Rahway, NJ, USA.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | May 31, 2002 |
| Order Number for Sorting: | 34 |
| Remarks: | |

## 2.1 MELTING POINT

**Test Substance**

| | |
|---|---|
| Identity: | Dimethyl stearamine (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Melting Point: | 68 - 73° F (19.6 – 22.4°C) |
| Decomposition: | Not stated |
| Sublimation: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was adequately characterized in a reliable review article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; endpoint provided in a reliable review article. |

**References** Final Report on the Safety Assessment of Dimethyl Stearamine. 14(6), December 1995. Cosmetic Ingredient Review, 1997.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 3, 2002 |
| Order Number for Sorting: | 38 |
| Remarks: | |

## 2.2 BOILING POINT

**Test Substance**

| | |
|---|---|
| Identity: | 1-Dodecanamine (CAS RN 124-22-1; Dodecylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | 1996 |
| Remarks: | |

**Results**

| | |
|---|---|
| Boiling Point: | 259° C |
| Pressure: | Not stated |
| Pressure Unit: | Not stated |
| Decomposition: | Not stated |
| Remarks: | |

**Conclusions** Boiling point was provided in a reliable reference text. The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; information provided in a reliable reference text. |

**References**

Lide, D.R. and H.P.R. Frederikse. 1996. CRC Handbook of Chemistry and Physics, 76th edition. CRC Press, Inc.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 4, 2002 |
| Order Number for Sorting: | 30 |
| Remarks: | |

## 2.2 BOILING POINT

**Test Substance**

| | |
|---|---|
| Identity: | NORAM SH (CAS No. 61788-45-2; Amines, hydrogenated tallow alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Boiling Point: | 348° C |
| Pressure: | 1013 hPa |
| Pressure Unit: | hPa |
| Decomposition: | Yes |
| Remarks: | |

**Conclusions** Boiling point was provided in a reliable text. The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; endpoint provided in a reliable review article. |

**References**

Weast, R.C. 1988. CRC Handbook of Chemistry and Physics, 69th edition, C-380.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 4, 2002 |
| Order Number for Sorting: | 78d |
| Remarks: | |

## 2.2 BOILING POINT

**Test Substance**

| | |
|---|---|
| Identity: | Octadecylamine (CAS RN 124-30-1) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | NA |
| Year: | 1996 |
| Remarks: | |

**Results**

| | |
|---|---|
| Boiling Point: | 346.8° C |
| Pressure: | Not stated |
| Pressure Unit: | Not stated |
| Decomposition: | Not stated |
| Remarks: | |

**Conclusions** Boiling point was provided in a reliable reference text. The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; information provided in a reliable reference text. |

**References**

Lide, D.R. and H.P.R. Frederikse. 1996. CRC Handbook of Chemistry and Physics, 76th edition. CRC Press, Inc.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 18, 2002 |
| Order Number for Sorting: | 41 |
| Remarks: | |

## 2.2 BOILING POINT

**Test Substance**

| | |
|---|---|
| Identity: | Stearamine (CAS RN 124-30-1; Octadecylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Boiling Point: | 348.8° C |
| Pressure: | 760 mm |
| Pressure Unit: | Not stated |
| Decomposition: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was adequately characterized in a reliable review article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; endpoint provided in a reliable review article. |

**References** Final Report on the Safety Assessment of Lauramine and Stearamine. 1997. Cosmetic Ingredient Review.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 18, 2002 |
| Order Number for Sorting: | 69 |
| Remarks: | |

## 2.2 BOILING POINT

**Test Substance**

| | |
|---|---|
| Identity: | Tallow amine (CAS No. 61790-33-8; Amines, tallow alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Boiling Point: | 200-230°C |
| Pressure: | Not stated |
| Pressure Unit: | Not stated |
| Decomposition: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was adequately characterized by a reliable reference text. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; endpoint was provided in a reliable reference textbook. |

**References**

Gerhartz, W. (ed.). 1985. Ullmann's Encyclopedia of Industrial Chemistry, 5th Edition. BCH Berlagsgesellschaft mgH, Weinheim, Germany.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 25, 2002 |
| Order Number for Sorting: | 202 |
| Remarks: | |

## 2.2 BOILING POINT

**Test Substance**

| | |
|---|---|
| Identity: | (Z)-9-Octadecenylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | 67% octacecenylamine, 14% octadecylamine and 3% octadecadienylamine |
| Remarks: | Purity based on commercial product Armeen O® or Armeen OD® |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | NA |
| Year: | 1983 |
| Remarks: | |

**Results**

| | |
|---|---|
| Boiling Point: | 275 - 344°C |
| Pressure: | Not stated |
| Pressure Unit: | NA |
| Decomposition: | NA |
| Remarks: | |

**Conclusions** The endpoint has been adequately characterized by a reputable source. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; information provided by manufacturer's product information. |

**References**

CRCS, Inc. 1983. Information Review: (Z)-9-Octadecenylamine. Prepared under EPA Contract No. 68-01-6650 for TSCA Interagency Testing Committee. [*product chemistry data provided in Armak, 1982. Physical Characteristics of Armeen Aliphatic Amines. Armak Product Data Bull. 78(5)1-25*.]

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 15, 2002 |
| Order Number for Sorting: | 7 |
| Remarks: | |

## 2.2 BOILING POINT

**Test Substance**

| | |
|---|---|
| Identity: | 9-Octadecenylamine, (Z)- (CAS No. 112-90-3; Cis-9-Octadecenylamine)) |
| Purity: | Not stated |
| Remarks: | Test substance referred to as Armeen OD and oleylamine in the article. |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Boiling Point: | 335° C |
| Pressure: | Not stated |
| Pressure Unit: | Not stated |
| Decomposition: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was adequately characterized in a reliable review article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; the results were provided in a reliable TSCA Section 4 Test Rule summary. |

**References**

Malshet, V.G. 1991. Risk Management Document for Oleylamine (CAS No. 112-90-3). In Memorandum from E. Bisinger, Akzo Chemical Co., Chicago, IL, USA. September 12, 1991.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 16, 2002 |
| Order Number for Sorting: | 7a |
| Remarks: | |

## 2.4 VAPOR PRESSURE

**Test Substance**

| | |
|---|---|
| Identity: | Amines, hydrogenated tallow alkyl (CAS No. 61788-45-2) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Vapor Pressure: | 0.000012 hPa |
| Temperature: | 20°C |
| Decomposition: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was adequately characterized in a product data article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; the endpoint was provided in a product data bulletin based on a published study. |

**References** Davis. 1942. Ind. Eng. Chem., 34, 1414 as cited in: BUA-Stoffdossier Kokosalkanamin und primaere gradzahlige Alkanamine (C8-C18) (01/18/91).

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 26, 2002 |
| Order Number for Sorting: | 78a |
| Remarks: | |

## 2.4 VAPOR PRESSURE

**Test Substance**

| | |
|---|---|
| Identity: | Octadecylamine (CAS RN 124-30-1) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Vapor Pressure: | 0.000012 hPa |
| Temperature: | 20°C |
| Decomposition: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was adequately characterized in a reliable European ICCA IUCLID Data Set (2001). (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; endpoint provided in a reliable review article. |

**References** Davis. 1942. Ind. Eng. Chem. 34:1414. Cited in European ICCA IUCLID Data Set (2001).

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 18, 2002 |
| Order Number for Sorting: | 70 |
| Remarks: | |

## 2.4 VAPOR PRESSURE

**Test Substance**

| | |
|---|---|
| Identity: | Armeen® T (CAS No. 61790-33-8; Amines, tallow alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Vapor Pressure: | less than 1 mm Hg (<1.3 hPa) |
| Temperature: | 20°C |
| Decomposition: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was adequately characterized in a product data article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; the endpoint was provided in a product data bulletin from the manufacturer. |

**References**

Armak Industries. 1978. Physical and Chemical Characteristics of Armeen Aliphatic Amines. Product Data Bulletin 78-5. Armak Industries, Chicago, IL, USA.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 6, 2002 |
| Order Number for Sorting: | 205 |
| Remarks: | |

## 2.4 VAPOR PRESSURE

**Test Substance**

| | |
|---|---|
| Identity: | (Z)-9-Octadecenylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | 67% octacecenylamine, 14% octadecylamine and 3% octadecadienylamine |
| Remarks: | Purity based on commercial product Armeen O® or Armeen OD® |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | NA |
| Year: | 1983 |
| Remarks: | |

**Results**

| | |
|---|---|
| Vapor Pressure: | Less than 1 mmHg (<1.3 hPa) |
| Temperature: | 20° C |
| Decomposition: | Not stated |
| Remarks: | |

**Conclusions** The endpoint has been adequately characterized by a reputable source. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; information provided by manufacturer's product information. |

**References**

CRCS, Inc. 1983. Information Review: (Z)-9-Octadecenylamine. Prepared under EPA Contract No. 68-01-6650 for TSCA Interagency Testing Committee. [*product chemistry data provided in Armak, 1982. Physical Characteristics of Armeen Aliphatic Amines. Armak Product Data Bull. 78(5)1-25*.]

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 15, 2002 |
| Order Number for Sorting: | 7 |
| Remarks: | |

## 2.4 VAPOR PRESSURE

**Test Substance**

| | |
|---|---|
| Identity: | 9-Octadecenylamine, (Z)- (CAS No. 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | Not stated |
| Remarks: | Test substance referred to as Armeen OD and oleylamine in the article. |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Vapor Pressure: | $1 \times 10^{-4}$ mm Hg (estimated) (0.00013 hPa) |
| Temperature: | 25° C |
| Decomposition: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was adequately characterized in a reliable review article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; the results were provided in a reliable TSCA Section 4 Test Rule summary. |

**References**

Malshet, V.G. 1991. Risk Management Document for Oleylamine (CAS No. 112-90-3). In Memorandum from E. Bisinger, Akzo Chemical Co., Chicago, IL, USA. September 12, 1991.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 16, 2002 |
| Order Number for Sorting: | 7a |
| Remarks: | |

## 2.5 PARTITION COEFFICIENT

**Test Substance**

| | |
|---|---|
| Identity: | Armeen® T (CAS No. 61790-33-8; Amines, tallow alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Log $P_{ow}$: | 7.5 |
| Temperature: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was adequately characterized in a product data article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; the endpoint was provided in a product data bulletin from the manufacturer. |

**References**

Armak Industries. 1978. Physical and Chemical Characteristics of Armeen Aliphatic Amines. Product Data Bulletin 78-5. Armak Industries, Chicago, IL, USA.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 6, 2002 |
| Order Number for Sorting: | 205 |
| Remarks: | |

## 2.5 PARTITION COEFFICIENT

**Test Substance**

| | |
|---|---|
| Identity: | Oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Methods of Leo, A., C. Hansch and D. Elkins. 1971. Partition coefficients and their uses. Chem. Rev. 71(6):525-616, and Lyman, W.J., W. F. Reehl and D. H. Rosenblatt. 1982. Handbook of Chemical Property Estimation Methods. Environmental behavior of organic compounds. Chapter 1: Octanol/water partition coefficient. New York: McGraw-Hill. |
| GLP: | NA |
| Year: | 1984 |
| Remarks: | Used two estimation methods cited in reputable sources. |

**Results**

| | |
|---|---|
| Log $P_{ow}$: | 7.5 (estimate based on methods of Leo et al.)<br>8.1 (estimate based on method of Lyman et al.) |
| Temperature: | Not stated |
| Remarks: | Values of 7.5 and 8.1 based on methods of Leo, A. et al. and Lyman, W. J. et al., respectively. |

**Conclusions** The endpoint has been adequately characterized by two independent estimation methods. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; information provided in EPA review article. |

**References**

U.S. EPA. 1984. Assessment of Testing Needs: Oleylamine (9-Octadecenylamine). Support Document, Proposed Health Effects Test Rule, TSCA Section 4. U.S. EPA Document I.D. No. 40-8484001.

## Other Available Reports

### Other

| | |
|---|---|
| Last Changed: | July 16, 2002 |
| Order Number for Sorting: | 10 |
| Remarks: | |

## 2.5 PARTITION COEFFICIENT

**Test Substance**

| | |
|---|---|
| Identity: | (Z)-9-Octadeceneylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | 67% octacecenylamine, 14% octadecylamine and 3% octadecadienylamine |
| Remarks: | Purity based on commercial product Armeen O® or Armeen OD® |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | NA |
| Year: | 1983 |
| Remarks: | |

**Results**

| | |
|---|---|
| Log $P_{ow}$: | 7.5 (estimated) |
| Temperature: | Not stated |
| Remarks: | Value estimated by the method of Leo et al. 1971. Chem. Rev. 71(6):525-615. |

**Conclusions** The endpoint has been adequately characterized by a reputable source. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; information provided by manufacturer's product information. |

**References**

CRCS, Inc. 1983. Information Review: (Z)-9-Octadecenylamine. Prepared under EPA Contract No. 68-01-6650 for TSCA Interagency Testing Committee. [*product chemistry data provided in Armak, 1982. Physical Characteristics of Armeen Aliphatic Amines. Armak Product Data Bull. 78(5)1-25*.]

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 15, 2002 |
| Order Number for Sorting: | 7 |
| Remarks: | |

## 2.5 PARTITION COEFFICIENT

**Test Substance**

| | |
|---|---|
| Identity: | Armeen OD (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | Not stated |
| Remarks: | Test substance also referred to as oleylamine in the article. |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Modified OECD protocol, but no details were provided. |
| GLP: | Not stated |
| Year: | 1984 |
| Remarks: | |

**Results**

| | |
|---|---|
| Log $P_{ow}$: | >3.11 |
| Temperature: | Not stated |
| Remarks: | The author of the article indicated that the test chemical had migrated into the octanol phase and was highly lipophilic. |

**Conclusions** The endpoint was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; the endpoint was provided in a reliable laboratory report submitted as part of a TSCA test rule. |

**References**

Akzo Chemie America. 1984. Letter of submittal to US EPA, TSCA Test Rules Development Branch (TS-778). US EPA Document Title: Physical Property Laboratory Report with Cover Letter, Document ID No. 40-8484006.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 16, 2002 |
| Order Number for Sorting: | 8 |
| Remarks: | |

## 2.6 WATER SOLUBILITY

**Test Substance**

| | |
|---|---|
| Identity: | 1-Dodecanamine (CAS RN 124-22-1; Dodecylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | 1996 |
| Remarks: | |

**Results**

| | |
|---|---|
| Value: | 2 g/l |
| Solubility: | Not stated |
| pH value and concentration: | Not stated |
| pKa value at 25°C: | Not stated |
| Remarks: | |

**Conclusions** Water solubility was provided in a reliable reference text. The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; information provided in a reliable reference text. |

**References**

Lide, D.R. and H.P.R. Frederikse. 1996. CRC Handbook of Chemistry and Physics, 76th edition. CRC Press, Inc.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 4, 2002 |
| Order Number for Sorting: | 30 |
| Remarks: | |

## 2.6 WATER SOLUBILITY

**Test Substance**

| | |
|---|---|
| Identity: | Octadecylamine (CAS RN 124-30-1) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | NA |
| Year: | 1996 |
| Remarks: | |

**Results**

| | |
|---|---|
| Value: | 1 g/l |
| Solubility: | 1 g/l |
| pH value and concentration: | Not stated |
| pKa value at 25°C: | Not stated |
| Remarks: | |

**Conclusions** Water solubility was provided in a reliable reference text. The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; information provided in a reliable reference text. |

**References**

Lide, D.R. and H.P.R. Frederikse. 1996. CRC Handbook of Chemistry and Physics, 76th edition. CRC Press, Inc.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 18, 2002 |
| Order Number for Sorting: | 41 |
| Remarks: | |

## 2.6 WATER SOLUBILITY

**Test Substance**

| | |
|---|---|
| Identity: | Octadecylamine (CAS RN 124-30-1) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Value: | qualitatively stated as “not soluble” |
| Solubility: | qualitatively stated as “not soluble” |
| pH value and concentration: | Not stated |
| pKa value at 25°C: | 10.6 |
| Remarks: | |

**Conclusions** The endpoint was adequately characterized in a reliable European ICCA IUCLID Data Set (2001). (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; endpoint provided in a reliable review article. |

**References** Davis. 1942. Ind. Eng. Chem. 34:1414. Cited in European ICCA IUCLID Data Set (2001).

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 18, 2002 |
| Order Number for Sorting: | 70 |
| Remarks: | |

## 2.6 WATER SOLUBILITY

**Test Substance**

| | |
|---|---|
| Identity: | Armeen® T (CAS No. 61790-33-8; Amines, tallow alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Value: | Qualitatively described as "insoluble in water". |
| Solubility: | Qualitatively described as "insoluble in water". |
| pH value and concentration: | Not stated |
| pKa value at 25°C: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was adequately characterized in a product data article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; the endpoint was provided in a product data bulletin from the manufacturer. |

**References**

Armak Industries. 1978. Physical and Chemical Characteristics of Armeen Aliphatic Amines. Product Data Bulletin 78-5. Armak Industries, Chicago, IL, USA.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 6, 2002 |
| Order Number for Sorting: | 205 |
| Remarks: | |

## 2.6 WATER SOLUBILITY

**Test Substance**

| | |
|---|---|
| Identity: | Oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | NA |
| Year: | 1984 |
| Remarks: | Based on estimation method using log P values. |

**Results**

| | |
|---|---|
| Value: | $0.5 \times 10^{-3}$ mg/l (estimate)<br>$0.7 \times 10^{-5}$ mg/l (estimate) |
| Solubility: | Not stated |
| pH value and concentration: | Not stated |
| pKa value at 25°C: | Not stated |
| Remarks: | Estimates of solubility made by EPA for ODA using respective log P values of 7.5 and 8.1. |

**Conclusions**

The endpoint has been adequately characterized by an estimation method. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; information provided in EPA review article. |

**References**

U.S. EPA. 1984. Assessment of Testing Needs: Oleylamine (9-Octadecenylamine). Support Document, Proposed Health Effects Test Rule, TSCA Section 4. U.S. EPA Document I.D. No. 40-8484001. *[product chemistry data provided in: Armak company. 1978. Industrial Chemicals Division. Product data bulletin: Physical and chemical characteristics of ARMEEN® aliphatic amines. Bulletin 78-5. Box 1805, Chicago, IL, USA.]*

## Other Available Reports

### Other

| | |
|---|---|
| Last Changed: | July 16, 2002 |
| Order Number for Sorting: | 10 |
| Remarks: | |

## 2.6 WATER SOLUBILITY

**Test Substance**

| | |
|---|---|
| Identity: | (Z)-9-Octadecenylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | 67% octacecenylamine, 14% octadecylamine and 3% octadecadienylamine |
| Remarks: | Purity based on commercial product Armeen O® or Armeen OD® |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | NA |
| Year: | 1983 |
| Remarks: | |

**Results**

| | |
|---|---|
| Value: | Not stated |
| Solubility: | Insoluble |
| pH value and concentration: | Not stated |
| pKa value at 25°C: | Not stated |
| Remarks: | |

**Conclusions** The endpoint has been adequately characterized by a reputable source. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; information provided by manufacturer's product information. |

**References**

CRCS, Inc. 1983. Information Review: (Z)-9-Octadecenylamine. Prepared under EPA Contract No. 68-01-6650 for TSCA Interagency Testing Committee. [*product chemistry data provided in Armak, 1982. Physical Characteristics of Armeen Aliphatic Amines. Armak Product Data Bull. 78(5)1-25*.]

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 15, 2002 |
| Order Number for Sorting: | 7 |
| Remarks: | |

## 2.6 WATER SOLUBILITY

**Test Substance**

| | |
|---|---|
| Identity: | 9-Octadecenylamine, (Z)- (CAS No. 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | Not stated |
| Remarks: | Test substance referred to as Armeen OD and oleylamine in the article. |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Value: | Not stated |
| Solubility: | Very insoluble |
| pH value and concentration: | Not stated |
| pKa value at 25°C: | Not stated |
| Remarks: | Solubility was qualitatively characterized as very insoluble, but since it has hydrophilic and hydrophobic groups, it could readily form a stable dispersion in water. |

**Conclusions** The endpoint was adequately characterized in a reliable review article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; the results were provided in a reliable TSCA Section 4 Test Rule summary. |

**References**

Malshet, V.G. 1991. Risk Management Document for Oleylamine (CAS No. 112-90-3). In Memorandum from E. Bisinger, Akzo Chemical Co., Chicago, IL, USA. September 12, 1991.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 16, 2002 |
| Order Number for Sorting: | 7a |
| Remarks: | |

2.6 WATER SOLUBILITY

**Test Substance**

| | |
|---|---|
| Identity: | Dimethyl stearamine (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| GLP: | Not stated |
| Year: | Not stated |
| Remarks: | |

**Results**

| | |
|---|---|
| Value: | qualitatively stated as "not soluble in water" |
| Solubility: | qualitatively stated as "not soluble in water" |
| pH value and concentration: | Not stated |
| pKa value at 25°C: | Not stated |
| Remarks: | |

**Conclusions** The endpoint was adequately characterized in a reliable review article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; endpoint provided in a reliable review article. |

**References** Final Report on the Safety Assessment of Dimethyl Stearamine. 14(6), December 1995. Cosmetic Ingredient Review, 1997. [Physical chemical properties obtained from: National Technical Information Service. 1978. Physical and Chemical Characteristics of Armeen Aliphatic Amines. Product Data Bulletin No. 78-5, 1978. Report No. OTS0526854.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 18, 2002 |
| Order Number for Sorting: | 38 |
| Remarks: | |

## 3.5 BIODEGRADATION

**Test Substance**

Identity: Genamin 12R 100D (CAS RN 124-22-1; Dodecylamine)
Purity: >99.9%
Remarks:

**Method**

Method/Guideline followed: Essentially OECD Guideline 301D, Ready Biodegradability: Closed Bottle Test
Test Type: Aerobic biodegradation
GLP: Not stated
Year: 1988
Contact Time: 28 Days
Inoculum: Activated sludge, domestic, non-adapted, 1 drop/l test mixture
Remarks: Test mixtures were incubated in completely filled closed bottles at 20 ± 1°C for 28 days. The test was conducted in triplicate using the test substance (1.672 to 5.772 mg/l; ThOD[$NO_3$]), a mineral medium (as prescribed by OECD 301) and activated sludge. The following controls were included: a control without the test substance but with the inoculum (the inoculum blank) and the positive control (sodium benzoate 5.19 mg/L ThOD) with inoculum. BOD/ThOD was determined electrometrically on day 0, 7, 14, 21 and 28. No abiotic control was included and no mention of experiment being performed in the dark so photodegradation cannot be ruled out.

**Results**

Degradation: 55% at 28 days
Results: The guideline criteria for the test were met. Test substance is readily biodegradable.
Kinetic:

| Time (Days) | Test Substance (% BOD/ThOD) | Sodium Benzoate (% BOD/ThOD) |
|---|---|---|
| 0 | 0 | 0 |
| 7 | 63 | 75 |
| 14 | 57 | 70 |
| 21 | 59 | 72 |
| 28 | 55 | 61 |

Breakdown Products: None stated
Remarks: No abiotic control was included. Since in the report it

is not explicitly mentioned that the test was performed in the dark, photodegradation cannot be excluded. After degradation was >60% on day 7, it dropped again to slightly <60% from day 14 onwards. This may be explained by the fact that in the solution containing TS degradation stopped after day 7 whereas the inoculum blank still consumed some oxygen. However, as the criterion of >60% degradation within 28 days was met, TS can be considered readily biodegradable. Later measurements can be disregarded.

**Conclusions**

The test substance was readily biodegradable based on > 60% degradation within 28 days. The endpoint was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 2D

Remarks: Reliable with restrictions; limited data available and photodegradation cannot be ruled out.

**References**

Dr. Voelskow. 1994. Pruefung der leichten biologischen Abbaubarkeit von Genamin 12R 100D. [Ready Biodegradability Study with Genamin 12R 100D] Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other**

Last Changed: September 13, 2002

Order Number for Sorting: 30e

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Armeen HTD (CAS RN 61788-45-2; Amines, hydrogenated tallow alkyl) |
| Purity: | 99.2% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 301D: Ready Biodegradability, Closed Bottle Test, and EEC, Official Journal of the European Communities, L251, Method C.6. Degradation-biotic degradation: Closed Bottle Test. |
| Test Type: | Aerobic ready biodegradability |
| GLP: | Yes |
| Year: | 1992 |
| Contact Time: | 28 days |
| Inoculum: | Secondary activated sludge from the RWZI Nieuwgraaf in Duiven. |
| Remarks: | Secondary activated sludge was collected and preconditioned in the laboratory by aerating the material for a period of one week. Sludge was diluted to a concentration of 2 mg dry weight/l. Treatment groups included: 1) mineral solution without test material and without inoculum, 2) mineral nutrient solution without test material but with inoculum, 3) mineral nutrient solution with test material (2.0 mg/l) and with inoculum, and 4) mineral nutrient solution with sodium acetate (reference substance at 6.7 mg/l) and with inoculum. The test was carried out in 280-ml BOD bottles with two replicate bottles per experimental group. On days 0, 5, 15 and 28, dissolved oxygen concentrations were measured in each bottle. Biodegradation was calculated as the ratio of the BOD to the theoretical BOD (ThOD) based on the formula of the chemical. The ThOD of the test substance was 3.2 g $O_2$/g test substance. |

**Results**

| | |
|---|---|
| Degradation: | 75% at Day 28 in the Closed Bottle Test. |
| Results: | Based on the percent degradation, the test substance was classified readily biodegradable. |

Kinetic:

| Time (Days) | Armeen HTD (% BOD/ThOD) | Sodium Acetate (% BOD/ThOD) |
|---|---|---|
| 5 | 34 | 73 |
| 15 | 58 | 87 |
| 28 | 75 | 92 |

Breakdown Products: Not stated

Remarks: The validity of the test was demonstrated by complete mineralization of sodium acetate and an endogenous respiration of 0.6 mg/l. The pH of the medium at Day 28 was 6.9.

**Conclusions**

The biodegradability of Armeen HTD was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN HTD. Report/Project No. CRL F91050. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 23, 2002

Order Number for Sorting: 78

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | NORAM SH (CAS RN 61788-45-2; Amines, hydrogenated tallow alkyl) |
| Purity: | 97% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | ISO DIS 9439 which is in agreement with OECD Guideline No. 301B: Ready Biodegradability |
| Test Type: | Aerobic ready biodegradability |
| GLP: | Yes |
| Year: | 1992 |
| Contact Time: | 48 days |
| Inoculum: | Domestic sewage |
| Remarks: | Duplicate test mixtures (in 3 liter flasks) were incubated at constant temperature (20 – 25 °C ± 1 °C) for 48 days with continuous stirring. Test mixture contained: test substance (50 mg/l, ~40 mg $ThCO_2$/l); volatile solvent (1,1-dichloro-1-fluoroethane); emulsifying agent (Symperonic P103, 25 mg/L); mineral medium (as prescribed in OECD 301); inoculum from domestic wastewater treatment plant (1 x $10^6$ bacteria/l). Flasks were aerated before the test with $CO_2$-free air. Three barium hydroxide (0.0125 M) traps were connected to collect $CO_2$. The following controls were included: inoculum blank, positive control [sodium benzoate (10.4 g/l) with inoculum], emulsifier control (emulsifying agent with inoculum), and toxicity control (test substance and sodium benzoate with inoculum). The three traps were replaced and analyzed for $CO_2$ on day 0, 1, 4, 6, 8, 11, 15, 19,22, 25, 28, 33, 40, 47 and 48. Corrections were made for $CO_2$ in emulsifier control. Only results up to day 28 are provided in this summary.<br>No abiotic control was included. |

**Results**

| | |
|---|---|
| Degradation: | 64% at Day 28 |
| Results: | Based on the percent degradation, the test substance was classified biodegradable but not readily biodegradable because the criterion of degradation >60% within 10 day window after start of biodegradation phase (10%) was not met. |

Kinetic:

| Time (Days) | NORAM SH (% degradation) | Sodium Benzoate (% degradation) |
|---|---|---|
| 0 | 0 | 0 |
| 4 | 11 | 52 |
| 15 | 50 | 66 |
| 22 | 60 | 67 |
| 28 | 64 | 66 |

Breakdown Products: Not stated

Remarks: The emulsifying agent was not biodegraded and was not inhibited. Report did not state that test was performed in the dark, but since an adaptation phase is observed during which no degradation yielding $CO_2$ occurs, photodegradation is not expected to have occurred. In the method description, carbon content of sodium benzoate is said to be 58.3%, whereas in the table and further calculations it is said to be 57.7%. A reviewer calculated the correct value to be 58.3%; however, criterion of >60% within 28 days of ThOD is still met when the correct value is used.

**Conclusions**

The biodegradability of NORAM SH was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Boutonnet, J.C. 1994. NORAM SH Détermination de la biodégradabilité facile, essai de dégagement de $CO_2$. [Determination of the ready biodegradability, $CO_2$ evolution assay] Report No. 4656/92/A. ELF Atochem.

**Other Available Reports**

**Other**

Last Changed: August 13, 2002

Order Number for Sorting: 78e

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

Identity: Octadecylamine (CAS RN 124-30-1)
Purity: Not stated
Remarks:

**Method**

Method/Guideline followed: Biodegradation measured as a function of oxygen consumption (BOD) in a respirometer, similar to that described in OECD Guideline 302C, Modified MITI Test.
Test Type: Aerobic biodegradation
GLP: No
Year: 1980
Contact Time: 12 days
Inoculum: Activated sludge from municipal sewage plant in Tokyo
Remarks: To 3 liters of basal nutrient medium, 30 ppm of activated sludge was added along with test substance at 100 ppm. Biodegradation experiments were carried out with an oxygen consumption measuring apparatus at 25°C. Biodegradation was assessed as the ratio of the BOD measured to the theoretical BOD based upon the chemical structure of the test substance.

**Results**

Degradation: > 60% degradation by day 12
Results: Based on the percent biodegradation, the test substance was considered to be Readily Biodegradable.
Kinetic:

| Time (Days) | Test Substance (% BOD/ThOD) |
|---|---|
| 5 | ~30 |
| 10 | >50 |
| 12 | >60 |

Breakdown Products: Not stated
Remarks:

**Conclusions** The biodegradability of Octadecylamine was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2B |
| Remarks: | Reliable with restrictions; basic data given, comparable to guideline standards. |

**References**

Yoshimura, K., S. Machida and F. Masuda. Biodegradation of Long Chain Alkylamines. J. Am. Oil Chem. Soc. 57:238-241.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 17, 2002 |
| Order Number for Sorting: | 51 |
| Remarks: | |

## 3.5 BIODEGRADATION

**Test Substance**

Identity: Genamin 18R 100D (CAS RN 124-30-1; Octadecylamine)
Purity: >99% primary amines (of which >90% C18)
Remarks:

**Method**

Method/Guideline followed: Essentially OECD Guideline 301F
Test Type: Aerobic biodegradation
GLP: No
Year: 1992
Contact Time: 28 Days
Inoculum: Activated sludge, domestic, non-adapted, 30 mg/l dry matter
Remarks: The determination of the ultimate aerobic biodegradability of the test substance was tested by measuring the BOD. The test was conducted in duplicate using the test substance (126.5 –127.1 mg/l; 437 - 438 mg/l ThOD[$NO_3$]), a mineral medium (as prescribed by OECD 301) and activated sludge. A control without the test substance but with the inoculum (the inoculum blank, 3 flasks) and the positive control of sodium benzoate (292 mg/L ThOD) and inoculum were included. Test mixtures were incubated at 20 ± 1°C for 28 days. BOD/ThOD was determined manometrically on day 7, 14, 21 and 28. No abiotic control was included and no mention of the experiment being performed in the dark so photodegradation cannot be ruled out. This review is based on abstract only so OECD guidelines cannot be verified.

**Results**

Degradation: 70% after 28 days
Results: The guideline criteria for the test were met. Test substance is considered readily biodegradable.
Kinetic:

| Time (Days) | % Degradation (% ThOD($NO_3$) | |
|---|---|---|
| | Test Substance | Sodium Benzoate |
| 7 | 26 (28)* | 83 |
| 14 | 50 (53) | 89 |
| 21 | 65 (70) | 87 |
| 28 | 70 (76) | 86 |

* Value in () = %ThOD($NH_3$)

| | |
|---|---|
| Breakdown Products: | None stated |
| Remarks: | It could not be verified whether the criterion of >60% degradation within 10 days of start of degradation (10% degradation) was met because too few data points were available. |

**Conclusions**

The test substance was readily biodegradable based on > 60% degradation within 28 days. The endpoint was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 2D<br>Reliable with restrictions; report based on abstract only minimal data available; photodegradation cannot be ruled out. |
| Remarks: | |

**References**

Dr. Voelskow. 1994. Pruefung der leichten biologischen Abbaubarkeit von Genamin 18R 100D. [Ready Biodegradability Study with Genamin 18R 100D] Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other**

| | |
|---|---|
| Last Changed: | June 24, 2002 |
| Order Number for Sorting: | 51a |
| Remarks: | |

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Armeen CD (CAS RN 61788-46-3; Amines, coco alkyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Test methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 301D: Ready Biodegradability, Closed Bottle Test, and EEC, Official Journal of the European Communities, L251, Method C.6. Degradation-biotic degradation: Closed Bottle Test. |
| Test Type: | Aerobic ready biodegradability |
| GLP: | Yes |
| Year: | 1992 |
| Contact Time: | 42 days |
| Inoculum: | Secondary activated sludge from the RWZI Nieuwgraaf in Duiven |
| Remarks: | Secondary activated sludge was collected and preconditioned in the laboratory by aerating the material for a period of one week. Sludge was diluted to a concentration of 2 mg dry weight/l. Treatment groups included: 1) mineral solution without test material and without inoculum, 2) mineral nutrient solution without test material but with inoculum, 3) mineral nutrient solution with test material (2.0 mg/l) and with inoculum, and 4) mineral nutrient solution with sodium acetate (reference substance at 6.7 mg/l) and with inoculum. The test was carried out in 280-ml BOD bottles with two replicate bottles per experimental group. On days 0, 5, 15, 28, and 42 dissolved oxygen concentrations were measured in each bottle. Biodegradation was calculated as the ratio of the BOD to the theoretical BOD (ThOD) based on the formula of the chemical. The ThOD of the test substance was 3.1 g $O_2$/g test substance. |

**Results**

| | |
|---|---|
| Degradation: | The test substance was degraded 56% at day 28 and 74% at day 42. |
| Results: | Based on the percent degradation,, close to 60%, the test substance was classified readily biodegradable. (Author of report) |

Kinetic:

| Time (Days) | Armeen CD (%BOD/ThOD) | Sodium Acetate (%BOD/ThOD) |
|---|---|---|
| 5 | 42 | 69 |
| 15 | 42 | 75 |
| 28 | 56 | 90 |
| 42 | 74 | -- |

Breakdown Products:
Remarks: The validity of the test was demonstrated by 90% degradation of sodium acetate by day 28 and an endogenous respiration of 0.3 mg/l. The pH of the medium at day 28 was 6.8.

**Conclusions** The biodegradability of Amines, coco alkyl was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**
Reliability: 1A
Remarks: Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN CD. Report/Project No. CRL F91125. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**
Last Changed: July 24, 2002
Order Number for Sorting: 88
Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Genamin CC 100 D (CAS RN 61788-46-3; Amines, coco alkyl) |
| Purity: | ≥96% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | OECD Guideline No. 301B: Ready Biodegradability, Modified Sturm Test ($CO_2$ Evolution) |
| Test Type: | Aerobic ready biodegradability |
| GLP: | Yes |
| Year: | 1992 |
| Contact Time: | 29 days |
| Inoculum: | Activated sludge, domestic, non-adapted |
| Remarks: | Duplicate test mixtures were incubated in 5 L brown glass bottles at 22 ± 2 °C for 29 days. Test mixtures were 3 L and contained test substance (13 mg/l; ~ 10.1 mg C/l), filtrate of pre-conditioned activated sludge, and mineral medium as prescribed by Guideline. Before the test, mixtures were aerated with $CO_2$-free air for 24 hours and aeration continued throughout test. Controls included: 1) inoculum blank; 2) positive control (sodium acetate (35 mg/l; ~10.2 mg C/l) with inoculum); and 3) toxicity control (test substance (13 mg/l), reference substance (35 mg/l) and inoculum). Released $CO_2$ was quantified by backtitration of residual $Ba(OH)_2$ with 0.05 N HCl on days 1, 3, 6, 8, 10, 13, 16, 20, 23 and 28. |

**Results**

| | |
|---|---|
| Degradation: | The test substance was degraded 58% at day 28. |
| Results: | Based on the percent degradation, the test substance was classified as biodegradable, but not readily biodegradable as the criterion of >60% degradation within the 10 day window after start of degradation (10%) was not met. |

Kinetic:

| Time (Days) | Genamin CC 100 D (%$ThCO_2$)* | Genamin CC 100 D + Sodium Acetate (%$ThCO_2$) | Sodium Acetate (%$ThCO_2$) |
|---|---|---|---|
| 1 | 0 | 0 | 0 |
| 3 | 3 | 14 | 22 |
| 6 | 18 | 33 | 51 |
| 10 | 35 | 52 | 69 |
| 20 | 47 | 64 | 77 |
| 28 | 58 | 75 | 82 |
| 29** | 61 | 80 | 85 |

* Mean of two replicates calculated by reviewer.
** After acidification with HCl.

Breakdown Products: Not stated

Remarks: The applied cell density was 18 x $10^5$ CFU/l, which is below the advised density in the guideline 1 x $10^7$ to 1 x $10^8$ cells/l; however, the results for the positive control indicate that the applied density provided a good test system.

**Conclusions**

The biodegradability of test substance was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

1996. Genamin CC 100 D Ready Biodegradability, Modified Sturm Test. Hoechst, AG, Dr. U. Noack-Laborratorium.

**Other Available Reports**

**Other**

Last Changed: August 14, 2002

Order Number for Sorting: 88b

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Genamin TA 100 D (CAS RN 61790-33-8; Amines, tallow alkyl) |
| Purity: | 99% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | OECD Guideline 301B, Ready Biodegradability: Modified Sturm Test ($CO_2$ Evolution) |
| Test Type: | Aerobic biodegradation |
| GLP: | Yes |
| Year: | 1992 |
| Contact Time: | 28 Days |
| Inoculum: | Activated sludge, domestic, from a municipal wastewater treatment plant, non-adapted, 1800 CFU/ml |
| Remarks: | The determination of the ultimate aerobic biodegradability of the test substance was tested by measuring the $CO_2$ evolution. The test was conducted in duplicate in brown glass bottles using the test substance (13 mg/l), a mineral medium (as described in guidelines) and activated sludge. The test temperatures were 22 ± 2°C. The following controls were also included: 1) a control without the test substance but with the inoculum (the inoculum blank, 3 flasks); 2) the positive control, sodium acetate (35 mg/l), and inoculum; and 3) a toxicity control. Released $CO_2$ was quantified by back-titration of residual $Ba(OH)_2$ with 0.05N HCl. On day 28, HCl was added to release all formed $CO_2$. Test mixtures were aerated with $CO_2$-free air for 24-hours prior to test and for the duration if the test. |

**Results**

| | |
|---|---|
| Degradation: | 56% after 28 days |
| Results: | The guideline criteria for the test were met. Test substance is biodegradable, but not readily biodegradable. |

Kinetic:

| Time (Days | Degradation (% $ThCO_2$) | | |
|---|---|---|---|
| | Test Substance | Sodium Acetate | Test Substance + Sodium Acetate |
| 1 | 0 | 0 | 0 |
| 8 | 27 | 63 | 44 |
| 16 | 50 | 74 | 54 |
| 23 | 55 | 81 | 60 |
| 28 | 56 | 82 | 61 |
| 28* | 61 | 85 | 65 |

* After acidification with HCl.

Breakdown Products: None stated
Remarks:

**Conclusions** The endpoint was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**
Reliability: 1A
Reliable without restriction, guideline study.
Remarks:

**References**

Noack, M. 1996. Genamin TA 100 D Ready Biodegradability, Modified Sturm Test. Hoechst AG, Dr. U. Noack-Laboratorium

**Other**
Last Changed: August 9, 2002
Order Number for Sorting: 211a
Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Armeen TD (CAS RN 61790-33-8; Amines, tallow alkyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | OECD Guideline 301D, Ready Biodegradability: Closed Bottle Test |
| Test Type: | Aerobic biodegradation |
| GLP: | Yes |
| Year: | 1992 |
| Contact Time: | 42 Days |
| Inoculum: | Activated sludge, domestic, 2 mg/l dry matter |
| Remarks: | The determination of the ultimate aerobic biodegradability of the test substance was tested by measuring the BOD in 280 ml bottles. The test was conducted in duplicate in 280 ml BPD bottles using the test substance (2 mg/l), a mineral medium (probably as prescribed by guidelines though without ammonium chloride) and activated sludge. The following controls were included: 1) a control without the test substance but with the inoculum (the inoculum blank); 2) the positive control, sodium acetate (6.7 mg/l), and inoculum; and 3) a blank without test substance or inoculum. $O_2$ consumed was measured electrochemically. The sludge was aerated for one week prior to the test. The pH on day 28 was 6.9. |

**Results**

| | |
|---|---|
| Degradation: | >51% after 28 days |
| Results: | The guideline criteria for the test were met. The test material is biodegradable, but not readily biodegradable. |

Kinetic:

| Time (Days | Degradation (% BOD/ThOD($NH_3$)) | |
|---|---|---|
| | Test Substance | Sodium Acetate |
| 5 | 47 (44)* | 69 |
| 15 | 41 (38) | 75 |
| 28 | 55 (51) | 90 |
| 42 | 72 (67) | Not reported |

* Value in () = %BOD/ThOD($NO_3$), calculated by reviewer

Breakdown Products: None stated

Remarks: Based on the information provided in the article, could not check if OECD guidelines were followed, although stated that they were followed. The test temperatures were not mentioned. Not stated whether an abiotic control was included. Not stated whether test was performed in the dark so photodegradation cannot be ruled out.

**Conclusions**

The endpoint was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 2D
Reliable with restrictions; photodegradation cannot be ruled out..

Remarks:

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of Armeen TD. Akzo Chemicals Internationals BV, Akzo Research Laboratories Arnhem.

**Other**

Last Changed: August 9, 2002

Order Number for Sorting: 211b

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

Identity: Tallow alkyl amine (CAS RN 61790-33-8)
Purity: 99 - 100%
Remarks:

**Method**

Method/Guideline followed: OECD Guideline 301F
OECD Guideline 302B
Test Type: Aerobic biodegradation
GLP: No
Year: 1981
Contact Time: 42 Days
Inoculum: Activated sludge, industrial waste water treatment plant, non-adapted, 470 mg/l dry matter
Remarks: The determination of the ultimate aerobic biodegradability of the test substance was tested by measuring the BOD. The test was conducted in duplicate using the test substance [226 mg/l (~774 mg/l ThOD($NO_3$)) and 177 mg/l (~606 mg/l ThOD($NO_3$))], a mineral medium (probably as described in guideline) and activated sludge. The following controls were included: 1) a control without the test substance but with the inoculum (the inoculum blank); 2) the positive control, diethylene glycol (ThOD 288 mg/l) and inoculum were included. $O_2$ consumed was measured manometrically. Temperature during the 28 day test was 20 ± 1°C.

**Results**

Degradation: 73% after 28 days
Results: The guideline criteria for the test were met. Test substance is inherently biodegradable.

Kinetic:

| Time (Days | Degradation (% BOD/ThOD($NO_3$)) | |
|---|---|---|
| | Test Substance | Sodium Acetate |
| 1 | 6 (6)* | 28 |
| 5 | 38 (41) | 36 |
| 10 | 57 (61) | 82 |
| 15 | 71 (77) | 101 |
| 20 | 66 (71) | 98 |
| 28 | 73 (79) | 101 |

* Value in () = % ThOD($NH_3$).

Breakdown Products: None stated
Remarks:

**Conclusions** The endpoint was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**
Reliability: 2D
Remarks: Reliable with restrictions; photodegradation cannot be ruled out..
Limited report based on archived data (1988). Cannot check if OECD guidelines were followed. Not stated whether test was performed in the dark so photodegradation cannot be ruled out. No abiotic control was included. Performance of the test is in compliance with OECD 301F, except for the inoculum, which comes from an industrial wastewater plant and is applied in the test at a concentration prescribed in the Zahn-Wellens test for inherent biodegradability (OECD 302B). The test has therefore been considered as a test on inherent biodegradability. Since the first measurement was not taken until day 1, adsorption could not be evaluated; however, adsorption could not have been substantial as the % elimination on day 1 was 6%. The test substance was tested in duplicate showing a large difference of extreme (38%) for the duplicates on day 28. According to OECD 301F, the test would therefore be invalid; however, it is acceptable for a test on inherent biodegradability.

**References**
Voelskow. 1994. Pruefung der biologischen Abbaubarkeit von Genamin TA 100 D. [Ready Biodegradability Study with Genamin TA 100 D] Hoechst AG.

**Other**
Last Changed: August 9, 2002
Order Number for Sorting: 211c
Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

Identity: Octadecenylamine, (Z)- (CAS No. 112-90-3; Cis-9-Octadecenylamine)
Purity: Not stated
Remarks:

**Method**

Method/Guideline followed: Biodegradation measured as a function of oxygen consumption (BOD) in a respirometer, similar to that described in OECD Guideline 302C, Modified MITI Test.
Test Type: Aerobic biodegradation
GLP: No
Year: 1980
Contact Time: 12 days
Inoculum: Activated sludge from municipal sewage plant in Tokyo
Remarks: To 3 liters of basal nutrient medium, 30 ppm of activated sludge was added along with test substance at 100 ppm. Biodegradation experiments were carried out with an oxygen consumption measuring apparatus at 25°C. Biodegradation was assessed as the ratio of the BOD measured to the theoretical BOD based upon the chemical structure of the test substance.

**Results**

Degradation: > 60% degradation by day 12
Results: Based on the percent biodegradation, the test substance was considered to be Readily Biodegradable.
Kinetic:

| Day | Test Substance (% BOD/ThOD) |
|---|---|
| 5 | ~50 |
| 10 | ~60 |
| 12 | >60 |

Breakdown Products: Not stated
Remarks:

**Conclusions**

The biodegradability of Octadecenylamine was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 2B

Remarks: Reliable with restrictions; basic data given, comparable to guideline standards

**References**

Yoshimura, K., S. Machida and F. Masuda. Biodegradation of Long Chain Alkylamines. J. Am. Oil Chem. Soc. 57:238-241.

**Other Available Reports**

**Other**

Last Changed: July 17, 2002

Order Number for Sorting: 13

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Armeen OD (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | 98% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Methods corresponded to OECD Guideline 301D: Ready biodegradability, Closed Bottle Test, and EEC Official Journal of the European Communities L251, 1984, Part C, Method C.6. Degradation-biotic degradation: Closed Bottle Test. |
| Test Type: | Aerobic ready biodegradability |
| GLP: | Yes |
| Year: | 1992 |
| Contact Time: | 42 days |
| Inoculum: | Secondary activated sludge |
| Remarks: | The test assessed the biodegradability of the test substance in the Closed Bottle Test. The test was performed in 280-ml BOD bottles. Duplicate bottles were prepared for each of the following treatments: 1) control blank without inoculum, 2) control with inoculum, 3) test material at 2 mg/l, and 4) reference substance (sodium acetate) at 6.7 mg/l). All solutions were prepared in mineral nutrient solution. Inoculum was preconditioned in the laboratory by aerating the activated sludge for one week, then diluting to a concentration of 2 mg dry weight/l in the BOD bottles. Dissolved oxygen concentrations in the BOD bottles were measured on days 0, 5, 15, 28 and 42. Biodegradation was calculated as the ratio of the biochemical oxygen demand to the theoretical oxygen demand (ThOD) based upon the chemical structure of the test substance. The ThOD of the test substance was 3.2 g $O_2$/g test substance. |

**Results**

| | |
|---|---|
| Degradation: | The biodegradation of the test substance was 44% at day 28 and 72% at day 42. |
| Results: | The authors claim the test substance should be classified as biodegradable. |

Kinetic:

| Day | % BOD/ThOD | |
|---|---|---|
| | Test Substance | Reference Substance |
| 5 | 17 | 69 |
| 15 | 41 | 75 |
| 28 | 44 | 90 |
| 42 | 72 | -- |

Breakdown Products: Not stated

Remarks: The validity of the test was demonstrated by the oxygen consumption in the control bottle with sodium acetate and an endogenous respiration of 0.3 mg/l. The pH of the medium at day 28 was 6.9.

**Conclusions**

The biodegradability of Octadecenylamine was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN OD. Report No. CRL F91123. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 17, 2002

Order Number for Sorting: 12

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | NORAM O (CAS No. 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | 98% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | ISO 9439, which is in agreement with OECD Guideline 301B |
| Test Type: | Aerobic biodegradation |
| GLP: | Yes |
| Year: | 1992 |
| Contact Time: | 41 days |
| Inoculum: | Activated sludge, domestic wastewater treatment plant |
| Remarks: | Duplicate test mixtures (in 3 L flasks) were incubated at constant temperature (20 – 25 ± 1 °C) for 41 days with continuous stirring. Test mixtures contained test substance (24.6 mg/L; ~110 mg $ThCO_2$/1.5 l), volatile solvent (1,1-dichloro-1fluoroethane), emulsifying agent (Symperonic P94, 12.3 mg/L), mineral medium (as prescribed in OECD 301), and inoculum. Before the test, mixtures were aerated with $CO_2$-free air overnight. Three barium hydroxide traps were connected to collect $CO_2$. Controls included: 1) inoculum blank; 2) positive control (sodium benzoate (34.7 mg/l) and inoculum); 3) emulsifier control (emulsifier and inoculum); and 4) toxicity control (test substance, inoculum and sodium benzoate). For the test mixture, corrections were made for $CO_2$ in emulsifier control. The three traps were replaced and analyzed for CO2 on days 0, 1, 4, 5, 8, 11, 14, 18, 22, 28, 33, 36, 40 and 41.<br>No abiotic control was included. In the report it was not explicitly mentioned that the test was performed in the dark, but since an adaptation phase was observed, during which no degradation yielding $CO_2$ occurred, photodegradation was not expected to have occurred.<br>In the method description, carbon content of sodium benzoate is said to be 58.3%, whereas in the table and further calculations it is said to be 57.7%. 58.3% is the correct value (calculated by reviewer); however, criterion of >60% within 14 days of ThOD is still met when the correct value is used. |

**Results**

Degradation: 66% degradation by day 28

Results: Based on the percent biodegradation, the test substance was considered to be biodegradable, but not readily biodegradable under these test conditions. (Author of report)

Kinetic:

| Day | Test Substance (% $ThCO_2$) | Sodium Benzoate (% $ThCO_2$) |
|---|---|---|
| 4 | -1 | 69 |
| 5 | 0 | 69 |
| 11 | 13 | 71 |
| 18 | 43 | 70 |
| 22 | 60 | 70 |
| 28 | 66 | 69 |

Breakdown Products: Not stated

Remarks: The emulsifying agent was not biodegradable and was no inhibitor. The test substance was biodegradable, though not readily biodegradable because the criterion of degradation, >60% with 10 day window after start of biodegradation phase (10%), was not met.

**Conclusions**

The biodegradability of Noram O was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Boutonnet, J.C. 1994. NORAM O Détermination de la biodégradabilité facile essai de dégagement de $CO_2$. [NORAM O Determination of the Ready Biodegradability by the $CO_2$ evolution assay] Laboratoire accrédité par le Résseau. Study Report Elf Atochem/CAL 4658/93/A.

**Other Available Reports**

**Other**

Last Changed: August 14, 2002

Order Number for Sorting: 11a

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Genamin OL 100 D (CAS No. 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | OECD Guideline 301F; OECD Guideline 302B/ 92/69/EWG (Teil C.4-D), EG Amtsblatt L 383 A. |
| Test Type: | Aerobic biodegradation |
| GLP: | Not stated |
| Year: | 1992 |
| Contact Time: | 28 days |
| Inoculum: | Activated sludge, industrial, non adapted |
| Remarks: | Duplicate test mixtures were incubated at constant temperature (20 ± 1 °C) for 28 days. Test mixtures contained test substance [177 mg/L (~604 m/l ThOD($NO_3$) and 165 mg/L (~562 mg/l ThOD($NO_3$)], mineral medium (as prescribed by OECD 301), and inoculum. Controls included: 1) inoculum blank and 2) positive control (diethylene glycol (ThOD 288 mg/l) and inoculum). BOD was determined manometrically on day 1, 5, 10, 15, 20 and 28.<br>The report was stated to have followed the OECD guidelines, but limited information was provided so this cannot be fully verified. No abiotic control was included. Performance of the test was in compliance with OECD 301F, except for the inoculum, which was from an industrial wastewater plant and was applied in the test at a higher concentration than prescribed in the guideline. However, the concentration was comparable to the concentration prescribed in the Zahn-Wellens test for inherent biodegradability (OECD 302B). Adsorption could not be taken into account because the first measurement took place on day 1. |

**Results**

| | |
|---|---|
| Degradation: | 69% degradation by day 28 |
| Results: | Based on the percent biodegradation, the test substance was considered to be inherently biodegradable. |

Kinetic:

| Day | Test Substance (% ThOD($NO_3$) | Diethylene Glycol (% ThOD($NO_3$) |
|---|---|---|
| 1 | 7 (7) | 28 |
| 5 | 39 (42) | 36 |
| 10 | 55 (59) | 82 |
| 20 | 67 (72) | 98 |
| 28 | 69 (74) | 101 |

* Value in () = % ThOD($NH_3$)

Breakdown Products: Not stated

Remarks: Adaptation phase – two to three days.
The test substance was evaluated induplicate showing a large difference in results (41%) for the duplicates on day 28. According to OECD 301F, the test would thus be invalid; however, non-homogeneity of the sludge makes such a deviation unavoidable, which is acceptable in OECD 302B.

**Conclusions**

The biodegradability of Genamin OL 100 D was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 2D

Remarks: Reliable with restrictions; limited report and photodegradation cannot be ruled out.

**References**

Voelskov, H. 1994. Pruefung der biologischen Abbaubarkeit von Genamin OL 100 D. [Ready Biodegradability Study with Genamin OL 100D] Hoechst AG, Hoechst AG, Dr. Voelskov.

**Other Available Reports**

**Other**

Last Changed: August 14, 2002

Order Number for Sorting: 11b

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Dodecyldimethylamine, distilled (CAS RN 112-18-5; N,N-Dimethyl-1-dodecanamine) |
| Purity: | 98.7% tertiary amine |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | OECD Guideline 301D, Ready Biodegradability, Closed Bottle Test. |
| Test Type: | Aerobic biodegradability |
| GLP: | Yes |
| Year: | 1992 |
| Contact Time: | 28 days |
| Inoculum: | Activated sludge |
| Remarks: | The test assessed the biodegradability of the test substance in the Closed Bottle Test. The test was performed in 280-ml BOD bottles. Duplicate bottles were prepared for each of the following treatments: 1) control blank without inoculum, 2) control with inoculum, 3) test material at 2 mg/l, and 4) reference substance (sodium acetate) at 6.7 mg/l). All solutions were prepared in mineral nutrient solution. Inoculum was preconditioned in the laboratory by aerating the activated sludge for one week, then diluting to a concentration of 2 mg dry weight/l in the BOD bottles. The test compound and reference substance were added to the bottles using stock solutions of 1.0 g/l. The test substance stock solution was prepared by mixing the material in demineralized water at 50°C then acidified. Due to the use of the acidified stock, the pH in the closed bottle medium dropped to approximately 4. This medium was titrated to pH 7 with a 1N NaOH solution. Dissolved oxygen concentrations in the BOD bottles were measured on days 0, 5, 15, and 28. Biodegradation was calculated as the ratio of the biochemical oxygen demand to the theoretical oxygen demand (ThOD) based upon the chemical structure of the test substance. The ThOD of the test substance was 3.2 g $O_2$/g test substance. |

**Results**

| | |
|---|---|
| Degradation: | The test substance was degraded 67% at day 28 in the closed bottle test. |
| Results: | Based on the percent biodegradation, the test substance was considered to be Readily Biodegradable. |

Kinetic:

| Time (Days) | Test Substance (% BOD/ThOD) | Sodium Acetate (% BOD/ThOD) |
|---|---|---|
| 5 | 52 | 69 |
| 15 | 63 | 75 |
| 28 | 67 | 90 |

Breakdown Products: Not stated

Remarks: The validity of the test was demonstrated by oxygen consumption in the control bottles with reference substance, and an endogenous respiration of 0.3 mg/l. The oxygen depletion in the bottle without inoculum slightly exceeded the guideline recommendation. The pH of the medium at day 28 was 6.6.

**Conclusions**

The biodegradability of the test substance was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of Armeen DM12D. Report No. CRL F91121. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 29, 2002

Order Number for Sorting: 122

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Farmin DM20 (CAS RN 112-18-5; *N,N*-Dimethyl-1-dodecanamine) |
| Purity: | Not stated. |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Carbon dioxide ($CO_2$) Evolution Test (Modified Sturm Test): OECD Procedure 301B and Procedure C.4-C of the Annex to Directive 92/69/EEC. |
| Test Type: | Aerobic biodegradation |
| GLP: | Not stated |
| Year: | 1996 |
| Contact Time: | 29 Days |
| Inoculum: | Activated sludge (30 mg solids/l from domestic sewage works at Oakley, Suffolk, UK). |
| Remarks: | Preliminary study: A 5-day bacterial inhibition test was performed using the biochemical oxygen demand (BOD) method (OECD Guideline No 301D (Closed Bottle Test) and EC Procedure C.4-E of the Annex to Directive 92/69/EEC). The test was conducted using bacterial inoculum [sewage effluent (final effluent, 1 drop/l, trickling filter plant at Thorndon, Suffolk, UK)], the test substance (10 mg C/l), and a reference substance (sodium benzoate, 10 mg C/l). The test mixtures were prepared with or without the test substance and included the bacterial inoculum and reference substance. Solution vessels were incubated for 5 days at 20°C in the dark.<br>Definitive study: The determination of the ultimate aerobic biodegradability of the test substance was tested using the $CO_2$ evolution method. The test was conducted using activated sludge, the test substance (10 mg C/l), a reference substance (sodium benzoate, 10 mg C/l), and/or mineral salts medium. Specifically, the test included the following: 1) two test vessels containing the test material, activated sludge and mineral salts medium; 2) two control vessels containing activated sludge and mineral salts medium; and 3) one control containing activate sludge, mineral salts medium and sodium benzoate. Solution vessels were aerated with air treated to remove $CO_2$ and connected to $CO_2$ traps (a series of Drechsel bottles with barium hydroxide) and incubated at 19.7 to 24.0°C. (Lowest temperature value falls outside the |

minimum recommended for this assay, but it is not thought to be significant or to have affected the integrity of the test.) Ultimate biodegradability of the test substance was determined after 29 days. The residual barium hydroxide was determined at intervals by titration.

**Results**

Degradation: 33% at 5 days; 72% after 29 days.

Results: *Preliminary study*: The guideline criteria for the test were met. The test substance did not significantly inhibit the degradation of the bacteria and the test substance showed no evidence of degradation.
*Definitive study*: The guideline criteria for the test were met. Mean cumulative $CO_2$ production by mixtures containing the test substance was equivalent to 10% of the theoretical value after three days and 63% (extrapolated) after 13 days. Test substance was considered to be readily biodegradable.

Kinetic:

| Time (Days) | Sodium Benzoate (10 mg C/l) | | Test Substance (Farmin DM20) (10 mg C/l) | |
|---|---|---|---|---|
| | $CO_2$ (mg) | %$TCO_2$ | $CO_2$ (mg) | %$TCO_2$ |
| 2 | 22.8 | 21 | 0 | 0 |
| 5 | 65.8 | 60 | 35.9 | 33 |
| 10 | 86.9 | 79 | 65.0 | 59 |
| 22 | 95.7 | 87 | 78.3 | 71 |
| 29 | 100.3 | 91 | 78.4 | 72 |

Breakdown Products: None stated

Remarks:

**Conclusions**

*Definitive study:* The test substance was readily biodegradable since $CO_2$ production was ≥60% of the theoretical value within ten days of the level achieving 10%. (Author of report)
The endpoint was adequately characterized.
(American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 1A |
| Remarks: | Reliable without restriction; guideline study. |

**References**

Jenkins, W.R. 1996. Farmin DM20: Assessment of Ready Biodegradability – Modified Sturm Test. Report No. 96/KAS162/0292. Huntingdon Life Sciences Ltd., Eye, Suffolk, UK.

Jenkins, W.R. 1996. Farmin DM20: Assessment of Biotic/Abiotic degradability. Biochemical Oxygen Demand (BOD) and Chemical Oxygen Demand (COD). Report No. 96/KAS164/0313. Huntingdon Life Sciences Ltd., Eye, Suffolk, UK.

**Other**

| | |
|---|---|
| Last Changed: | July 11, 2002 |
| Order Number for Sorting: | 124b (124c preliminary study) |
| Remarks: | |

## 3.5 BIODEGRADATION

### Test Substance

| | |
|---|---|
| Identity: | Genamin LA 302 D (CAS RN 112-18-5; N,N-Dimethyl-1-dodecanamine) |
| Purity: | Approximately 100% |
| Remarks: | |

### Method

| | |
|---|---|
| Method/Guideline followed: | Methods correspond to 79/831/EWG (Part C), OECD – Guidelines for testing of Chemicals, Guideline 301 F. |
| Test Type: | Ready biodegradability |
| GLP: | Yes |
| Year: | 1992 |
| Contact Time: | 28 days |
| Inoculum: | Dry substance from communal effluent water purification plants |
| Remarks: | The test assessed the biodegradability of the test substance in the Closed Bottle Test. BOD bottles were used as vessels and were incubated in a WTW-BOD device at 20 ± 1°C. The content of the reaction medium followed the requirements for the cited EEC Directive. The inoculum was preconditioned for 5 days in the laboratory by stirring in a nutrient solution. The activity of the inoculum was tested using a reference substance, and a control was run with the inoculum and no addition of test substance. The biodegradability analysis occurred through the use of manometric calculation of oxygen-use.<br>The test substance was measured directly into the BOD bottles. The averages of the parallel assays were as follows:<br>Test concentration: 13 mg/l<br>In relation to the theoretical BOD: 40 mg/l ($O_2$)<br>In relation to the theoretical N-BOD: 44 mg/l ($O_2$)<br>No analysis of COD was completed because of the limited solubility of the test substance.<br>BOD per 1 g test substance: $2.58 \times 10^3$ mg/g ($O_2$)<br>The BOD per gram of test substance was ascertained by introduction of the probe directly into the BOD bottle. This method delivers only restricted accuracy of the ascertained value.<br>The BOD could not be ascertained because of the limited solubility of the test substance.<br>Theoretical BOD: $3.16 \times 10^3$ mg/g ($O_2$)<br>Theoretical N-BOD: $3.45 \times 10^3$ mg/g ($O_2$) |

(N-BOD = BOD with nitrification: N-oxidation to nitrate).
Dissolved oxygen content in the bottles was measured on days 7, 14, 21 and 28.

**Results**

Degradation: The biodegradation of the test substance was 67% at day 28.

Results: The authors claim the test substance should be classified as readily biodegradable.

Kinetic:

| Test Day | ThBOD (%) | ThN-BOD (%) |
|---|---|---|
| 7 | 48 | 44 |
| 14 | 53 | 48 |
| 21 | 64 | 59 |
| 28 | 74 | 67 |

Breakdown Products: None

Remarks:

**Conclusions** The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Voelskow, H. 1992. Short Report on the Study of Ready Biodegradability of Genamin LA 302 D in the Respirometer Test. Report Number 92-0067-R1/R2. Hoechst AG, Germany.

**Other Available Reports**

**Other**

Last Changed: June 7, 2002

Order Number for Sorting: 124f

Remarks:

## 3.5 BIODEGRADATION

### Test Substance

| | |
|---|---|
| Identity: | Genamin 14 R 302 D (CAS RN 112-75-4; 1-Tetradecanamine, N,N-dimethyl) |
| Purity: | Approximately 100% |
| Remarks: | |

### Method

| | |
|---|---|
| Method/Guideline followed: | 84/449/EWG (Part C), OECD Guideline 301 D ("Closed Bottle Test"); COD determination followed the DIN-Norm 38 409 Part 3 and BOD determination followed the DIN Norm 38 409 Part 41. |
| Test Type: | Ready biodegradability |
| GLP: | Yes |
| Year: | 1992 |
| Contact Time: | 28 days |
| Inoculum: | Activated sludge from the communal wastewater purification plant in Frankfurt, Germany. |
| Remarks: | The test assessed the ready biodegradability of the test substance in the Closed Bottle Test. Inoculum was purification plant effluent, filtered over a folded filter. The inoculum was not acclimatized to the test substance or reference substance. COD determination of the stock solution = 45 mg/l ($O_2$). COD determination per 1 gram of test substance = 2.25 mg/g ($O_2$). In solutions of defined weight (not filtered), the results are calculated per gram of the measured values per liter of the stock solution. Test substance was added to the test assay in the amount of 132 ml/l, which in relation to the measured COD, equals a test concentration of 5.94 mg/l ($O_2$). Incubation occurred at 20 ± 1°C. The content of the reaction medium conformed to the details of the cited EEC directive. The activity of the inoculum was checked by the use of a reference assay and a control was run using an assay without addition of test substance. Reaction vessels were BOD bottles with caps. They were filled to the rim without bubbles. The degradation analysis occurred by determining the decay of the dissolved oxygen content. |

**Results**

Degradation: Degradation was less than or equal to 2% COD during the 28-day test.

Results: According to the criteria of this test, Genamin 14 R 302 D is not readily biodegradable. The oxygen consumption remained under 20% during the 28-day test.

Kinetics:

| Time (Days) | Consumption (% COD) |
|---|---|
| 7 | 0 |
| 14 | 2 |
| 21 | 0 |
| 28 | 0 |

Breakdown Products: Not stated

Remarks: The oxygen consumption of the reference substance reached >60% in less than 14 days after adaptation.

**Conclusions**

The test substance was not readily biodegradable. (Author of report)
The results of this study are dramatically inconsistent with results for other related chemicals (most being readily biodegradable). This study is not considered representative of the biodegradation of 1-Tetradecanamine, N,N-dimethyl. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 2D

Remarks: Although this is a guideline study, the results are scientifically unjustifiable.

**References**

Stuhlfauth, T. 1992. Short Report on the Study of the Ready Biodegradability of Genamin 14 R 302 D in the "Closed Bottle-Test". Report No. 92-0069-G1. Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other Available Reports**

**Other**

Last Changed: June 7, 2002

Order Number for Sorting: 260c

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Armeen DM16D (CAS RN 112-69-6; 1-Hexadecanamine, N,N-dimethyl) |
| Purity: | 98.2% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 301D: Ready Biodegradability, Closed Bottle Test. Also conformed with EEC Official Journal of the European Communities L251, Method C.6. Degradation-Biotic Degradation: Closed Bottle Test and ISO/TC 147/SC 5WG 4N152. |
| Test Type: | Aerobic biodegradation in the Closed Bottle Test |
| GLP: | Yes |
| Year: | 1991 |
| Contact Time: | 42 days |
| Inoculum: | Secondary activated sludge |
| Remarks: | The experiment measured the biodegradability of the test substance in the Closed Bottle Test. Prior to the start of the test, activated sludge was collected and preconditioned by aerating the sludge for a period of one week. The sludge was diluted to a concentration of 2 mg dry weight/l and used in the test. Solutions of the test substance were prepared at 2 mg/l. This was equivalent to a theoretical oxygen demand of 3.2 g $O_2$/g test substance. A solution of sodium acetate was prepared at 6.7 mg/l and was used as a reference material. At test initiation, four experimental groups were made using duplicate 280-ml BOD bottles. Experimental groups were 1) mineral nutrient without test substance and without inoculum, 2) mineral nutrient solution without test substance but with inoculum, 3) mineral nutrient solution with test substance and with inoculum, and 4) mineral nutrient solution with sodium acetate and with inoculum. Ammonium chloride was omitted from the medium to prevent nitrification. Due to the omission, the pH of the medium decreased slightly. Dissolved oxygen concentrations were measured in each bottle on days 0, 5, 15, 28, and 42 using an oxygen electrode. |

**Results**

| | |
|---|---|
| Degradation: | The test substance was degraded 59% at day 28 and |

70% at day 42.

Results: Based on the degradation percentages, the test substance was considered readily biodegradable.

Kinetics:

| Day | Test Substance (% BOD/ThOD) | Sodium Acetate (% BOD/ThOD) |
|---|---|---|
| 5 | 47 | 69 |
| 15 | 53 | 75 |
| 28 | 59 | 90 |
| 42 | 70 | -- |

Breakdown Products: Not stated.

Remarks: The validity of the test was demonstrated by the degradation of sodium acetate and an endogenous respiration of 0.3 mg/l.

**Conclusions**

The ready biodegradability of the test substance in the Closed Bottle Test was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN DM16D. Project/Study No. CRL F91120; Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 9, 2002

Order Number for Sorting: 2a

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Farmin DM60 (CAS RN 112-69-6; 1-Hexadecanamine, N,N-dimethyl) |
| Purity: | Not stated. |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | OECD Procedure 301B and Procedure C.4-C of the Annex to Directive 92/69/EEC (Modified Sturm Test). |
| Test Type: | Aerobic biodegradation |
| GLP: | Not stated |
| Year: | 1996 |
| Contact Time: | 29 Days |
| Inoculum: | Activated sludge (30 mg solids/l from domestic sewage works at Oakley, Suffolk, UK). |
| Remarks: | Preliminary study: A 5-day bacterial inhibition test was performed using the biochemical oxygen demand (BOD) method (OECD Guideline No 301D (Closed Bottle Test) and EC Procedure C.4-E of the Annex to Directive 92/69/EEC). The test was conducted using bacterial inoculum [sewage effluent (final effluent, 1 drop/l, trickling filter plant at Thorndon, Suffolk, UK)], the test substance (10 mg C/l), and a reference substance (sodium benzoate, 10 mg C/l). The test mixtures were prepared with or without the test substance and included the bacterial inoculum and reference substance. Solution vessels were incubated for 5 days at 20°C in the dark.<br>Definitive study: The determination of the ultimate aerobic biodegradability of the test substance was tested using the $CO_2$ evolution method. The test was conducted using activated sludge, the test substance (10 mg C/l), a reference substance (sodium benzoate, 10 mg C/l), and/or mineral salts medium. Specifically, the test included the following: 1) two test vessels containing the test material, activated sludge and mineral salts medium; 2) two control vessels containing activated sludge and mineral salts medium; and 3) one control containing activate sludge, mineral salts medium and sodium benzoate. Solution vessels were aerated with air treated to remove $CO_2$ and connected to $CO_2$ traps (a series of Drechsel bottles with barium hydroxide) and incubated at 21.2 to 23.9°C. Ultimate biodegradability of the test substance was determined after 29 days. The residual |

barium hydroxide was determined at intervals by titration.

**Results**

Degradation: 107% after 29 days.

Results: *Preliminary study*: The guideline criteria for the test were met. The test substance did not significantly inhibit the degradation of the bacteria and the test substance showed no evidence of degradation.
*Definitive study*: The guideline criteria for the test were met. Mean cumulative $CO_2$ production by mixtures containing the test substance was equivalent to 60% of the theoretical value after eight days; a degradation plateau was not obtained by the end of the test. The highest degradation result (>100%) obtained from Farmin DM60 and the absence of a plateau after 29 days suggests that the initial estimate of its carbon content may have been slightly lower than the true value. The test substance was considered to be readily biodegradable.

Kinetic:

| Time (Days) | Test Substance (Farmin DM60) (10 mg C/l) | | Sodium Benzoate (10 mg C/l) | |
|---|---|---|---|---|
| | $CO_2$ (mg) | %$TCO_2$ | $CO_2$ (mg) | %$TCO_2$ |
| 2 | 0 | 0 | 22.3 | 20 |
| 4 | 17.9 | 16 | 57.5 | 52 |
| 8 | 66.2 | 60 | 81.8 | 74 |
| 18 | 100.5 | 91 | 92.5 | 84 |
| 29 | 117.8 | 107 | 98.2 | 89 |

Breakdown Products: None stated

Remarks:

**Conclusions**

The test substance was readily biodegradable since $CO_2$ production was ≥60% of the theoretical value within ten days of the level achieving 10%. (Author of report)
The endpoint was adequately characterized.
(American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Jenkins, W. R. 1996. Farmin DM60: Assessment of Ready Biodegradability – Modified Sturm Test. Report No. 96/KAS176/0293. Huntingdon Life Sciences Ltd., Eye, Suffolk, UK.

Jenkins, W. R. 1996. Farmin DM60: Assessment of Biotic/Abiotic Degradability, Biochemical Oxygen Demand (BOD) and Chemical Oxygen Demand (COD). Report No. 96/KAS178/0316. Huntingdon Life Sciences Ltd., Eye, Suffolk, UK.

**Other**

| | |
|---|---|
| Last Changed: | July 11, 2002 |
| Order Number for Sorting: | 4b (4c preliminary study) |
| Remarks: | |

## 3.5 BIODEGRADATION

### Test Substance

| | |
|---|---|
| Identity: | Octadecylamine (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl) |
| Purity: | Not Stated |
| Remarks: | |

### Method

| | |
|---|---|
| Method/Guideline followed: | Non-specific test method for measuring $CO_2$ evolution. |
| Test Type: | Aerobic biodegradability |
| GLP: | Not stated |
| Year: | 1985 |
| Contact Time: | 40 days (screening test), 7 days (definitive test) |
| Inoculum: | Sludge |
| Remarks: | A screening level test (run for 40 days at 10 and 20 mg/l) and a definitive test (run for 7 days at 0.2 and 2.0 mg/l) were run. The reference provided basic data from the definitive $CO_2$ evolution test with $^{14}C$-labelled test substance and the study report from the screening test using nonradiolabelled test substance. In the screening test, glucose was used as a reference material, while in the definitive test stearic acid was used as the reference material. Details provided for the screening test follow: Four, 4-liter Erlenmeyer flasks were prepared to contain the following: 1) Blank control, 2) Glucose control at 20 mg/l, 3) test substance at 10 mg/l and 4) test substance at 20 mg/l. All flasks received acclimated inoculum (20 ml containing $6.3 \times 10^6$ organisms/ml) and were brought to volume (2000 ml) with mineral salts medium. Flasks were incubated at 20 to 23°C except on one day when the temperature dropped to 16°C due to inadvertent shut down of the furnace. The study director reported that this deviation did not affect the integrity of the study. The headspace of each flask was aerated with $CO_2$-free air and any $CO_2$ evolved from the biodegradation of the test substance was collected in $Ba(OH)_2$ traps. Traps were periodically removed and the amount of $CO_2$ collected was determined titrimetrically. After $CO_2$ production ceased, solutions were acidified and aerated overnight. The amount of soluble organic carbon remaining in the flasks was also determined at the end of the test. The glucose control in the screening test produced a below normal percent $TCO_2$ over the test period of 43.1%. The Study Director indicated that this low value was |

probably caused by a technician error in adding only 20 ml of 1000 ppm glucose stock solution instead of 40 ml. The study director indicated that this deviation did not affect the validity of the study. The screening study was extended to 40 days due to additional $CO_2$ production in the test flasks beyond the 25 day test period.

**Results**

Degradation: In the screening test, the 10 and 20 mg/l treatments were degraded to 118 and 51%, respectively. In the definitive test, the 0.2 and 2.0 mg/l treatments were degraded to 91.1 and 79.4%, respectively.

Results: In the definitive test, biodegradability was confirmed using radiolabeled techniques and realistic trace level concentrations (0.2 and 2.0 mg/l). The indigenous microflora in sludge rapidly and extensively mineralized the test substance. Greater than 80% of the amine was converted to $^{14}CO_2$ with a half-life of 17 to 20 hours. The residual $^{14}C$ activity was associated with the biomass or dissolved in solution. The kinetics of mineralization and distribution of the radioactivity were similar to those of readily degradable stearic acid, demonstrating the biodegradable nature of the amine.

Kinetic: Not provided for the definitive test

| Screening Study Kinetics | | | |
|---|---|---|---|
| **Time (Days)** | **Test Substance 10 mg/l (% $TCO_2$)** | **Test Substance 20 mg/l (% $TCO_2$)** | **Glucose (% $TCO_2$)** |
| 6 | 7.1 | -0.8 | 22.5 |
| 18 | 40.8 | 30.6 | 42.1 |
| 26 | 79.0 | 43.8 | 43.1 |
| 40 | 118.0 | 50.6 | 43.1 |

Breakdown Products: Not stated

Remarks:

**Conclusions** The biodegradable nature of Octadecylamine was adequately characterized in this study. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 2B

Remarks: Reliable with restrictions; basic data given, comparable

to guidelines/standards.

**References**

Mooney, T.W. 1988. Letter from Proctor & Gamble Co. to U.S. EPA Regarding Request for Information on Tertiary Amines. The Proctor & Gamble Co. EPA Doc ID No. FYI-OTS-0794-1165. Also included in EPA document: Pence, W. H. 1985. $CO_2$ Production Test on B0793.01. Study Reference 85-0245-11, Hill Top Research, Inc., Cincinnati, OH, USA.

**Other Available Reports**

**Other**

Last Changed: July 18, 2002
Order Number for Sorting: 35
Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Farmin DM80 (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl) |
| Purity: | Not stated. |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Carbon dioxide ($CO_2$) Evolution Test: OECD Procedure 301B and Procedure C.4-C of the Annex to Directive 92/69/EEC (Modified Sturm Test). |
| Test Type: | Aerobic biodegradation |
| GLP: | Not stated |
| Year: | 1996 |
| Contact Time: | 29 Days |
| Inoculum: | Activated sludge (30 mg solids/l from domestic sewage works at Oakley, Suffolk, UK). |
| Remarks: | Preliminary study: The 5-day bacterial inhibition test was performed using the biochemical oxygen demand (BOD) method (OECD Guideline No 301D (Closed Bottle Test) and EC Procedure C.4-E of the Annex to Directive 92/69/EEC). The test was conducted using bacterial inoculum [sewage effluent (final effluent, 1 drop/l, trickling filter plant at Thorndon, Suffolk, UK)], the test substance (10 mg C/l), and a reference substance (sodium benzoate, 10 mg C/l). The test mixtures were prepared with or without the test substance and included the bacterial inoculum and reference substance. Solution vessels were incubated for 5 days at 20°C in the dark..<br>Definitive study: The determination of the ultimate aerobic biodegradability of the test substance was made using the $CO_2$ evolution method. The test was conducted using activated sludge, the test substance (10 mg C/l), a reference substance (sodium benzoate, 10 mg C/l), and/or mineral salts medium. Specifically, the test included the following: 1) two test vessels containing the test material, activated sludge and mineral salts medium; 2) two control vessels containing activated sludge and mineral salts medium; and 3) one control containing activate sludge, mineral salts medium and sodium benzoate. Solution vessels were aerated with air treated to remove $CO_2$ and connected to $CO_2$ traps (a series of Drechsel bottles with barium hydroxide) and incubated at 21.2 to 23.9°C. Ultimate biodegradability of the test |

substance was determined after 29 days. The residual barium hydroxide was determined at intervals by titration.

**Results**

Degradation: 49% after 29 days

Results: *Preliminary study*: The guideline criteria for the test were met. The test substance did not significantly inhibit the degradation of the bacteria and the test substance showed no evidence of degradation.
*Definitive study*: The guideline criteria for the test were met. Mean cumulative $CO_2$ production by mixtures containing the test substance was equivalent to 10% of the theoretical value after five days and 49% after 29 days; a degradation plateau was not obtained by the end of the test. Test substance cannot be considered to be readily degradable, but because significant degradation occurred it can be considered to be inherently degradable.

Kinetic:

| Time (Days) | Test Substance (Farmin DM80) (10 mg C/l) | | Sodium Benzoate (10 mg C/l) | |
|---|---|---|---|---|
| | $CO_2$ (mg) | %$TCO_2$ | $CO_2$ (mg) | %$TCO_2$ |
| 2 | 0 | 0 | 22.3 | 20 |
| 5 | 10.9 | 10 | 67.6 | 61 |
| 15 | 40.1 | 37 | 90.1 | 82 |
| 29 | 53.3 | 49 | 98.2 | 89 |

Breakdown Products: None stated

Remarks:

**Conclusions**

The test substance was not readily biodegradable, but because significant degradation occurred it can be considered to be inherently degradable. (Author of report)
The endpoint was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Jenkins, W. R.. 1996. Farmin DM80: Assessment of Ready Biodegradability – Modified Sturm Test. Report No. 96/KAS183/0317, Huntingdon Life Sciences Ltd., Eye, Suffolk, UK.

Jenkins, W. R.. 1996. Farmin DM80: Assessment of Biotic/Abiotic degradability. Biochemical Oxygen Demand (BOD) and Chemical Oxygen Demand (COD). Report No. 96/KAS185/0318, Huntingdon Life Sciences Ltd., Eye, Suffolk, UK.

**Other**

| | |
|---|---|
| Last Changed: | July 11, 2002 |
| Order Number for Sorting: | 38a (38b preliminary study) |
| Remarks: | |

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Cocodimethylamine, distilled (CAS RN 61788-93-0; Amines, coco alkyldimethyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Methods corresponded to OECD Guideline 301D: Ready biodegradability, Closed Bottle Test, and EEC Official Journal of the European Communities L251, 1984, Part C, Method C.6. Degradation-biotic degradation: Closed Bottle Test. |
| Test Type: | Aerobic ready biodegradability |
| GLP: | Yes |
| Year: | 1991 |
| Contact Time: | 28 days |
| Inoculum: | Secondary activated sludge |
| Remarks: | The test assessed the biodegradability of the test substance in the Closed Bottle Test. The test was performed in 280-ml BOD bottles. Duplicate bottles were prepared for each of the following treatments: 1) control blank without inoculum, 2) control with inoculum, 3) test material at 2 mg/l, and 4) reference substance (sodium acetate) at 6.7 mg/l). All solutions were prepared in mineral nutrient solution. Inoculum was preconditioned in the laboratory by aerating the activated sludge for one week, then diluting to a concentration of 2 mg dry weight/l in the BOD bottles. Dissolved oxygen concentrations in the BOD bottles were measured on days 0, 5, 15 and 28. Biodegradation was calculated as the ratio of the biochemical oxygen demand to the theoretical oxygen demand (ThOD) based upon the chemical structure of the test substance. The ThOD of the test substance was 3.2 g $O_2$/g test substance. |

**Results**

| | |
|---|---|
| Degradation: | The biodegradation of the test substance was 81% at day 28. |
| Results: | The authors claim the test substance should be classified as readily biodegradable. |

Kinetic:

| Time (Days) | Test Substance (% BOD/ThOD) | Sodium Acetate (% BOD/ThOD) |
|---|---|---|
| 5 | 45 | 73 |
| 15 | 61 | 87 |
| 28 | 81 | 90 |

Breakdown Products: Not stated

Remarks: The validity of the test was demonstrated by the oxygen consumption in the control bottle with sodium acetate and an endogenous respiration of 0.6 mg/l. The pH of the medium at day 28 was 6.8.

**Conclusions**

The biodegradability of cocodimethylamine was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN M2C. Report No. CRL F91068. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 25, 2002

Order Number for Sorting: 127

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Cocodimethylamine, distilled (CAS RN 61788-93-0; Amines, coco alkyldimethyl) |
| Purity: | 99.5% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Methods corresponded to OECD Guideline 301D: Ready biodegradability, Closed Bottle Test, and EEC Official Journal of the European Communities L251, 1984, Part C, Method C.6. Degradation-biotic degradation: Closed Bottle Test. |
| Test Type: | Aerobic ready biodegradability |
| GLP: | Yes |
| Year: | 1991 |
| Contact Time: | 28 days |
| Inoculum: | Secondary activated sludge |
| Remarks: | The test assessed the biodegradability of the test substance in the Closed Bottle Test. The test was performed in 280-ml BOD bottles. Duplicate bottles were prepared for each of the following treatments: 1) control blank without inoculum, 2) control with inoculum, 3) test material at 2 mg/l, and 4) reference substance (sodium acetate) at 6.7 mg/l). All solutions were prepared in mineral nutrient solution. Inoculum was preconditioned in the laboratory by aerating the activated sludge for one week, then diluting to a concentration of 2 mg dry weight/l in the BOD bottles. Dissolved oxygen concentrations in the BOD bottles were measured on days 0, 5, 15 and 28. Biodegradation was calculated as the ratio of the biochemical oxygen demand to the theoretical oxygen demand (ThOD) based upon the chemical structure of the test substance. The ThOD of the test substance was 3.2 g $O_2$/g test substance. |

**Results**

| | |
|---|---|
| Degradation: | The biodegradation of the test substance was 69% at day 28. |
| Results: | The authors claim the test substance should be classified as readily biodegradable. |

Kinetic:

| Time (Days) | Test Substance (% BOD/ThOD) | Sodium Acetate (% BOD/ThOD) |
|---|---|---|
| 5 | 38 | 73 |
| 15 | 55 | 87 |
| 28 | 69 | 90 |

Breakdown Products: Not stated

Remarks: The validity of the test was demonstrated by the oxygen consumption in the control bottle with sodium acetate and an endogenous respiration of 0.6 mg/l. The pH of the medium at day 28 was 6.8.

**Conclusions**

The biodegradability of cocodimethylamine was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN DMCD. Report No. CRL F91069. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 25, 2002

Order Number for Sorting: 128

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Tallowdimethylamine, distilled (hydrogenated tallow-alkyl) [CAS RN 61788-95-2; Amines, (hydrogenated tallow alkyl) dimethyl] |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Test methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 301D: Ready Biodegradability, Closed Bottle Test, and EEC, Official Journal of the European Communities, L251, Method C.6. Degradation-biotic degradation: Closed Bottle Test. |
| Test Type: | Aerobic ready biodegradability |
| GLP: | Yes |
| Year: | 1991 |
| Contact Time: | 42 days |
| Inoculum: | Secondary activated sludge from the RWZI Nieuwgraaf in Duiven |
| Remarks: | Secondary activated sludge was collected and preconditioned in the laboratory by aerating the material for a period of one week. Sludge was diluted to a concentration of 2 mg dry weight/l. Treatment groups included: 1) mineral solution without test material and without inoculum, 2) mineral nutrient solution without test material but with inoculum, 3) mineral nutrient solution with test material (2.0 mg/l) and with inoculum, and 4) mineral nutrient solution with sodium acetate (reference substance at 6.7 mg/l) and with inoculum. The test was carried out in 280-ml BOD bottles with two replicate bottles per experimental group. On days 0, 5, 15, 28, and 42, dissolved oxygen concentrations were measured in each bottle. Biodegradation was calculated as the ratio of the BOD to the theoretical BOD (ThOD) based on the formula of the chemical. The ThOD of the test substance was 3.2 g $O_2$/g test substance. |

**Results**

| | |
|---|---|
| Degradation: | The degradation of the test substance was 58% at day 28 and 66% at day 42. |
| Results: | Based on the percent biodegradation, the test substance was considered to be readily biodegradable. |

Kinetic:

| Time (Days) | Armeen M2C (% BOD/ThOD) | Sodium Acetate (% BOD/ThOD) |
|---|---|---|
| 5 | 27 | 69 |
| 15 | 47 | 75 |
| 28 | 58 | 90 |
| 42 | 66 | -- |

Breakdown Products: Not stated

Remarks: Validity of the test was demonstrated by the oxygen consumption in the sodium acetate reference treatment and by an endogenous respiration of 0.3 mg/l. The oxygen depletion in the bottle without inoculation exceeded the values laid down in the guideline slightly. The pH of the medium on day 28 was 7.0.

**Conclusions**

The biodegradability of amines, (hydrogenated tallow alkyl) dimethyl was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN DMHTD. Study/Report No. CRL F91119, Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 25, 2002

Order Number for Sorting: 105

Remarks:

## 3.5 BIODEGRADATION

### Test Substance

| | |
|---|---|
| Identity: | Genamin SO 302 D (CAS RN 61788-91-8; Amines, dimethylsoya alkyl) |
| Purity: | Approximately 100% |
| Remarks: | The report included the CAS RN as 61788-93-0, which corresponds to the FND Amines category supporting chemical, Amines, dimethyl coco alkyl; however, based on the product name and chemical name it was ascertained that the correct CAS RN was 61788-91-8. |

### Method

| | |
|---|---|
| Method/Guideline followed: | OECD Guideline 301 F; EEC 84/449 |
| Test Type: | Ready biodegradability |
| GLP: | Yes |
| Year: | 1992 |
| Contact Time: | 28 days |
| Inoculum: | Activated sludge from the purification plant FfM-Sindlingen (communal). |
| Remarks: | The test assessed the ready biodegradability of the substance using the Closed Bottle Test. The BOD per gram of test substance equaled 3.06 x $10^3$ mg/g ($O_2$), and was measured by directly placing the probe in the BOD bottle. This method delivers a restricted accuracy of the determined value. The DOC could not be measured because of the limited solubility of the test substance. Inoculum was added to the test vessels in the amount of 7 mg/l dry weight after being aerated and stirred in nutrient salt solution. The inoculum was not acclimatized to the test substance or the reference substance in the laboratory. An average of 11 mg/l of the test substance was added directly to the vessels. In relation to the theoretical COD = 35 mg/l ($O_2$). In relation to the theoretical N-biological oxygen demand = 37 mg/l ($O_2$). Incubation occurred at 20 ± 1°C. The composition of the reaction medium corresponded to the requirements of the cited EEC Directive. The activity of the inoculum was evaluated by using a reference assay and a control with no addition of test substance. Reaction vessels were BOD Bottles incubated in WTW BOD machine. The degradation analysis occurred by manometric determination of the oxygen demand.<br>Theoretical COD: 3.19 x $10^3$ mg/g ($O_2$)<br>Theoretical N-Biological Oxygen Demand:<br>3.41 x $10^3$ mg/g ($O_2$). |

**Results**

Degradation: The oxygen demand in assays containing the reference substance reached oxygen consumption of > 60% in less than 10 days after adaptation. Length of adaptation phase (consumption < 10%): 5 days

Results: Genamin SO 302 D is readily biodegradable. (Author of report)

Kinetic:

| Time (days) | Consumption - ThCOD (%) | Consumption – N-BOD (%) |
|---|---|---|
| 7 | 33 | 31 |
| 14 | 47 | 44 |
| 21 | 59 | 55 |
| 28 | 98 | 91 |

Breakdown Products: Not stated

Remarks: The author stated the following: The evaluation barrier of 60% was exceeded. The "10 day window" (degradation within 10 days after adaptation) is not useful in the preceding case since the test substance is a blend of different chain lengths. These need different adaptation times. The adaptation times overlap and are not individually distinguishable. The control showed no sign of toxicity in the test concentration.

**Conclusions** The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Voelskow, H. 1992. Short Report on the Study of the Ready Biodegradability of Genamin SO 302 D in the Respirometer Test. Report Number 92-0068-R1. Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other Available Reports**

**Other**

Last Changed: June 7, 2002

Order Number for Sorting: 104a

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Oleyldimethylamine, distilled (CAS RN 28061-69-0; Octadecen-1-amine, N,N-dimethyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Methods corresponded to OECD Guideline 301D: Ready biodegradability, Closed Bottle Test, and EEC Official Journal of the European Communities L251, 1984, Part C, Method C.6. Degradation-biotic degradation: Closed Bottle Test. |
| Test Type: | Aerobic ready biodegradability |
| GLP: | Yes |
| Year: | 1992 |
| Contact Time: | 70 days |
| Inoculum: | Secondary activated sludge |
| Remarks: | The test assessed the biodegradability of the test substance in the Closed Bottle Test. The test was performed in 280-ml BOD bottles. Duplicate bottles were prepared for each of the following treatments: 1) control blank without inoculum, 2) control with inoculum, 3) test material at 2 mg/l, and 4) reference substance (sodium acetate) at 6.7 mg/l). All solutions were prepared in mineral nutrient solution. Inoculum was preconditioned in the laboratory by aerating the activated sludge for one week, then diluting to a concentration of 2 mg dry weight/l in the BOD bottles. Dissolved oxygen concentrations in the BOD bottles were measured on days 0, 5, 15, 28, 42 and 70. Biodegradation was calculated as the ratio of the biochemical oxygen demand to the theoretical oxygen demand (ThOD) based upon the chemical structure of the test substance. The ThOD of the test substance was 3.2 g $O_2$/g test substance. |

**Results**

| | |
|---|---|
| Degradation: | The biodegradation of the test substance was 50% at day 28 and 59% at day 70. |
| Results: | The authors claim the test substance should be classified as biodegradable. |

Kinetic:

| Day | Armeen DMDO (% BOD/ThOD) | Sodium Acetate (% BOD/ThOD) |
|---|---|---|
| 5 | 19 | 69 |
| 15 | 39 | 75 |
| 28 | 50 | 92 |
| 70 | 59 | -- |

Breakdown Products: Not stated

Remarks: The validity of the test was demonstrated by the oxygen consumption in the control bottle with sodium acetate and an endogenous respiration of 0.2 mg/l. The pH of the medium at day 28 was 6.8.

**Conclusions**

The biodegradability of Oleyldimethylamine was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN DMOD. Report No. CRL F92007. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 18, 2002

Order Number for Sorting: 125

Remarks:

## 3.5 BIODEGRADATION

### Test Substance

| | |
|---|---|
| Identity: | Dicocomethylamine (CAS RN 61788-62-3; Amines, dicoco alkylmethyl) |
| Purity: | 100% |
| Remarks: | |

### Method

| | |
|---|---|
| Method/Guideline followed: | Methods corresponded to OECD Guideline 301D: Ready biodegradability, Closed Bottle Test, and EEC Official Journal of the European Communities L251, 1984, Part C, Method C.6. Degradation-biotic degradation: Closed Bottle Test. |
| Test Type: | Aerobic ready biodegradability |
| GLP: | Yes |
| Year: | 1992 |
| Contact Time: | 28 days |
| Inoculum: | Secondary activated sludge |
| Remarks: | The test assessed the biodegradability of the test substance in the Closed Bottle Test. The test was performed in 280-ml BOD bottles. Duplicate bottles were prepared for each of the following treatments: 1) control blank without inoculum, 2) control with inoculum, 3) test material at 2 mg/l, and 4) reference substance (sodium acetate) at 6.7 mg/l). All solutions were prepared in mineral nutrient solution. Inoculum was preconditioned in the laboratory by aerating the activated sludge for one week, then diluting to a concentration of 2 mg dry weight/l in the BOD bottles. Dissolved oxygen concentrations in the BOD bottles were measured on days 0, 5, 15 and 28. Biodegradation was calculated as the ratio of the biochemical oxygen demand to the theoretical oxygen demand (ThOD) based upon the chemical structure of the test substance. The ThOD of the test substance was 3.3 g $O_2$/g test substance. |

### Results

| | |
|---|---|
| Degradation: | The biodegradation of the test substance was 82% at day 28. |
| Results: | The authors claim the test substance should be classified as readily biodegradable. |

Kinetic:

| Time (Days) | Test Substance (% BOD/ThOD) | Sodium Acetate (% BOD/ThOD) |
|---|---|---|
| 5 | 15 | 69 |
| 15 | 67 | 75 |
| 28 | 82 | 90 |

Breakdown Products: Not stated

Remarks: The validity of the test was demonstrated by the oxygen consumption in the control bottle with sodium acetate and an endogenous respiration of 0.3 mg/l. The pH of the medium at day 28 was 6.7.

**Conclusions**

The biodegradability of dicocomethylamine was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN M2C. Report No. CRL F91122. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 24, 2002

Order Number for Sorting: 126

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | NORAM M2SH (CAS RN 61788-63-4; Dihydrogenated tallow methylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | AFNOR NF T 90-306 in compliance with Method C5 of the European Commission of Communities 84/449/CEE (Modified Sturm Assay) |
| Test Type: | Aerobic biodegradation |
| GLP: | Not stated |
| Year: | 1991 |
| Contact Time: | 28 and 40 Days |
| Inoculum: | Secondary effluent of the residential waste water treatment facility of Versailles (final concentration of bacteria in the test medium was 4 x $10^6$ bacteria/ml) |
| Remarks: | The determination of the ultimate aerobic biodegradability of the test substance was made using the $CO_2$ evolution method. The test was conducted using the test substance, a reference substance (sodium acetate), or a mixture of the two (to study possible inhibitory effects). Since the test substance was insoluble in water, it was tested as an emulsion in Symperonic 94 and Symperonic P103. Specifically, the test included the following: 1) duplicate blanks consisting of medium only; 2) duplicate samples of the test substance (19.8 mg/l organic carbon); 3) the positive control, Na Acetate (19.9 mg/l organic carbon); 4) the test substance and Na Acetate, which served as the inhibition control (19.8 and 19.9 mg/l organic carbon, respectively); and 5) one flask containing Symperonic 94 and Symperonic P103 (5.8 mg/l each), which served as the emulsion control. Solutions were freshly prepared in glass flasks connected to $CO_2$ traps and incubated at 30 to 35°C. Ultimate biodegradability of the test substance was determined after 28 and 40 days. The following deviation from the method was noted: The method assumes the test substance is water soluble. The emulsions were made according to the method described in the guideline. This deviation was believed not to affect the verification of the aerobic biodegradation of the test substance. $CO_2$ was quantified from trapping solutions by titration with |

HCl (0.05 M) after making the solution alkaline. The traps contained 0.05 M $Ba(OH)_2$ to react with the evolved $CO_2$ to form $BaCO_3$ precipitate in the traps. The amount of $CO_2$ trapped was determined by the amount of $Ba(OH)_2$ remaining. Following 28 days, after replacement of the traps, the solutions were acidified to decompose the carbonates and bicarbonates; and aeration continued for 24 hours to collect all $CO_2$ in the last trap. Total evolved $CO_2$ in the test material, positive control, inhibition control, and emulsion control samples was calculated by the difference in the test and appropriate controls.

**Results**

Degradation: 75% at 28 days; 85% at 40 days

Results: The guideline criteria for the test were met. The test substance did not inhibit the bacteria with > 25% degradation in the inhibition control at 28 days (89% actual). The degradation of the positive control, Na Acetate, was > 50% at 28 days (100% actual). The difference at the 28$^{th}$ day in the % degradation in the emulsion control was < 30%. The emulsion control showed that the emulsion did not affect the $CO_2$ evolution of the test substance.

Kinetic:

| Time (Days) | Test Substance (% BOD/ThOD) | Sodium Acetate (% BOD/ThOD) |
|---|---|---|
| 2 | 1 | 39 |
| 7 | 38 | 77 |
| 12 | 56 | 94 |
| 26 | 74 | 103 |
| 33 | 78 | 104 |
| 43 | 85 | 102 |

Breakdown Products: None stated

Remarks:

**Conclusions**

The test substance was readily biodegradable based on > 60% degradation in 28 days. (Author of report) The endpoint was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Boutonnet, M. 1991. Evaluation en milieu aqueux de la biodegradatbilite aerobie "ultime" du Noram M2SH DNS; Methode par analyse du dioxide de carbone degage.. [Evaluation of the aqueous aerobic ultimate biodegradability of Noram M2SH DNS using the $CO_2$ evolution method] in Report No. 34028. Atochem D.R.D.I.

**Other**

| | |
|---|---|
| Last Changed: | July 25, 2002 |
| Order Number for Sorting: | 103b |
| Remarks: | |

## 3.5 BIODEGRADATION

### Test Substance

| | |
|---|---|
| Identity: | Armeen M2HT (CAS RN 61788-63-4; Dihydrogenated tallow methylamine) |
| Purity: | 97.3% |
| Remarks: | |

### Method

| | |
|---|---|
| Method/Guideline followed: | Test methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 301D: Closed Bottle Test. |
| Test Type: | Aerobic Ready Biodegradability |
| GLP: | No, but the document incorporated many GLP characteristics |
| Year: | 1987 |
| Contact Time: | 42 days |
| Inoculum: | Activated sludge |
| Remarks: | The closed bottle test was carried out in 280-ml glass BOD bottles. Inoculum originated from an activated sludge municipal wastewater treatment plant. The sludge was preconditioned by aerating a sludge suspension (s.s) of 1 g s.s./l in dilution water for one week in order to reduce high residual respiration rates. The density of the inoculum in the test was 3 mg s.s./l. The dilution water was the medium as prescribed by the test guideline without ammonia. Because the test substance was not soluble in water, the test substance was emulsified with a nonbiodegadable emulsifier (Genapol PF40) and nonylphenol ethoxylate (10E05PO) and a stock solution was made. Stock solution was added to a mineral nutrient solution to achieve a test substance concentration of 1.6 mg/l. Due to the preparation method, the concentration might have been up to 10% less than 1.6 mg/l.) Additional test groups included sodium acetate as a reference substance in addition to the test substance with emulsifier and a blank, which contained mineral nutrient solution without test chemical. Each experimental group was run in triplicate BOD bottles, and dissolved oxygen measurements were carried out on days 0, 14, 28, and 42. To determine biodegradation, the measured COD was used for the calculations to determine biodegradation (BOD/COD). COD was determined according to the Kelkenberg method. The COD of the test suspension was 4.76 mg $O_2$/l. |

**Results**

Degradation: Biodegradation of the test substance reached 86% after 14 days and 102% after 28 days.

Results: The test substance was shown to be readily biodegradable.

Kinetic:

| Time (Days) | Armeen M2HT (% BOD/COD) |
|---|---|
| 14 | 86 |
| 28 | 102 |
| 42 | 99 |

Breakdown Products: Not stated

Remarks: The emulsifier was shown to be non-biodegradable and no toxicity was seen as evidenced by biodegradation of sodium acetate. The extremely high biodegradation values may be explained by an overestimation of the concentration of Armeen M2HT in the test suspension. (Author of report)

**Conclusions**

The biodegradability of Armeen M2HT was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Balk, F. and E.E. Hantink-De Rooij. 1987. Biodegradability of a Number of Nitrogen Derivatives (MU-30, Akzo Chemie). Unpublished Report, Project No. T 86-6-1. Akzo, Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 25, 2002

Order Number for Sorting: 98

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Genamin SH 200 [CAS RN 61789-79-5;Amines, bis(hydrogenated tallow alkyl)] |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Guideline 92/69/EWG (Part C.4-D), EG Official Gazette L 383 A and the OECD Guideline 301 F ("Respirometric Method") |
| Test Type: | Ready biodegradability |
| GLP: | Yes |
| Year: | 1995 |
| Contact Time: | 28 days |
| Inoculum: | Activated sludge from Communal Purification Plant in Frankfurt am Main, Sindlingen |
| Remarks: | The test assessed the ready biodegradability of the test substance using the Respirometric Method. Centrifuged sediment from activated sludge was washed, re-centrifuged, re-suspended and used as the inoculum. Pretreatment included seven days aeration under stirring. Because of the minimal solubility of the test substance, no stock solution was prepared. Instead, the BOD was determined by weight. BOD [Direct weighing-in = 3.08 x $10^3$ mg/g ($O_2$)]. 32.5 mg/l of the test substance was placed in each of three BOD bottles. The BOD of the test substance was 100 mg $O_2$/l in each bottle. Incubation occurred at 22 ± 1°C. The composition of the reaction medium complied with the cited EEC directive. The activity of the inoculum was checked by using a reference assay and the control was an assay without test substance. Reaction vessels were BOD bottles and they were incubated in a WTW BOD Machine. The biodegradability analysis was achieved by manometric calculation of the oxygen demand. |

**Results**

| | |
|---|---|
| Degradation: | The biodegradability of the test substance reached 16% after 28 days. |
| Results: | The oxygen demand of the reference substance reached > 60% in less than 10 days after adaptation. In the assays containing test substance the adaptation phase in which the demand reached 10%, was 20 days. The rate of oxygen demand reached a value in the range |

of 10 to 30%.

Kinetic:

| Time (Days) | % $O_2$ |
|---|---|
| 3 | 2 |
| 10 | 5 |
| 17 | 7 |
| 21 | 12 |
| 28 | 16 |

Breakdown Products: Not stated

Remarks:

**Conclusions**

Genamin SH 200 is not readily, but very slowly or partially biodegradable. (Author of report)
Due to inconsistency with related chemicals it is considered possible that solubility of the test substance was inadequate for biodegradation. Similar studies frequently employ surfactants to suspend the test material and greater degradation is observed. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Voelskow, H. and K. Demming. 1996. Study on the Ready Biodegradability of Genamin SH 200. Study Number 95-0060-45. Hoechst AG.

**Other Available Reports**

**Other**

Last Changed: June 7, 2002

Order Number for Sorting: 131c

Remarks:

## 3.5 BIODEGRADATION

### Test Substance

| | |
|---|---|
| Identity: | Dicocoamine (CAS RN 61789-76-2; Amines, dicoco alkyl) |
| Purity: | 87.8% |
| Remarks: | |

### Method

| | |
|---|---|
| Method/Guideline followed: | Methods corresponded to OECD Guideline 301D: Ready biodegradability, Closed Bottle Test, and EEC Official Journal of the European Communities L251, 1984, Part C, Method C.6. Degradation-biotic degradation: Closed Bottle Test. Method was adapted for poorly soluble compounds by the use of silica gel as described in ISO document ISO/TC 147SC5/WG4 (1989). |
| Test Type: | Aerobic ready biodegradability |
| GLP: | Yes |
| Year: | 1991 |
| Contact Time: | 42 days |
| Inoculum: | Secondary activated sludge |
| Remarks: | The test assessed the biodegradability of the test substance in the Closed Bottle Test. The test was performed in 280-ml BOD bottles. Duplicate bottles were prepared for each of the following treatments: 1) control blank without inoculum, 2) control with inoculum, 3) test material adsorbed onto silica gel at 2 mg/l, 4) reference substance (sodium acetate) at 6.7 mg/l) and 5) control with inoculum and silica gel. All solutions were prepared in mineral nutrient solution. The test substance was poorly soluble in water and therefore the test substance was first dissolved in dichloromethane. The test substance in dichloromethane was added to 2 g silica gel (100-200 mesh). The solvent was allowed to evaporate and the contents were added to the BOD bottle. Inoculum was preconditioned in the laboratory by aerating the activated sludge for one week, then diluting to a concentration of 2 mg dry weight/l in the BOD bottles. Dissolved oxygen concentrations in the BOD bottles were measured on days 0, 5, 15, 28 and 42. Biodegradation was calculated as the ratio of the biochemical oxygen demand to the theoretical oxygen demand (ThOD) based upon the chemical structure of the test substance. The ThOD of the test substance was 3.3 g $O_2$/g test substance. |

**Results**

Degradation: The biodegradation of the test substance was 20% at day 28 and 18% at day 42.

Results: The test substance was not considered to be readily biodegradable under the conditions of this study.

Kinetic:

| Time (Days) | Test Substance (% BOD/ThOD) | Sodium Acetate (% BOD/ThOD) |
|---|---|---|
| 5 | 2 | 75 |
| 15 | 5 | 83 |
| 28 | 20 | 85 |
| 42 | 18 | -- |

Breakdown Products: Not stated

Remarks: The validity of the test was demonstrated by the oxygen consumption in the control bottle with sodium acetate and an endogenous respiration of 0.8 mg/l. The pH of the medium at day 28 was 7.7.

**Conclusions**

This test result is inconsistent with expected results based on similar chemicals. The use of adsorption to silica may have had significant impact on the bioavailability of the test material since these types of surfactants are known to adsorb tenaciously to solids. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN 2C. Report No. CRL F92004. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 25, 2002

Order Number for Sorting: 130

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Genamin TAP 100 (CAS RN 61791-55-7;Amines, N-tallow alkyltrimethylenedi-) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | 88/302/EWG (Part C); OECD Guidelines for testing of chemicals, Guideline 302 B. |
| Test Type: | Inherent biodegradability |
| GLP: | Not stated |
| Year: | 1990 |
| Contact Time: | 28 days |
| Inoculum: | Activated sludge from the Hoechst purification plant |
| Remarks: | The test assessed the inherent biodegradability of the test substance using the Zahn-Wellens-Test. The inoculum was centrifuged activated sludge containing ≈ 480 mg/l dry weight. Test substance was added in the amount of 704 ml of stock solution to 2 L. The calculated start concentration was 200 mg C/l (DOC). The actual start concentration was 208 mg/l DOC. |

**Results**

| | |
|---|---|
| Degradation: | The results do not allow a prediction on the ready biodegradability of the test substance. |
| Results: | Adsorption in activated sludge after three hours was 87%. DOC elimination in three hours was approximately 90%. |
| Kinetics: | Not stated |
| Breakdown Products: | Not stated |
| Remarks: | As a result of the high adsorption, no prediction on the biodegradation is possible. Expected elimination in industrial purification plants in approximately 90% due to the high adsorption. DOC degradation is not assignable. |

**Conclusions**

| | |
|---|---|
| Remarks: | The results do not allow a prediction on the ready biodegradability of the test substance. (Author of report)<br>Adsorption significantly affected the conduct and interpretation of this test. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability: | 1A |
| Remarks: | Reliable without restriction; guideline study. |

**References**

Voelskow, H. 1990. Study of the Biodegradability in the Zahn-Wellens-Test. Report Number 90-0093-W-1. Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 7, 2002 |
| Order Number for Sorting: | 282 |
| Remarks: | |

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Ethomeen C/12 (CAS RN 61791-31-9; Ethanol, 2,2'-iminobis-, N-coco alkyl derivs.) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Test methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 301D: Ready Biodegradability, Closed Bottle Test. Modifications to the method were described in Blok et al. (1985). |
| Test Type: | Aerobic ready biodegradability |
| GLP: | Yes |
| Year: | 1989 |
| Contact Time: | 42 days |
| Inoculum: | Activated sludge. |
| Remarks: | Two tests were run, the first test used inoculum originating from a municipal sewage treatment plant, while the second test used a composite inoculum originating from several industrial wastewater treatment plants. The sludge was preconditioned by aerating a sludge suspension (s.s) of 1 g s.s./l in dilution water for a period of three days. Sludge was diluted to a concentration of 3 mg s.s./l for use in the test. The test substance was poorly water soluble, and emulsions were made in stock solutions using Genapol PF-40 and nonylphenol ethoxylate. The emulsifiers are non-toxic to bacteria and not biodegradable under test conditions. Each biodegradation test was set-up using three replicates of each of the following treatment groups: 1) mineral solution without test material and without inoculum, 2) mineral nutrient solution with sodium acetate as a biodegradable reference material, 3) mineral nutrient solution with emulsifier, and 4) mineral nutrient solution with test substance at 1.0 mg/l (for the domestic sludge test) or at 2.4 mg/l (for the industrial sludge test). On days 0, 14, 28, and 42, dissolved oxygen concentrations were measured in each bottle. Biodegradation was calculated as the ratio of the BOD to the COD (x 100) of the test substance. |

**Results**

| | |
|---|---|
| Degradation: | <u>Domestic sludge test:</u><br>The test substance was degraded by 61% by day 28 |

and 62% by day 42.
Industrial sludge test:
The test substance was degraded by 61% by day 28 and 60% by day 42.

Results: The test substance may be regarded as readily biodegradable.

Kinetic:

| Biodegradation with Industrial Sludge | | |
|---|---|---|
| **Time (Week)** | **Test Substance (% BOD/COD)** | **Sodium Acetate (% BOD/COD)** |
| 2 | 44 | 81 |
| 4 | 61 | 83 |
| 6 | 60 | 85 |

| Biodegradation with Domestic Sludge | | |
|---|---|---|
| **Time (Week)** | **Test Substance (% BOD/COD)** | **Sodium Acetate (% BOD/COD)** |
| 2 | 24 | 81 |
| 4 | 61 | 83 |
| 6 | 62 | 85 |

Breakdown Products: Not stated

Remarks: The tests were considered valid due to the reference compound sodium acetate being degraded to >80% by day 13.

**Conclusions**

The biodegradability of Ethomeen C/12 has been adequately characterized by this study. In addition, biodegradation was demonstrated for municipal and industrial activated sludge sources. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Balk, F. and E.E. Hantink-de Rooij. 1989. Biodegradability of ETHOMEEN C/12. Study/Report No. F89012. Akzo Corporate Research.

**Other Available Reports**

**Other**

Last Changed: July 26, 2002

Order Number for Sorting: 108

Remarks:

## 3.5 BIODEGRADATION

**Test Substance**

| | |
|---|---|
| Identity: | Tallowbis (2-hydroxyethyl) amine (CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.) |
| Purity: | 98% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Test methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 301D: Ready Biodegradability, Closed Bottle Test, and EEC, Official Journal of the European Communities, L251, Method C.6. Degradation-biotic degradation: Closed Bottle Test. |
| Test Type: | Aerobic ready biodegradability |
| GLP: | Yes |
| Year: | 1990 |
| Contact Time: | 35 days |
| Inoculum: | Activated sludge |
| Remarks: | The closed bottle test was carried out in 280-ml glass BOD bottles. Activated sludge was preconditioned by aerating a suspension of the material for one week in order to reduce high residual respiration rates. The density of the inoculum in the test was 2 mg dry weight/l. The test substance was soluble at the test concentration, and an aqueous stock solution was prepared at 1.0 g/l. The biodegradation test was set-up using two replicates of each of the following treatment groups: 1) mineral solution without test material and without inoculum, 2) mineral nutrient solution without test material but with inoculum, 3) mineral nutrient solution with test substance (2 mg/l) and with inoculum, and 4) mineral nutrient solution with sodium acetate at 6.7 mg/l as a biodegradable reference material. On days 0, 5, 15, 28, and 35, dissolved oxygen concentrations were measured in each bottle. Biodegradation was calculated as the ratio of the BOD to the theoretical BOD of the test substance (×100). |

**Results**

| | |
|---|---|
| Degradation: | The percent biodegradation of the test substance was 52% at day 28 and 62% at day 35. |
| Results: | The results indicate that the test substance should be classified as readily biodegradable. The plot of the biodegradation curve indicated that following a lag |

phase of approximately 15 days, biodegradation of the test substance proceeded rapidly.

Kinetic:

| Time (Days) | Test Substance (% BOD/ThOD) | Sodium Acetate (% BOD/ThOD) |
|---|---|---|
| 5 | 0 | 79 |
| 15 | 0 | 83 |
| 28 | 52 | 88 |
| 35 | 62 | -- |

Breakdown Products: Not stated

Remarks: The validity of the test was demonstrated by oxygen consumption in the bottles containing sodium acetate and an endogenous respiration of 0.4 mg/l. The pH of the medium was 6.8 on day 28.

**Conclusions**

The biodegradability of Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs. was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. 1990. Biodegradability of ETHOMEEN T/12. Report/Study No. CRL F90192. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 27, 2002

Order Number for Sorting: 111

Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Genamin 12 R 100 D (CAS RN 124-22-1; Dodecylamine) |
| Purity: | >99.9% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 203, Fish, Acute Toxicity Test |
| Type: | Static |
| GLP: | Yes |
| Year: | 1984 |
| Species/Strain/Supplier: | Zebra Fish (*Brachydanio rerio*)/Supplier: Hoechst AG |
| Analytical Monitoring: | Not stated |
| Exposure Period: | 96 hours |
| Statistical Methods: | Not stated |
| Remarks: | The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. Dilution water was reconstituted water according to ISO/DIN 7346/1 with the following chemistry parameters: pH = 7.9 to 8.2; $O_2$ = 100%. The vehicle was ethanol. The study consisted of four separate tests performed within a period of one month under the same conditions and with comparable results. The four tests included:<br>test 1: 0 (untreated), 0 (vehicle), 2.5, 3.5 mg/l<br>test 2: 0 (untreated), 1.0, 1.8 mg/l<br>test 3: 0 (untreated), 0.5, 0.71 mg/l<br>test 4: 0 (untreated), 0.25, 0.35 mg/l<br>Each test was run with 16-liter glass vessels containing 10 liters of test medium with 10 fish/treatment. The fish, measuring 26 – 34mm, were fed twice daily in the pretreatment but were unfed during the test. Throughout the test, the test temperature was 21 to 22°C, dissolved oxygen ≥ 69%, pH = 7.4 to 8.3 and the photoperiod was 12 at ~700 lux. The fish were evaluated for mortality and symptoms of toxicity. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (untreated), 0 (vehicle), 0.25, 0.35, 0.5, 0.71, 1.0, 1.8, 2.5, and 3.5 mg/l |
| Measured concentrations (mg/l): | Not determined |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ = 0.42 mg/l |
| Remarks: | At concentrations ≥0.5 mg/l, symptoms and 100% |

mortality occurred. Fish exposed to 0.25 and 0.35 mg/l showed some symptoms but no mortality. Symptoms observed in these groups included swimming at the water surface with the nose up and decreased activity. Fish in the 0.5 to 2.5 mg/l groups exhibited the following symptoms: fish at the bottom or at surface, upside-down position, swimming with the nose up, decreased activity, irregular or increased respiration, open gill, dark discoloration, decreased fright reaction, turning and darting around with flight behavior. Additional endpoints included:
$LC_0$ = 0.35 mg/l
$LC_{100}$ = 0.5 mg/l

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1D

Remarks: Reliable with restriction; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

**References**

Markert, Dipl.-Ing. and R. Jung. 1988. Genamin 12R 100D Pruefung der akuten Toxizitaet am Fisch Zebrabaerbling (Brachydanio rerio) ueber 96. [Study of the Acute Toxicity to Fish – Zebra Fish (*Brachydanio rerio*) – over 96 Hours.] Stunden 88.0256/87.1503. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other Available Reports**

**Other**

Last Changed: June 24, 2002

Order number for sorting: 30b

Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Armeen HT (CAS RN 61788-45-2; Amines, hydrogenated tallow alkyl) |
| Purity: | 99% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Test methods complied with OECD Test Guideline No. 203 and EEC Test Guideline C.1. |
| Type: | Static-renewal, renewal at 48 hours |
| GLP: | Yes |
| Year: | 1991 |
| Species/Strain/Supplier: | Zebra fish (*Brachydanio rerio*)/Local aquarium retailer (Rasbora, Veenendaal) |
| Analytical Monitoring: | No |
| Exposure Period: | 96 hours |
| Statistical Methods: | $LC_{50}$ calculations made by computer program (Akzo programme SKBT, V1.0) using trimmed Spearman-Karber and binomial test methods. |
| Remarks: | The test measured the acute toxicity of the test substance to Zebra fish. Testing was conducted in 5-liter glass vessels containing 3 liters of test solution. Single vessels were used per treatment level with 7 fish in each vessel. Vessels were covered with glass plates during testing. Fish were approximately 3 cm in length and weighed approximately 0.3 – 0.4 g. Fish were held in the laboratory for at least 12 days and fed one to three times per day, six days/week. Feed was withheld the 24 hours prior to testing and during the test. Dilution water used in the test was Dutch Standard Water, having a pH of approximately 8.2 and a hardness of 11.7°dH. Exposure concentrations of the test substance were made as aqueous emulsions using Tween 80 as an emulsifier. An aqueous stock solution of the test substance was prepared by adding 1 gram of test substance with 1 g of Tween 80/l in 100 ml of deionized water. The mixture was ultrasonically treated; thereafter, deionized water was added to bring the volume to 1 liter. Test concentrations were made by addition of aliquots of the stock solution to 3 liters of dilution water. Two control groups were included, one of dilution water and one of dilution water containing an amount of Tween 80 equivalent to that used to prepare the test concentrations. This procedure was repeated at 48 hours and the fish were transferred |

to the fresh solutions. Biomass loading of the test vessels was approximately 0.7 g of biomass/l. Test solutions were aerated during the test. The test was carried out in a temperature-controlled incubator. The light regime in the room was 12 hours of ambient light per day, provided by fluorescent tubes. Measurements of pH and the dissolved oxygen concentration were carried out daily, and during the renewal day, measurements were done in both new and old solutions. The temperature ranged from 22.7 to 23.8°C, the pH ranged from 8.0 to 8.3, and the dissolved oxygen concentrations were ≥79% of the air saturation value. Mortalities were recorded at least at 24, 48, 72 and 96 hours.

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0 (Tween 80 control), 0.1, 0.18, 0.32, 0.58, and 1.05 mg/l |
| Measured concentrations (mg/l): | NA |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ = 0.88 mg/l<br>(95% confidence limit of 0.72 to 1.1 mg/l) |
| Remarks: | After 96 hours, 5/7 fish had died in the highest test concentration. No fish died in any of the other test concentrations or controls. However, fish in the 0.18, 0.32, 0.58 and 1.05 mg/l showed reduced activity. The NOEC based on mortality was 0.58 mg/l; the NOEC based on the finding of reduced activity in the fish was 0.1 mg/l.<br>Additional endpoints included:<br>72-hour $LC_{50}$ = 0.88 mg/l<br>(95% confidence limit of 0.72 to 1.1 mg/l) |

**Conclusions**

| | |
|---|---|
| Remarks: | The 96-hour acute toxicity of Amines, hydrogenated tallow alkyl to Zebra fish was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1D |
| Remarks: | Reliable with restriction; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline. |

**References**

Mark, U. and I. Arends. 1991. Acute Toxicity of ARMEEN HT to *Brachydanio rerio*. Report/Study No. CRL F91082. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 23, 2002
Order number for sorting: 106
Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Amine KK (CAS RN 61788-46-3; Amines, coco alkyl) |
| Purity: | ≥ 94% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 203, Fish, Acute Toxicity Test |
| Type: | Semistatic |
| GLP: | Yes |
| Year: | 1984 |
| Species/Strain/Supplier: | Onchorhynchus mykiss/Parkwood Trout Farm, Wigmore, Kent, UK |
| Analytical Monitoring: | No |
| Exposure Period: | 96 hours |
| Statistical Methods: | Thomson 1947. |
| Remarks: | The study measured the acute toxicity of the test substance to Rainbow Trout during a 96-hour exposure period. The vehicle was 1% Tween 80-acetone. Fish size: 44 ± 1 mm; 1.13 ± 0.15 g. Loading was 0.56 g/l. Fish were fed until 24-hours pretest but were unfed during the test. Ten fish per group were exposed to the test substance at concentrations of 0 (untreated control), 0 (vehicle control at 0.1 ml/l), 0.10, 0.18, 0.32, 0.56 and 1.0 mg/l for 96 hours with daily renewal. Dilution water was dechlorinated laboratory tap water with the following chemistry parameters: hardness = 50 mg $CaCO_3$/l; TOC = 0.9 mg/l; Ca/mg ratio = 1/3; Na/K ratio = 24/1 and pH =8.7. Test conditions were: temperature = 14°C; Dissolved oxygen = 95-97%; pH = 7.3 to 7.6; and photoperiod = 16 hours. Tests were conducted in glass aquaria with 20-l test medium and 10 fish/treatment. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (untreated), 0 (vehicle), 0.10, 0.18, 0.32, 0.56, 1.0 mg/l |
| Measured concentrations (mg/l): | NA |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ = 0.16 mg/l (95% confidence limit of 0.13 to 0.19 mg/l) |

Remarks: No fish died at concentrations ≤ 0.10 mg/l. Seventy percent mortality occurred at the 0.18 mg/l concentration and 100% mortality at concentration ≥ 0.32 mg/l. Dose-related effects at concentrations ≥ 0.18 mg/l included loss of equilibrium, swimming at bottom, increased pigmentation and /or lethargy. NOEC = 0.10 mg/l

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1D

Remarks: Reliable with restrictions; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

**References**

Handley, J.W. and P.M. Wetton. 1991. The acute toxicity of Amine KK to Rainbow trout (Onchorhynchus mykiss). Project No 116/69. Berol Nobel Nacka AB, Safepharm Laboratories.

**Other Available Reports**

**Other**

Last Changed: June 26, 2002

Order number for sorting: 91a

Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Genamin CC 100D (CAS RN 61788-46-3; Amines, coco alkyl) |
| Purity: | 99 - 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 203, Fish, Acute Toxicity Test |
| Type: | Static |
| GLP: | Yes |
| Year: | 1984 |
| Species/Strain/Supplier: | Zebra Fish (*Brachydanio rerio*)/Hamilton-Buchanan/ Hoechst AG |
| Analytical Monitoring: | No |
| Exposure Period: | 96 hours |
| Statistical Methods: | Probit Analyses (Linder and Weber, Fieller) |
| Remarks: | The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. The vehicle was ethanol (concentration of vehicle/solvent = 0.1 ml/l).<br>Fish size: 25 – 31mm.<br>Fish were fed twice daily in the pretreatment but were unfed during the test.<br>Five tests in 16-L glass vessels containing 10-L of test medium with 10 fish/treatment:<br>test 1: 0 (untreated), 0 (vehicle), 10 mg/l<br>test 2: 0 (untreated), 1.0 mg/l<br>test 3: 0 (untreated), 0.35, 0.5 mg/l<br>test 4: 0 (untreated), 0.01 mg/l<br>test 5: 0 (untreated), 0.12, 0.18, 0.25 mg/l.<br>Test conditions: temperature = 21 to 23°C; dissolved oxygen ≥65%; pH = 7.1 to 8.3; photoperiod = 12 hours at ~700 lux. The five separate tests were performed within a period of two months under the same conditions and with comparable results. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (untreated), 0 (vehicle), 0.01, 0.12, 0.18, 0.25, 0.35, 0.5, 1.0, 10 mg/l |
| Measured concentrations (mg/l): | Not stated |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ = 0.24 mg/l<br>(95% confidence limit of 0.20 to 0.30 mg/l) |
| Remarks: | At concentrations ≤0.12 mg/l all fish survived; 30% |

mortality was noted at 0.18 and 0.25 mg/l; and 100% mortality was observed at concentrations ≥0.35 mg/l. Clinical signs were noted in 0.12 to 1.0 mg/l concentrations and included irregular respiration, decreased or increased activity, fish at bottom or surface, open gill, dark coloration, swim attitude with difficult tail, increased or decreased shock reaction, laying on the back, problems with the fins and/or convulsions.
Additional endpoints included:
$LC_0$ = 0.12 mg/l
$LC_{100}$ = 0.35 mg/l

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1D

Remarks: Reliable with restrictions; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

**References**

Markert, M. and R. Jung. 1988. Genaminox CC 100 D Pruefung der akuten Toxizitaet am Fisch Zebraaerbling (Brachydanio rerio). [Genaminox CC 100D Acute toxicity study in Zebra fish (Brachydanio rerio)] Study No 88.0558/88.0093. Hoechst AG, Hoechst AG.

**Other Available Reports**

**Other**

Last Changed: June 26, 2002

Order number for sorting: 91b

Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Tallow amine (CAS No. 61790-33-8; Amines, tallow alkyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | U.S. EPA 600/3-75-009: Methods for acute toxicity tests with fish, macroinvertebrates, and amphibians. |
| Type: | Static |
| GLP: | Not stated |
| Year: | 1985 |
| Species/Strain/Supplier: | Bluegill (*Lepomis macrochirus*)/commercial supplier |
| Analytical Monitoring: | No |
| Exposure Period: | 96 hours |
| Statistical Methods: | Computer program, developed by C.E Stephan to calculate $LC_{50}$ by moving average, probit and binomial probability (Stephan, C.E. 1982. US EPA Environmental Research Laboratory, Duluth, MN. Personal communication to Dr. Lowell Bahner, Chairman ASTM Task Group on Calculating $LC_{50}$'s) |
| Remarks: | The test measured the acute toxicity of the test substance to juvenile bluegill during a 96 hour static exposure period. Juvenile bluegills were exposed to six concentrations of the test substance, a solvent and negative control. Test chambers were 19.6-l glass jars holding 15 l of test solution. Solution depth was 27.5 cm and the surface area was 545 $cm^2$. No replicates were used in the test. Dilution water was river water having the following characteristics: total hardness 50 mg/l as $CaCO_3$, alkalinity 24 mg/l as $CaCO_3$, pH 7.7 and specific conductance 360 µmhos/cm. Exposure concentrations of the test substance were prepared by diluting a working stock solution that had been prepared in acetone. Aliquots of the stock were added to dilution water, stirred and apportioned among triplicate test chambers for each treatment group. The test was run at a temperature of 22±1°C under a 16 h light/8 h dark photoperiod. At test initiation, 10 fish were impartially distributed to each test chamber. Fish were not fed during testing, and mortalities were recorded at 24, 48, 72 and 96 hours. Dissolved oxygen and pH were measured at 0, 48, 72 and 96 hours in one replicate vessel of the control, solvent control, and the low, middle and high |

exposure groups. Temperature was measured in one control vessel at 0, 24, 48, 72 and 96 hours. All water quality factors were within the correct ranges during the test.

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (negative control), 0 (solvent control), 8.0, 12, 24, 36, 60, 100 mg/l |
| Measured concentrations (mg/l): | Not determined |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ = 9.3 mg/l (95% confidence interval of 6.3 to 12 mg/l) |
| Remarks: | The no-observed-effect level was <8.0 mg/l based on 30% mortality occurring at that concentration. Complete mortality occurred in the 100, 60, 36, and 24 mg/l treatments. 80% mortality occurred at 12 mg/l. |

**Conclusions**

| | |
|---|---|
| Remarks: | The acute toxicity of the test substance to bluegill was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1D |
| Remarks: | Reliable with restriction; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline. |

**References**

Springborn Bionomics, Inc. 1986. Acute Toxicity of Adogen 170D to Bluegill (*Lepomis macrochirus*) in River Water. Toxicity test report submitted to Sherex Chemical Company, Dublin, Ohio. Bionomics Report No. BW-86-3-1955; Study No. 11,187-0585-6101-100.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 25, 2002 |
| Order number for sorting: | 214a |
| Remarks: | |

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Genamin TA 100 D (CAS No. 61790-33-8; Amines, tallow alkyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD 203 "Fish, Acute Toxicity Test" |
| Type: | Static |
| GLP: | Yes |
| Year: | 1984 |
| Species/Strain/Supplier: | *Brachydanio rerio*/Hoechst AG |
| Analytical Monitoring: | Not stated |
| Exposure Period: | 96 hours |
| Statistical Methods: | Probit analyses (Linder and Weber, Fieller) |
| Remarks: | The fish were 24-31 mm in length; fed twice daily *ad libitum* with Tetra Min pretreatment and were not fed during treatment. Tween 80 was used as the vehicle/solvent at a concentration of 0.1 ml/l. Dilution water was reconstituted water according to ISO/DIN 7346/1; pH of 7.8 to 8.2; $O_2$ 100%. Exposure conditions: vessels were 16 L glass vessels containing 10 liters of test medium; 10 fish per treatment level; temperature = 21 to 23 °C; dissolved oxygen = ≥60%; pH = 7.2 to 8.2; photoperiod = 12 hour at ~ 700 lux. The test consisted of six separate tests performed within a period of 2 months under the same conditions and with comparable results. Each test run included an untreated control group. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (negative control), 0 (vehicle control), 0.01, 0.12, 0.18, 0.25, 0.35, 0.5,1 and 10 mg/l |
| Measured concentrations (mg/l): | Not determined |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ >0.18 mg/l and < 0.25 mg/l |
| Remarks: | At 1 and 10 mg/l test substance was observed at the water surface (the test substance was stated as insoluble); at the relevant test concentrations (around the $LC_{50}$), slight turbidity was observed. Following are the mortality results (number dead/number treated):<br>0 (untreated control) = 0/60<br>0 (vehicle control) = 0/10<br>0.01 mg/l = 0/10 |

0.12 mg/l = 0/10
0.18 mg/l = 0/10
0.25 mg/l = 8/10
0.35 mg/l = 10/10
0.5 mg/l = 10/10
1 mg/l = 10/10
10 mg/l = 10/10

Other effects include: Clinical signs including, swimming with the nose up, decreased or increased activity, respiration or shock reaction, irregular respiration, fish at the bottom or at surface, active movement upwards and passive movement downwards, open gill, dark discoloration, problems with the fins, white tops of fins and/or convulsions, were noted in the 0.12 to 1 mg/l dose groups. At 0.01 mg/l some fish showed open gills until 48 hours after start of test.

**Conclusions**

Remarks: The acute toxicity of the test substance was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1D

Remarks: Reliable with restrictions; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

**References**

Markert, M. and R. Jung. 1988. Genamin TA 100 D Pruefung der akuten Toxizitaet am Fisch Zebrabaerbling (Brachydanio rerio) ueber 96 [Genamin TA 100 D Acute toxicity study in Zebra fish over 96 hours] Stunden (88.0614/88.0098). Hoechst AG.

**Other Available Reports**

**Other**

Last Changed: August 9, 2002

Order number for sorting: 214b

Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | 9-Octadecen-1-amine; oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | 94% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Test methods conformed to U.S. EPA Ecological Effects Test Guideline: OPPTS 850.1085: Fish Acute Toxicity Mitigated by Humic Acid. |
| Type: | Static |
| GLP: | Yes |
| Year: | 1995 |
| Species/Strain/Supplier: | Fathead minnow (*Pimephales promelas*)/NA/SP Inc., Salem, Massachusetts |
| Analytical Monitoring: | Yes, in the control, low, mid and high test concentrations |
| Exposure Period: | 96 hours |
| Statistical Methods: | NA |
| Remarks: | The study measured the acute toxicity of the test substance to fathead minnows during a 96-hour exposure period. Exposures were conducted without humic acid and with humic acid in the dilution water at 10 and 20 mg/l. The summary includes data only for the portion of the study that reports the exposure without humic acid present in the dilution water. The dilution water used in the test was synthetic water (Dutch Standard Water). Test fish were received from the supplier and held in the laboratory until testing. During holding, fish were fed a commercial fish diet one to three times daily, five to seven times per week. Fish were not fed during the test. The mean length and wet weight of fish used in the test were 2.1 cm and 0.16 g, respectively. The fish appeared in good health prior to the test. To prepare the test concentrations, an aqueous stock of the test substance (0.11 g/l) was made and aliquots of the stock were diluted with dilution water. Test vessels were 9.9-liter containers holding 5 liters of test solution. Concentrations were replicated twice, with each replicate holding 10 fish (20 per concentration). Fish loading per chamber was 0.32 g/l. The treatment groups were 0 (control), 0.05, 0.09, 0.15, 0.27, and 0.49 mg/l. The test solutions were prepared, the fish were randomly placed in the test solutions and the test vessels were randomly placed in |

the testing area. All test vessels were covered with a glass plate during the test. Test solutions were aerated during the test period. The testing area had a lighting regime of 16 hours light/8 hours dark. Dissolved oxygen and pH were measured daily, and temperature was measured continuously. Concentrations were measured in the control, 0.05, 0.15, and 0.49 mg/l test groups at 0, 24, 48 and/or 96 hours. Mortality and sublethal effects were recorded at a minimum at 0, 24, 48, 72 and 96 hours. Fish were considered dead when a lack of opercular movement was observed. Sublethal effects included erratic swimming, loss of reflex, increased excitability, lethargy, changes in physiology, discoloration, pigmentation, excessive mucus production, hyperventilation, opaque eyes, curved spine and haemorrhaging. Water quality parameters measured in the dilution water included acidity (0.3 mmol/l), alkalinity (1.6 mmol/l), conductivity (607 µS/cm), water hardness (12.06°dH, equivalent to 215 mg $CaCO_3$/l), total suspended solids (0.03 mg/l), and nonpurgeable organic carbon (1.022 mg/l). Dissolved oxygen ranged from 8.4 to 9.0 mg/l and pH ranged from 8.0 to 8.2. Endpoint results are given based on nominal concentrations.

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0.05, 0.09, 0.15, 0.27, and 0.49 mg/l |
| Measured concentrations (mg/l): | Measured concentrations were 13 to 82% below the nominal concentrations. The control water measured 0.014 mg/l at 0 and 96 hours; the 0.05 mg/l test level measured 0.032 and 0.018 mg/l at 0 and 96 hours, respectively; the 0.15 mg/l test level measured 0.12, 0.05, and 0.02 mg/l at 0, 24 and 48 hours, respectively; and the 0.49 mg/l test level measured 0.40 and 0.21 mg/l at 0 and 24 hours, respectively. |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ = 0.11 mg/l (95% confidence limit of 0.09 to 0.15 mg/l) |
| Remarks: | Complete mortality occurred at 0.15, 0.27, and 0.49 mg/l. No mortality or sublethal effects were noted in the fish at concentrations up to and including 0.09 mg/l. |

Additional endpoints included:
72-hour NOEC = 0.09 mg/l
24-h $LC_{50}$ = 0.12 mg/l (0.11 – 0.12 mg/l)
48-h $LC_{50}$ = 0.11 mg/l (0.09 – 0.15 mg/l)
72-h $LC_{50}$ = 0.11 mg/l (0.09 – 0.15 mg/l)

**Conclusions**

Remarks: The 96-hour acute toxicity of 9-Octadecen-1-amine to fathead minnows was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study.

**References**

Mark, U.E., I.C.M. Garttener, M.G.J. Geurts, M.W.F. Nielen, C.A. Stroo and A.G.M. Kroon. 1995. Acute Toxicity of Oleylamine to *Pimephales promelas*. Report No. RGL F95031. Akzo Nobel Central Research, Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 17, 2002
Order number for sorting: 14
Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | FARMIN DM20 (CAS RN 112-18-5; N,N-Dimethyl-1-dodecanamine) |
| Purity: | Approximately 97%. |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated. |
| Type: | Static |
| GLP: | No |
| Year: | 1996 |
| Species/Strain/Supplier: | Rainbow trout (*Oncorhynchus mykiss*)/Fish Network Ltd., Devon. |
| Analytical Monitoring: | Not stated. |
| Exposure Period: | 96 hours |
| Statistical Methods: | Non-linear interpolation between two concentrations, which bracket the 50% effect level. |
| Remarks: | The study measured the acute lethal toxicity of the test substance to rainbow trout during a 96-hour exposure period. Groups of five fish were exposed to the test substance; mean wet-weight of the fish was 2.3 g and mean length was 5.8 cm. The test was conducted at 13.0 – 13.9 °C in treated tap water with the hardness of 216 to 244 mg/l as $CaCO_3$ and the pH in the range of 7.8 – 8.5. The test media were gently aerated during the test. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0, 0.1, 0.32, 1.0, 3.2, 10, 32, and 100 mg/l |
| Measured concentrations (mg/l): | Not determined |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ = 0.57 mg/l |
| Remarks: | At concentrations ≥1.0 mg/l, there was 100% mortality by 24 hours of exposure. At 0.32 mg/l, all fish exhibited treatment-related effects, including darkened pigmentation and immobility. At 100 mg/l, the test media was hazy; lower concentrations were clear and colorless.<br>NOEC = 0.1 mg/l<br>96-hour $LC_0$ = 0.32 mg/l<br>96-hour $LC_{100}$ = 1.0 mg/l |

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 2A

Remarks: Reliable with restrictions; acceptable, well documented study report which meets basic scientific principles.

**References**

Jenkins, C. A. 1996. FARMIN DM20: Acute Toxicity to Rainbow Trout. Report No. 96/KAS163/0891. Huntingdon Life Sciences Ltd. Eye, Suffolk, UK. Including cover letter from High Point Chemical to U.S. E.P.A. concerning reference report. January 22, 1999.

**Other Available Reports**

**Other**

Last Changed: June 12, 2002

Order number for sorting: 124a

Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | FARMIN DM40 (CAS RN 112-75-4; 1-Tetradecanamine, N,N-dimethyl) |
| Purity: | Approximately 97%. |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated. |
| Type: | Static |
| GLP: | No |
| Year: | 1996 |
| Species/Strain/Supplier: | Rainbow trout (*Oncorhynchus mykiss*)/Fish Network Ltd., Devon. |
| Analytical Monitoring: | Not stated. |
| Exposure Period: | 96 hours |
| Statistical Methods: | Non-linear interpolation between two concentrations, which bracket the 50% effect level. |
| Remarks: | The study measured the acute lethal toxicity of the test substance to rainbow trout during a 96-hour exposure period. There were 5 fish/group; mean wet-weight of the fish was 2.3 g and mean length was 5.7 cm. The test was conducted at 13.0 to 14 °C in treated tap water with a hardness of 234 to 252 mg/l as $CaCO_3$ and the pH in the range of 7.8 to 8.3. The media were gently aerated during the test. Water hardness slightly exceeded 250 mg/l recommended for this test but it was not thought to have affected the integrity of the test. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0, 0.1, 0.32, 1.0, 3.2, 10, 32, and 100 mg/l |
| Measured concentrations (mg/l): | Not determined |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ = 0.18 mg/l |
| Remarks: | At concentrations ≥3.2 mg/l, all fish were adversely affected exhibiting hyperventilation, darkened pigmentation and/or loss of coordination. At concentrations ≥1.0 mg/l there was100% mortality after 24 hours exposure and at 0.32 mg/l there was 100% mortality after 48 hours. At 32 and 100 mg/l, the test media were hazy dispersions; other concentrations were clear and colorless. |

NOEC < 0.1 mg/l
96-hour $LC_0$ = 0.1 mg/l
96-hour $LC_{100}$ = 0.32 mg/l

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 2A

Remarks: Reliable with restrictions; acceptable, well-documented study report which meets basic scientific principles.

**References**

Jenkins, C. A. 1996. FARMIN DM40: Acute Toxicity to Rainbow Trout. Report No. 96/KAS177/0230. Huntingdon Life Sciences Ltd. Eye, Suffolk, UK. Including cover letter from High Point Chemical to U.S. E.P.A. concerning reference report. January 22, 1999.

**Other Available Reports**

**Other**

Last Changed: June 12, 2002

Order number for sorting: 255

Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Genamin MY 302 D (CAS RN 112-75-4; 1-Tetradecanamine, N,N-dimethyl) |
| Purity: | approximately 99% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD 203; 84/449/EWG C.1.; UBA VV May 1984 |
| Type: | Static |
| GLP: | Not stated |
| Year: | 1988 |
| Species/Strain/Supplier: | Zebra Fish (*Brachydanio rerio*)/Not stated/Not stated |
| Analytical Monitoring: | Not stated |
| Exposure Period: | 96 hours |
| Statistical Methods: | Not stated |
| Remarks: | The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0.1 and 1 mg/l |
| Measured concentrations (mg/l): | Not stated |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ >0.1 and < 1.0 mg/l |
| Remarks: | Symptoms and 100% mortality occurred at 1 mg/l. At 0.1 mg/l symptoms, but no mortality occurred. Additional endpoints included: 48-hour $LC_{50}$ >0.1 and < 1.0 mg/l; $LC_0$ = 0.1 mg/l after 48 and 96 hours, $LC_{100}$ = 1 mg/l; after 48 and 96 hours. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability: | 1D |
| Remarks: | Reliable without restriction; guideline study with minimal details provided. |

**References**

Jung, R. 1988. Short Report: Acute Fish Toxicity. Report Number 88.0057. Pharma Forschung Toxikologie, Germany.

## Other Available Reports

### Other

| | |
|---|---|
| Last Changed: | June 7, 2002 |
| Order number for sorting: | 259 |
| Remarks: | |

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Genamin 14 R 302 D (CAS RN 112-75-4; 1-Tetradecanamine, N,N-dimethyl) |
| Purity: | approximately 99% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD 203; 84/449/EWG C.1.; UBA May 1984 |
| Type: | Static |
| GLP: | Not stated |
| Year: | 1988 |
| Species/Strain/Supplier: | Zebra Fish (*Brachydanio rerio*)/Not stated/Not stated |
| Analytical Monitoring: | Not stated |
| Exposure Period: | 96 hours |
| Statistical Methods: | Not stated |
| Remarks: | The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. Tween 80 was used as the solvent in the test chambers. The control group was exposed to Tween 80 at 0.1 ml/l. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0, 0.01, 0.1 and 1 mg/l |
| Measured concentrations (mg/l): | Not stated |
| Unit: | mg/l |
| Element value: | $LC_{50}$ |
| Statistical Results: | The 48-hour $LC_{50}$ >0.01 mg/l and <0.1 mg/l<br>The 96-hour $LC_{50}$ >0.01 mg/l and <0.1 mg/l |
| Remarks: | At 0.1 and 1 mg/l, symptoms and mortality occurred (100% each). At 0.01 mg/l, symptoms but no mortality occurred. $LC_0$ = 0.01 mg/l, after 48 and 96 hours; $LC_{100}$ = 0.1 mg/l after 48 and 96 hours.<br>Additional endpoints included:<br>$LC_0$ = 0.01 mg/l after 48 and 96 hours<br>$LC_{100}$ = 0.1 mg/l after 48 and 96 hours |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability: | 1D |
| Remarks: | Reliable without restriction; guideline study with minimal details provided. |

**References**

Jung, R. 1988. Short report: Acute Fish Toxicity – Zebra Fish, 96 Hours, Static. Report Number 88.0115. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 7, 2002 |
| Order number for sorting: | 260g |
| Remarks: | |

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Genamin 14 R 302 D (CAS RN 112-75-4; 1-Tetradecanamine, N,N-dimethyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 203 |
| Type: | Static renewal |
| GLP: | Yes |
| Year: | 1992 |
| Species/Strain/Supplier: | Zebra Fish (*Brachydanio rerio*)/Not stated/Zoo-Stumpe, Hildesheim |
| Analytical Monitoring: | No |
| Exposure Period: | 96 hours |
| Statistical Methods: | "Methoden der Wasseruntersuchungen" Bd. II (1982), VEB Gustav Fischer Verlag, Jena. |
| Remarks: | The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. Animals were kept in a temperature range of 20 – 23°C in diffused light (≈5.5 µmol/m$^2$, natural day periodic). The test water was changed weekly. The tap water was prepared by activated charcoal filtration followed by aeration in a light resistant container over at least 24 hours. Feeding occurred six times per week. Food amount consisted of 2% of the fish weight. Test vessels were 15-liter tanks covered with glass plates. Ten zebra fish were placed in each of nine vessels. A parallel control was run with dilution water without addition of test substance. A test with a reference substance was not performed. The test substance was tested in the following concentrations: 0; 0.032; 0.058; 0.10; 0.18 and 0.32 mg/l. Since 100% mortality was not achieved with these concentrations, the test substance was also tested at 0.58 and 1.0 mg/l. An additional parallel control group was tested with these two additional concentrations. The test substance was treated with ultrasound for 30 minutes at 40°C until emulsification. Mortality and behavior of the fish, as well as water pH, temperature and oxygen saturation were logged after 24, 48, 72 and 96 hours. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0; 0.032; 0.058; 0.10; 0.18; 0.32; 0.58 and 1 mg/l |
| Measured concentrations (mg/l): | Not determined |

Unit: mg/l
Element Value: 96-hour $LC_{50}$
Statistical Results: 96-hour $LC_{50}$ = 0.35mg/l
Remarks: At concentrations of 1.0 and 0.58 mg/l 100% mortality occurred at 24 hours. At 0.32 mg/l 20% mortality occurred at 72 and 96 hours. At 0.18 mg/l symptoms, but no mortality were observed. Oxygen saturation ranged from 65 – 99%; pH values ranged from 7.61 – 8.31 and temperature ranged from 20 – 23°C.
Other endpoints included:
96-hour $LC_0$ = 0.18 mg/l
96-hour $LC_{100}$ = 0.58 mg/l

| Time (hours) | $LC_{50}$ (mg/l) | 95% confidence limit |
|---|---|---|
| 24 | 0.43 | 0.39 to 0.47 |
| 48 | 0.43 | 0.39 to 0.47 |
| 72 | 0.35 | 0.29 to 0.41 |
| 96 | 0.35 | 0.29 to 0.41 |

**Conclusions**
Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**
Reliability: 1D
Remarks: Reliable with restrictions; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

**References**

Bauer, S. and U. Noack. 1992. Acute Toxicity Test on Fish (Zebra Fish) of Genamin 14 R 302 D. Project Number 920703HK. Study no. FAZ29691. Dr. U. Noack-Laboratories for Applied Biology, Hildesheim, Germany.

**Other Available Reports**

**Other**
Last Changed: June 7, 2002
Order number for sorting: 260h
Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | FARMIN DM60 (CAS RN 112-69-6; 1-Hexadecanamine, N,N-dimethyl) |
| Purity: | Approximately 97%. |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated. |
| Type: | Static |
| GLP: | No |
| Year: | 1996 |
| Species/Strain/Supplier: | Rainbow trout (*Oncorhynchus mykiss*)/ Fish Network Ltd., Devon. |
| Analytical Monitoring: | Not stated. |
| Exposure Period: | 96 hours |
| Statistical Methods: | Non-linear interpolation between two concentrations, which bracket the 50% effect level. |
| Remarks: | The study measured the acute lethal toxicity of the test substance to rainbow trout during a 96-hour exposure period. There were 5 fish/group; mean wet-weight of the fish was 2.3 g and mean length was 5.8 cm. The test was conducted at 13.2 to 14 °C in treated tap water with a hardness of 234 to 250 mg/l as $CaCO_3$ and the pH in the range of 7.9 to 8.3. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0, 0.1, 0.32, 1.0, 3.2, 10, 32, and 100 mg/l |
| Measured concentrations (mg/l): | Not determined |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ = 0.18 mg/l |
| Remarks: | At concentrations ≥3.2 mg/l, all fish were adversely affected exhibiting hyperventilation, darkened pigmentation and/or loss of coordination. At concentrations ≥0.32 mg/l, there was100% mortality after 24 hours exposure. At concentrations ≥3.2 mg/l, the test media were hazy or opaque dispersions; other concentrations were clear and colorless; at ≥0.32 mg/l there was froth on the surfaces.<br>NOEC < 0.1 mg/l<br>96-hour $LC_0$ = 0.1 mg/l<br>96-hour $LC_{100}$ = 0.32 mg/l |

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 2C

Remarks: Reliable with restrictions; comparable to guideline study with acceptable restrictions.

**References**

Jenkins, C. A. (1996) FARMIN DM60: Acute Toxicity to Rainbow Trout. Report No. 96/KAS177/0231. Huntingdon Life Sciences Ltd. Eye, Suffolk, UK.
Including cover letter from High Point Chemical to U.S. E.P.A. concerning referenced report. January 23, 1999.

**Other Available Reports**

**Other**

Last Changed: June 12, 2002

Order number for sorting: 4a

Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Genamin 16 R 302 D (CAS RN 112-69-6; 1-Hexadecanamine, N,N-dimethyl) |
| Purity: | approximately 99% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD 203; 84/449/EWG C.1./ UBA VV May 1984 |
| Type: | Static |
| GLP: | Not stated |
| Year: | 1988 |
| Species/Strain/Supplier: | *Brachydanio rerio*/Not stated/Not stated |
| Analytical Monitoring: | Not stated |
| Exposure Period: | 96 hours |
| Statistical Methods: | Not stated |
| Remarks: | The study tested the acute toxicity of the test substance to the Zebra Fish under static exposure conditions. Tween 80 was used as the solvent in the test chambers. The control group was exposed to Tween 80 at 100 mg/l. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0.1, 1.0 and 10 mg/l |
| Measured concentrations (mg/l): | Not stated |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ >0.1 mg/l and <1 mg/l |
| Remarks: | At 1 and 10 mg/l symptoms and death occurred. On the last study day, symptoms, but no mortality, occurred at 0.1 mg/l.<br>$LC_0$ = 0.1 mg/l after 48 and 96 hours.<br>$LC_{100}$ = 1 mg/l after 48 and 96 hours. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability: | 1D |
| Remarks: | Reliable without restriction; guideline study with minimal details provided. |

**References**

Jung, R. 1988. Short Report: Acute Fish Toxicity. Report Number 87.1814. Pharma Forschung Toxikologie, Germany.

**Other Available Reports**

**Other**

Last Changed: June 7, 2002
Order number for sorting: 4g
Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | FARMIN DM80 (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl) |
| Purity: | Approximately 97%. |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated. |
| Type: | Static |
| GLP: | Not stated |
| Year: | 1996 |
| Species/Strain/Supplier: | Rainbow trout (*Oncorhynchus mykiss*)/Fish Network Ltd., Devon. |
| Analytical Monitoring: | No. |
| Exposure Period: | 96 hours |
| Statistical Methods: | Non-linear interpolation between two concentrations, which bracket the 50% effect level. |
| Remarks: | The study measured the acute lethal toxicity of the test substance to rainbow trout during a 96-hour exposure period. There were 5 fish/group; mean wet-weight of the fish was 0.88 g and mean length was 4.3 cm. The test was conducted at 13.4 to 16.3 °C in treated tap water with a hardness of 238 to 252 mg/l as $CaCO_3$ and the pH in the range of 7.9 to 8.4. The media was gently aerated during the test. Water hardness slightly exceeded 250 mg/l recommended for this test but it was not thought to have affected the integrity of the test. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0, 0.1, 0.32, 1.0, 3.2, 10, 32, and 100 mg/l |
| Measured concentrations (mg/l): | Not determined |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ = 0.18 mg/l |
| Remarks: | At concentrations ≥1.0 mg/l, there was 100% mortality after 24 hours exposure and at 0.32 mg/l there was 100% mortality after 48 hours. No sub-lethal, treatment-related effects were noted during the test. At ≥3.2 mg/l, the test media were hazy or opaque dispersions; other concentrations were clear and colorless.<br>NOEC = 0.1 mg/l<br>96-hour $LC_0$ = 0.1 mg/l<br>96-hour $LC_{100}$ = 0.32 mg/l |

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 2C

Remarks: Reliable with restrictions; comparable to guideline study with acceptable restrictions.

**References**

Jenkins, C. A. 1996. FARMIN DM80: Acute Toxicity to Rainbow Trout. Report No. 96/KAS184/0232. Huntingdon Life Sciences Ltd. Eye, Suffolk, UK. Including cover letter from High Point Chemical to U.S. E.P.A. concerning referenced report. January 23, 1999.

**Other Available Reports**

**Other**

Last Changed: June 12, 2002

Order number for sorting: 38c

Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Genamin 18 R 302 D (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Test methods conformed to OECD 203; 84/449/EWGC.1.; UBA VV, May 1984 |
| Type: | Static |
| GLP: | Not stated |
| Year: | 1987 |
| Species/Strain/Supplier: | *Brachydanio rerio*/Not stated |
| Analytical Monitoring: | Not stated |
| Exposure Period: | 96 hours |
| Statistical Methods: | Not stated |
| Remarks: | The study measured the acute toxicity of the test substance to the Zebra Fish. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0.1 and 1.0 mg/l |
| Measured concentrations (mg/l): | Not stated |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ >0.1 and <1.0 mg/l |
| Remarks: | Symptoms and mortality developed at 0.1 and 1.0 mg/l. Additional endpoints included:<br>48-hour $LC_{50}$ >0.1 and <1.0 mg/l<br>$LC_{100}$ = 1.0 mg/l<br>$LC_{10}$ = 0.1 mg/l. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability: | 1D |
| Remarks: | Reliable without restriction; guideline study with minimal details provided. |

**References**

Jung, R. 1987. Short Report: Acute Fish Toxicity. Report Number 87.1464. Pharma Forschung Toxikologie, Germany.

## Other Available Reports

### Other

| | |
|---|---|
| Last Changed: | June 7, 2002 |
| Order number for sorting: | 38e |
| Remarks: | |

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Genamin CS 302 D (CAS RN 61788-93-0; Amines, coco alkyldimethyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD 203, 84/449/EWG C.1. and UBA VV May 1984 |
| Type: | Static |
| GLP: | Not stated |
| Year: | 1987 |
| Species/Strain/Supplier: | Zebra Fish (*Brachydanio rerio*)/Not stated/Not stated |
| Analytical Monitoring: | Not stated |
| Exposure Period: | 96 hours |
| Statistical Methods: | Not stated |
| Remarks: | The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0, 0.1 and 1 mg/l |
| Measured concentrations (mg/l): | Not stated |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ > 0.1 mg/l and < 1 mg/l |
| Remarks: | At 1 mg/l symptoms and 100% mortality occurred. Fish exposed to 0.1 mg/l showed symptoms on the first test day.<br>Additional endpoint included:<br>48-hour $LC_{50}$ > 0.1 mg/l and < 1 mg/l |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability: | 1D |
| Remarks: | Reliable without restriction; guideline study with minimal details provided. |

**References**

Jung, R. 1987. Genamin CS 302 D: Study of the Acute Toxicity to Fish – Zebra Fish (*Brachydanio rerio*) – over 96 Hours. Report Number 87.1463. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other Available Reports**

**Other**

Last Changed: June 7, 2002
Order number for sorting: 228d
Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Genamin SO 302 D (CAS RN 61788-91-8; Amines, dimethylsoya alkyl) |
| Purity: | Approximately 99% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD 203, 84/449/EWG C.1. and UBA VV May 1984 |
| Type: | Static |
| GLP: | Not stated |
| Year: | 1987 |
| Species/Strain/Supplier: | Zebra Fish (*Brachydanio rerio*)/Not stated |
| Analytical Monitoring: | Not stated |
| Exposure Period: | 96 hours |
| Statistical Methods: | Not stated |
| Remarks: | The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0, 0.1, 1.0 and 10 mg/l |
| Measured concentrations (mg/l): | Not stated |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ >0.1 and < 1 mg/l |
| Remarks: | At 1 and 10 mg/l, symptoms and 100% mortality occurred. Fish exposed to 0.1 mg/l showed symptoms but no mortality.<br>Additional endpoints included:<br>48-hour $LC_{50}$ >0.1 and < 1 mg/l<br>$LC_0$ = 0.1 mg/l, after 48 and 96 hours;<br>$LC_{100}$ = 1 mg/l after 48 and 96 hours. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability: | 1D |
| Remarks: | Reliable without restriction; guideline study with minimal details provided. |

**References**

Jung, R. 1987. Genamin SO 302 D: Study of the Acute Toxicity to Fish – Zebra Fish (*Brachydanio rerio*) – over 96 Hours. Report Number 87.1813. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other Available Reports**

**Other**

Last Changed: June 7, 2002
Order number for sorting: 104b
Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Genamin SH 301 (CAS RN 4088-22-6; 1-Octadecanamine, N-methyl-N-octadecyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | EG-Guideline C.1. Acute Toxicity to Fish; Guideline 85/559/EWG; OECD Guideline for testing of chemicals, 203 Fish, Acute Toxicity Test |
| Type: | Static |
| GLP: | Yes |
| Year: | 1987 |
| Species/Strain/Supplier: | Zebra Fish (*Brachydanio rerio*)/Hamilton-Buchanan/HOECHST AG, Kastengrund |
| Analytical Monitoring: | No |
| Exposure Period: | 96 hours |
| Statistical Methods: | None |
| Remarks: | The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. The fish were held in dilution water for at least 14 days before the beginning of the study. Water was maintained at 22 ± 1°C by using a water bath calibrated thermometer and with ≥ 80% oxygen saturation. Lighting regime was 12-hour day/night cycles at approximately 700 lux. Feeding was twice daily. Immediately before the study start, as representatives for the batch of fish, 10 fish from each of two trials were measured for body length. These fish were not used in the study. The mean body length of the fish was 2.8 cm.<br>The study was conducted with the following concentrations of test substance: 0, 100 and 500 mg/l. Dilution water was reconstituted water mixed to provide a composition following ISP/DIS 7346/l. The prepared dilution water was saturated with oxygen and the pH was measured before each trial. The pH was between 8.0 and 8.1. Test vessels were 10-liter glass aquariums (30 x 22 x 24 cm). Vessels were not aerated during the entire test time.<br>Since the test substance is insoluble in water and since no better distribution was achieved using solvents and emulators, the test substance and dilution water were homogenized using the Ultra-Turrax and ultrasonic bath. This solution was added to the test vessel while |

being stirred with at glass stirring rod. Finally, the contents of the test vessels were stirred for approx. 2 hours with a KPG-stirrer and a glass stir rod. The test assays showed substance depositing on the water surface. 10 fish were randomly distributed in each test vessel and in the control vessel. During the entire study time, the fish were not fed. After 2, 4, 24, 48 72 and 96 hours, mortality and visible changes in appearance and behavior were noted. Dead fish were removed from the vessels. Fish were counted as dead when breathing was no longer seen and the fish no longer responded to a light mechanical stimulation. Water parameters were also measured at these times. pH values ranged from 7.5 to 8.2 in the test groups and 7.6 to 8.1 in the control. Oxygen content was 6.8 to 9.0 mg/l in the test groups and 7.5 to 9.1 mg/l in the control. Temperature ranged from 21.6 to 22.0°C in the test groups and 21.5 to 22.0°C in the control groups.

**Results**

Nominal concentrations (mg/l): 0, 100 and 500 mg/l
Measured concentrations (mg/l): Not determined
Unit: mg/l
Element Value: 96-hour $LC_{50}$
Statistical Results: 96-hour $LC_{50}$ > 100 mg/l and < 500 mg/l
Remarks: In the 500 mg/l group, symptoms and 90% mortality were observed after 96 hours. The 100 mg/l group displayed symptoms, but no mortality. Due to the insolubility of the test substance, no analytical determination of the substance concentration in the test water was carried out.
Additional endpoints included:
48-hour $LC_{50}$ = 500 mg/l
48-hour $LC_0$ = 100 mg/l; 96-hour $LC_0$ = 100 mg/l

| Concentration (mg/l) | Mortality | | | |
|---|---|---|---|---|
| | 48 hours | | 96 hours | |
| | Absolute | Percent | Absolute | Percent |
| 0 | 0/20 | 0 | 0/20 | 0 |
| 100 | 0/10 | 0 | 0/10 | 0 |
| 500 | 5/10 | 50 | 9/10 | 90 |

**Conclusions**

Remarks: The inability to dispense or solubilize the test substance may have resulted in lower mortality as seen with similar chemicals. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1D

Remarks: Reliable with restriction; guideline study but only two concentrations tested.

**References**

Markert, I. and R. Jung. 1991. Genamin SH 301: Orientation Test of the Acute Toxicity of Fish – Zebra Fish (*Brachydanio rerio*) – over 96 Hours. Report Number 91.0956. Pharma Entwicklung Toxikologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other Available Reports**

**Other**

Last Changed: June 7, 2002

Order number for sorting: 77f

Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Genamin CS 301 (CAS RN 61788-62-3;Amines, dicoco alkylmethyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | EG-Guideline C.1. Acute Toxicity to Fish; Guideline 84/449/EWG; OECD Guideline for testing of chemicals, 203 Fish, Acute Toxicity Test |
| Type: | Static |
| GLP: | Yes |
| Year: | 1990 |
| Species/Strain/Supplier: | Zebra Fish (*Brachydanio rerio*)/Hamilton-Buchanan/West Aquarium, Bad Lauterberg |
| Analytical Monitoring: | Not stated |
| Exposure Period: | 96 hours |
| Statistical Methods: | Probit analysis (Linder and Weber, confidence interval Fieller) |
| Remarks: | The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. The fish were held in dilution water for at least 14 days before the beginning of the study. Water was maintained at 22 ± 1°C by using a water bath calibrated thermometer and with ≥80% oxygen saturation. Lighting regime was 12-hour day/night cycles at approximately 700 lux. Feeding was twice daily. Immediately before the study start, as representatives for the batch of fish, 10 fish were measured for body length. These fish were not used in the study. The mean body length of the fish was 3.0 cm.<br>The study was conducted with the following concentrations of test substance: 0, 2.2, 5, 10 and 50 mg/l. Dilution water was reconstituted water mixed to provide a composition following ISP/DIS 7346/l. The prepared dilution water was saturated with oxygen and the pH was measured before each trial. The pH was between 8.0 and 8.3. Test vessels were 10-liter glass aquariums (30 x 22 x 24 cm). Vessels were not aerated during the entire test time.<br>Since the test substance is insoluble in water and since no better distribution was achieved using solvents and emulators, the test substance mixed with dilution water was homogenized using the Ultra-Turrax and |

ultrasonic bath. This solution was added to the test vessel while being stirred with at glass stirring rod. Finally, the contents of the test vessels were stirred for approx. 2 hours with a KPG-stirrer and a glass stir rod. At 2.2 and 10 mg/l, test substance deposits were observed. Ten fish were randomly distributed in each test vessel and in the control vessel. During the entire study time, the fish were not fed. After 2, 4, 24, 48, 72 and 96 hours, mortality and visible changes in appearance and behavior were noted. Dead fish were removed from the vessels. Fish were counted as dead when breathing was no longer seen and the fish no longer responded to a light mechanical stimulation. Water parameters were also measured at these times.

**Results**

Nominal concentrations (mg/l): 0, 2.2, 5, 10 and 50 mg/l
Measured concentrations (mg/l): Not stated
Unit: mg/l
Element Value: 96-hour $LC_{50}$
Statistical Results: 96-hour $LC_{50}$ = 6.15 mg/l (confidence interval 4.5 to 8.3 mg/l)
Remarks: In all the test substance groups, impaired swimming, breathing as well as changed appearance and behavior were observed. Fish that died were pale or darkly colored and showed red gills and lockjaw.

| Concentration (mg/l) | Mortality | | | |
|---|---|---|---|---|
| | 48 hours | | 96 hours | |
| | Absolute | Percent | Absolute | Percent |
| 0 | 0/30 | 0 | 0/30 | 0 |
| 2.2 | 0/10 | 0 | 0/10 | 0 |
| 5 | 0/10 | 0 | 3/10 | 30 |
| 10 | 3/10 | 30 | 9/10 | 90 |
| 50 | 10/10 | 100 | 10/10 | 100 |

Additional endpoints included:
48-hour $LC_0$ = 5 mg/l; 96-hour $LC_0$ = 2.2 mg/l
48-hour $LC_{50}$ = > 10 mg/l and < 50 mg/l
48-hour $LC_{100}$ = 50 mg/l; 96-hour $LC_{100}$ = 50 mg/l

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability: | 1D |
| Remarks: | Reliable with restriction; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline. |

**References**

Nölken, G. and R. Jung. 1990. Genamin CS 301: Study of the Acute Toxicity to Fish – Zebra Fish (*Brachydanio rerio*) over 96 Hours. Report Number 90.0502. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | June 7, 2002 |
| Order number for sorting: | 126d |
| Remarks: | |

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Ditallowmethylamine, hydrogenated (CAS RN 61788-63-4; Dihydrogenated tallow methylamine) |
| Purity: | 100.2% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Testing conformed to EEC Directive 779/831, Annex V, Part C.1. Acute toxicity to fish; and OECD Guidelines for Testing of Chemicals, Guideline 203: Fish, Acute Toxicity Test. |
| Type: | Static-renewal, renewal of solutions at 48 hours. |
| GLP: | Yes |
| Year: | 1990 |
| Species/Strain/Supplier: | Zebra fish (*Brachydanio rerio*)/Local aquarium retailer (Rasbora, Veenendaal). |
| Analytical Monitoring: | No |
| Exposure Period: | 96 hours |
| Statistical Methods: | None |
| Remarks: | The test measured the acute toxicity of the test substance to Zebra fish. Range-finding tests were conducted prior to the definitive study. In the range-finding tests, 1.0 mg/l was the highest concentration tested at which no solid particles of the test substance could be observed in the test fluid and all test substance appeared to be dispersed. At 100 and 1008 mg/l, solid particles were present in the test solutions. The definitive test was conducted as a limit test (single concentration) at 1000 mg/l. Testing was conducted in 5-liter glass vessels containing 3 liters of test solution. Dilution water used in the test was Dutch Standard Water, having a pH of approximately 8.2 and a hardness of 13°dH. Duplicate vessels containing 1000 mg/l of the test substance and a single vessel with dilution water were used in the test. The test substance was described as "practically insoluble" in water. The 1000 mg/l test concentration was prepared by heating the dilution water to approximately 45°C and adding the melted test substance to the dilution water under stirring. Once the temperature was reduced to testing temperature, the test substance solidified again and fat-like particles were formed. To each vessel was added 7 fish. Biomass loading per vessel was approximately 0.23 g of biomass/l. During the test the solutions were |

aerated; fish were not fed. The vessels were placed in a temperature-controlled incubator between 21 and 25°C. The lighting regime was 12 hours of ambient light/day provided by fluorescent lights. Measurements of pH and the dissolved oxygen concentration were carried out daily. The temperature ranged from 22.9 to 23.7°C, the pH ranged from 8.1 to 8.3, and the dissolved oxygen concentrations were ≥8.4 mg/l. One control group with seven fish was included in the test. The quality of the batch fish used in this test was checked by means of a test with potassium dichromate as the reference substance.

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control) and 1000 mg/l |
| Measured concentrations (mg/l): | NA |
| Unit: | mg/l |
| Statistical Results: | NA |
| Result: | 96-hour $LC_{50}$ = > 1000 mg/l |
| Remarks: | No mortality or adverse effects were observed in any of the fish used in the test. |

**Conclusions**

| | |
|---|---|
| Remarks: | Solubility problems preclude definitive determination of the LC50 in this study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1D |
| Remarks: | Reliable with restriction; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline. |

**References**

Mark, U., and E.E. Hantink-de Rooij. 1990. Acute Toxicity of ARMEEN M2HT to *Brachydanio rerio*. Study/Report No. CRL F90146, Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 25, 2002 |
| Order number for sorting: | 99 |
| Remarks: | |

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Genamin SH 200 [CAS RN 61789-79-5;Amines, bis(hydrogenated tallow alkyl)] |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD 203 and 92/69/EWG C.1. |
| Type: | Static |
| GLP: | Yes |
| Year: | 1995 |
| Species/Strain/Supplier: | Zebra Fish (*Brachydanio rerio*)/Hamilton-Buchanan/HOECHST AG, Kastengrund |
| Analytical Monitoring: | None |
| Exposure Period: | 96 hours |
| Statistical Methods: | Not stated |
| Remarks: | The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. The fish had a mean body length of 3.4 cm. The test substance was not soluble in water and could not be dispersed equally. The test substance was weighed into a beaker, mixed with dilution water, homogenized with the Ultra-Turrax and transferred quantitatively into a 10-liter glass vessel. After filling to 10 liters with test water, the assay was stirred with a magnetic stirrer for approximately 72 hours. The assay was filtered through a folded filter and placed in the test vessel. The test assays were clear solutions with substance deposits on the water surface. pH values ranged from 7.6 to 8.3 in the test groups and 7.8 to 8.2 in the control groups. Oxygen content ranged from 5.8 to 9.1 mg/l in the test groups and 6.6 to 9.7 mg/l in the control groups. Temperature ranged from 21.3 to 21.8°C in the test groups and 21.0 to 21.8°C in the control groups. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0, 100, 220, 500 and 1000 mg/l |
| Measured concentrations (mg/l): | Not determined |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ is between 220 and 500 mg/l |
| Remarks: | In the 220, 500 and 1000 mg/l exposure groups, symptoms and mortality occurred. The 100 mg/l test |

substance group showed reversible symptoms and no mortality.
Additional endpoints included:

| Endpoint (mg/l) | 24 Hours | 48 Hours | 72 Hours | 96 Hours |
|---|---|---|---|---|
| $LC_0$ | 100 | 100 | 100 | 100 |
| $LC_{50}$ | 220 to 500 | 220 to 500 | 220 to 500 | 220 to 500 |
| $LC_{100}$ | 500 | 500 | 500 | 500 |

**Conclusions**

Remarks: Solubility problems may preclude determination of an accurate $LC_{50}$ in this study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1D

Remarks: Reliable with restriction; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

**References**

Jung, R and Zok. 1995. Genamin SH 200: Study of the Acute Toxicity to Fish – Zebra Fish (*Brachydanio rerio*) – over 96 Hours. Report Number 95.0693. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other Available Reports**

**Other**

Last Changed: June 7, 2002

Order number for sorting: 131a

Remarks:

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | DA-1618 [CAS RN 52898-18-7; 1,3-Propanediamine, N-(3-(dodecyloxy)propyl)-] |
| Purity: | Primary amine = 51%<br>Secondary + tertiary amine = 49%<br>Tertiary amine = 2% |
| Remarks: | Test substance was part of a formulated product. Report does not mention a chemical name, just the trade name. |

**Method**

| | |
|---|---|
| Method/guideline followed: | Method consistent with OECD Guideline 203: Fish, Acute Toxicity Test. |
| Type: | Static |
| GLP: | Yes |
| Year: | 1999 |
| Species/Strain/Supplier: | Fathead minnow (*Pimephales promelas*)/NA/Laboratory culture |
| Analytical Monitoring: | No |
| Exposure Period: | 96 hours |
| Statistical Methods: | $LC_{50}$ determined using the Trimmed Spearman-Karber calculation. |
| Remarks: | The acute toxicity of the test substance was determined for fathead minnows under static exposure conditions. Fish used in testing were from an in-house culture and had a mean weight and total length of 0.009 g and 11 mm, respectively. Fish were fed daily during holding but not during the 48-hour acclimation period prior to the test or during the test. No mortality occurred during the acclimation period. Dilution water used in the test was moderately hard freshwater prepared by blending naturally hard well water with well water that had been demineralized. The blended water yielded a total hardness of 130 to 160 mg/l as $CaCO_3$. Testing was conducted in 3.8-l glass vessels containing 3.0 l of test solution. Each treatment was replicated twice. Test solutions were prepared by diluting aliquots of an aqueous stock solution of the test substance with dilution water. Ten fish were impartially distributed to each replicate vessel. Vessels were placed in a waterbath at a temperature of 23±1°C. Fluorescent lighting was maintained on a 16-hour light/8 hour dark photoperiod and 30-minute simulated dawn and dusk periods. Light intensity during testing was 528 lux. Observations for mortality |

and sublethal responses were made at approximately 24, 48, 72 and 96 hours. During testing, dissolved oxygen remained above 6.5 mg/l (>80% saturation), water pH ranged from 8.4 to 8.5, and temperature ranged from 23.1 to 23.8°C.

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0.0031, 0.0063, 0.013, 0.025 and 0.050 µg/l |
| Measured concentrations (mg/l): | NA |
| Unit: | µg/l converted to mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ = 0.033 mg/l |
| Remarks: | After 24 hours, complete mortality occurred in the 0.050 mg/l treatment level. Mortality in the lower test levels ranged from 5 to 10% at the end of the test. No mortality occurred in the control group. The 96-hour $LC_{50}$ was 0.033 mg/l and the 95% confidence limits were 0.029 and 0.039 mg/l. The 96-hour no-observed-effect concentration (NOEC) was <0.031 mg/l and the slope of the dose-response line was 13. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized by this study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1D |
| Remarks: | Reliable with restriction; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline. |

**References**

Rhodes, J.E. and J.E. Whitaker. 1999. Acute Toxicity of DA 1618 to the Fathead Minnow, *Pimephales promelas*, Determined Under Static Conditions. Report No. 45354. Analytical Bio-Chemistry Laboratories Inc., Columbia, Missouri.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 19, 2002 |
| Order number for sorting: | 163 |
| Remarks: | |

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Test Substance**

| | |
|---|---|
| Identity: | Sododecyloxypropylaminopropylamine (CAS RN 68479-04-9; 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched) |
| Purity: | NA |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Test methods were based on ASTM Standard 4729-80, Standard Practice for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates and Amphibians, and EPA-660/3-75-009, Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. |
| Type: | Static-renewal, renewal daily |
| GLP: | Yes |
| Year: | 1993 |
| Species/Strain/Supplier: | Fathead minnow (*Pimephales promelas*)/NA/FBS, Florida |
| Analytical Monitoring: | NA |
| Exposure Period: | 96 hours |
| Statistical Methods: | $LC_{50}$ values calculated using a computer program that performs probit, moving average, and binomial methods. |
| Remarks: | The test measured the acute toxicity of the test substance to fathead minnows. The test was conducted in 400-ml polypropylene cups filled with 300 ml of test solution. Ten fish were used in each of four replicate containers (40 fish per test concentration). Test solutions were renewed every 24 hours. The dilution water used in testing was spring water diluted with deionized water. Test concentrations were prepared by adding aliquots of an aqueous stock solution to moderately-hard spring water. Dissolved oxygen, pH, temperature and conductivity were measured daily in all test levels. A photoperiod of 16 hours light/8 hours dark was provided during testing. Alkalinity was measured initially in the control and all test concentrations. Dissolved oxygen ranged from 6.6 to 9.2 mg/l, pH ranged from 7.6 to 8.1, temperature remained steady at 21°C. Conductivity and alkalinity was not provided in the reviewed report. Test chambers were monitored for mortalities daily. Death was defined as the absence of movement. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0.04, 0.07, 0.15, 0.3, 0.6, and 1.0 mg/l. |
| Measured concentrations (mg/l): | NA |
| Unit: | mg/l |
| Element Value: | 96-hour $LC_{50}$ |
| Statistical Results: | 96-hour $LC_{50}$ = 0.16 mg/l (95% confidence limit of 0.139 to 0.186 mg/l) |
| Remarks: | Additional endpoints measured were:<br>48-hour $LC_{50}$ = 0.172 mg/l (0.148 – 0.199 mg/l)<br>96-hour NOEC = 0.07 mg/l |

**Conclusions**

| | |
|---|---|
| Remarks: | The 96-hour acute toxicity of fathead minnows to 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1D |
| Remarks: | Reliable with restriction; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline. |

**References**

MacGregor, R., III. 1993. Alkyl Amine DA-16, Evaluation of the Static Renewal Acute Toxicity to *Ceriodaphia dubia* and *Pimephales promelas*. Final Report No. ATR-30-93-034, Halliburton NUS Environmental Corporation, Houston, Texas, USA. EPA Document No. 88-930000335

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 27, 2002 |
| Order number for sorting: | 118a |
| Remarks: | |

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | FARMIN TH (CAS RN 61788-45-2; Amines, hydrogenated tallow alkyl) |
| Purity: | >98% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 202 (I), *Daphnia* sp. Acute Immobilisation Test. |
| Type: | Static |
| GLP: | Yes |
| Year: | 1995 |
| Species/Strain/Supplier: | *Daphnia magna*/not stated/Centro de Investigcion y Desarrollo Aplicado, S.A.L laboratories |
| Analytical Monitoring: | No |
| Exposure Period: | 48 hours |
| Statistical Methods: | Litchfield and Wilcoxon |
| Remarks: | The test measured the $EC_{50}$, the $EC_0$ and the $EC_{100}$ of the test substance to *Daphnia magna*. Daphnia cultures were grown in glass containers with a maximum capacity of 84 liters. Twenty-four hours before the test began, a suitable number of adult Daphnia with eggs were separated and transferred to 10 ml test tubes. Daphnia were fed during pretreatment but not during treatment. Test vessels were filled with 75 ml test medium. Five test concentrations were run; 0.05, 0.10, 0.19, 0.39, and 0.78 mg/l. Two replicates of each concentration were run. Ten animals (< 24 hours old) were inserted into each test concentration. In addition, untreated and vehicle (100 mg Tween 80/liter) controls were included with four replicates per treatment. Dilution water was reconstituted water according to ISO 6341 with the following chemistry parameters: alkalinity = 0.8 mmol/l; hardness = 249 to 285 mg $CaCO_3$/l; Ca/Mg ratio = 4/1; Na/K ratio = 10/1; pH = 7.8; and $O_2$ = 100%. The test conditions were as follows: temperature = 22°C; dissolved oxygen = 62 to 100% and pH = 7.3 to 8.1. The study was run as two separate tests performed one week apart. Both tests were performed with untreated and vehicle control groups. The first test included test concentrations of 0.05 through 0.39 mg/l and the second test was run with only the highest concentrations, 0.78 mg/l |

**Results**

Nominal concentrations (mg/l): 0 (untreated), 0 (vehicle), 0.05, 0.10, 0.19, 0.39, 0.78 mg/l
Measured concentrations (mg/l): Not determined
Unit: mg/l
$EC_{50}$ (48 hour): 0.16 mg/l
NOEC (48 hour): 0.05 mg/l
Result: Additional endpoints included:
48-hour $EC_{100}$ = 0.78 mg/l;
48-hour $EC_0$ = 0.05 mg/l
Percent inhibition at 48-hours is provided in the following table:

| **Nominal Concentration (mg/l)** | **0 (untreated)** | **0 (vehicle)** | **0.05** | **0.10** | **0.19** | **0.39** | **0.78** |
|---|---|---|---|---|---|---|---|
| **Inhibition (%) at 48-hours** | 0 | 0 | 0 | 30 | 70 | 85 | 100 |

Remarks:

**Conclusions** The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A
Remarks: Reliable without restriction; guideline study.

**References**

Mayordomo, L. 1995. Acute Immobilization Test in Daphnia. Test Substance: FARMIN TH. Report No CD-95/4307T. KAO Corporation S.A..

**Other Available Reports**

**Other**

Last Changed: September 16, 2002
Order number for sorting: 106a
Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | NORAM SH (CAS RN 61788-45-2; Amines, hydrogenated tallow alkyl) |
| Purity: | >95% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 202 (I), *Daphnia* sp. Acute Immobilisation Test. |
| Type: | Static |
| GLP: | Yes |
| Year: | 1984 |
| Species/Strain/Supplier: | *Daphnia magna*/STRAUS clone 5 or A/Centre Technique du Bois et de l'Ameublement, France |
| Analytical Monitoring: | Yes |
| Exposure Period: | 48 hours |
| Statistical Methods: | Probit Analysis (Finney's method, Bliss's method, Fieller's method) |
| Remarks: | The test measured the $EC_{50}$, the $EC_0$ and the $EC_{100}$ of the test substance to *Daphnia magna*. Daphnia cultures were grown in M4 medium. Daphnia were not fed during treatment. The test consisted of six test concentrations; 1.0, 2.2, 4.8, 10.6, 23 and 50 mg/l; with four replicates of each concentration. Five animals (6 to 24 hours old) were inserted into each replicate. In addition, and untreated control group was included with four replicates per treatment. Dilution water was reconstituted water (M4) with the following chemistry parameters: hardness = 291 to 354 mg $CaCO_3$/l; Ca/Mg ratio = 4/1; Na/K ratio = 10/1; and conductance = <10 µS/cm. The test substance was heated to 65°C before being added to M4 water at 60 to 70°C. The stock solutions were allowed to cool to room temperature overnight under continuous stirring. Before dilution, the stock solution was centrifuged for one hour and the subnatant was collected. Test vessels were beakers containing 50 ml of the test solution. The test conditions were as follows: temperature = 19.5 to 20°C; dissolved oxygen > 95%; and pH = 7.5 to 8.4; and the photoperiod was 16 hours. Analysis method: extraction followed by GC-FID and quantified as the sum of four peaks (mixture of amines with different chain lengths). Sampling times were 0, 24 and 48 hours. |

**Results**

Nominal concentrations (mg/l): 0, 1, 2.2, 4.8, 10.6, 23, 50 mg/l
Measured concentrations (mg/l): All below LOQ (1 mg/l)
Unit: mg/l
$EC_{50}$ (48 hour): <1 mg/l (LOQ)
NOEC (48 hour): Not determined
Result: At 23 mg/l, one daphnid was found dead, stuck to the wall of the beaker.
Additional endpoint included:
48-hour $EC_{100}$ = <1 mg/l
Percent inhibition at 48-hours is provided in the following table:

| **Nominal Concentration (mg/l)** | **0** | **1** | **2.2** | **4.8** | **10.6** | **23** | **50** |
|---|---|---|---|---|---|---|---|
| **Inhibition (%) at 48-hours** | 5 | 20 | 0 | 30 | 80 | 100 | 100 |

Remarks:

**Conclusions**

Based on analytical values less than the LOQ of 1.0 mg/l, the test substance was not solubilized in the system. Therefore, the $EC_{50}$ is stated as less than the LOQ, which provides a value consistent with other tests for this and similar chemicals. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A
Remarks: Reliable without restriction; guideline study.

**References**

Thomas, P.C. 1995. Acute Toxicity of Daphnia; NORAM SH. Study No. 12947 EAM. Centre International de Toxicologie (C.I.T), France.

**Other Available Reports**

**Other**

Last Changed: September 16, 2002
Order number for sorting: 106b
Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | Adogen-160, coco oil (primary) amine (CAS RN 61788-46-3; Amines, coco alkyl) |
| Purity: | NA |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | No specific guideline followed |
| Type: | Static |
| GLP: | No |
| Year: | 1970 |
| Species/Strain/Supplier: | *Culex pipiens quinquefasciatus*/NA/Laboratory bred<br>*Aedes aegypti*/NA/Laboratory bred<br>*Aedes nigromaculis*/NA/Field collected from pastureland<br>*Anopheles albimanus*/NA/Laboratory bred |
| Analytical Monitoring: | No |
| Exposure Period: | 24 hours |
| Statistical Methods: | Estimation of $LC_{50}$ and $LC_{90}$ values made from plot of percent mortality versus log concentration on probit log paper |
| Remarks: | Stock solutions of the test substance were prepared in acetone. Twenty 4th-instar larvae or 24-hour old pupae were placed in 4-oz. Dixie® cups containing 100 ml of tap water. Stock solutions were added (1 ml or less) to each cup to achieve the required concentration. Each concentration was tested three times and replicated twice in each test. Twenty-four hours after application of the test substance, mortality counts were made. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | Not stated |
| Measured concentrations (mg/l): | NA |
| Unit: | ppm |
| $LC_{50}$ (24 hour): | *C. p. quinquefaciatus*<br>$LC_{50}$ larvae = 2.2 ppm<br>$LC_{50}$ pupae = 13.0<br>*A. aegypti*<br>$LC_{50}$ larvae = 2.0<br>$LC_{50}$ pupae = 10.0<br>*A. albimanus*<br>$LC_{50}$ larvae = 3.0<br>$LC_{50}$ pupae = 3.5 |

*A. nigromaculis*
$LC_{50}$ larvae = 3.0
$LC_{50}$ pupae = 3.5

Result: Additional endpoints included:
*C. p. quinquefaciatus*
$LC_{90}$ larvae = 4.4
$LC_{90}$ pupae = 30.0
*A. aegypti*
$LC_{90}$ larvae = 5.2
$LC_{90}$ pupae = 18.0
*A. albimanus*
$LC_{90}$ larvae = 6.0
$LC_{90}$ pupae = 7.0
*A. nigromaculis*
$LC_{90}$ larvae = 6.0
$LC_{90}$ pupae = 7.0

Remarks:

**Conclusions**

The multiple mosquito species used in the study and the agreement of the endpoints provides a weight of evidence for adequate characterization of the acute toxicity of Amines, coco alkyl to aquatic invertebrates. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2D
Remarks: Reliable with restrictions: used nonstandard test species.

**References**

Mulla, M.S., H.A. Darwazeh and P.A. Gillies. 1970. Evaluation of Aliphatic Amines Against Larvae and Pupae of Mosquitoes. J. Economic Entomology. 63:1472-1475

**Other Available Reports**

**Other**

Last Changed: July 24, 2002
Order number for sorting: 92
Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | Genamin SH 100 D (CAS RN 124-30-1; Octadecylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 202 (I), *Daphnia* sp. Acute Immobilisation Test. |
| Type: | Static |
| GLP: | Yes |
| Year: | 1984 |
| Species/Strain/Supplier: | *Daphnia magna*/Straus/Institut fuer Wasser-, Boden- and Lufthygiene des Bundesgesundheitsamtes, Berlin |
| Analytical Monitoring: | No |
| Exposure Period: | 48 hours |
| Statistical Methods: | Could not be adequately translated. |
| Remarks: | The test measured the $EC_{50}$, the $EC_0$ and the $EC_{100}$ of the test substance to *Daphnia magna*. Daphnia were 2 to 24 hours old at the start of the test and were fed algae during pretreatment; feeding during treatment was not specified in the study report. Test vessels were 50-ml beakers filled with 20 ml test medium. Dilution water was EWG 84/449 with the following chemistry parameters: hardness = 236 mg $CaCO_3$/l; pH = 7.7; $O_2$ concentration = 95% and conductance = 638 µS/cm. No vehicle or solvent was used. Eight test concentrations were run; 0, 0.018, 0.032, 0.058, 0.10, 0.18, 0.32, and 0.58 mg/l with four replicates of each concentration. Five daphnids were inserted into each test concentration. In addition, the reference substance, $K_2Cr_2O_7$, was tested at concentrations of 0.32 – 3.2 mg/l; 2 replicates per treatment and 10 animals per replicate. During the 48 hours of the study, the assays were stored in a temperature controlled room with a 10 hour photoperiod. The test conditions were as follows: temperature = 21 to 22°C; dissolved oxygen ≥ 89%; and pH = 7.5 to 7.6. The test parameter evaluated was immobility. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0, 0.018, 0.032, 0.058, 0.10, 0.18, 0.32, 0.58 mg/l |
| Measured concentrations (mg/l): | NA |
| Unit: | mg/l |
| $EC_{50}$ (48 hour): | 0.13 mg/l (95% confidence limit of 0.10 to 0.18 mg/l) |

NOEC (48 hour): Not determined

Result: Additional endpoints included:
48-hour $EC_{100}$ = 0.58 mg/l;
48-hour $EC_0$ = 0.018 mg/l (report indicated $EC_0$ = 0.032 mg/l)
Percent immobility at 48-hours is provided in the following table:

| **Nominal Concentration (mg/l)** | **0** | **0.018** | **0.032** | **0.058** | **0.10** | **0.18** | **0.32** | **0.58** |
|---|---|---|---|---|---|---|---|---|
| **Immobility (%) at 48-hours** | 0 | 0 | 10 | 15 | 20 | 45 | 75 | 100 |

Remarks: The 24-hour $EC_{50}$ of the reference substance was 1.1 mg/l

**Conclusions** The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Noack, M. 1994. Akuter Immobilisierungstest (48h) an *Daphnia magna* STRAUS von Genamin SH 100D. [Acute immobilization study (48 hours) in *Daphnia magna* STRAUS with Genamin SH 100D] Study No. 940905HM/DAI42621. Dr. U. Noack-Laboratory for Applied Biology. Sarstedt, Germany.

**Other Available Reports**

**Other**

Last Changed: June 24, 2002

Order number for sorting: 55a

Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | Amine KK (CAS RN 61788-46-3; Amines, coco alkyl) |
| Purity: | > 94% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 202, Part 1, Daphnia sp., Acute Immobilization Test. |
| Type: | Static |
| GLP: | Yes |
| Year: | 1991 |
| Species/Strain/Supplier: | Daphnia magna/ STRAUS/ Institut National de Recherché Chimique Appliquee (I.R.CH.A), France. |
| Analytical Monitoring: | No |
| Exposure Period: | 48 hours |
| Statistical Methods: | Thomson, W.R. 1947. |
| Remarks: | Daphnia were bred in dechlorinated and aged tap water (21°C) and were less than 24 hours old at the start of the test. Animals were fed mixed algae during pretreatment; feeding during the test was not discussed in the report. Stock solutions of the test substance were prepared in 1% Tween 80-Acetone. Vessels were covered glass jars with 200 ml test solution. Dilution water was dechlorinated and aged laboratory tap water with the following chemistry parameters: hardness = 50 mg $CaCO_3$/l; TOC = 0.9 mg/l; Ca/Mg ratio = 1/3; Na/K ratio = 24/1; and pH = 8.7. There were 10 fish per replicate and 2 replicates per treatment group. Test conditions were as follows: temperature = 21°C; dissolved oxygen = 90 to 94%; pH = 7.5 to 7.7; and photoperiod = 16 hour light. Daphnia were observed for immobility. |

**Results**

Nominal concentrations (mg/l): 0.010, 0.018, 0.032, 0.056, 0.10, 0.18, 0.32, 0.56, and 1.0 mg/l
Measured concentrations (mg/l): NA
Unit: mg/l
$EC_{50}$ (48 hour): 0.045 mg/l
(95% confidence limit of 0.042 to 0.049mg/l)
NOEC (48 hour): 0.032 mg/l
Results: Percent immobility at 48-hours is provided in the following table:

| **Nominal Concentration (mg/l)** | **0** | **0.010** | **0.018** | **0.032** | **0.056** | **0.10** | **0.18** | **0.32** | **0.56** | **1.0** |
|---|---|---|---|---|---|---|---|---|---|---|
| **Immobility (%) at 48-hours** | 0 | 0 | 0 | 0 | 90 | 100 | 100 | 100 | 100 | 100 |

Remarks:

**Conclusions** The end point was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study.

**References**

Handley, J.W. and P.M. Wetton. 1991. The Acute Toxicity of Amine KK to Daphnia magna. Project No 116/68. Safepharm Laboratories.

**Other Available Reports**

**Other**

Last Changed: August 12, 2002
Order number for sorting: 92c
Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | Genamin CC 100 D (CAS RN 61788-46-3; Amines, coco alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 202, Part 1, Daphnia sp., Acute Immobilization Test. |
| Type: | Static |
| GLP: | Yes |
| Year: | 1984 |
| Species/Strain/Supplier: | Daphnia magna/ STRAUS/ Institut fur Wasser-, Boden- und Lufthygiene des Bundesgesundheitsamtes, Berlin. |
| Analytical Monitoring: | No |
| Exposure Period: | 48 hours |
| Statistical Methods: | Probitanalyse, Methoden der Wasseruntersuchungen Bd. II, 1982. |
| Remarks: | Daphnia were bred in glass beakers containing culture medium (Elendt) at 20-25°C and 10 hour light. Animals were fed algae during pretreatment; feeding during the test was not discussed in the report. No vehicle was used during the test. The reference substance was calcium dichromate. Dilution water source was EWG 84/449 with the following chemistry parameters: hardness = 236 mg $CaCO_3$/l; $O_2$ = 95%; pH = 8.7; and conductance = 638 uS/cm. There were five fish per replicate and four replicates per treatment group; the reference substance contained 10 fish per replicate and two replicates per treatment. Test conditions were as follows: temperature = 21 to 22°C; dissolved oxygen ≥89%; pH = 7.5 to 7.7; and photoperiod = 10 hour light. Daphnia were observed for immobility. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0, 0.018, 0.032, 0.058, 0.10, 0.18, 0.32, 0.58 mg/l |
| Measured concentrations (mg/l): | Not stated |
| Unit: | mg/l |
| $EC_{50}$ (48 hour): | 0.09 mg/l (95% confidence limit of 0.08 to 0.10 mg/l) |
| Result: | Additional endpoints included:<br>$EC_0$ = 0.018 mg/l<br>$EC_{100}$ = 0.18 mg/l<br>24 hour $EC_{50}$ = 1.1 mg/l |

Percent immobility at 48-hours is provided in the following table:

| **Nominal Concentration (mg/l)** | **0** | **0.018** | **0.032** | **0.058** | **0.10** | **0.18** | **0.32** | **0.58** |
|---|---|---|---|---|---|---|---|---|
| **Immobility (%) at 48-hours** | 0 | 0 | 5 | 5 | 60 | 100 | 100 | 100 |

Remarks:

**Conclusions**

The end point was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study.

**References**

Noack, M. 1994. Akuter Immobilisierungstest (48h) an Daphnia magna STRAUS von Genamin CC 100 D. [Acute immobilization study (48 hours) with *Daphnia magna* STRAUS with Genamin CC 100 D] Project No. 940905HM/DAI4259-.

**Other Available Reports**

**Other**

Last Changed: August 12, 2002
Order number for sorting: 92d
Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | Tallow amine (CAS No. 61790-33-8; Amines, tallow alkyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | U.S. EPA 600/3-75-009: Methods for acute toxicity tests with fish, macroinvertebrates, and amphibians. |
| Type: | Static |
| GLP: | Not stated |
| Year: | 1985 |
| Species/Strain/Supplier: | *Daphnia magna* /In-house cultures |
| Analytical Monitoring: | No |
| Exposure Period: | 48-hours |
| Statistical Methods: | Computer program, developed by C.E Stephan, (1982. US EPA Environmental Research Laboratory, Duluth, MN. Personal communication to Dr. Lowell Bahner, Chairman ASTM Task Group on Calculating LC50's), to calculate $LC_{50}$ by moving average, probit and binomial probability |
| Remarks: | The test measured the acute toxicity of the test substance to *Daphnia magna* under static test conditions. Daphnids less than 24 hours old were exposed to six concentrations of the test substance, a solvent control and a negative control for a period of 48 hours. Each treatment groups consisted of three replicate test chambers. Test chambers were 250-ml glass beakers holding 200 ml of test solution. Dilution water was river water having the following characteristics: total hardness 50 mg/l as $CaCO_3$, alkalinity 24 mg/l as $CaCO_3$, pH 7.7 and specific conductance 360 µmhos/cm. Exposure concentrations of the test substance were prepared by diluting a working stock solution that had been prepared in acetone. Aliquots of the stock were added to dilution water, stirred and apportioned among triplicate test chambers for each treatment group. The test was run at a temperature of 21±1°C under a 16 h light:8 h dark photoperiod. Light intensity was 7 hectolux during the light period. At test initiation, five daphnids were impartially distributed to each test chamber. Daphnids were not fed during testing, and mortalities were recorded at 24 and 48 hours. Dissolved oxygen and pH were measured at 0 and 48 hours in one replicate |

vessel of the control, solvent control, and the low, middle and high exposure groups. Temperature was measured in one control vessel at 0, 24 and 48 hours. All water quality factors were within the correct ranges during the test.

**Results**

Nominal concentrations (mg/l): 0 (negative control), 0 (solvent control), 0.04, 0.065, 0.11, 0.18, 0.30, and 0.50 mg/l.
Measured concentrations (mg/l): Not determined
Unit: mg/l
$EC_{50}$ (48 hour): Toxicity reported as $LC_{50}$.
$LC_{50}$ (48 hour): 0.093 mg/l (95% confidence interval of 0.076 to 0.11 mg/l)
NOEC (48 hour): 0.040 mg/l
Result: Percent mortality at 48-hours is provided in the following table:

| **Nominal Concentration (mg/l)** | **0 (Negative control)** | **0 (Solvent control)** | **0.04** | **0.065** | **0.11** | **0.18** | **0.30** | **0.50** |
|---|---|---|---|---|---|---|---|---|
| **Mortality (%)at 48 Hours** | 0 | 0 | 0 | 53 | 67 | 73 | 100 | 100 |

Remarks: After 24 hours, the $LC_{50}$ was 0.23 mg/l with 95% confidence interval of 0.040 to 0.30 mg/l.

**Conclusions**

The acute toxicity of the test substance to *Daphnia magna* was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B
Remarks: Reliable without restriction; comparable to guideline study.

**References**

Springborn Bionomics, Inc. 1986. Acute Toxicity of Adogen 170D to Daphnids (*Daphnia magna*) in River Water. Toxicity test report submitted to Sherex Chemical Company, Dublin, Ohio. Bionomics Report No. BW-86-3-1956; Study No. 11,187-0585-6101-110.

## Other Available Reports

### Other

| | |
|---|---|
| Last Changed: | July 25, 2002 |
| Order number for sorting: | 214 |
| Remarks: | |

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | Genamin TA 100 D (CAS No. 61790-33-8; Amines, tallow alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 202 (I), *Daphnia* sp. Acute Immobilisation Test. |
| Type: | Static |
| GLP: | Yes |
| Year: | 1994 |
| Species/Strain/Supplier: | *Daphnia magna* STRAUS/Institut fuer Wasser-, Boden- und Lefthygiene des Bundesgesundheitsamtes, Berlin. |
| Analytical Monitoring: | No |
| Exposure Period: | 48 hours |
| Statistical Methods: | Probit analysis, Methoden der Wasseruntersuchungen Bd. II (1982). |
| Remarks: | Daphnids were bred in glass beakers containing culture medium (Elendt) at 20 to 25°C and 10 hour light. Daphnids, 2 to 24 hours old, were fed algae during pretreatment but feeding during the test was not specified. Dilution water information: Source was EWG 84/449; hardness = 236 mg $CaCO_3$/l; pH = 7.7; $O_2$ = 95%; conductivity = 638 S/cm. Exposure vessels were 50 ml glass beakers containing 20 ml test medium. Number of animals = 5 per replicate; 4 replicates per treatment; reference substance with 10 daphnids per replicate (2 replicates per treatment). Test conditions: temperature = 21 to 22°C; dissolved oxygen = ≥89%; pH = 7.5 to 7.6; photoperiod = 12 hours. Immobility was the test parameter evaluated. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0, 0.032, 0.058, 0.10, 0.18, 0.32 and 0.58 mg/l |
| Measured concentrations (mg/l): | NA |
| Unit: | mg/l |
| $EC_{50}$ (48 hour): | 0.09 mg/l (95% confidence limit of 0.07 to 0.11 mg/l) |
| NOEC (48 hour): | Not determined |

Result: Percent immobility at 48-hours is provided in the following table:

| **Nominal Concentration (mg/l)** | **0** | **0.032** | **0.058** | **0.10** | **0.18** | **0.32** | **0.58** |
|---|---|---|---|---|---|---|---|
| **Immobility (%) at 48-hours** | 0 | 5 | 10 | 70 | 80 | 100 | 100 |

Remarks:

**Conclusions** The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Noack, M. 1994. Akuter Immobilisierungstest (48 h) an Daphnia magna STRAUS von Genamin TA 100 D [Acute immobilization study (48 hours) in *Daphnia magna* STRAUS with Genamin TA 100 D] (940905HM/DAI42611).

**Other Available Reports**

**Other**

Last Changed: August 9, 2002

Order number for sorting: 214c

Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | NORMAN S(CAS No. 61790-33-8; Amines, tallow alkyl) |
| Purity: | >95% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 202 (I), *Daphnia* sp. Acute Immobilisation Test. |
| Type: | Static |
| GLP: | Yes |
| Year: | 1995 |
| Species/Strain/Supplier: | *Daphnia magna* STRAUS-clone 5 or A/Centre Technique du Bois et de l'Ameublement, France. |
| Analytical Monitoring: | Yes |
| Exposure Period: | 48 hours |
| Statistical Methods: | Probit analysis, (Finney's method, Bliss's method, Fieller's method) |
| Remarks: | Daphnids were bred in culture M4-medium with pH of 7.5 to 8.5, 18 - 22°C; 02 >80%; and 16 hour light. Daphnids, 6 to 24 hours old and were not fed during the test. The test substance was heated to 65°C before being added to preheated water. The stock solutions were allowed to cool to room temperature overnight under continuous stirring. Before dilution, the stock solution was centrifuged and the subnate was collected. Dilution water information: Reconstitued water (M4); hardness = 296 to 401 mg $CaCO_3$/l; Ca/Mg ratio = 4/1; Na/K ratio = 10/1; conductivity = <10uS/cm. Exposure vessels were beakers containing 50 ml test medium. Number of daphnia = 5 per replicate; 4 replicates per treatment. Test conditions: temperature = 19 to 20°C; dissolved oxygen = >81%; pH = 7.8 to 8.3; photoperiod = 16 hours. Immobility was the test parameter evaluated.<br>Analytical method: Extraction followed by GC-FID and quantified as the sum of 4 peaks (mixture of amines with different chain lengths); sampled a 0, 24 and 48 hours. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0, 1, 2.2, 4.8, 4.8, 10.6, 23 and 50 mg/l |
| Measured concentrations (mg/l): | All below LOQ (<0.25 mg/l) |
| Unit: | mg/l |
| $EC_{50}$ (48 hour): | < LOQ (0.25 mg/l) |

NOEC (48 hour): Not determined
Result: Percent immobility at 48-hours is provided in the following table:

| **Nominal Concentration (mg/l)** | **0** | **1** | **2.2** | **4.8** | **10.6** | **23** | **50** |
|---|---|---|---|---|---|---|---|
| **Immobility (%) at 48-hours** | 0 | 0 | 0 | 0 | 20 | 100 | 100 |

Remarks:

**Conclusions**

Based on analytical values less than the LOQ of 0.25 mg/l, the test substance was not solubilized in the system. Therefore, the $EC_{50}$ is stated as less than the LOQ, which provides a value consistent with other tests for this and similar chemicals. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A
Remarks: Reliable without restriction; guideline study.

**References**

Thomas, P.C. 1995. Acute Toxicity in Daphnia NORAM S. Study No. 12946 EAM. Centre International de Toxicologie (C.I.T.), France.

**Other Available Reports**

**Other**

Last Changed: August 9, 2002
Order number for sorting: 214d
Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | 9-Octadecen-1-amine; oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | 94% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Test methods conformed to OECD Guidelines for Testing of Chemicals, Guideline 202 and U.S. EPA Ecological Effects Test Guideline, OPPTS 850.1085: Fish acute toxicity mitigated by humic acid. |
| Type: | Static |
| GLP: | Yes |
| Year: | 1995 |
| Species/Strain/Supplier: | *Daphnia magna* from Laboratory culture |
| Analytical Monitoring: | Yes, in the control, low, mid and high concentration levels |
| Exposure Period: | 48 hours |
| Statistical Methods: | NA |
| Remarks: | The study measured the acute toxicity of the test substance to *Daphnia magna* during a 48-hour exposure period. Exposures were conducted without humic acid and with humic acid in the dilution water at 10 and 20 mg/l. The summary includes data only for the portion of the study that reports the exposure without humic acid present in the dilution water. The dilution water used in the test was synthetic water (Dutch Standard Water) having a pH of 8.2 and a hardness of approximately 12°dH (214 mg $CaCO_3$/l). Daphnids had been cultured in synthetic culture medium M4-medium and fed with algae (*Chlorella* sp.). Daphnids used in the test were between 6 and 24 hours old at the beginning of the test. To prepare the test concentrations, an aqueous stock of the test substance (0.1 g/l) was made and aliquots of the stock were diluted with dilution water. Test vessels were 250-ml beakers holding 200 ml of test solution. Concentrations were replicated four times, with each replicate holding 5 daphnids (20 per concentration). The treatment groups were 0 (control), 0.006, 0.011, 0.023, 0.045, and 0.090 mg/l. The test solutions were prepared, the daphnids were randomly placed in the test solutions and the test vessels were randomly placed in the testing area. All test vessels were covered with a glass plate during the test. Test |

solutions were not aerated during the test period. The testing area had a lighting regime of 16 hours light/8 hours dark. Dissolved oxygen and pH were measured at the beginning and end, and temperature was measured continuously in one replicate test vessel. The target temperature was 20±2°C. Observations of immobilization were recorded at a minimum at 0, 24, and 48 hours. Daphnids were considered immobile if they were not able to swim within 15 seconds after gentle agitation of the test vessel. If daphnids were trapped at the air-water interface, they were gently pushed under the surface with a drop of test solution. Water quality parameters measured in the dilution water included acidity (0.3 mmol/l), alkalinity (1.5 mmol/l), conductivity (605 µS/cm), water hardness (11.5°dH, equivalent to 205 mg $CaCO_3$/l), total suspended solids (0.12 mg/l), and nonpurgeable organic carbon (2.269 mg/l). Dissolved oxygen ranged from 9.0 to 9.1 mg/l, pH ranged from 8.0 to 8.1 and temperature ranged from 19.1 to 19.6°C. Measurements of the test substance in the exposure solutions were made at 0 and 48 hours in the control, low, mid and high treatment levels. Endpoint results are given based on nominal concentrations.

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0.006, 0.011, 0.023, 0.045, and 0.090 mg/l. |
| Measured concentrations (mg/l): | Measured concentrations of the test substance decreased between 0 and 48 hours. 0-hour measured concentrations in the control, 0.011, 0.023 and 0.090 mg/l nominal solutions were 0.007, 0.013, 0.020, and 0.077 mg/l, respectively, while 48-hour measured concentrations in those same exposure solutions were 0.007, 0.010, 0.011, and 0.048 mg/l, respectively. Percentages of nominal concentrations ranged 48 to 118%. |
| Unit: | mg/l |
| $EC_{50}$ (48 hour): | 48-h $EC_{50}$ = 0.011 mg/l (95% confidence interval of 0.009 to 0.013 mg/l) |
| NOEC (48 hour): | 0.0056 mg/l |
| Result: | Additional endpoints included:<br>24-h $EC_{50}$ = 0.029 mg/l (0.026 – 0.032 mg/l) |

Percent immobility at 48-hours is provided in the following table:

| **Nominal Concentration (mg/l)** | **0** | **0.006** | **0.011** | **0.023** | **0.045** | **0.090** |
|---|---|---|---|---|---|---|
| **Immobility (%) at 48-hours** | 5 | 0 | 60 | 95 | 100 | 100 |

Remarks:

**Conclusions**

The 48-hour toxicity of 9-Octadecen-1-amine to *Daphnia magna* was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study.

**References**

Mark, U.E., I.C.M. Garttener, M.G.J. Geurts, M.W.F. Nielen, C.A. Stroo and A.G.M. Kroon. 1995. Acute Toxicity of Oleylamine to *Daphnia magna*. Report No. RGL F95063. Akzo Nobel Central Research, Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 17, 2002
Order number for sorting: 15
Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | Genamin LA 302 D (CAS RN 112-18-5; N,N-Dimethyl-1-dodecanamine) |
| Purity: | 99.9% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | DIN 38 412 Part 11, Guideline 84/449/EWG (C2), OECD Guideline 202 (I ) and ISO 6341. |
| Type: | Acute |
| GLP: | Yes |
| Year: | 1994 |
| Species/Strain/Supplier: | *Daphnia magna*/Straus/Daphnia Breeders Hoechst AG, Environmental Protection Division |
| Analytical Monitoring: | Yes |
| Exposure Period: | 48 hours |
| Statistical Methods: | Not stated |
| Remarks: | The test measured the $EC_{50}$, the $EC_0$ and the $EC_{100}$ of the test substance to *Daphnia magna*. Test vessels were 150-ml beakers filled with 100 ml test volume. Eight test concentrations were run; 0.10, 0.14, 0.20, 0.28, 0.40, 0.57, 0.80 and 1.13 mg/l. Duplications of each concentration were run. Twenty animals were inserted into each test concentration. A control assay consisting of water without test substance, and a parallel consisting of 100 mg/l of the carrier solution, Tween 80, were run. In addition, the reference substance, $K_2Cr_2O_7$, was tested at concentrations of 0.9, 1.9 and 2.4 mg/l. During the 48 hours of the study, the assays were stored in a temperature controlled, darkened clean room with activated charcoal-filtered air. The test temperature was 20°C. After 24 and 48 hours, the mobility of the *Daphnia* were checked. The nominal concentrations of 0.10, 0.14, 0.80 and 1.13 mg/l were measured by gas chromatography |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0.10, 0.14, 0.80 and 1.13 mg/l |
| Measured concentrations (mg/l): | At 0 hour: 0.09, 0.14, 0.87 and 1.14 mg/l<br>At 48 hour (mean): 0.06, 0.075, 0.52 and 0.565 mg/l (Standard deviation: 16.7, 6.7, 0 and 6.2%, respectively) |
| Unit: | mg/l |

$EC_{50}$ (48 hour): 0.083 mg/l
NOEC (48 hour): < 0.06 mg/l
Result: Additional endpoints included:
48-hour $EC_{100}$ = 0.16 mg/l;
24-hour $EC_{100}$ 0.33 to 0.57 mg/l;
24-hour $EC_{50}$ = 0.16 to 0.40 mg/l; and
24-hour $EC_0$ = 0.16 to 0.28 mg/l.
Percent immobility at 48-hours is provided in the following table:

| **Nominal Concentration (mg/l)** | **0.10** | **0.14** | **0.20** | **0.28** | **0.40** | **0.57** | **0.80** | **1.13** |
|---|---|---|---|---|---|---|---|---|
| **Measured Concentration (mg/l)** | **0.06** | **0.075** | | | | | **0.52** | **0.565** |
| **Immobility (%) at 48-hours** | 5 | 12 | 90 | 100 | 100 | 100 | 100 | 100 |

Remarks: The carrier solution of 100 mg/l of Tween 80 resulted in 0% inhibition at 24 and 48 hours. The reference substance resulted in 10, 80 and 100% inhibition at 24 hours at concentrations of 0.9, 1.9 and 2.4 mg/l, respectively.
The measured test concentrations at 48 hours were 66.7, 53.6, 59.8 and 49.6% of the nominal test concentrations of 0.10, 0.14, 0.80 and 1.13 mg/l, respectively. At 0 and 48 hours, pH values were 7.8 and 7.6, respectively, at all concentrations. Dissolved oxygen ranged from 8.9 to 9.0 at 0 hours, and 8.6 to 8.9 at 48 hours. After 48 hours, the following inhibition to mobility resulted:

**Conclusions**

The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A
Remarks: Reliable without restriction; guideline study.

**References**

Stuhlfauth. 1995. Study of the Toxic Effect of Genamin LA 302 D to *Daphnia magna*. Study Number 93-0161-32. Hoechst AG, Frankfurt, Germany.

## Other Available Reports

### Other

| | |
|---|---|
| Last Changed: | June 7, 2002 |
| Order number for sorting: | 124g |
| Remarks: | |

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | Octadecylamine (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Test methods conformed to ASTM Standard E729-80, Standard Practice for Conducting Acute Toxicity Tests with Fish, Macroinvertebrates, and Amphibians. |
| Type: | Static |
| GLP: | Yes |
| Year: | 1987 |
| Species/Strain/Supplier: | *Mysidopsis bahia*/NA/Laboratory culture |
| Analytical Monitoring: | No |
| Exposure Period: | 96 hours |
| Statistical Methods: | Derivation of $LC_{50}$ values by either probit, moving average or nonlinear interpolation methods using computer program (Stephan 1977). |
| Remarks: | The study measured the acute toxicity of the test substance to the saltwater mysid. Juvenile mysids, less than 24 hours old were selected for use in the test. Individuals were impartially distributed to each test concentration within 20 minutes after the test solutions had been prepared. Test vessels consisted of 1.6-l glass containers holding 1000 ml of test solution. Test vessels were not aerated and were covered with a glass plate during testing. Each treatment and control were replicated twice and each replicate vessel held 10 mysids (total 20/concentration). Mysids were fed brine shrimp each day of the test. Test solutions were prepared by diluting a stock solution of the test substance dissolved in isopropyl alcohol with dilution water. Dilution water was natural filtered seawater having a salinity of 30 parts/thousand (ppt) and a pH of 8.0. Water pH, dissolved oxygen concentration, salinity and temperature were measured at 0-hours and at each 24-hour interval during the test. Lighting was established at a 16 hour light/8 hour dark cycle with an intensity of 40 – 100 foot-candles at the surface of the test solutions. Water pH ranged from 7.9 to 8.0, dissolved oxygen ranged from 5.0 to 7.5, salinity ranged from 30 – 32 ppt and temperature ranged from 24 - 25°C. Observations of the test organisms were made at the beginning of the test and at 24, 48, 72 and 96 hours. |

**Results**

Nominal concentrations (mg/l): 0 (control), 0 (solvent control), 0.052, 0.088, 0.140, 0.240, and 0.400 mg/l
Measured concentrations (mg/l): NA
Unit: µg/l converted to mg/l
$EC_{50}$ (96 hour): NA
$LC_{50}$ (96 hour): 0.074 mg/l
(95% confidence limit of 0.062 to 0.085 mg/l)
NOEC (96 hour): NA
Result: Percent mortality at 96-hours is presented in the following table:

| **Nominal Concentration (mg/l)** | **0** | **0** | **0.052** | **0.088** | **0.140** | **0.240** | **0.400** |
|---|---|---|---|---|---|---|---|
| **Mortality (%) at 96-hours** | 0 | 0 | 20 | 60 | 100 | 100 | 100 |

Remarks:

**Conclusions**

The 96-hour acute toxicity of Octadecylamine to the saltwater mysid was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2C
Remarks: Reliable with restrictions; comparable to guideline study with acceptable restrictions

**References**

Springborn Laboratories. 1987. Acute Toxicity of B0793.02 to Mysid Shrimp (*Mysidopsis bahia*). Unpublished Report No. BW-87-4-2359. Springborn Bionomics, Inc., MA, USA. Contained in: Initial Submission, Toxicological Investigation of N,N-dimethyloctyldecylamine. U.S. EPA Doc. No. FYI-OTS-0794-1164.

**Other Available Reports**

**Other**

Last Changed: July 18, 2002
Order number for sorting: 36
Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | Ditallowmethylamine, hydrogenated (CAS RN 61788-63-4; Dihydrogenated tallow methylamine) |
| Purity: | 100.2% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Test methods conformed to EEC Method C.2. and OECD Guideline 202 |
| Type: | Static |
| GLP: | Yes |
| Year: | 1990 |
| Species/Strain/Supplier: | *Daphnia magna*/NA/Laboratory cultures |
| Analytical Monitoring: | No |
| Exposure Period: | 48 hours |
| Statistical Methods: | $LC_{50}$ values were calculated using the binomial method (described in Stephan 1977) and the trimmed Spearman-Karber method (Hamilton et al. 1977). |
| Remarks: | The study measured the acute toxicity of the test substance to *Daphnia magna* during a 48-hour exposure period. The dilution water used in the test was synthetic water (Dutch Standard Water) having a pH of 8.2 and a hardness of approximately 13°dH. Daphnids used in the test were less than 24 hours old at the beginning of the test and were obtained from parent animals having an age of 2 – 4 weeks. Test vessels were 400-ml beakers holding 250 ml of test solution. Vessels were partly covered with a glass plate. Concentrations were replicated four times, with each replicate holding 5 daphnids (20 per concentration). To prepare the test concentrations, a stock solution of the test substance (320 g/l) was made by adding the test substance to methylethylketone and bringing the mixture to the boiling point (79.6°C). Aliquots of the stock were added to dilution water to achieve the desired test concentrations. Five test concentrations of the test substance, a dilution water control, and a solvent control, which contained methylethylketone at 21.8 µl/l were used. All exposure solutions containing the test substance contained fat-like particles that floated at the surface or stuck to the sides of the test vessels. Once the test solutions were prepared, the daphnids were placed in the test solutions and the test vessels were placed in a temperature-controlled room |

at 20°C. A lighting regime of 16 hours light/8 hours dark was provided by fluorescent tubes. Dissolved oxygen and pH were measured at the beginning and end of the test in one random beaker per test concentration and control. Dissolved oxygen concentrations ranged from 9.0 to 9.2 mg/l, water pH ranged from 7.7 to 7.9, and the air temperature in the test room ranged from 19 to 20°C. Observations of immobilization were recorded at a minimum at 0, 24, and 48 hours. Daphnids were considered immobile if they were not able to swim within 15 seconds after gentle agitation of the test vessel. Endpoint results are given based on nominal concentrations.

**Results**

Nominal concentrations (mg/l): 0 (control), 0 (solvent control), 2.2, 4.6, 10, 22, and 46 mg/l.
Measured concentrations (mg/l): Not determined
Unit: mg/l
$EC_{50}$ (48 hour): 35.2 mg/l (95% confidence limit of 29.1 to 42.6 mg/l)
NOEC (48 hour): 10 mg/l
Result: Percent immobility at 48-hours is presented in the following table:

| **Nominal Concentration (mg/l)** | **0 (negative control)** | **0 (solvent control)** | **2.2** | **4.6** | **10** | **22** | **46** |
|---|---|---|---|---|---|---|---|
| **Immobility (%) at 96-hours** | 0 | 0 | 5 | 0 | 0 | 15 | 70 |

Remarks:

**Conclusions**

The solubility problems may preclude identification of an accurate $EC_{50}$. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study.

**References**

Mark, U. and E.E. Hantink-de Rooij. 1990. Acute Toxicity of ARMEEN M2HT to *Daphnia magna*. Study/Report No. CRL F90215, Akzo Research Laboratories Arnhem, The Netherlands.

## Other Available Reports

### Other

| | |
|---|---|
| Last Changed: | July 25, 2002 |
| Order number for sorting: | 100 |
| Remarks: | |

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | NORAM M2SH ND8 (CAS RN 61788-63-4; Dihydrogenated tallow methylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | ISO 6341 |
| Type: | Static |
| GLP: | Not stated |
| Year: | 1991 |
| Species/Strain/Supplier: | *Daphnia magna* |
| Analytical Monitoring: | Not stated |
| Exposure Period: | 48 hours |
| Statistical Methods: | Not stated |
| Remarks: | Young *Daphnia*, 24-hours old, were exposed to the test substance at concentrations of 0, 0.15, 0.3, 0.45, 0.6, 0.75 and 0.9 g/l for 48 hours. Immobility was examined at 48 hours. The following criteria must be met in order for the test to be valid: 1) the $EC_{50}$ at 24 hours of the reference substance, potassium dichromate, must be 0.9 to 2.0 mg/l ; 2) the dissolved oxygen content at the lowest concentration giving 100% immobility must be > 2.0 mg/l; and 3) the percent immobilization in the control vessels at the end of 24 hours must be ≤ 10%. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0, 150, 300 450, 600, 750, 950 mg/l |
| Measured concentrations (mg/l): | Not stated |
| Unit: | mg/l |
| $EC_{50}$ (48 hour): | 790 mg/l |
| $LC_{100}$ (24 and 48 hours): | > 900 mg/l |
| NOEC (24 and 48 hours): | 100 mg/l and 50 mg/l, respectively |
| Result: | $EC_{50}$ (48 hours) = 790 mg/l |
| Remarks: | Precipitation was observed between 450 and 900 mg/l |

**Conclusions** The solubility problems may preclude identification of an accurate $EC_{50}$. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1A |
| Remarks: | Reliable without restriction; guideline study. |

**References**

Moncel, N. and J.C. Boutonnet. 1991. Rapport d'essai inhibition de la mobilite de *Daphnia magna*. [Report for the study of the inhibition of mobility of *Daphnia magna*] Atochem.

**Other**

| | |
|---|---|
| Last Changed: | July 25, 2002 |
| Order number for sorting: | 103a |
| Remarks: | |

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | DA-1618 [CAS RN 52898-18-7; 1,3-Propanediamine, N-(3-(dodecyloxy)propyl)-] |
| Purity: | Primary amine = 51%<br>Secondary + tertiary amine = 49%<br>Tertiary amine = 2% |
| Remarks: | Test substance was part of a formulated product. Robust summary does not mention a chemical name, just the trade name. |

**Method**

| | |
|---|---|
| Method/guideline followed: | Method consistent with OECD Guideline 202, Part I: Daphnia sp., Acute Immobilization Test and Reproduction Test. |
| Type: | Static |
| GLP: | Yes |
| Year: | 1999 |
| Species/Strain/Supplier: | *Daphnia magna*/NA/Laboratory culture |
| Analytical Monitoring: | No |
| Exposure Period: | 48 hours |
| Statistical Methods: | $LC_{50}$ determined using the Trimmed Spearman-Karber calculation. |
| Remarks: | The acute toxicity of the test substance was determined for *Daphnia magna* under static exposure conditions. Daphnids used in testing were from an in-house culture and were less than 24 hours old at test initiation. Adult daphnids were fed algae at least every three days during culturing. Temperature, dilution water and lighting were the same in culturing as used during testing. Dilution water used in the test was moderately hard freshwater prepared by blending naturally hard well water with well water that had been demineralized. The blended water yielded a total hardness of 130 to 160 mg/l as $CaCO_3$. Testing was conducted in 250-ml glass vessels containing 200 ml of test solution. Each treatment was replicated four times. Test solutions were prepared by diluting aliquots of an aqueous stock solution of the test substance with dilution water. Five daphnids were impartially distributed to each replicate vessel. Vessels were placed in a waterbath at a temperature of 20±1°C. Fluorescent lighting was maintained on a 16-hour light/8 hour dark photoperiod and 30-minute simulated dawn and dusk periods. Light intensity during testing was 507 lux. Observations for |

immobility/mortality were made at approximately 24and 48 hours. During testing, dissolved oxygen remained above 7.6 mg/l (>89% saturation), water pH ranged from 8.4 to 8.7, and temperature ranged from 19.6 to 20.8°C.

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0.0038, 0.0075, 0.015, 0.030 and 0.060 mg/l |
| Measured concentrations (mg/l): | NA |
| Unit: | µg/l converted to mg/l |
| $EC_{50}$ (48 hour): | 0.021 mg/l |
| NOEC (48 hour): | 0.015 mg/l |
| Remarks: | After 48 hours, 100% immobility/mortality was observed at concentrations of 0.030 and 0.060 mg/l. Immobility/mortality in the remaining treatments was 0%. The 48-hour $EC_{50}$ was 0.021 mg/l. The 95% confidence limits could not be calculated. The no-observed-effect concentration (NOEC) was 0.015 mg/l and the slope of the dose-response line was 15. |

**Conclusions**

The endpoint has been adequately characterized by this study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1A |
| Remarks: | Reliable without restriction; guideline study. |

**References**

Rhodes, J.E. and J.E. Whitaker. 1999. Acute Toxicity of DA 1618 to the Water Flea, *Daphnia magna*, Determined Under Static Conditions. Report No. 45356. Analytical Bio-Chemistry Laboratories Inc., Columbia, Missouri.

**Other Available Reports**

**Other**

| | |
|---|---|
| Last Changed: | July 19, 2002 |
| Order number for sorting: | 164 |
| Remarks: | |

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

**Test Substance**

| | |
|---|---|
| Identity: | Sododecyloxypropylaminopropylamine (CAS RN 68479-04-9; 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched) |
| Purity: | NA |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Test methods were based on ASTM Standard 4729-80, Standard Practice for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates and Amphibians, and EPA-660/3-75-009, Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. |
| Type: | Static-renewal, renewal at 24 hours |
| GLP: | Yes |
| Year: | 1993 |
| Species/Strain/Supplier: | *Ceriodaphnia dubia*/NA/Laboratory culture |
| Analytical Monitoring: | No |
| Exposure Period: | 48 hours |
| Statistical Methods: | $LC_{50}$ values calculated using a computer program that performed the moving average method. |
| Remarks: | The test measured the acute toxicity of the test substance to *Ceriodaphnia dubia*. The test was conducted in 30-ml polypropylene cups filled with 25 ml of test solution. Ten animals were used in each of four replicate containers (40 fish per test concentration). Test solutions were renewed at 24 hours. The dilution water used in testing was spring water diluted with deionized water. Test concentrations were prepared by adding aliquots of an aqueous stock solution to moderately-hard spring water. Dissolved oxygen, pH, temperature and conductivity were measured daily in all test levels. A photoperiod of 16 hours light/8 hours dark was provided during testing. Alkalinity was measured initially in the control and all test concentrations. Dissolved oxygen ranged from 7.8 to 9.2 mg/l, pH ranged from 8.0 to 8.1, temperature remained steady at 21°C. Conductivity and alkalinity was not provided in the reviewed report. Test chambers were monitored for mortalities daily. Death was defined as the absence of movement. |

**Results**

Nominal concentrations (mg/l): 0 (control), 0.04, 0.07, 0.15, 0.3, and 0.6 mg/l
Measured concentrations (mg/l): NA
Unit: mg/l
$LC_{50}$ (48 hour): 0.132 mg/l
(95% confidence limit of 0.113 to 0.153 mg/l)
NOEC (48 hour): 0.07 mg/l
Result: Percent mortality at 48-hours is presented in the following table:

| **Nominal Concentration (mg/l)** | **0** | **0.04** | **0.07** | **0.15** | **0.3** | **0.6** |
|---|---|---|---|---|---|---|
| **Mortality (%) at 96-hours** | 0 | 2.5 | 7.5 | 45 | 100 | 100 |

Remarks:

**Conclusions**

The 48-hour acute toxicity of *Ceriodaphnia dubia* to 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2C
Remarks: Reliable with restrictions; comparable to guideline study with acceptable restrictions.

**References**

MacGregor, R., III. 1993. Alkyl Amine DA-16, Evaluation of the Static Renewal Acute Toxicity to *Ceriodaphia dubia* and *Pimephales promelas*. Final Report No. ATR-30-93-034, Halliburton NUS Environmental Corporation, Houston, Texas. EPA Document No. 88-930000335

**Other Available Reports**

**Other**

Last Changed: July 27, 2002
Order number for sorting: 118a
Remarks:

## 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

**Test Substance**

| | |
|---|---|
| Identity: | Amine HBG (CAS RN 61788-45-2; Amines, hydrogenated tallow alkyl) |
| Purity: | >95% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline No. 201. Algal Growth Inhibition Test |
| Type: | Static |
| GLP: | Yes |
| Year: | 1984 |
| Species/Strain/Supplier: | *Scenedesmus subspicatus*/CCAP 276/20/Culture centre of Algae and Protozoa (CCAP) c/o Institute of Freshwater Ecology, Cumbria, UK |
| Analytical Monitoring: | Not stated |
| Exposure Period: | 96 hours |
| Statistical Methods: | Not stated |
| Remarks: | The study measured the growth inhibition of *Scenedesmus subspicatus* during a 96-hour exposure period to the test substance. Concentrations of the test substance were 0.001, 0.002, 0.004, 0.008, 0.016 mg/l and untreated and vehicle (100 µl/l isopropyl alcohol) controls. Pretreatment: culture medium inoculated from a master culture, incubated under continuous illumination(7000 lux) aerated, 24°C to give an algal suspension with an exponential growth. The initial ell concentration was 2.8 x $10^4$ cells/ml.<br>Test conditions: The incubation took place in 250-ml flasks with 100-ml test medium shaken constantly at 24°C over a 3 day period during which the solutions were continuously exposed to light (~7000 lux). The pH of the test solutions was 8.0 to 9.0. Dilution water was nutrient medium as described in OECD 201. Test medium chemistry: Hardness = 0.18 mmol/l Ca & Mg; EDTA = 3 x 10-4 mmol/l; P = 0.36 mg/l; and N = 4 mg/l. The test was run with three replicates.<br>Cell growth was measured spectrophotometrically at 0-, 24-, 48-, 72- and 96-hours. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (untreated), 0(vehicle), 0.001, 0.002, 0.004, 0.008, 0.016 mg/l |
| Measured concentrations (mg/l): | Not reported |
| Unit: | µg/l |

Element value: 96-hour $E_bC_{50}$ (biomass)
96-hour $E_rC_{50}$ (growth rate)
NOEC

Result: $E_bC_{50}$ = 0.012 mg/l
$E_rC_{50}$ = ca. 0.016 mg/l
NOEC = 0.008 mg/l

Remarks: At 0.16 mg/l, the cells were clumped together, paler in color with visible cell debris.

| Concentration (mg/l) | 96-hour Biomass Inhibition (%) | 96-hour Growth Rate Inhibition (%) |
|---|---|---|
| **0 (untreated)** | 0 | 0 |
| **0 (vehicle)** | 0 | 1 |
| **0.001** | -1 | 1 |
| **0.002** | -3 | 0 |
| **0.004** | 0 | 1 |
| **0.008** | 4 | 0 |
| **0.016** | 85 | 50 |

**Conclusions**

The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study

**References**

Handley, J.W. and C. Mead. 1991. Assessment of the Algistatic Effect of Amine. Project No. 116/78. Berol Nobel Nacka AB, Safepharm Laboratories Limited, HBG.

**Other**

Last Changed: September 16, 2002
Order number for sorting: 106c
Remarks:

## 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

**Test Substance**

| | |
|---|---|
| Identity: | Genamin SH 100 D (CAS RN 124-30-1; Octadecylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline No. 201. Algal Growth Inhibition Test |
| Type: | Static |
| GLP: | Yes |
| Year: | 1984 |
| Species/Strain/Supplier: | *Scenedesmus subspicatus* – CHODAT SAG 86.81 /Supplier: Pflanzenphysiologischen Institut der Universitaet, Goettingen |
| Analytical Monitoring: | No |
| Exposure Period: | 72 hours |
| Statistical Methods: | SigmaPlot, Jandel Scientific Version 5.0, 1992. |
| Remarks: | The study measured the growth inhibition of *Scenedesmus subspicatus* during a 72-hour exposure period to the test substance. Concentrations of the test substance were 0, 1, 3.2, 10, 32, 100 and 320 µg/l. Test conditions: The incubation took place in 20-ml plastic cuvettes with 10-ml test medium at 23°C (pH = 7.9 to 8.2) over a 3 day period during which the solutions were continuously exposed to light (2333 to 4667 lux). The test was run with four replicates. Cell density was measured at 24-hours, 48-hours and 72-hours by chlorophyll a-fluorescence. The light intensity (2333 – 4667 lux) was lower than recommended in the OECD 201 guideline (8000 lux). Since the control growth rate was acceptable, factor 23 in 72 hours (OECD = at least factor 16 in 72 hours) the lower light intensity did not affect the integrity of the study. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0.001, 0.0032, 0.01, 0.032, 0.1 and 0.32 mg/l |
| Measured concentrations (mg/l): | NA |
| Unit: | mg/l |
| Element value: | 72-hour $E_bC_{50}$ (biomass)<br>72-hour $E_rC_{50}$ (growth rate) |
| Result: | $E_bC_{50}$ = 0.062 mg/l<br>$E_rC_{50}$ = 0.12 mg/l |

Remarks:

| Concentration (mg/l) | 72-hour Biomass Inhibition (%) | 72-hour Growth Rate Inhibition (%) |
|---|---|---|
| **0** | 0 | 0 |
| **0.001** | 9 | 4 |
| **0.0032** | 4 | 5 |
| **0.01** | 4 | 5 |
| **0.032** | 16 | 10 |
| **0.1** | 74 | 45 |
| **0.32** | 100 | 100 |

Additional endpoints included the following:
$E_bC_0$ = 0.01 mg/l
$E_bC_{10}$ = 0.018 mg/l
$E_rC_{10}$ = 0.029 mg/l

**Conclusions**

The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study.

**References**

Scheerbaum, D. 1994. Pruefung auf Hemmung der Algencellvermehrung von Genamin SH 100 D. [Algae inhibition study with Genamin SH 100 D] Study No. 94905HM/SS042621. Dr. U. Noack-Laboratory for Applied Biology. Sarstedt, Germany

**Other**

Last Changed: June 24, 2002
Order number for sorting: 56a
Remarks:

## 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

**Test Substance**

| | |
|---|---|
| Identity: | Genamin CC100 D (CAS RN 61788-46-3 Amines, coco alkyl) |
| Purity: | 99.1% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline No. 201. Algal Growth Inhibition Test |
| Type: | Static |
| GLP: | Yes |
| Year: | 1984 |
| Species/Strain/Supplier: | *Scenedesmus subspicatus* /CHODAT SAG 86.81/ Pflanzenphysiologischen Institut der Universitaet, Goettingen |
| Analytical Monitoring: | No |
| Exposure Period: | 72 hours |
| Statistical Methods: | SigmaPlot, Jandel Scientific Version 5.0, 1992. |
| Remarks: | The study measured the growth inhibition of *Scenedesmus subspicatus* to the test substance during a 72-hour exposure period. Concentrations of the test substance were 0, 3.2, 10, 32, 100, 320, and 1000 µg/l. Source of the dilution water was OECD medium. The test took place in 20-ml plastic cuvettes with 10-ml test medium at 23°C over a 3-day period during which the solutions were continuously exposed to light (2333 to 4667 lux). The pH was 7.9 to 8.1 during the test. The test was run with four replicates. Initial cell concentration was 6 to 7 x $10^3$ cells/ml. Cell density was measured at 24-hours, 48-hours and 72-hours by chlorophyll a-fluorescence. The light intensity (2333 – 4667 lux) was lower than recommended in the OECD 201 guideline (8000 lux). Since the control growth rate was acceptable, factor 23 in 72 hours (OECD = at least factor 16 in 72 hours) the lower light intensity did not affect the integrity of the study. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0.0032, 0.01, 0.032, 0.1, 0.32 and 1.0 mg/l |
| Measured concentrations (mg/l): | Not reported |
| Unit: | mg/l |
| Element value: | 72-hour $E_bC_{50}$ (biomass)<br>72-hour $E_rC_{50}$ (growth rate) |
| Result: | $E_bC_{50}$ = 0.14 mg/l |

$E_rC_{50}$ = 0.17 mg/l

Remarks: The growth factor for the control was 23 in 72 hours.

| Concentration (mg/l) | 72-hour Growth Rate Inhibition (%) | 72-hour Biomass Inhibition (%) |
|---|---|---|
| **0** | 0 | 0 |
| **0.0032** | 4 | 0 |
| **0.01** | 3 | -1 |
| **0.032** | 3 | 4 |
| **0.1** | 13 | 32 |
| **0.32** | 100 | 100 |
| **1.0** | 100 | 100 |

Additional endpoints included the following:
$E_bC_0$ = 0.032 mg/l
$E_bC_{10}$ = 0.041 mg/l
$E_rC_{10}$ = 0.07 mg/l

**Conclusions**

The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A

Remarks: Reliable without restriction; guideline study.

**References**

Scheerbaum, D. 1994. Pruefung auf der Algenzellvermehrung von Genamin CC 100 D. [Algae inhibition study with Genamin CC 100 D] Project No. 40905HM/SS042591. Hoechst AG, Dr. U. Noack-Laboratorium fuer angewandte biologie.

**Other**

Last Changed: June 26, 2002

Order number for sorting: 92a

Remarks:

## 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

**Test Substance**

| | |
|---|---|
| Identity: | Amine KK (CAS RN 61788-46-3; Amines, coco alkyl) |
| Purity: | 94% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline No. 201. Algal Growth Inhibition Test |
| Type: | Static |
| GLP: | Yes |
| Year: | 1984 |
| Species/Strain/Supplier: | *Scenedesmus subspicatus*/CCAP 276/20/Culture Centre of Algae and Protozoa (CCAP) c/o Institute of Freshwater Ecology, Cumbria, UK. |
| Analytical Monitoring: | No |
| Exposure Period: | 96 hours |
| Statistical Methods: | SigmaPlot, Jandel Scientific Version 5.0, 1992. |
| Remarks: | The study measured the growth inhibition of *Scenedesmus subspicatus* to the test substance during a 96-hour exposure period. Concentrations of the test substance were 0 (untreated control), 0 (vehicle control), 0.1, 0.2, 0.4, 0.8, 1.6 µg/l. The vehicle was 1% Tween 80 acetone. Test conditions: The incubation took place in 250-ml flasks with 100-ml test medium at 24°C over a 3 day period during which the solutions were continuously exposed to light (7000 lux). The test was run with three replicates. Test vessels were pre-rinsed with test solution because the test substance can sorb to the glass surface. Cell growth was measured spectrophotometrically. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (untreated), 0 (vehicle) 0.0001, 0.0002, 0.0004, 0.0008, 0.0016 mg/l |
| Measured concentrations (mg/l): | Not reported |
| Unit: | mg/l |
| Element value: | 96-hour $E_bC_{50}$ (biomass)<br>96-hour $E_rC_{50}$ (growth rate) |
| Result: | $E_bC_{50}$ = 0.00075 mg/l<br>$E_rC_{50}$ = .0011 mg/l |

Remarks: Additional endpoints include the following:
$E_bC_{10}$ = 0.00021 mg/l
$E_rC_{10}$ = 0.00024 mg/l
Control growth factor was 21 to 25 in 96 hours.

| Concentration (mg/l) | 96-hour Biomass Inhibition (%) | 96-hour Growth Rate Inhibition (%) |
|---|---|---|
| **0 (untreated)** | 0 | 0 |
| **0 (vehicle)** | 1 | 1 |
| **0.0001** | -1 | 1 |
| **0.0002** | 1 | 0 |
| **0.0004** | 20 | 7 |
| **0.0008** | 49 | 32 |
| **0.0016** | 83 | 75 |

Additional endpoints included the following:
LOEC: 0.0002 mg/l
$E_bC_{10}$ = 0.00021 mg/l
$E_rC_{10}$ = 0.00024 mg/l

**Conclusions**

The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study.

**References**

Handley, J.W. and C. Mead. 1991. Assessment of the Algistatic Effect of Amine KK. Project No. 116/70. Berol Nobel Nacka AB, Safepharm Laboratories.

**Other**

Last Changed: June 26, 2002
Order number for sorting: 92b
Remarks:

## 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

**Test Substance**

| | |
|---|---|
| Identity: | Genamin TA 100 D (CAS RN 61790-33-8; Amines, tallow alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline No. 201. Algal Growth Inhibition Test |
| Type: | Static |
| GLP: | Yes |
| Year: | 1984 |
| Species/Strain/Supplier: | *Scenedesmus subspicatus* – CHODAT SAG 86.81/ Pflanzenphysiologischen Institut der Universitaet, Goettingen |
| Element Basis: | Biomass and growth rate |
| Analytical Monitoring: | Not stated |
| Exposure Period: | 72 hours |
| Statistical Methods: | SigmaPlot, Jandel Scientific Version 5.0, 1992. |
| Remarks: | The study measured the growth inhibition of *Scenedesmus subspicatus* to the test substance during a 72-hour exposure period. Concentrations of the test substance were 0, 0.32, 1.0, 3.2, 10, 32 and 100 µg/l. Test conditions: The incubation took place in 20-ml plastic cuvettes with 10-ml test medium at 23°C, with a pH of 8.0 to 8.2, over a 3 day period during which the solutions were continuously exposed to light (2333 to 4667 lux). The test was run with three replicates. Initial cell concentration was 7 to 8 E3 cells/ml. Dilution water source was OECD-medium. Cell density was measured at 24-hours, 48-hours and 72-hours by chlorophyll-a fluorescence. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0.00032, 0.001, 0.0032, 0.010, 0.032 and 0.1 mg/l |
| Measured concentrations (mg/l): | Not reported |
| Unit: | mg/l |
| Element value: | 72-hour $E_bC_{50}$ (biomass)<br>72-hour $E_rC_{50}$ (growth rate) |
| Result: | $E_bC_{50}$ = 0.052 mg/l<br>$E_rC_{50}$ = 0.059 mg/l |

Remarks: The light intensity was lower than recommended (2333 to 4667 lux, OECD 201 8000 lux). Since the control growth was acceptable (factor 39 in 72 hours) this did not affect the integrity of the study.

| Concentration (mg/l) | 72-hour Biomass Inhibition (%) | 72-hour Growth Rate Inhibition (%) |
|---|---|---|
| **0** | 0 | 0 |
| **0.00032** | 2 | 1 |
| **0.0010** | -6 | -1 |
| **0.0032** | -8 | 1 |
| **0.01** | 4 | 5 |
| **0.032** | 14 | 6 |
| **0.100** | 97 | 88 |

Additional endpoints included the following:
$E_bC_{10}$ = 0.021 mg/l
$E_rC_{10}$ = 0.033 mg/l

**Conclusions**

The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study.

**References**

Scheerbaum, D. 1994. Pruefung auf der Algenzellvermehrung von Genamin TA 100 D [Algae inhibition study with Genamin TA 100 D] (940905HM/SS042611). Dr U. Noack-laboratorium fuer angewandte biologie. Hoechst AG.

**Other**

Last Changed: August 9, 2002
Order number for sorting: 217a
Remarks:

## 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

**Test Substance**

| | |
|---|---|
| Identity: | Genamin TA 100 D (CAS RN 61790-33-8; Amines, tallow alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline No. 201. Algal Growth Inhibition Test |
| Type: | Static |
| GLP: | Yes |
| Year: | 1984 |
| Species/Strain/Supplier: | *Scenedesmus subspicatus* – CHODAT SAG 86.81 / Pflanzenphysiologischen Institut der Universitaet, Goettingen |
| Element Basis: | Biomass and growth rate |
| Analytical Monitoring: | No |
| Exposure Period: | 72 hours |
| Statistical Methods: | SigmaPlot, Jandel Scientific Version 5.0, 1992. |
| Remarks: | The study measured the growth inhibition of *Scenedesmus subspicatus* to the test substance during a 72-hour exposure period. Concentrations of the test substance were 0, 1.0, 3.2, 10, 32, 100, and 320 µg/l. Test conditions: The incubation took place in 20-ml plastic cuvettes with 10-ml test medium at 22-23°C, with a pH of 7.6 to 8.4, over a 3 day period during which the solutions were continuously exposed to light (2333 to 4667 lux). The test was run with three replicates. Initial cell concentration was 0.9 to 1.1 E4 cells/ml. Dilution water source was OECD-medium. Cell density was measured at 24-hours, 48-hours and 72-hours by chlorophyll-a fluorescence. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0.001, 0.0032, 0.01, 0.032, 0.1, 0.32 mg/l |
| Measured concentrations (mg/l): | NA |
| Unit: | Mg/l |
| Element value: | 72-hour $E_bC_{50}$ (biomass)<br>72-hour $E_rC_{50}$ (growth rate) |
| Result: | $E_bC_{50}$ = 0.068 mg/l<br>$E_rC_{50}$ = 0.083 mg/l |

Remarks: The light intensity was lower than recommended (2333 to 4667 lux, OECD 201 = 8000 lux). Since the control growth was acceptable (factor 39 in 72 hours) this did not affect the integrity of the study.

| Concentration (mg/l) | 72-hour Biomass Inhibition (%) | 72-hour Growth Rate Inhibition (%) |
|---|---|---|
| **0** | 0 | 0 |
| **0.001** | 3 | -1 |
| **0.0032** | -3 | -2 |
| **0.01** | -5 | 1 |
| **0.032** | 5 | 3 |
| **0.1** | 80 | 40 |
| **0.32** | 103 | 114 |

Additional endpoints included the following:
$E_bC_{10}$ = 0.036 mg/l
$E_rC_{10}$ = 0.045 mg/l

**Conclusions** The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**
Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study.

**References**

Scheerbaum, D. 1996. Genamin TA 100 D Algen, Zellvermehrungs-Hemtest. Study [Genamin TA 100 D Algae inhibition study] No. 960105HM/SS049481. Hoechst AG, Dr. U. Noack-Laboratorium fuer angewandte biologie.

**Other**
Last Changed: August 9, 2002
Order number for sorting: 217b
Remarks:

## 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

**Test Substance**

| | |
|---|---|
| Identity: | 9-Octadecen-1-amine; oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | 94% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Test methods conformed to U.S. EPA Test Guideline No. 797.1075, which conforms to OECD Guideline No. 201. Test methods also adapted from U.S. EPA OPTS Guideline No. 850.1085, Fish Acute Toxicity Mitigated by Humic Acid. |
| Type: | Static acute |
| GLP: | Yes |
| Year: | 1995 |
| Species/Strain/Supplier: | *Selenastrum capricornutum*/CCAP 276/4B/Culture Collection of Algae and Protozoa, The Ferry House, Cumbria, Ambleside, United Kingdom |
| Element Basis: | Area under the growth curve ($E_bC$) or growth rate ($E_rC$) |
| Exposure Period: | 96 hours |
| Analytical Monitoring: | Yes |
| Statistical Methods: | $EC_{50}$ values determined by probit analysis. The NOEC and LOEC were determined using Williams test (Biometrics 28:519-531.). |
| Remarks: | The study measured the growth inhibition of the test substance to *Selenastrum capricornutum* during a 96-hour exposure period. Exposures were conducted without humic acid and with humic acid in the dilution water at 5 and 10 mg/l. The summary includes data only for the portion of the study that reports the exposure without humic acid present in the dilution water. The dilution water used in the test was a mineral salts medium described by EPA Guideline No. 797.1075. Test flasks were 100-ml Erlenmeyer flasks containing 40-ml of test solution. The test was run with six replicate flasks of the control group and three replicate flasks of each test solution. The test solutions were prepared by diluting an aqueous stock solution of the test substance (1.001 g/l target concentration) with nutrient medium. Test solutions were distributed to the flasks, and the flasks were inoculated with *Selenastrum capricornutum* cells to achieve an initial cell density of $2 \times 10^3$ cells/ml. Algal cells used in preparation of the inoculum were |

obtained from a culture of exponentially growing algal cells. Test flasks were placed in a testing area having continuous uniform illumination of 150 to 200 $\mu molm^{-2}s^{-1}$ and a temperature of 20±2°C. The spectral range of light was 400 to 700 nm produced by 30 W fluorescent lamps of the type "universal white" (color temperature approximately 4000 K). Flasks were continuously rotated at 100 rpm to prevent sedimentation of the algal cells. Cell densities were determined photometrically using a UV/VIS spectrophotometer. Chemical analyses of the test solutions were made at 0 and 96 hours in the control, low level, mid level and high level test concentration. Cell densities obtained by the photometric analysis were converted to growth and growth rate. Nominal concentrations were used in the calculation of endpoints values.

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0.01, 0.02, 0.04, 0.08, and 0.15 mg/l |
| Measured concentrations (mg/l): | 0-hour measurements in control, 0.01, 0.04 and 0.15 mg/l were 0, 0.006, 0.011, and ND mg/l, respectively.<br>96-hour measurements in control, 0.01, 0.04 and 0.15 mg/l were 0, ND, 0.016, and 0.11 mg/l, respectively. ND indicates that the samples were not properly analyzed and contained analytical disturbances. Percent of nominal concentrations ranged from 28 to 73%. |
| Unit: | mg/l |
| Element value: | 96-hour $E_bC_{50}$ (endpoint based on area under the growth curve)<br>96-hour $E_rC_{50}$ (endpoint based on growth rate) |
| Result: | $E_bC_{50}$ = 0.03 mg/l (95% confidence limit of 0.03 to 0.03 mg/l)<br>$E_rC_{50}$ = 0.04 mg/l (95% confidence limit of 0.04 to 0.04 mg/l) |
| NOEC, LOEC: | LOEC = 0.02 mg/l<br>NOEC = 0.01 mg/l |
| Satisfactory control response: | Yes |
| Remarks: | Additional endpoints included the following:<br>$E_bC_{20}$ = 0.02 mg/l (0.02 – 0.02 mg/l)<br>$E_bC_{80}$ = 0.04 mg/l (0.04 – 0.04 mg/l)<br>$E_rC_{20}$ = 0.03 mg/l (0.03 – 0.03 mg/l)<br>$E_rC_{80}$ = 0.05 mg/l (0.05 – 0.05 mg/l) |

**Conclusions**

The 96-hour toxicity of 9-Octadecen-1-amine to *Selenastrum capricornutum* was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study.

**References**

Kroon, A.G.M., M.G.J. Geurts and C. de Ruiter. 1995. Toxicity of Oleylamine to the Freshwater Alga *Selenastrum capricornutum*. Report No. RGL F95037. Akzo Nobel Central Research, Arnhem, The Netherlands.

**Other**

Last Changed: July 17, 2002
Order number for sorting: 16
Remarks:

## 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

**Test Substance**

| | |
|---|---|
| Identity: | Genamin LA 302 D (CAS RN 112-18-5; N,N-Dimethyl-1-dodecanamine) |
| Purity: | 99.3% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Modified OECD Guideline No. 201. Algal Growth Inhibition Test |
| Type: | Static |
| GLP: | Yes |
| Year: | 2000 |
| Species/Strain/Supplier: | *Scenedesmus subspicatus* CHODAT SAG 86.81/Algae cultures (SAG) from Pflanzenphysiologisches Institut der Universität, Nikolausberger Weg 18, D-37073 Göttingen, and fresh cultures prepared every month on Z-Agar. |
| Element Basis: | Biomass and growth rate |
| Analytical Monitoring: | No |
| Exposure Period: | 72 hours |
| Statistical Methods: | NOEC: One way analysis of variance (ANOVA) and DUNNETT'S test of biomass integrals and growth rate ($\alpha = 0.05$).<br>$EC_{50}$-values: confidence intervals. |
| Remarks: | The study measured the growth inhibition of the test substance to *Scenedesmus subspicatus* during a 72-hour exposure period. Two different natural waters (rivers Elbe and Böhme) were used as the test medium. Tests with Elbe water used seven concentrations of the test substance ranging from 10 to 640 µg/l. Tests with Böhme water used six concentrations of the test substance ranging from 10 to 320 µg/l. Three replicates were tested for each concentration and six replicated for the control. No vehicle was used to dissolve the test substance. In addition, a parallel test with OECD-medium and two concentrations of test substance (10 and 100 µg/l and control) was carried out. Initial cell density was nominally $10^4$ cells/ml. Test conditions: The incubation took place in Erlenmeyer flasks in accordance with quoted guidelines at 23 ± 2°C over a 3 day period during which the solutions were shaken on a rotary shaker and oscillated at approximately 70 rpm. Light intensity was 60 – 120 $\mu E/m^2$ at the water surface for 24 hours/day. Test flasks were 250 ml Erlenmeyer flasks |

containing 100 ml solution. The algae were acclimated to the test substance for three days prior to the test. Fluorescence was measured prior to application of the test item, and after 24, 48 and 72 hours.
Biomass and growth rate were measured after 24, 48 and 72 hours.

**Results**

Nominal concentrations (mg/l): 0 (control), 0.01, 0.02, 0.04, 0.08, 0.16, and 0.32 mg/l plus 0.64 mg/l for Elbe water only.
Measured concentrations (mg/l): NA
Unit: mg/l
Element value: 72-hour $E_bC_{50}$ (biomass)
72-hour $E_rC_{50}$ (growth rate)
NOEC (biomass and growth rate)
Satisfactory control response: Yes
Result:

| | **Inhibition of biomass (mg/l)** | | |
|---|---|---|---|
| | **Elbe** | **Böhme** | **OECD-Medium** |
| **$E_bC_{50}$** | 0.056 | 0.034 | 0.006 |
| **95% confidence interval** | 51 to 62 | 0.03 to 0.038 | NA |
| **NOEC** | 0.02 | 0.01 | <0.01 |
| | **Growth rate-related inhibition (mg/l)** | | |
| | **Elbe** | **Böhme** | **OECD-Medium** |
| **$E_rC_{50}$** | 0.092 | 0.056 | 0.014 |
| **95% confidence interval** | 0.082 to 0.102 | 0.051 to 0.062 | NA |
| **NOEC** | 0.02 | 0.02 | <0.01 |

Remarks:

**Elbe Water:**

| **Concentration (mg/l)** | **72-hour Biomass Inhibition (%)** | **72-hour Growth Rate Inhibition (%)** |
|---|---|---|
| **0.64** | 100.00 | 100.00 |
| **0.32** | 100.00 | 100.00 |
| **0.16** | 95.63 | 84.86 |
| **0.08** | 58.53 | 26.72 |
| **0.04** | 35.83 | 15.01 |
| **0.02** | -3.62 | 1.38 |
| **0.01** | -2.24 | 3.77 |

**Böhme Water:**

| Concentration (mg/l) | 72-hour Biomass Inhibition (%) | 72-hour Growth Rate Inhibition (%) |
|---|---|---|
| **0.32** | 100.00 | 100.00 |
| **0.16** | 97.22 | 100.00 |
| **0.08** | 89.63 | 74.29 |
| **0.04** | 55.30 | 25.18 |
| **0.02** | 25.32 | 5.13 |
| **0.01** | -0.06 | -1.87 |

**OECD-Medium:**

| Concentration (mg/l) | 72-hour Biomass Inhibition (%) | 72-hour Growth Rate Inhibition (%) |
|---|---|---|
| **0.1** | 97.64 | 100.00 |
| **0.01** | 65.23 | 26.20 |

**Conclusions**

The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1D

Remarks: Reliable without restriction; modified OECD 201 guideline study

**References**

Noack, U. 2000. Genamin LA 302 D. Alga, Growth Inhibition Test with 2 Natural River Waters, with *Scenedesmus subspicatus*, 72 h.. Study No. SSO7535N. Dr. U. Noack-Laboratory for Applied Biology. Sarstedt, Germany.

**Other**

Last Changed: June 12, 2002

Order number for sorting: 124d

Remarks:

## 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

**Test Substance**

| | |
|---|---|
| Identity: | Genamin LA 302 D (CAS RN 112-18-5; N,N-Dimethyl-1-dodecanamine) |
| Purity: | 99.9% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline No. 201. Algal Growth Inhibition Test |
| Type: | Static |
| GLP: | Yes |
| Year: | 1995 |
| Species/Strain/Supplier: | *Scenedesmus subspicatus* – Nr. 8681 SAG/supplier not stated. |
| Element Basis: | Biomass and growth rate |
| Exposure Period: | 72 hours |
| Analytical Monitoring: | Yes |
| Statistical Methods: | Not stated |
| Remarks: | The study measured the growth inhibition of the test substance to *Scenedesmus subspicatus* during a 72-hour exposure period. Five concentrations of the test substance ranging from 2.6 to 40 µg/l were evaluated. In addition, two controls groups were evaluated; one with untreated water and one containing 1 mg/l of Tween 80.<br>Test conditions: The incubation took place in Erlenmeyer flasks in accordance with quoted guidelines at 23 ± 1°C over a 3 day period during which the solutions were stirred. Test flasks were 100 ml Erlenmeyer flasks containing 100 ml solution. The algae were not acclimated to the test substance prior to the test. The test was run with six replicate flasks of the control group and three replicate flasks of each test solution and the Tween 80 test group. Biomass and growth ratio were measured after 24, 48 and 72 hours. |

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0.0026, 0.005, 0.01, 0.02 and 0.04 mg/l |
| Measured concentrations (mg/l): | Immediately after the start of the test, the highest test concentration was analyzed by gas chromatographic analysis giving a concentration of 80% of the nominal concentration. Since the measured concentrations were below the nominal concentrations, all effect concentrations ($E_bC$ and $E_rC$) were reported with the symbol "≤". |

Unit: mg/l
Element value: 72-hour $E_bC_{50}$ (biomass)
72-hour $E_rC_{50}$ (growth rate)
Result: $E_bC_{50} \leq 0.0133$ mg/l
$E_rC_{50} \leq 0.0235$ mg/l
NOEC $NOE_bC > 0.0026$ mg/l
$NOE_rC > 0.0026$ mg/l
Satisfactory control response: Yes
Remarks:

| Concentration | 72-hour Biomass Inhibition (%) | 72-hour Growth Rate Inhibition (%) |
|---|---|---|
| **Tween 80** | -3.34 | -0.78 |
| **0.0026 mg/l** | 3.38 | 0.61 |
| **0.005 mg/l** | 7.12 | 1.64 |
| **0.01 mg/l** | 24.80 | 5.86 |
| **0.02 mg/l** | 66.56 | 26.74 |
| **0.04 mg/l** | 94.82 | 74.98 |

Additional endpoints included the following:
$E_bC_{10} \leq 0.0047$ mg/l
$E_bC_{90} \leq 0.0308$ mg/l
$E_rC_{10} \leq 0.007$ mg/l
$E_rC_{90} \leq 0.0786$ mg/l

**Conclusions**

Genamin LA 302 D was very toxic to algae, *Scenedesmus subspicatus*. (Author of report) The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study.

**References**

Reinhardt, D.I. 1995. Prüfung der Schadwirkung gegenüber Algen (Algentoxizität) von Genamin LA 302D. [Study of the adverse effects in algae (algae toxicity) with Genamin LA 302D] Report No. 93-0161-22. Hoechst AG, Abteilung Umweltschutz Biologische Laboratorien, Germany.

**Other**

Last Changed: June 7, 2002
Order number for sorting: 124L
Remarks:

## 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

**Test Substance**

| | |
|---|---|
| Identity: | Octadecylamine (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Method developed by Payne, A.G. and R.H. Hall. 1979. A Method for Measuring Algal Toxicity and its Application to the Safety Assessment of New Chemicals. American Society for Testing and Materials, ASTM STP 667. |
| Type: | Static |
| GLP: | No, but appeared to follow spirit of GLPs. |
| Year: | 1986 |
| Species/Strain/Supplier: | *Selenastrum capricornutum*/NA/Laboratory culture<br>*Microcystis aeruginosa*/UTEX L2061/Laboratory culture |
| Element Basis: | Biomass |
| Exposure Period: | 5 days exposure, 9 days recovery |
| Analytical Monitoring: | No |
| Statistical Methods: | Algistatic and algicidal concentrations defined using an inverse estimation method and computer program developed by the sponsor of the study. |
| Remarks: | Test vessels were 250-ml Erlenmeyer flasks holding 50 ml of test solution. Test solutions were made by adding aliquots of a test substance stock solution made in dimethylformamide to U.S. EPA AAP growth medium. Treatment groups were replicated three times. An inoculum of each species of algae was prepared in AAP medium and each flask was inoculated with an aliquot of the inoculum. The nominal initial cell density was 20,000 cells/ml for *Selenastrum* and 50,000 cells/ml for *Microcystis*. Flasks were kept in a controlled temperature incubator at 24±2°C. Flasks were continuously shaken at 100 oscillations/minute. Illumination was 4304 ± 650 lumens/$m^2$ for *Selenastrum* and 2152 ± 323 lumne/$m^2$ for *Microcystis* using cool-white fluorescent lights. Flasks were randomly repositioned each day to minimize spatial effects of light variation. At the end of the 5-day exposure period, samples from the flasks containing cell densities similar to or less than the initial inoculum level were taken, washed with AAP medium and resuspended in test material-free |

AAP medium for a 9-day recovery period. Those flasks were replaced in the incubator under original environmental conditions. Biomass measurements during the test were estimated from cell counts using an electronic particle counter. Measurements were made on days 3 and 5 of the exposure and on days 2, 6 and 9 of the recovery period.

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | *Selenastrum*: 0 (control), 0 (solvent control, 0.5 ml/l), 0.001, 0.002, 0.004, 0.008, 0.016, and 0.032 mg/l<br>*Microcystis*: 0 (control), 0 (solvent control, 0.5 ml/l), 0.01, 0.02, 0.04, 0.08, 0.16, and 0.32 mg/l |
| Measured concentrations (mg/l): | Not determined |
| Unit: | mg/l |
| Element value: | Algistatic Concentration |
| Result: | Algistatic Concentration (*Selenastrum*) = 0.029 mg/l (95% confidence interval of 0.015 to 0.064 mg/l)<br>Algicidal Concentration (*Selenastrum*) = >0.032 mg/l<br>Algistatic Concentration (*Microcystis*) = 0.11 mg/l (95% confidence interval of 0.04 to 0.27 mg/l)<br>Algicidal Concentration (*Microcystis*) = 0.16 mg/l |
| NOEC | Not available |
| Satisfactory control response: | Yes |
| Remarks: | The endpoints of the test were defined as the following:<br>Algistatic Concentration = The concentration that causes no net increase in cell numbers after the 5-day exposure period, but permits regrowth when the cells are resuspended in test material-free medium.<br>Algicidal Concentration = The lowest concentration tested which causes no net increase in cell numbers during either the exposure or recovery period (i.e. cells do not recover when transferred to test material-free medium). |

**Conclusions**

The study provides useful information on the toxicity of the test substance to *Selenastrum capricornutum* and *Microcystis aeruginosa*. Additional studies are needed to define an $EC_{50}$. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2D |
| Remarks: | Reliable with restrictions; endpoint of the test was not defined in terms of an $EC_{50}$. |

**References**

Hughes, J.S. 1986. Toxicity of B0793.02 to *Selenastrum capricornutum* and *Microcystis aeruginosa*. Malcom Pirnie Report Nos. 165-14-1100-1 and -2. Contained in: Initial Submission, Toxicological Investigation of N,N-dimethyloctyldecylamine. U.S. EPA Doc. No. FYI-OTS-0794-1164.

**Other**

| | |
|---|---|
| Last Changed: | July 10, 2002 |
| Order number for sorting: | 36 |
| Remarks: | |

## 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

**Test Substance**

| | |
|---|---|
| Identity: | Ditallowmethylamine, hydrogenated (CAS RN 61788-63-4; Dihydrogenated tallow methylamine) |
| Purity: | ca. 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Test methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 201, Alga, Growth Inhibition Test, and EEC Method, Algal Inhibition Test, Official Journal of the European Communities, L133. |
| Type: | Static |
| GLP: | Yes |
| Year: | 1990 |
| Species/Strain/Supplier: | *Selenastrum capricornutum*/ATCC 22662/Laboratory cultures |
| Element Basis: | Growth rate and area under the growth curve |
| Exposure Period: | 72 hours |
| Analytical Monitoring: | No |
| Statistical Methods: | The $EC_{50}$ values were computed from the best fitted line (least square method) through the points given by the probit of the percentage inhibition and the logarithm of the concentration of the test substance. |
| Remarks: | Test vessels were 100-ml Erlenmeyer flasks holding 40 ml of test solution. Test solutions were made by adding aliquots of a test substance stock solution made in deionized water at 50°C to 40 ml of mineral salts medium. Flasks were inoculated with *Selenastrum* taken from a culture of exponentially growing cells. Flasks were kept in a controlled temperature incubator at 22 - 24°C. Flasks were continuously shaken at 100 rpm to prevent sedimentation of the cells. Continuous illumination in the range 6000 to 10000 lux was provided by 30W fluorescent lamps (color temperature of approximately 4300 K). Cell densities were measured spectrophotometrically using a relationship established for light extinction and cell density. Measurements were taken from each test flask at 0, 24, 48 and 72 hours of the test. The measured extinction values were used to determine growth of the cultures by the area under the curve method and growth rate. $EC_{50}$ values were determined for the area under the growth curve ($E_bC_{50}$) and for the growth rate ($E_rC_{50}$). A range-finding study was conducted to |

determine dose levels for the definitive study.

**Results**

| | |
|---|---|
| Nominal concentrations (mg/l): | 0 (control), 0.010, 0.030, 0.090, 0.270, and 0.810 mg/l. |
| Measured concentrations (mg/l): | Not stated |
| Unit: | mg/l |
| Element value: | 72-hour $E_bC_{50}$ (biomass)<br>72-hour $E_rC_{50}$ (growth rate) |
| Result: | 72-hour $E_bC_{50}$ = 0.05 mg/l (95% confidence limit of 0.04 to 0.06 mg/l)<br>72-hour $E_rC_{50}$ = 0.12 mg/l (0.10 to 0.14 mg/l)<br>Additional endpoints included the following:<br>72-hour $E_bC_{20}$ = 0.02 mg/l (0.01 to 0.02 mg/l)<br>72-hour $E_bC_{80}$ = 0.14 mg/l (0.11 to 0.18 mg/l)<br>72-hour $E_rC_{20}$ = 0.04 mg/l (0.03 to 0.05 mg/l)<br>72-hour $E_rC_{80}$ = 0.32 mg/l (0.26 to 0.42 mg/l) |
| NOEC | ~0.01 mg/l |
| Satisfactory control response: | Yes |
| Remarks: | The growth rate, μ, was calculated to be 0.069 $h^{-1}$. |

**Conclusions**

The 72-hour growth inhibition of Amines, bis(hydrogenated tallow alkyl) methyl to *Selenastrum capricornutum* has been adequately characterized by this study. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1A |
| Remarks: | Reliable without restriction; guideline study. |

**References**

Kroon, A.G.M. and C.G. van Ginkel. 1990. Algal Growth Inhibition Test with ARMEEN M2HT. Study/Report No. CRL F90155, Akzo Research Laboratories Arnhem, The Netherlands.

**Other**

| | |
|---|---|
| Last Changed: | July 25, 2002 |
| Order number for sorting: | 101 |
| Remarks: | |

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | PA-14 Acetate (CAS RN 28701-67-9; 1-Propanamine, 3-(isodecyloxy)-, acetate) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | EPA Guideline Series 81-1 |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1993 |
| Species/Strain: | Rat/HSD:SD |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Not used. |
| Route of administration: | Oral gavage by syringe and stainless steel ball-tipped gavage needle |
| Remarks: | Groups of rats (five males and five females plus one additional group of 5 females) were administered a single dose of the test substance at dosages of 500 (females only), 1000, 1500, and 2000 mg/kg body weight. Rats weighing 210 to 250 g (males) and 198 to 232 g (females) were acclimated to the laboratory for a period at least five days prior to test initiation. Rats were young adults at initiation of the study. Food was available *ad libitum*, except for a period of 16 hours prior to test substance administration. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats. $LD_{50}$ Analysis was conducted using: Litchfield, J.T., Jr. and F. Wilcoxon. 1949. A Simplified Method of Evaluating Dose-Effect Experiments. *J. Pharm. and Exp. Ther*. 96: 99-115. |

**Results**

| | |
|---|---|
| Value: | Male: $LD_{50}$ = 1457 mg/kg (95% confidence limits: 1271 to 1670 mg/kg)<br>Female: $LD_{50}$ = 1033 mg/kg (95% confidence limits: 881 to 1212 mg/kg)<br>Combined: $LD_{50}$ = 1216 mg/kg (95% confidence limits: 1061 to 1393 mg/kg) |
| Number of deaths: | 500 mg/kg = 0/5 (females only)<br>1000 mg/kg = 0/5 males; 2/5 females<br>1500 mg/kg = 3/5 males; 5/5 females |

| | |
|---|---|
| | 2000 mg/kg = 5/5 males; 5/5 females |
| Remarks: | Decreased activity, diarrhea, gasping, piloerection, lacrimation, nasal discharge, polyuria, and salivation were present at all dose levels and generally persisted through Day 7 in surviving animals. Body tremors were also evident and cleared by Day 2. Body weight changes of survivors were generally normal. Gross necropsy findings (including external and internal findings) of the animals that died during the study included: signs of diarrhea, lacrimation, nasal discharge, polyuria and salivation; discolored lungs, discoloration of the contents of the gastrointestinal tract, gastrointestinal tract distended with gas and/or fluid. Necropsy of survivors revealed no observable abnormalities. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1A |
| Remarks: | Reliable without restrictions; guideline study. |

**References**

Kuhn, J. O. 1993. Acute Oral Toxicity Study in Rats. Unpublished report (No. 0317-93). Stillmeadow, Inc., Sugar Land, TX, USA.

**Other**

| | |
|---|---|
| Last changed: | July 8, 2002 |
| Order number for sorting: | 137b |
| Remarks: | |

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | 1-Dodecyl amine (CAS RN 124-22-1; Dodecylamine) |
| Purity: | Not stated |

**Remarks:**

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | $LD_{50}$ |
| GLP: | No |
| Year: | 1953 |
| Species/Strain: | Rat and mouse/Strain not stated |
| Sex: | Female |
| No. of animals per sex per dose: | 6 |
| Vehicle: | Propylene glycol |
| Route of administration: | Oral gavage |
| Remarks: | Animals were administered 1-dodecylamine dissolved in propylene glycol by gavage (total volume ≤20 ml/kg). Animals were observed for ten days. The $LD_{50}$ values and confidence limits were calculated by the method of Litchfield, J.T. Jr. and F. J.Wilcoxon, [*Pharmacol. and Exper. Therap.*, 96:101 (1949)]. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ in rats = 1020 mg/kg (confidence intervals 840 to 1240 mg/kg)<br>$LD_{50}$ in mice = 1160 mg/kg (confidence intervals 1030 to 1310 mg/kg) |
| Number of deaths: | Not stated |
| Remarks: | Irritation of the stomach and duodenum were noted. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2D |
| Remarks: | Reliable with restrictions; basic data provided, with minimal details. |

**References**

Anderson, H.H. and G.K. Hurwitz. 1953. Dodecylamine and Other Agents Active Against Ascaris lumbricoides and Their Toxicity to Mammals. Arch. Exper. Path. U. Pharmakol. 219:119-129.

**Other available reports**

**Other**

Last changed: June 4, 2002
Order number for sorting: 32
Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | 1-Dodecyl amine (CAS RN 124-22-1; Dodecylamine) |
| Purity: | >99.9% |
| **Remarks:** | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 401, Acute Oral Toxicity |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1987 |
| Species/Strain: | Rat/Wistar |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Sesame oil |
| Route of administration: | Oral gavage, single dose, 10 ml/kg |
| Remarks: | A group of ten rats (five males and five females) were administered a single gavage dose of the test substance in sesame oil at a dose of 2000 mg/kg and a dose volume of 10 ml/kg. Male rats were 6 weeks of age and weighed 184 to 190 g and female rats were 7 weeks of age and weighed 178 to 186 g. All animals were examined for clinical signs several times on day 1 and daily thereafter for 14 days following dose administration. Body weights were obtained on days 1 and 14. All animals were subjected to a complete necropsy following the 14-day observation period. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ >2000 mg/kg bw |
| Number of deaths: | None |
| Remarks: | All animals showed diarrhea, piloerection, hunched posture, abnormal gait, reduced activity, flanks drawn in, and irregular breathing. One male rat showed crusted eyelids and crusted snout on day 3. Necropsy findings were normal except one male showed growing together of the stomach with the liver, spleen, pancreas and abdominal wall. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1A |
| Remarks: | Reliable without restrictions; guideline study. |

**References**

Hofmann, Th. and R. Jung. 1988. Genamin 12 R 100 D, Pruefung der akuten oralen Toxizitaet an der Wistar-Ratte. [Genamin 12 R 100 D; Acute oral toxicity study in the Wistar rat] Report No. 88.0146. Hoechst Pharma Forschung Toxikologie und Pathologie.

**Other available reports**

**Other**

| | |
|---|---|
| Last changed: | August 12, 2002 |
| Order number for sorting: | 32a |
| Remarks: | |

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Lilamin AC-HBG/P (CAS RN 61788-45-2; Amines, hydrogenated tallow alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 401, Acute Oral Toxicity |
| Type: | $LD_{50}$ |
| GLP: | No |
| Year: | 1984 |
| Species/Strain: | Rat/HC/CFY remote Sprague-Dawley |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | 1% methyl cellulose |
| Route of administration: | Oral gavage |
| Remarks: | A group of ten rats (five males and five females) were administered a single gavage dose of the test substance in 1% methyl cellulose at a dose of 5000 mg/kg (limit test) and a dose volume of 10 ml/kg. At study initiation, the animals were 4 to 6 weeks of age and weighed 100 to 128 g. After dosing, the animals were observed for clinical signs several times on day 1 and then once daily thereafter for 14 days. Bodyweights were obtained in day 1, 8, and 15. A necropsy was performed on all animals. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ >5000 mg/kg |
| Number of deaths: | None |
| Remarks: | The animals showed diarrhea, piloerection, hunched posture, abnormal gait and pallor of extremities. Complete recovery from these clinical signs was observed by day 5. Body weights were initially reduced but body weight gain was normal by the end of the study (day 15). No treatment-related effects were observed at necropsy. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1A |
| Remarks: | Reliable without restrictions; guideline study. |

**References**

Kynoch, S.R. 1984. Acute Oral Toxicity to Rats of Lilamin AC-HBG/P. Report No. 84592D/KND 1/AC. Huntingdon Research Centre.

**Other available reports**

**Other**

| | |
|---|---|
| Last changed: | September 17, 2002 |
| Order number for sorting: | 106d |
| Remarks: | |

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Stearyl Amine (CAS RN 61788-45-2; Amines, hydrogenated tallow alkyl) |
| Purity: | Not stated |
| **Remarks:** | [Stearyl amine is CAS RN 124-30-1 but the European ICCA IUCLID includes this study under CAS RN 61788-45-2] |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | $LD_{50}$ |
| GLP: | No |
| Year: | 1979 |
| Species/Strain: | Rat/Sprague-Dawley |
| Sex: | Male |
| No. of animals per sex per dose: | 6 |
| Vehicle: | Water |
| Route of administration: | Oral gavage, single dose, 20 ml/kg |
| Remarks: | Groups of six male rats were administered a single gavage dose of the test substance in water at concentrations of 3000, 3900, 5070, 6590 or 8560 mg/kg at a dose volume of 20 ml/kg. At study initiation, the animals weighed 127 to 150 g. The animals were observed for clinical signs for 14 days following dosing. Each animal was subjected to a necropsy at the end of the 14-day postdosing observation period. The $LD_{50}$ was calculated using the method of Thompson Moving Average Interpolation. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = 4800 mg/kg |
| Number of deaths: | 0/6 (3000 mg/kg)<br>1/6 (3900 mg/kg)<br>4/6 (5070 mg/kg)<br>5/6 (6590 mg/kg)<br>6/6 (8560 mg/kg) |
| Remarks: | All deaths occurred within one to three days following dosing. Clinical observations included: piloerection and hyperkinesea in all dose groups; epistaxis in the 3900 mg/kg group and higher; diarrhea and soiled coat in the 5070 mg/kg group and higher. All animals recovered by day 2 (2300 mg/kg), day 3 (3900 mg/kg) or day 11 (5070 and 6590 mg/kg). Necropsy findings were normal at 3000 mg/kg; gut contents fluid and red stain in gut at 3900 mg/kg; TS in stomach, gut contents |

fluid, red stain in gut, lungs patchy, kidneys pale colored at >5070 mg/kg.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B

Remarks: Reliable without restrictions; comparable to guideline study.

**References**

Cuthbert, J.A. 1979. Safety Tests on Commercial Stearyl Amine. Report No. 1375. Berol Kemi AB, Inveresk Research International.

**Other available reports**

**Other**

Last changed: September 17, 2002

Order number for sorting: 106e

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Farmin TH (CAS RN 61788-45-2; Amines, hydrogenated tallow alkyl) |
| Purity: | >98% |
| **Remarks:** | |

**Method**

| | |
|---|---|
| Method/guideline followed: | 92/69/EEC, Annex, Part B, method B.1. bis – fixed dose method |
| Type: | Acute oral toxicity |
| GLP: | Yes |
| Year: | 1995 |
| Species/Strain: | Rat/Sprague-Dawley |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | 5% Tween 80 in bidistilled water |
| Route of administration: | Oral gavage |
| Remarks: | Groups of ten rats (five male and five female) were administered a single gavage dose of the test substance in 5% Tween 80 at doses of 500 or 2000 mg/kg in a dose volume of 10 ml/kg. The animals were four weeks of age at arrival and weighed 90-100g (500 mg/kg) and 141 to 169 g (2000 mg/kg) at study initiation. All animals were observed for clinical signs at least twice daily for 14 days postdosing. Body weights were obtained on days 1, 2, 3, 7, 14 and at the time of necropsy. All animals were subjected to a necropsy at the end of the 14-day observation period. The body weight range of the animals at the beginning of the experiment was too large (90-159 g; OECD requires ± 20% from mean body weight); however, the body weight range within treatment groups was acceptable. |

**Results**

| | |
|---|---|
| Value: | $LD_0$ = 500 mg/kg<br>$LD_{50}$ >2000 mg/kg |
| Number of deaths: | 0/10 at 500 mg/kg and 1/10 at 2000 mg/kg. |
| Remarks: | The following clinical signs were observed in the animals dosed at 2000 mg/kg: hunched back, soft feces, rattling in throat, salivation during the first two hours; some females also showed decreased motor activity and muscle tone, ataxia, dispnea, swollen abdomen and traces of blood in the snout. At 500 mg/kg the following clinical signs were observed: |

hunched back, soft feces rattling in the throat, piloerection, ataxia, decreased motor activity and muscle tone, pallor and traces of blood in the shout. Weight gain was normal at 500 mg/kg but two females lost weight at 2000 mg/kg in second week of treatment. Necropsy findings were normal.

**Conclusions**

Remarks: According to the results obtained and the guidelines set for by the test method, the test substance is free of any significant toxicity (Author or report).
The endpoint has been adequately characterized.
(American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restrictions; guideline study.

**References**

Tortajada, A. 1995. Acute Oral Toxicity Test in Rats, Fixed Dose Method, Farmin TH. Report No. CD-95/4308T. KAO Corporation S.A., Centro de Investigacion y Desarrollo aplicado.

**Other available reports**

**Other**

Last changed: September 17, 2002
Order number for sorting: 106f
Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | 1-Octadecyl amine (CAS RN 124-30-1; Octadecylamine) |
| Purity: | Not stated |
| **Remarks:** | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | $LD_{50}$ |
| GLP: | Not stated |
| Year: | 1981 |
| Species/Strain: | Rat and mouse/Strain not stated |
| Sex: | Not stated |
| No. of animals per sex per dose: | Not stated |
| Vehicle: | Not stated |
| Route of administration: | Oral gavage |
| Remarks: | |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$= approximately 1000 mg/kg (rat)<br>$LD_{50}$= approximately 1000 mg/kg (mouse) |
| Number of deaths: | Not stated |
| Remarks: | Not stated |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2D |
| Remarks: | Reliable with restrictions; data from summary document; acceptable because data consistent with other data in subcategory. |

**References**

Beard, R.R. and J. T. Noe. 1981. Aliphatic and Alicyclic Amines. Cited in: Clayton, G. D. and Clayton, F.E., ed. Patty's Industrial Hygiene and Toxicology, 3rd ed., John Wiley & Sons, New York, 3135-3173. As cited in German Chemical Society. 1994. Primary Fatty Amines. GDCh-Advisory Committee on Existing Chemicals of Environmental Relevance (BUA). BUA Report 177; December. S. Hirzel, Wissenschaftliche Verlagsgesellschaft Stuttga.

## Other available reports

### Other

| | |
|---|---|
| Last changed: | June 5, 2002 |
| Order number for sorting: | 40a |
| Remarks: | |

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | 1-Octadecyl amine (CAS RN 124-30-1; Octadecylamine) |
| Purity: | Not stated |
| **Remarks:** | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 401 |
| Type: | $LD_{50}$ |
| GLP: | Not stated |
| Year: | 1988 |
| Species/Strain: | Rat/Strain not stated |
| Sex: | Male and female |
| No. of animals per sex per dose: | Not stated |
| Vehicle: | Sesame oil |
| Route of administration: | Oral gavage |
| Remarks: | Male and female rats were dosed with a single oral dose of 2000 mg/kg of the test substance in sesame oil. |

**Results**

| | |
|---|---|
| Value: | $LD_{50} > 2000$ mg/kg |
| Number of deaths: | 0 |
| Remarks: | A dose of 2000 mg/kg of 1-octadecylamine in sesame oil was non-lethal; however, for up to 7 hours following treatment, reduced spontaneity, crouching and retracted flanks were observed in the animals. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2D |
| Remarks: | Reliable with restrictions; data from summary document; acceptable because data consistent with other data in subcategory. |

**References**

Hoechst. 1988. Genamin SH 100 D. Kurzbericht zur Prüfung der akuten oralen Toxizatät an der Wistar-Ratte (Unveröffentlichte untersuchung. Bericht Nr. 88.0969). Hoechst AG, Pharma Forschung Toxikoligie, Frankfurt/Main, 1 S. As cited in German Chemical Society. 1994. Primary Fatty Amines. GDCh-Advisory Committee on Existing Chemicals of Environmental Relevance (BUA). BUA Report 177; December. S. Hirzel, Wissenschaftliche Verlagsgesellschaft Stuttga.

**Other available reports**

**Other**

| | |
|---|---|
| Last changed: | June 5, 2002 |
| Order number for sorting: | 40a2 |
| Remarks: | |

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Genamin 18 R 100 D (CAS RN 124-30-1; Octadecylamine) |
| Purity: | 100% |
| **Remarks:** | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 401; Acute Oral Toxicity |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1981 |
| Species/Strain: | Rat/Wistar |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Sesame oil |
| Route of administration: | Oral gavage, single dose |
| Remarks: | Five male and five female rats received a single oral dose of the test substance at a dose level of 2000 mg/kg at a constant dose volume of 10 ml/kg. The test substance was mixed with sesame oil. At the start of the study the males were 7 weeks old and weighed 179 to 208 g and the females were 8 weeks old and weighed 186 to 192 g. All animals were observed several times on day 1 and daily thereafter for a total of 14 days following dosing. Body weights were obtained on days 1, 8 and 15 of the study. A necropsy was performed on all animals at the end of the study (Day 15). |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$= >2000 mg/kg bw |
| Number of deaths: | 1 male died on day 4 |
| Remarks: | All animals showed reduced spontaneous activity, piloerection, hunched posture, abnormal gait, reduced activity, and irregular breathing. One male had a swollen abdomen. All animals recovered by Day 9. The animal that died had a decrease in body weight on day 4. No other effects on body weight were noted. The following observations were noted at necropsy for the animal that died: stomach filled with test substance and gas, flanks drawn in, dark-colored liver, red staining of lungs, intestine and pancreas, intestines filled with gas, and shrunken spleen. All surviving animals had no remarkable findings at necropsy. |

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1a

Remarks: Reliable without restrictions; guideline study.

**References**

Hofmann, Th. and R. Jung. 1989. Genamin 18 R 100 D, Pruefung der akuten oralen Toxizitaet an der Wistar-Ratte. [Genamin 18 R 100 D; Acute oral toxicity study in the Wistar rat] Report No. 89.0840. Hoechst Pharma Forschung Toxicologie und Pathologie.

**Other available reports**

**Other**

Last changed: August 12, 2002

Order number for sorting: 40b

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Armeen C (CAS RN 61788-46-3; Amines, coco alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| Type: | $LD_{50}$ |
| GLP: | Not stated |
| Year: | 1983 |
| Species/Strain: | Wistar rat |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Oleum arachidis |
| Route of administration: | Oral gavage |
| Remarks: | Based on the results of a range-finding test, the test substance was administered to male (170.1 – 190.8 g) and female rats (140.0 – 162.6 g) as a 20% dilution in oleum arachidis at dose levels of 0.5, 1.0, 1.5 and 2.0 g/kg. Animals were fasted 16 hours prior to dosing and were given food ad libitum four hours after dosing. Animals were observed for a total of 14 days. Body weights were measured for each animal at the start and end of the study. A gross necropsy was performed on each animal at the end of the 14-day observation period. The $LD_{50}$ was determined by probit analysis. |

**Results**

| | |
|---|---|
| Value: | Combined $LD_{50}$ = 1.30 g/kg<br>Male $LD_{50}$ = 1.24 g/kg<br>Female $LD_{50}$ = 1.39 g/kg |
| Number of deaths: | 2.0 g/kg = 5/5 males, 5/5 females<br>1.5 g/kg = 2/5 males, 2/5 females<br>1.0 g/kg = 1/5 males, 1/5 females<br>0.5 g/kg = 1/5 males, 0/5 females |
| Remarks: | The following moralities were observed:<br>Within 48 hours = two males and one female at 2.0 g/kg; one male and one female at 1.5 g/kg; one male at 1.0 g/kg; and one male at 0.5 g/kg;<br>Within 5 days = 3 males and 3 females at 2.0 g/kg; one male and one female at 1.5 g/kg; and one female at 1.0 g/kg;<br>Within 7-14 days = one female at 2.0 g/kg.<br>Clinical signs observed during the observation period included disturbance in consciousness with apathy, |

predominant coordination disturbances, clear reduction of reflexes, cyanosis, shortly-persisting massive salivation, predominant piloerection, slightly decreased respiration and hypothermia. These symptoms were evident approximately 20 minutes post-dose and, for the most part, had subsided by day 7. By the end of the 14-day observation period animals that had survived the study appeared normal. Gross necropsy findings noted in animals that died during the study included a reddening discoloration and a small amount of fluid in the stomach and intestinal tract. No gross necropsy findings were noted in animals that survived until study termination.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2D

Remarks: Reliable with restrictions; translation of German study report.

**References**

Sterner, W. and G. Chibanguza. 1983. Akute orale Toxizitaet an Ratten mit Armeen C. [Acute oral toxicity in the rat with Armeen C] Project No. 1-4-299-83. Akzo Chemie BV, IBR Forschungs GmbH, Hannover, Krumme.

**Other available reports**

**Other**

Last changed: July 24, 2002

Order number for sorting: 94

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Amines, coco alkyl (CAS RN 61788-46-3) |
| Purity: | >99% |
| **Remarks:** | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 401 |
| Type: | $LD_{50}$ |
| GLP: | Not stated |
| Year: | 1994 |
| Species/Strain: | Rat/Wistar |
| Sex: | Male and female |
| No. of animals per sex per dose: | Five |
| Vehicle: | Not stated |
| Route of administration: | Oral gavage |
| Remarks: | |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ > 2000 mg/kg (male)<br>= 2820 mg/kg (female) |
| Number of deaths: | Not stated |
| Remarks: | The animals showed impaired movements and respiration, as well as diarrhea, blood-colored encrusted snouts and eyelid edges, reduced spontaneity, retracted flanks, ruffled fur, and a long-legged, staggering gait. In females, the following symptoms of toxicity also were observed: salivation, splayed attitude of the legs, partially closed eyelids, bloody nasal discharge, prostrate and lateral attitude, uncoordinated gait, forward movement in creeping position, gasping for breath, jerky respiration and tonic cramps. Necropsy of animals that had died revealed discoloring of the liver and spleen, as well as blood in the gastrointestinal tract. Eleven days after treatment, the surviving animals were free of symptoms. Animals sacrificed following termination of the experiment showed no gross changes. Body weight gain among female animals was reduced during the first week of the experiment. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2D |
| Remarks: | Reliable with restrictions; data from summary document; acceptable because data consistent with other data in subcategory. |

**References**

Hoechst. 1988. Genamin CC 100 D. Prüfung der akuten oralen Toxizatät an der Wistar-Ratte (Unveröffentlichte untersuchung. Bericht Nr. 88.0414). Hoechst AG, Pharma Forschung Toxikoligie und Pathologie, Frankfurt/Main, 24S. As cited in German Chemical Society. 1994. Primary Fatty Amines. GDCh-Advisory Committee on Existing Chemicals of Environmental Relevance (BUA). BUA Report 177; December. S. Hirzel, Wissenschaftliche Verlagsgesellschaft Stuttga.

**Other available reports**

**Other**

| | |
|---|---|
| Last changed: | June 5, 2002 |
| Order number for sorting: | 79a |
| Remarks: | |

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Tallow alkyl amine (CAS RN 61790-33-8) |
| Purity: | >99% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 401 "Acute Oral Toxicity" |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1987 |
| Species/Strain: | Rat/Wistar |
| Sex: | Male and female |
| No. of animals per sex per dose: | Five |
| Vehicle: | Sesame oil |
| Route of administration: | Oral gavage |
| Remarks: | Male rats (7 weeks old, 167 to 189 g) and female rats (8 weeks old, 171 to 181 g) received a single oral dose of 2000 mg/kg (males and females) or 2500 mg/kg (males only). Animals were observed for 14 days postdosing. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = >2500 mg/kg (male)<br>= >2000 mg/kg (female) |
| Number of deaths: | 1 male per dose group. No females died. |
| Remarks: | One in five males per group died within six days of treatment. The following clinical signs were observed following dosing: hunched posture, flanks drawn in, pilo-erection, irregular breathing, abnormal gait, diarrhea, crusted eyelids and snout (both males and females); decreased spontaneous activity, uncontrolled movements, crawling-like movements, emaciation, drowsiness, gasping (males). All symptoms disappeared by day 11 or 12. Decreased body weight gain was observed the first week postdosing. Necropsy of animals that had died revealed stained liver, pale-colored lungs and gastro-intestinal tract swollen with gasses. Animals sacrificed following termination of the experiment showed no gross changes. |

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2D

Remarks: Reliable with restrictions; data from summary document; acceptable because data consistent with other data in subcategory.

**References**

1988. Genamin TA 100 D. Prüfung der akuten oralen Toxizatät an der Wistar-Ratte [Genamin TA 100 D Acute oral toxicity study in the Wistar rat] (Unveröffentlichte untersuchung. Bericht Nr. 88.0358). Hoechst AG, Hoechst Pharma Forschung Toxikoligie und Pathologie, Frankfurt/Main, 18 S.

**Other available reports**

**Other**

Last changed: June 5, 2002

Order number for sorting: 1 and 218a

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

Identity: Armeen T (CAS RN 61790-33-8; Amines, tallow alkyl)
Purity: Not stated
Remarks:

**Method**

Method/guideline followed: Not stated
Type: $LD_{50}$
GLP: No
Year: 1983
Species/Strain: Rat/WISW – SPF TNO
Sex: Male and female
No. of animals per sex per dose: 5
Vehicle: Not stated
Route of administration: Oral gavage
Remarks: Groups of 5 male and 5 female rats were dosed with the test substance by oral gavage at the following concentrations: 1.5, 2.5, 3.5, and 5.0 ml/kg. Animals had access to food *ad libitum* except for a period of 16 hours prior to dosing. Food was returned approximately 4 hour following dosing. Animals were observed for signs of toxicity at approximately 30 minutes; 1, 2, 3, 6, 24 and 48 hours; and Days 4, 6, 7 and 14 following dosing. Body weights were obtained on Day 0 and 14 for all surviving animals. The $LD_{50}$ value was determined by probit analysis (Finney, D.Y. 1971. Probit Analysis, 3. Auflage, Cambridge).

**Results**

Value: Males: $LD_{50}$ = 2.23 ml/kg bodyweight
Females: $LD_{50}$ = 2.61 ml/kg bodyweight
Combined $LD_{50}$ = 2.40 ml/kg bodyweight

Number of deaths: Mortality at 14 days following dosing:

| Dose (ml/kg) | Males | Females |
|---|---|---|
| 1.5 | 1/5 | 1/5 |
| 2.5 | 3/5 | 2/5 |
| 13.5 | 4/5 | 3/5 |
| 5.0 | 5/5 | 5/5 |

Remarks: Clinical observations included: incoordination, cyanosis, excessive salivation, piloerection, reduced respiration, and hypothermia. The surviving animals

appeared normal at the end of the 14-day post dosing observation period. Surviving animals showed a normal body weight gain.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2C

Remarks: Reliable with restrictions; comparable to guideline study with acceptable restrictions.

**References**

Sterner, W. and G. Chibanguza. 1983. Akute Orale Toxizitat an Ratten mit Armeen T. [Acute oral toxicity study in the rat with Armeen T] Unpublished report (1-4-298-83). IBR Forschungs GmbH.

**Other available reports**

**Other**

Last changed: July 25, 2002

Order number for sorting: 132

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Oleyl amine (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | 97.9% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 401, Acute Oral Toxicity |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1987 |
| Species/Strain: | Rat/Sprague-Dawley |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Corn oil |
| Route of administration: | Oral gavage, single dose |
| Remarks: | Doses: 200, 500, 1000, 2000 mg/kg bw. Dose volume was 10 ml/kg (2.5 ml/kg for dosage group 2000 mg/kg). Animals in groups 200, 500 and 1000 mg/kg were observed for 14 days postdosing. Animals in the 2000 mg/kg group were observed for 29 days postdosing. Body weights were obtained on days 1, 5, 8 and 15. Necropsy was performed on all animals. Data were analyzed by probit analysis. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = 1689 mg/kg bw<br>Female $LD_{50}$ = ~2000 mg/kg bw<br>Male $LD_{50}$ = ~1178 mg/kg bw |
| Number of deaths: | 200 mg/kg bw: 1/5 male; 0/5 females<br>500 mg/kg bw: 0/10 animals<br>1000 mg/kg bw: 2/5 males; 0/5 females<br>2000 mg/kg bw: 4/5 males, 3/5 females |
| Remarks: | Clinical signs included: hypokinesia and or sedation, piloerection and dyspnea, abdominal swelling. Decreases in body weight gain were noted between day 1 to 5 at 200 and 500 mg/kg, persisting in one male and one female at 200 mg/kg; and at 1000 mg/kg and returning to normal by day 8. Body weight gain was also decreased at 2000 mg/kg from day 1 to 8, returning to normal by day 15. No abnormalities were noted at necropsy. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. |

(American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restrictions; guideline study.

**References**

Chouteau, J. 1993. NORAM O Determination of Acute Oral Toxicity in Rats. Centre International de Toxicologie

**Other available reports**

**Other**

Last changed: August 14, 2002
Order number for sorting: 6b
Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Armeen DM12D (CAS RN 112-18-5; N,N-Dimethyl-1-dodecanamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1980 |
| Species/Strain: | Rat/Wistar |
| Sex: | Male |
| No. of animals per sex per dose: | 10 |
| Vehicle: | The report does not specify if a vehicle was used; however, the following statement was included: "The vehicle, if any, was chosen because of its lack of known toxicity, lack of physiological effect and because it is relatively unreactive with other chemical substances." |
| Route of administration: | Oral gavage |
| Remarks: | Ten male rats were administered a single dose of the test substance at dosages of 0.60, 0.96, 1.54, 2.47, and 5.0 g/kg bodyweight. Rats were approximately eight weeks old when received and were acclimated to the laboratory for a period at least one week prior to test initiation. Rats weighed 200 to 267 g at test initiation. Food was available *ad libitum*, except for a period of 16 to 20 hours prior to test substance administration. Water was available *ad libitum*. Rats were observed for signs of toxicity 3 to 4 hours after dosing and once daily for 14 days following test substance administration. Body weights were recorded at 0, 3, 7 and 14 days. A necropsy was performed on all rats. The LD50 was calculated according to the method of Litchfield, J.T. Jr., and F. Wilcoxon J PET 96:99, 1949. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = 1.22 g/kg (95% confidence limit of 0.92 to 1.61 g/kg) |
| Number of deaths: | 0.60 g/kg = 0/10<br>0.96 g/kg = 3/10<br>1.54 g/kg = 7/10<br>2.47 g/kg = 10/10<br>5.0 g/kg = 10/10 |

| | |
|---|---|
| Remarks: | Deaths occurred at the four higher dose levels with 100% mortality at the top two dose levels (2.47 and 4.0 g/kg). The deaths generally occurred by Day 2, with the exception that one rat each in the 1.54 and 0.96 g/kg groups died by day 3 and 7, respectively. Lethargy, diarrhea, ataxia and piloerection were present at all dose levels, generally persisted to day 2 and/or death. Body weight changes and necropsy findings of survivors were generally normal. One survivor in the 1.54 g/kg group had lung abnormalities and below normal weight gain. Animals that died had heart, lung and gastrointestinal abnormalities. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2A |
| Remarks: | Reliable with restrictions; comparable to guideline study with acceptable restrictions. |

**References**

1980. Test for Oral Toxicity in Rats – Armeen DM12D. Project No. MB 80-4821A. MB Research Laboratories Inc., Spinnerstown, PA, USA.

**Other**

| | |
|---|---|
| Last changed: | July 8, 2002 |
| Order number for sorting: | 123 |
| Remarks: | |

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | ADMA 2 (CAS RN 112-18-5; N,N-Dimethyl-1-dodecanamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| Type: | $LD_{50}$ |
| GLP: | Not stated |
| Year: | 1979 |
| Species/Strain: | Wistar rat |
| Sex: | Male |
| No. of animals per sex per dose: | 10 |
| Vehicle: | None or Mazola Oil |
| Route of administration: | Oral gavage |
| Remarks: | Wistar rats were at least 9 weeks old and 202-300 g at study initiation. Ten male rats per group were given a single oral dose of 0.072, 0.30, 1.22 and 5.0 g/kg of the test substance. The 0.072 g/kg group was dosed with a 10% w/v mixture of ADMA 2 in Mazola Oil. The rats were observed 3-4 hours after dosing and once daily for 14 days. Mortality, toxicity and pharmacological effects were recorded. Body weights were recorded at pretest and in the survivors at 14 days. At 14 days the survivors were sacrificed. All animals on study were examined for gross pathology. The $LD_{50}$ was calculated according to the method of Litchfield, J.T. Jr., & F. Wilcoxon, JPET 96:99, 1949. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = 0.79 g/kg (95% confidence limits = 0.44 to 1.42 g/kg) |
| Number of deaths: | 0.072 g/kg = 0/10<br>0.30 g/kg = 2/10<br>1.22 g/kg = 6/10<br>5.0 g/kg = 10/10 |
| Remarks: | All animals in the 5.0 g/kg group died. Predeath clinical observations included lethargy, ataxia, diarrhea, stiff when manipulated, irritable when touched, chromorhinorrhea, piloerection, ptosis and prostration. Six animals died in the 1.22 g/kg group. Predeath clinical observations included prostration, piloerection, ptosis, bulging eyes, diarrhea, ataxia chromorhinorrhea, dyspnea, lethargy, foaming at the |

mouth, gasping, oily bodies and tremors. The surviving animals exhibited (from days 1 through 6) isolated instances of the same clinical signs as those exhibited by the animals that died. All surviving animals appeared normal through the remainder of the 14-day observation period. Two animals in the 0.30 g/kg level died (Day 5 and 11). Predeath signs included lethargy, piloerection, dyspnea, chromorhinorrhea, ataxia, ptosis, diarrhea, emaciation and chromodacryorrhea. The surviving animals were normal throughout the testing period. All animals in the 0.072 g/kg dose group survived. Isolated instances of chromorhinorrhea and lethargy were noted 3 to 4 hours post dose. Isolated instances of respiratory rattle and chromorhinorrhea were noted in three animals. Animals were normal at all other time points. All surviving animals in the 0.072, 0.30 and 1.22 g/kg groups gained weight from Day 0 to 14. Significant necropsy findings observed in the animals that died included various intestinal irregularities and dilated hearts.

**Conclusions**

Remarks: The test material is toxic as defined in 16 CFR 1500.3, but not a Class B poison as defined in 49 CFR 173.343. (Author of report)
The acute oral $LD_{50}$ has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2A
Remarks: Reliable with restrictions; acceptable, well-documented publication/study report which meets basic scientific principles.

**References**

Test for Oral Toxicity in Rats with ADMA 2. 1979. Project Number: MB 79-3571. MB Research Laboratories, Inc. Spinnerstown, PA, USA.

**Other available reports**

**Other**

Last changed: June 7, 2002
Order number for sorting: 123c
Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | N,N-Dimethyldocecylamine (CAS RN 112-18-5; N,N-dimethyl-1-Dodecanamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Acute oral toxicity |
| GLP: | No |
| Year: | 1976 |
| Species/Strain: | Rat |
| Sex: | Male |
| No. of animals per sex per dose: | 3 |
| Vehicle: | None |
| Route of administration: | Oral gavage |
| Remarks: | Groups of three rats were administered a single dose of the undiluted test substance at concentrations of 0.316, 0.63, 1.26, 2.52 and 5.0 g/kg. Rats were in the weight range of 185 - 232 g. Rats were fasted overnight prior to dosing. Rats were weighed and observed for signs of toxicity at intervals over a two-week post dose period or until any weight loss was regained and the animals appeared healthy. One animal from each group (when available) was evaluated pathologically one day following dosing. |

**Results**

| | |
|---|---|
| Value: | $LC_{50}$ not determined |
| Number of deaths: | 0.316 g/kg = 0/2<br>0.63 g/kg = 0/2<br>1.26 g/kg = 0/2<br>2.52 g/kg = 2/2<br>5.0 g/kg = 3/3 |
| Remarks: | Clinical signs observed soon after dosing in rats treated with 2.52 and 5.0 g/kg of the test substance included lethargic behavior, urine soaked fur and enlarged eyes. At four hours post dose, one rat was gasping, blue in color, had slight diarrhea and was listless. One day post dose, rats treated with 1.26 and 2.52 g/kg of the test substance were listless and had dark red eye secretions. Clinical signs were not observed in the remaining rats. Rats in the 2.52 and 5.0 g/kg dose groups that died prior to scheduled sacrifice did so by days 3 and 1 post dose, respectively. Rats that |

survived the two-week observation period gained weight by study termination. Representative rats (one per group) from the 0.316, 0.63, 1.26 and 2.52 g/kg dose groups were killed 24 hours post dose and a gross macroscopic examined was performed. Examination of the rat from the 0.316 g/kg dose group revealed the stomach to be distended with fluid and submucosal edema of the squamous epithelial portion of the stomach such that the mucosa was separated from the rest of the stomach wall. Examination of the rat from the 0.63 g/kg dose group revealed fluid in the proximal one-half of the small intestines, stomach distended with fluid, and submucosal edema in the squamous epithelial portion of the stomach causing the mucosa to separate from the wall of the stomach. Examination of the rat from the 1.26 g/kg dose group revealed stomach congestion and sloughing of the nonglandular portion of the squamous epithelium from the mucosal surface, and gastric irritation. One rat from the 2.52 g/kg dose group that had died was examined macroscopically, which revealed moistened hair, distended abdomen, small intestines devoid of any normal ingesta, yellowish bile-colored fluid material within the lumen, hyperemia of the mucosal surface of the stomach, possible sloughing of the nonglandular portion of the squamous epithelium from the mucosal surface, and congested liver and kidneys.

**Conclusions**

Remarks: The $LD_{50}$ value was not determined; however, this report provided additional information on the acute oral toxicity of the test substance. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2C

Remarks: Reliable with restrictions; comparable to guideline study with acceptable restrictions.

**References**

Dow Chemical Co. 1988. Initial Submission: Letter from Dow Chem. Co. to US EPA regarding information on N,N-dimethyldodecylamine and Ethanamine, N,N-diethyl with attachments, dated 10/10/88. EPA Doc. No. FYI-OTS-0794-1133, Microfiche No. OTS0001133.

**Other**

| | |
|---|---|
| Last changed: | June 10, 2002 |
| Order number for sorting: | 123d |
| Remarks: | |

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Farmin DM40 (CAS RN 112-75-4; 1-Tetradecanamine, N,N-dimethyl) |
| Purity: | 97% |
| **Remarks:** | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guidelines for Testing of Chemicals - Section 4, Sub-section 401 |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1996 |
| Species/Strain: | Rat/CD Strain (remote Sprague-Dawley origin) |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Corn oil |
| Route of administration: | Oral gavage |
| Remarks: | Groups of ten rats (five males and five females) were administered a single dose of the test substance into the stomach lumen via a flexible catheter at dosages of 2000 mg/kg and 500 mg/kg bodyweight. The test substance was administered at a constant volume of 10 ml/kg body weight in corn oil. Rats weighing 106 to 134 g (males) and 103 to 129 g (females) were acclimated to the laboratory for a period at least five days prior to test initiation. Rats were approximately five weeks old at initiation of the study. Food was available *ad libitum*, except for the overnight period prior to test substance administration and three hours after dosing. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats. The $LD_{50}$ value was calculated using probit analysis (Finney, D.J. 1971. Probit Analysis. 3rd ed; Cambridge University Press). |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = 2116 mg/kg; slope of dose response curve 77º. |
| Number of deaths: | At 2000 mg/kg, mortality was: 2/5 males and 2/5 females. At 500 mg/kg, mortality was: 0/5 males and 0/5 females. |
| Remarks: | At 500 mg/kg, animals showed hunched posture on the day of dosing. At 2000 mg/kg, animals showed signs of abnormalities including hypoactivity, staggering gait, hyperpnoea, piloerection, hunched posture, |

pigmented orbital secretions, ungroomed appearance, pigmented staining of the snout, hair loss and thin body conformation. With the exception of hair loss, clinical signs had resolved by Day 7. Males in the 2000 mg/kg dose group had lower than expected weight gain. All other groups had normal weight gains. Necropsy of decedents revealed various areas of cannibalization and fur discoloration. Necropsy of the surviving animals revealed no gross lesions, only a single case of hair loss.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A

Remarks: Reliable without restrictions; guideline study.

**References**

Rees, P. B. 1996. Farmin DM40: Acute Oral Toxicity Study in the Rat. Report No. 96/KAS165/0652. Huntingdon Life Sciences Ltd. Eye, Suffolk, UK.
and
Letter from High Point Chemical to U.S. Environmental Protection Agency concerning test substance. January 22, 1999.

**Other available reports**

**Other**

Last changed: July 8, 2002

Order number for sorting: 256

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

Identity: Genamin 14R 302D (CAS RN 112-75-4; 1-Tetradecanamine, N,N-dimethyl)
Purity: 100%
Remarks:

**Method**

Method/Guideline followed: EG Guideline B.1. Acute Toxicity oral 84/449/EWG; OECD Guideline for testing of chemicals, 401 Acute Oral Toxicty; Guideline 83/467/EWG
Type: $LD_{50}$
GLP: Yes
Year: 1989
Species/Strain: Rat/Wistar
Sex: Male and female
No. of animals per sex per dose: 5 males and 15 females
Vehicle: Sesame Oil
Route of administration: Oral gavage
Remarks: Animals were kept in temperature and humidity controlled rooms in groups of five rats per cage. Temperature range was 22 ± 3°C, relative humidity was 50 ± 20 %, and animals received 12 hours of light per day. Food was removed about 16 hours before and approximately 3 to 4 hours after dosing. The test substance was ground in sesame oil with a mortar and pestle and then homogenized with a magnetic stirrer. The prepared solution was administered via oral gavage in the following doses:

| Dose (mg/kg) | Concentration (%) | Administered Volume (ml/kg) | Number of Males | Number of Females |
|---|---|---|---|---|
| 1250 | 12.5 | 10 | - | 5 |
| 1400 | 14.0 | 10 | 5 | 5 |
| 1600 | 16.0 | 10 | - | 5 |

Observation time was 14 days after dosing. Symptoms and death were recorded when they occurred. Body weight was determined weekly during this time. Animals that died during the test were dissected and inspected macroscopically. Surviving animals were terminated after the observation time by carbon dioxide asphyxiation, dissected and examined for macroscopically visible changes.

**Results**

Value: $LD_{50}$ = 1320 mg/kg body weight (95% confidence limits of 1090 to 1520 mg/kg)

Number of deaths:

| Dose (mg/kg) | Mortality | | | |
|---|---|---|---|---|
| | Males | | Females | |
| | Absolute | Percent | Absolute | Percent |
| 1250 | -- | -- | 1/5 | 20 |
| 1400 | 0/5 | 0 | 4/5 | 80 |
| 1600 | -- | -- | 5/5 | 100 |

Remarks: The following clinical symptoms were observed after dosing of Genamin 14R 302D: decreased spontaneous activity, ruffled fur, crouching (cowering), flanks pulled in, uneven breathing, decreased breath frequency, gasping, high-legged gait, uncoordinated gait, blood-colored crusted eye lid rims and diarrhea. In addition, females displayed blood-colored crusted snouts, splayed extremities, narrowed eyelids and staggering gait. The surviving female and male animals were free of symptoms by post dosing days 8 and 5, respectively. In some animals, body weight development was delayed in the first study week. By the end of the study, all animals had gained weight. The macroscopic examination of the dead males and females revealed the following: blood in the small intestine, small intestine filled with whitish yellow masses, distended stomach, bleeding in the stomach lining, blood and test substance remains in the stomach, white colored stomach mucous membrane, strongly reddened gut, reduced liver and paled adrenal glands.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Hofmann, Th. and R. Jung. 1989. Genamin 14R 302D: Study of the Acute Oral Toxicity in the Wistar Rat. Study Number 89.0793. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other available reports**

**Other**

Last changed: June 7, 2002
Order number for sorting: 260a
Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Armeen DM16D (CAS RN 112-69-6; 1-Hexadecanamine, N,N-dimethyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | $LD_{50}$ |
| GLP: | No |
| Year: | 1957 |
| Species/Strain: | Albino rat |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | 10% Aqueous Gum Arabic or none |
| Route of administration: | Oral gavage |
| Remarks: | Groups of ten rats (five males and five females) were administered a single dose of the test substance via a polyethylene stomach tube at concentrations of 0.50, 0.75, 1.0, 2.0, 4.0 or 8.0 ml/kg. The test substance administered at concentrations of 0.50, 0.75, 1.0 and 2.0 ml/kg was diluted in 10% aqueous Gum Arabic. The test substance administered at concentrations of 4.0 and 8.0 ml/kg was undiluted. Rats weighing approximately 95 g were acclimated to the laboratory for a period of 14 days prior to test initiation. Food was available *ad libitum*, except for a period of 24 hours prior to test substance administration. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = 0.80 ml/kg<br>(95% confidence limits = 0.678 to 0.943 ml/kg) |
| Number of deaths: | 0.50 ml/kg = 1/10<br>0.75 ml/kg = 2/10<br>1.0 ml/kg = 9/10<br>2.0, 4.0 and 8.0 ml/kg = 10/10 |
| Remarks: | $LD_{0.01}$ = 0.293 ml/kg<br>$LD_{99.99}$ = 2.15 ml/kg<br>All rats exhibited a generalized lassitude and inactivity within one hour post dose. Also, all rats showed signs of ptosis during the observation period. Severe diarrhea was observed in rats treated with 1.0, 2.0, 4.0 |

and 8.0 ml/kg of the test substance. Mild diarrhea was observed in rats treated at the lower dose levels. Rats in the four highest dose groups rapidly became moribund and death was preceded by a comatose state. In most cases where death occurred, it was within 19 hours post dose. Rats that survived for 24 to 36 hours usually recovered within the next day or two and no untoward signs or symptoms were observed thereafter. Necropsy examinations revealed intestines distended with fluid and the absence of formed feces in rats that died prior to scheduled sacrifice. All other tissues and organs examined appeared normal.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B

Remarks: Reliable without restriction; comparable to guideline study.

**References**

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

**Other**

Last changed: June 13, 2002

Order number for sorting: 3

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | $C_{16}$-alkyl dimethylamine (CAS RN 112-69-6; 1-Hexadecanamine, N,N-dimethyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline No. 401, Acute Oral Toxicity |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1989 |
| Species/Strain: | Rat/Sprague-Dawley |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Arachis oil B.P. |
| Route of administration: | Oral gavage |
| Remarks: | Ten rats (five males and five females) were administered a single dose of the test substance in Arachis oil B.P. by oral gavage at a concentration of 2000 mg/kg. At study initiation males and females weighed 135-172 g and 125-130 g, respectively. Rats were observed for signs of toxicity one and four hours post dose and subsequently once daily for 14 days. Individual body weights were recorded on the day of treatment and on days 7 and 14. A gross necropsy was performed on all rats. Temperature and humidity were monitored throughout the study. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ > 2000 mg/kg |
| Number of deaths: | 4/10 |
| Remarks: | Three male rats died prior to scheduled sacrifice on days 1, 3 and 8. One female died on day 2. Hunched posture, piloerection, lethargy and decreased respiratory rate were observed in one female at one and four hours post dose. Increased salivation also was observed in this female at one hour post dose. Hunched posture, piloerection and lethargy, and occasional or isolated signs of ptosis, diarrhea, emaciation and red/brown staining around the snout and eyes were observed in surviving rats during the 14-day observation period. All surviving rats appeared normal by day 13. One surviving male and female showed a loss in body weight during the first week of the observation period. All surviving rats showed |

body weight gain over the second week of the observation period. Necropsy findings in rats that died prior to scheduled sacrifice included abnormally red lungs, dark liver and kidneys, with hemorrhage of the gastric mucosa and small intestines, and incidents of hemorrhage of the nonglandular epithelium of the stomach and large intestine. No abnormalities were noted at necropsy of the rats that survived the 14-day, post-dose observation period.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A

Remarks: Reliable without restriction; guideline study.

**References**

Jones, J.R. 1991. Cesio Study: Fatty Amines and Derivatives. Acute Oral Toxicity Studies in the Rat. Safepharm Laboratories Limited, Derby, U.K.

**Other**

Last changed: June 10, 2002

Order number for sorting: 4

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Farmin DM60 (CAS RN 112-69-6; 1-Hexadecanamine, N,N-dimethyl) |
| Purity: | 97% |
| **Remarks:** | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guidelines for Testing of Chemicals - Section 4, Sub-section 401 |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1996 |
| Species/Strain: | Rat/CD Strain (remote Sprague-Dawley origin) |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Corn oil |
| Route of administration: | Oral gavage |
| Remarks: | Groups of ten rats (five males and five females) were administered a single dose of the test substance into the stomach lumen via a flexible catheter at dosages of 2000 mg/kg and 500 mg/kg. The test substance was administered at constant volume-dosage of 10 ml/kg bodyweight in corn oil. Rats weighing 107 to 139 g (males) and 106 to 129 g (females) were acclimated to the laboratory for a period of at least five days prior to test initiation. Rats were approximately five weeks old at initiation of the study. Food was available *ad libitum*, except for the overnight period prior to test substance administration and three hours after dosing. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats. The $LD_{50}$ value was calculated using probit analysis (Finney, D.J. 1971. Probit Analysis. 3rd ed; Cambridge University Press). |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = 1015 mg/kg; slope of does response curve 84º. |
| Number of deaths: | At 2000 mg/kg, mortality was: 5/5 males and 5/5 females. At 500 mg/kg, mortality was: 0/5 males and 0/5 females. |
| Remarks: | At 500 mg/kg, no animals showed signs of abnormalities. At 2000 mg/kg, all animals showed signs of abnormalities including hypoactivity, staggering gait, hyperpnoea, piloerection, pigmented |

stain of the snout, pigmented orbital secretion, and hunched posture. No lesions were found at necropsy in the surviving animals of the 500 mg/kg group or the animals that died in the 2000 mg/kg group.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A

Remarks: Reliable without restrictions; guideline study.

**References**

Rees, P. B. 1996. Farmin DM60: Acute Oral Toxicity Study in the Rat. Report No. 96/KAS172/0661. Huntingdon Life Sciences Ltd. Eye, Suffolk, UK.
and
Letter from High Point Chemical to U.S. Environmental Protection Agency concerning test substance. January 23, 1999.

**Other available reports**

**Other**

Last changed: July 9, 2002

Order number for sorting: 4d

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Armeen DM18D (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | $LD_{50}$ |
| GLP: | No |
| Year: | 1957 |
| Species/Strain: | Albino rat |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | 10% Aqueous Gum Arabic or none |
| Route of administration: | Oral gavage |
| Remarks: | Groups of ten rats (five males and five females) were administered a single dose of the test substance via a polyethylene stomach tube at concentrations of 0.50, 0.75, 1.0, 2.0, 4.0 or 8.0 ml/kg. The test substance was administered at concentrations of 0.50, 0.75, 1.0 and 2.0 ml/kg was diluted in 10% aqueous Gum Arabic. The test substance administered at concentrations of 4.0 and 8.0 ml/kg was undiluted. Rats weighing approximately 95 g were acclimated to the laboratory for a period of 14 days prior to test initiation. Food was available *ad libitum*, except for a period of 24 hours prior to test substance administration. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = 0.78 ml/kg<br>(95% confidence limits = 0.636 to 0.956 ml/kg) |
| Number of deaths: | 0.50 ml/kg = 0/10<br>0.75 ml/kg = 5/10<br>1.0 ml/kg = 7/10<br>2.0, 4.0 and 8.0 ml/kg = 10/10 |
| Remarks: | $LD_{0.01}$ = 0.23 ml/kg<br>$LD_{99.99}$ = 2.65 ml/kg<br>Generalized listless behavior was observed in all dose groups shortly after test substance administration. Diarrhea was observed in rats in degrees of severity more or less commensurate with the dose received. |

Rats in the higher dose groups became comatose within 4 to 10 hours and succumbed within the next 12 hours. Surviving rats in the lower dose groups showed signs of recovery within 24 to 48 hours post dose. Necropsy examinations of those animals that died prior to scheduled sacrifice revealed intestines distended with fluid. All other tissues and organs examined appeared normal.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B

Remarks: Reliable without restriction; comparable to guideline study.

**References**

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

**Other**

Last changed: June 13, 2002

Order number for sorting: 37

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Farmin DM80 (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl) |
| Purity: | 97% |
| **Remarks:** | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guidelines for Testing of Chemicals - Section 4, Sub-section 401 |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1996 |
| Species/Strain: | Rat/CD Strain (remote Sprague-Dawley origin) |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Corn oil |
| Route of administration: | Oral gavage |
| Remarks: | Groups of ten rats (five males and five females) were administered a single dose of the test substance into the stomach lumen via a flexible catheter at dosages of 2000 mg/kg and 500 mg/kg bodyweight. The test substance was administered at constant volume of 10 ml/kg body weight in corn oil. Rats weighing 113 to 130 g (males) and 110 to 123 g (females) were acclimated to the laboratory for a period at least five days prior to test initiation. Rats were approximately five weeks old at initiation of the study. Food was available *ad libitum*, except for the overnight period prior to test substance administration and three hours after dosing. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats. The $LD_{50}$ value was calculated using probit analysis (Finney, D.J. 1971. Probit Analysis. 3rd ed; Cambridge University Press). |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = 2116 mg/kg; slope of dose response curve 77º. |
| Number of deaths: | At 2000 mg/kg, mortality was: 2/5 males and 2/5 females. At 500 mg/kg, mortality was: 0/5 males and 0/5 females. |
| Remarks: | At 500 mg/kg, animals showed signs of abnormalities including hypoactivity, piloerection, hunched posture and ungroomed appearance, but all were normal by Day 4. At 2000 mg/kg, all animals showed signs of |

abnormalities including lower than expected weight gain, hypoactivity, piloerection, hunched posture, pigmented orbital secretions, ungroomed appearance, eyes closed and hair loss. With the exception of hair loss, surviving animals were overtly normal by Day 8. Necropsy of decedents revealed various areas of cannibalization and fur staining. There were no macroscopic abnormalities noted for the surviving animals in the 2000 and 500 mg/kg dose groups.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A

Remarks: Reliable without restrictions; guideline study.

**References**

Rees, P. B. 1996. Farmin DM80: Acute Oral Toxicity Study in the Rat. Report No. 96/KAS179/0656. Huntingdon Life Sciences Ltd. Eye, Suffolk, UK.
and
Letter from High Point Chemical to U.S. Environmental Protection Agency concerning test substance. January 23, 1999.

**Other available reports**

**Other**

Last changed: July 8, 2002

Order number for sorting: 38g

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Armeen DMMCD (CAS RN 61788-93-0; Amines, coco alkyldimethyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| Type: | $LD_{50}$ |
| GLP: | Not stated |
| Year: | 1984 |
| Species/Strain: | HC/CFY Sprague-Dawley rat |
| Sex: | Male and female |
| No. of animals per sex per dose: | Described below |
| Vehicle: | None |
| Route of administration: | Oral gavage |
| Remarks: | The test substance was administered to 4 – 6 week old male and female rats (83 – 128 g) at dose levels of 1.0 (one male and one female), 1.26 (two males and two females), 1.6 (4 males and 4 females), 2.0 (one male and one female) and 2.5 g/kg (one male and one female). First, one male and one female rat were administered the estimated $LD_{50}$. All subsequent dose levels were determined considering each sex individually. If an animal died or was considered moribund the next animal of that sex was dosed at a lower level. If the animal did not die the next animal was dosed at a higher level. Dosing was continued in this manner until a total of six animals per sex had been dosed, after reversal of the initial outcome. The next dose level was not determined until at least the day after the previous dose had been given. The test substance was administered undiluted. Animals were acclimated to the laboratory for at least five days, and were fasted prior to dosing and for approximately four hours after dosing. The animal room was temperature and humidity controlled. Animals were observed soon after dosing and at frequent intervals on the day of dosing and at least twice daily thereafter for a total of eight days. Body weights were measured for each animal on the day of dosing, on Day 8 or at the time of death. A gross necropsy was performed on each animal at the end of the eight-day observation period, or when an animal was found dead. |

**Results**

| | |
|---|---|
| Value: | Male $LD_{50}$ = 1.5 g/kg (95% confidence limits = 1.1 to 1.9 g/kg)<br>Female $LD_{50}$ = 1.3 g/kg (95% confidence limits = 1.0 to 1.7 g/kg) |
| Number of deaths: | 2.5 g/kg = 1/1 male, 1/1 female<br>2.0 g/kg = 1/1 male, 1/1 female<br>1.6 g/kg = 3/4 males, 4/4 females<br>1.26 g/kg = 0/2 males, 0/2 females<br>1.0 g/kg = 0/1 male, 0/1 female |
| Remarks: | Mortality was observed in rats treated at 1.6 g/kg and above within one and 3 days of dosing. Animals that survived the study gained weight during the study. Clinical signs observed shortly after dosing in all treated rats included piloerection, abnormal body carriage (hunched posture), abnormal gait (waddling), pallor of the extremities, lethargy and increased salivation. In addition, rats treated at 1.0, 1.6, 2.0 and 2.5 g/kg experienced decreased respiratory rate and ptosis. Diarrhea was observed in rats treated at 1.6 and 2.0 g/kg. Recovery was complete by Day 8 in those animals that survived the study. There were no gross necropsy findings noted in animals that survived the observation period. Gross necropsy findings in animals that died during the observation period included congestion or hemorrhage of the lungs and pallor of the liver, kidneys and spleen. Congestion of the blood vessels of the stomach was observed in two animals at 1.6 g/kg. Body weight loss was observed in all rats that died. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1B |
| Remarks: | Reliable without restriction; comparable to guideline study. |

**References**

Kynoch, S. R. and D. O. Chanter. 1984. Acute Oral Toxicity to Rats of Armeen DMMCD. Report No. 84015D. Huntingdon Research Centre Plc.

**Other available reports**

**Other**

| | |
|---|---|
| Last changed: | July 25, 2002 |
| Order number for sorting: | 129 |
| Remarks: | |

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Genamin CS 302 D (CAS RN 61788-93-0; Amines, coco alkyldimethyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | ES Guideline B.1. Acute Oral Toxicity 84/449/EWG; OECD Guideline for testing of chemicals, 401 Acute Oral Toxicity; Guideline 83/467/EWG |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1989 |
| Species/Strain: | Rat/Wistar [Hoe: WISKf(SPF71)] |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Sesame Oil (Oleum sesame Ph.Eur.III, Fa. Mainland Pharmzeutische Fabrik GmbH, Ffm.) |
| Route of administration: | Oral gavage |
| Remarks: | Animals were kept in temperature and humidity controlled rooms in groups of 5 rats per cage. Temperature range was 22 ± 3°C, relative humidity was 50 ± 20 %, and animals received 12 hours of light per day. Food was removed about 16 hours before and approximately 3 to 4 hours after application. The test substance was dissolved in sesame oil in the appropriate concentrations and homogenized using a magnetic stirrer. The prepared solution was administered via oral gavage. It was administered to five female animals per group in the following concentrations: 800, 1000, 1250 and 1600 mg/l. It also was administered to five male and five female animals at 2000 mg/l. Observation time was 14 days after dosing. Symptoms and death were recorded when they occurred. Body weight was determined weekly. Animals that died during the test were dissected and inspected macroscopically. Surviving animals were terminated after the observation time by carbon dioxide, dissected and examined for macroscopically visible changes. |

**Results**

Value: $LD_{50}$ > 1000 and < 1250 mg/kg

Number of deaths

| Dose (mg/kg body weight) | Mortality | | | |
|---|---|---|---|---|
| | Male animals | | Female animals | |
| | absolute | relative (%) | absolute | relative (%) |
| 800 | -- | -- | 0/5 | 0 |
| 1000 | -- | -- | 0/5 | 0 |
| 1250 | -- | -- | 4/5 | 80 |
| 1600 | -- | -- | 5/5 | 100 |
| 2000 | 4/5 | 80 | 5/5 | 100 |

Remarks: The following clinical symptoms were observed in the male and female animals after the application of Genamin CS 202 D: crouching, flanks drawn in, decreased spontaneous activity, ruffled fur, uneven breathing, long-legged and staggering gait, narrowed eyelids, blood-colored crusted lid rims and snouts as well as diarrhea. The symptoms were reversible in the male animals five days post application and in the female animals nine days post application.
The one surviving female rat lost weight by Day 7 but surpassed the initial body weight by Day 14. All other surviving animals in the 1000 and 800 mg/kg dose groups had normal body weight gain throughout the post dosing observation period. The macroscopic examination of the male and female rats that died revealed the following: dark-colored liver, reddened stomach mucous membrane, blood in the stomach and yellow liquid in the small intestine. Animals terminated after the end of the study displayed no unusual macroscopic changes.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Hofmann, Th. and R. Jung. 1989. Genamin CS 302 D: Study of the Acute Oral Toxicity in the Wistar Rat. Study Number 89.0588. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other available reports**

**Other**

Last changed: June 7, 2002
Order number for sorting: 228a
Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Armeen DMCD (CAS RN 61788-93-0; Amines, coco alkyldimethyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not Stated |
| Type: | $LD_{50}$ |
| GLP: | No |
| Year: | 1957 |
| Species/Strain: | Albino rat |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | 10% Aqueous Gum Arabic or none |
| Route of administration: | Oral gavage |
| Remarks: | Groups of ten rats (five males and five females) were administered a single dose of the test substance via a polyethylene stomach tube at concentrations of 1.0, 1.5, 1.75, 2.0, 4.0 or 8.0 ml/kg. The test substance administered at concentrations of 1.0, 1.5, 1.75 and 2.0 ml/kg was diluted in 10% aqueous Gum Arabic. The test substance administered at concentrations of 4.0 and 8.0 ml/kg was undiluted. Rats weighing approximately 95 g were acclimated to the laboratory for a period of 14 days prior to test initiation. Food was available *ad libitum*, except for a period of 24 hours prior to test substance administration. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = 1.58 ml/kg<br>(95% confidence limits = 1.31 to 1.90 ml/kg |
| Number of deaths: | 1.0 ml/kg = 1/10<br>1.5 ml/kg = 3/10<br>1.75 ml/kg = 7/10<br>2.0, 4.0 and 8.0 ml/kg = 10/10 |
| Remarks: | $LD_{0.01}$ = 0.52 ml/kg<br>$LD_{99.99}$ = 4.8 ml/kg (As stated in report; appears inaccurate.)<br>Generalized listless behavior was observed in all dose groups shortly after test substance administration. Diarrhea was observed in rats in degrees of severity |

more or less commensurate with the dose received. Ptosis was observed among the animals in all dose groups. Rats dosed at 1.0 ml/kg and higher that died became comatose within four to ten hours post dose and died within the next 12 hours. Surviving rats showed signs of recovery within 24 to 48 hours post dose. Necropsy examinations of those animals that died prior to scheduled sacrifice revealed intestines distended with fluid. All other tissues and organs examined appeared normal.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B

Remarks: Reliable without restriction; comparable to guideline study.

**References**

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

**Other**

Last changed: June 13, 2002

Order number for sorting: 228f

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Hydrogenated tallow alkyl dimethylamine [CAS RN 61788-95-2; Amines, (hydrogenated tallow alkyl)dimethyl] |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline No. 401, Acute Oral Toxicity |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1989 |
| Species/Strain: | Rat/Sprague-Dawley |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Arachis oil B.P. |
| Route of administration: | Oral gavage |
| Remarks: | Ten rats (five males and five females) were administered a single dose of the test substance in Arachis oil B.P. by oral gavage at a concentration of 2000 mg/kg. At study initiation males and females weighed 130-143 g and 122-140 g, respectively. Rats were observed for signs of toxicity one and four hours post dose and subsequently once daily for 14 days. Individual body weights were recorded on the day of treatment and on days 7 and 14. A gross necropsy was performed on all rats. Temperature and humidity were monitored throughout the study. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ > 2000 mg/kg |
| Number of deaths: | 2/10 |
| Remarks: | One male and one female rat died prior to scheduled sacrifice on days 3 and 1, respectively. Hunched posture, piloerection and red/brown staining around the snout, and occasional or isolated signs of lethargy, ptosis, emaciation and increased salivation were observed in rats during the first six days of the 14-day observation period. All surviving rats appeared normal five to seven days post dose. A loss in body weight or reduced body weight gain during the first week of the observation period was commonly noted. All surviving rats showed body weight gain over the second week of the observation period. Necropsy findings in rats that died prior to scheduled sacrifice |

included abnormally red lungs, dark liver and kidneys, and hemorrhage of the gastric mucosa and small intestines. No abnormalities were noted at necropsy of the rats that survived the 14-day, post-dose observation period.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A

Remarks: Reliable without restriction; guideline study.

**References**

Jones, J.R. 1991. Cesio Study: Fatty Amines and Derivatives. Acute Oral Toxicity Studies in the Rat. Safepharm Laboratories Limited, Derby, U.K.

**Other**

Last changed: June 10, 2002

Order number for sorting: 107

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Armeen DMSD (CAS RN 61788-91-8; Amines, dimethylsoya alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not Stated |
| Type: | $LD_{50}$ |
| GLP: | No |
| Year: | 1957 |
| Species/Strain: | Albino rat |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | 10% Aqueous Gum Arabic or none |
| Route of administration: | Oral gavage |
| Remarks: | Groups of ten rats (five males and five females) were administered a single dose of the test substance via a polyethylene stomach tube at concentrations of 0.50, 0.75, 1.0, 2.0, 4.0 or 8.0 ml/kg. The test substance administered at concentrations of 0.50, 0.75, 1.0 and 2.0 ml/kg was diluted in 10% aqueous Gum Arabic. The test substance administered at concentrations of 4.0 and 8.0 ml/kg was undiluted. Rats weighing approximately 95 g were acclimated to the laboratory for a period of 14 days prior to test initiation. Food was available *ad libitum*, except for a period of 24 hours prior to test substance administration. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = 0.835 ml/kg<br>(95% confidence limits = 0.745 to 0.935 ml/kg |
| Number of deaths: | 0.50 ml/kg = 0/10<br>0.75 ml/kg = 3/10<br>1.0 ml/kg = 8/10<br>2.0, 4.0 and 8.0 ml/kg = 10/10 |
| Remarks: | $LD_{0.01}$ = 0.41 ml/kg<br>$LD_{99.99}$ = 1.68 ml/kg<br>Generalized listless behavior was observed in all dose groups shortly after test substance administration. Diarrhea was observed in rats in degrees of severity more or less commensurate with the dose received. |

Ptosis was observed among the animals in all dose groups. Rats dosed at 1.0 ml/kg and higher that died became comatose within four to ten hours post dose and died within the next 12 hours. Surviving rats showed signs of recovery within 24 to 48 hours post dose. Necropsy examinations of those animals that died prior to scheduled sacrifice revealed intestines distended with fluid. All other tissues and organs examined appeared normal.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B

Remarks: Reliable without restriction; comparable to guideline study.

**References**

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

**Other**

Last changed: June 13, 2002

Order number for sorting: 104

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Genamin SH 301 (CAS RN 4088-22-6; 1-Octadecanamine, N-methyl-N-octadecyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | ES Guideline B.1. Acute Toxicity oral 84/449/EWG; OECD Guideline for testing of chemicals, 401 Acute Oral Toxicty; Guideline 83/467/EWG |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1988 |
| Species/Strain: | Rat/Wistar |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Sesame Oil (Oleum sesame Ph.Eur.III, Fa. Mainland Pharmzeutische Fabrik GmbH, Ffm.) |
| Route of administration: | Oral gavage |
| Remarks: | Animals were kept in temperature and humidity controlled rooms in groups of 5 rats per cage. Temperature range was 22 ± 3°C, relative humidity was 50 ± 20 %, and animals received 12 hours of light per day. Food was removed about 16 hours before and approximately 3 to 4 hours after application. The test substance was dissolved in sesame oil warmed to 35°C. The prepared solution was administered to five male and five female rats via oral gavage at 2000 mg/kg. The dose volume was 10 ml/kg. Observation time was 14 days after dosing. Symptoms and death were recorded when they occurred. Body weight was determined weekly during this time. Animals that died during the test were dissected and inspected macroscopically. Surviving animals were terminated after the observation time by carbon dioxide, dissected and examined for macroscopically visible changes. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ > 2000 mg/kg body weight |
| Number of deaths: | 0/10 |
| Remarks: | During the 14-day observation period, no deaths were observed. In addition, no symptoms of toxicity were observed. Body weight gain was not affected. The macroscopic examination revealed no visible changes. |

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Hofmann, Th. and R. Jung. 1988. Genamin SH 301: Study of the Acute Oral Toxicity in the Wistar Rat. Study Number 88.0225. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other available reports**

**Other**

Last changed: June 7, 2002

Order number for sorting: 77a

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Genamin CS 301 (CAS RN 61788-62-3; Amines, dicoco alkylmethyl) |
| Purity: | Not stated |
| Remarks: | The report identifies the product name as "Genamin CS 301", which corresponds to CAS RN 61788-62-3; however, the chemical name is listed as "methyldistearylamin". Based on all available information, the test substance evaluated in this study was Genamin CS 301 (CAS RN 61788-62-3) and the chemical name of "methyldistearylamin" was included in the report in error. |

**Method**

| | |
|---|---|
| Method/Guideline followed: | EG-Guideline B.1. "Acute Toxicity Oral" of the 84/449/EWG; OECD-Guideline 401 "Acute Oral Toxicity"; Guideline 83/467/EWG |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1990 |
| Species/Strain: | Rat/Wistar [WISKf (SPF71)] |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Sesame oil (Oleum Sesami Ph. Eur. III, Fa. Mainland Pharmaceutical Factory Ltd. |
| Route of administration: | Oral gavage |
| Remarks: | The test substance was administered to 5 male and 5 female rats as a 20% (w/v) mixture in sesame oil at a constant volume of 10 ml/kg to yield a dose level of 2000 mg/kg. All animals were observed for 14 days following dosing at which time they were killed by $CO_2$ inhalation and a necropsy was performed. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ > 2000 mg/kg body weight |
| Number of deaths: | 0/10 |
| Remarks: | No mortality occurred. The animals showed impaired breathing and motion, as well as blood-colored, crusty snouts. The symptoms were reversible by Day 4. The bodyweight gain was not influenced by test substance administration. The necropsy showed no macroscopically visible changes. |

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Nölken, G. and R. Jung. 1990. Short Report: Genamin CS 301 – Study of the Acute Oral Toxicity to the Wistar Rat. Report Number 90.0108. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other available reports**

**Other**

Last changed: July 25, 2002

Order number for sorting: 126a

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Armeen M2HT (CAS RN 61788-63-4; dihydrogenated tallow methylamine) |
| Purity: | 95% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline No. 401, Acute Oral Toxicity |
| Type: | $LD_{50}$ |
| GLP: | No |
| Year: | 1983 |
| Species/Strain: | Rat/HC/CFY (Sprague-Dawley) |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | 1% Methyl cellulose |
| Route of administration: | Oral gavage |
| Remarks: | Ten rats (five males and five females) were administered a single dose of the test substance via a syringe and plastic catheter at a concentration of 5.0 g/kg. The test substance was prepared as a 50% w/v suspension in the vehicle and administered at a volume not exceeding 10.0 ml/kg. Rats were in the weight range of 90 - 115 g and were approximately four to six weeks of age. All rats were acclimated to the laboratory for a minimum period of five days prior to the start of the study. Food was available *ad libitum*, except for overnight prior to administration and approximately four hours post dose. Water was available *ad libitum*. Temperature and humidity were monitored during the study. Rats were observed for signs of toxicity soon after dosing; then at frequent intervals on day 1 (day of dosing). Subsequent observations were made twice daily. Rats were observed for 14 days following test substance administration. Individual body weights were recorded on days 1, 8 and 15. A necropsy was performed on all rats on study day 15. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ > 5.0 g/kg |
| Number of deaths: | 0/10 |

| | |
|---|---|
| Remarks: | Piloerection and hunched posture were observed shortly after dosing in all treated rats. These signs were accompanied by pallor of the extremities and abnormal gait in three male and three female rats. All rats recovered from these symptoms by day 4 and gained weight over the observation period. No findings were noted at necropsy. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1A |
| Remarks: | Reliable without restriction; guideline study. |

**References**

Kynoch, S. R. 1984. Acute Oral Toxicity to Rats of Armeen M2HT. Report No. 8464D/AKZ 162/AC. Huntingdon Research Centre Plc., Huntingdon, Cambridgeshire, U.K.

**Other**

| | |
|---|---|
| Last changed: | June 10, 2002 |
| Order number for sorting: | 102 |
| Remarks: | |

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Armeen 2HT (CAS RN 61789-79-5; Amines, bis (hydrogenated tallow alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Regulations for the Enforcement of the Federal Hazardous Substances Act, 1964 |
| Type: | $LD_{50}$ |
| GLP: | No |
| Year: | 1971 |
| Species/Strain: | Albino rat |
| Sex: | Male |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Corn oil |
| Route of administration: | Oral gavage |
| Remarks: | The test substance was administered to male rats (222 to 252 g) as a 25% w/v suspension in corn oil at dose levels of 0.464, 1.0, 2.15, 4.64 and 10.0 g/kg body weight. Since the 10.0 g/kg dose level would have exceeded the capacity of the rat's stomach, this level was administered as a split-dose, i.e. one-half the dose was administered in the morning and the second half within 4 or 5 hours. Animals were fasted for approximately 18 hours prior to dosing. Food was available *ad libitum* following dosing. Animals were observed for gross signs of systemic toxicity and mortality at frequent intervals on the day of dosing and at least once daily thereafter for a total of 14 days. Body weights were measured for each animal on the day of dosing and at the end of the 14-day observation period. A gross necropsy was performed on each animal at the end of the 14-day observation period. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ > 10.0 g/kg body weight |
| Number of deaths: | 0/5 males in all dose groups |
| Remarks: | All animals survived the study and gained weight during the study. Clinical signs observed in two rats treated at the 2.15 g/kg dose level included slight diarrhea stains, seen on the first and/or second day post-dose. Signs of toxicity noted at the 10.0 g/kg dose level included depression, depressed righting and |

placement reflexes, ataxia, rapid or shallow respiration, excessive salivation, mucoid diarrhea and oily, unkempt hair coats. These signs were observed several hours following dosage or on the first day post-dose. All animals appeared normal from the fifth or sixth day post-dose through study termination. There were no gross necropsy findings noted in any animal.

**Conclusions**

Remarks: Based on these results, Armeen 2HT is classified as non-toxic by ingestion as these terms are defined in the above-cited regulations. (Author of study report)
The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2A
Remarks: Reliable with restrictions; acceptable, well-documented study report which meets basic scientific principles.

**References**

Daniels, C. L. 1971. Acute Oral Administration of Armeen 2HT to Rats. Report No. V-833. Hill Top Research, Inc., USA.

**Other available reports**

**Other**

Last changed: July 25, 2002
Order number for sorting: 131
Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | DA-1618 [CAS RN 52898-18-7; 1,3-Propanediamine, N-(3-(dodecyloxy)propyl)-] |
| Purity: | Not stated |
| Remarks: | Report does not mention a chemical name, just the trade name. |

**Method**

| | |
|---|---|
| Method/Guideline followed: | OECD 425 - "Up and Down Procedure" |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1999 |
| Species/Strain: | Crl:CD®(SD)IGS BR rat |
| Sex: | Male and female |
| No. of animals per sex per dose: | 1 to 3 |
| Vehicle: | None |
| Route of administration: | Oral gavage |
| Remarks: | Initially one animal/sex was dosed at 500 mg/kg of body weight. If either animal died or appeared moribund, the dose level for the next animal was decreased. If survival appeared apparent, the next dose was increased. In each case, the next dose was increased or decreased, using a dose multiplier of 1.3 depending upon the fate of the previous animal of that sex. Animals were fasted 17 to 20 hours prior to dosing and were given food following dosing. Animals were observed 1, 2.5 and 4 hours after test material administration and daily thereafter for 15 days. Body weights were measured prior to test substance administration (Day 0) and on Days 7 and 14 or at death (when survival exceeds 1 day). All animals were subjected to an abbreviated gross necropsy examination, no tissues were saved. |

**Results**

| | |
|---|---|
| Value: | Male $LD_{50}$ = 378 mg/kg<br>Female $LD_{50}$ = 299 mg/kg |
| Number of deaths: | 228 mg/kg = 0/1 females<br>296 mg/kg = 0/2 males, 1/3 females<br>385 mg/kg = 2/2 males, 3/3 females<br>500 mg/kg = 2/3 males, 1/1 females<br>650 mg/kg = 2/2 males; 1/1 females |

Remarks: Clinical signs of toxicity were observed at all dose levels. Slight hypoactivity, fecal staining, lacrimation, hunched posture, labored breathing, few and/or mucoid feces, chromodacryorrhea, red crust around nose and mouth, urine staining, thin appearance, rough haircoat and discolored urine occurred at all or most dose levels. One male and one female at the 296 mg/kg dose level appeared normal throughout the 15-day observation period. Of the six animals that survived to Day 14, one male dosed at 296 mg/kg lost weight (20 g); the remaining five animals in this group gained weight. The majority of the findings noted at necropsy for the animals that died involved discoloration of the mucosal surface of the stomach. Of the six animals that survived to termination, one female in the 296 mg/kg dose level had a thickening of the nonglandular stomach and adhesions in the peritoneal cavity, the remaining five animals had no gross lesions.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; Guideline study.

**References**

Vegarra, M.M. 1999. Acute Oral Toxicity ($LD_{50}$) Study of DA-1618 in Rats (Up and Down Procedure). Report No. 20557-0-801. Covance Laboratories Inc.

**Other available reports**

**Other**

Last changed: July 19, 2002
Order number for sorting: 165
Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Tallow alkyl trimethylene diamine (CAS RN 61791-55-7; Amines, N-tallow alkyltrimethylenedi-) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline No. 401, Acute Oral Toxicity |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1989 |
| Species/Strain: | Rat/Sprague-Dawley |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Arachis oil B.P. |
| Route of administration: | Oral gavage |
| Remarks: | Ten rats (five males and five females) were administered a single dose of the test substance in Arachis oil B.P. by oral gavage at a concentration of 5000 mg/kg. At study initiation males and females weighed 124-152 g and 120-140 g, respectively. Rats were observed for signs of toxicity one and four hours post dose and subsequently once daily for 14 days. Individual body weights were recorded on the day of treatment and on days 7 and 14. A gross necropsy was performed on all rats. Temperature and humidity were monitored throughout the study. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ > 5000 mg/kg |
| Number of deaths: | 2/10 |
| Remarks: | One male and one female rat died prior to scheduled sacrifice on days 5 and 2, respectively.<br>Hunched posture and piloerection were noted one to ten days after treatment. Red/brown staining around the snout was also commonly noted three to five days after treatment. An isolated incident of pallor of the extremities was noted in one male on day five. Surviving animals appeared normal eight to eleven days after treatment. Body weight loss was commonly noted at the end of the first week. All surviving animals showed expected weight gain during the second week post-dosing. The necropsy of the dead animals revealed abnormally red lungs, dark or patchy |

pallor of liver and hemorrhage of the gastric mucosa. No abnormalities were noted at necropsy of the rats that survived the 14-day, post-dose observation period.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A

Remarks: Reliable without restriction; guideline study.

**References**

Jones, J.R. 1991. Cesio Study: Fatty Amines and Derivatives. Acute Oral Toxicity Studies in the Rat. Safepharm Laboratories Limited, Derby, U.K.

**Other**

Last changed: June 10, 2002

Order number for sorting: 283a

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Cocodiethanolamide (CAS RN 61791-31-9; Ethanol, 2,2'iminobis-,N-coco alkyl derivs.) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Procedure by Hagen, E. D. 1959. Acute Toxicity; Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics, p. 17-25. |
| Type: | $LD_{50}$ |
| GLP: | No |
| Year: | 1978 |
| Species/Strain: | Rat/Wistar |
| Sex: | Male and female |
| No. of animals per sex per dose: | 3 |
| Vehicle: | Not stated |
| Route of administration: | Oral gavage |
| Remarks: | Groups of six rats (three males and three females) were administered a single dose of the test substance at concentrations of 5.0, 6.3, 7.01, 7.94 and 10.0 g/kg. At study initiation males and females weighed 188-300 g and 188-244 g, respectively. Rats were acclimated to the laboratory for a minimum of seven days. Food and water were available *ad libitum*, except overnight prior to test substance administration. Rats were observed for signs of toxicity one, three, six and 24 hours post dose and subsequently daily thereafter for 13 days. Individual body weights were recorded at study initiation and termination. A gross necropsy was performed on all rats. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ > 5 g/kg |
| Number of deaths: | 5.0 g/kg = 1/6<br>6.3 g/kg = 3/6<br>7.01 g/kg = 3/6<br>7.94 g/kg = 4/6<br>10.0 g/kg = 6/6 |
| Remarks: | Slight, moderate and/or severe depression were observed in rats in all dose groups during the 14-day observation period. These symptoms were observed within six hours in rats treated with 5.0 and 7.94 g/kg of the test substance. Rats treated with 6.3, 7.01 and 10.0 g/kg of the test substance exhibited these |

symptoms within on hour post dose. Surviving rats in the 5.0, 6.3, 7.01 and 7.94 g/kg dose groups recovered from these symptoms within four, three, three and seven days post-dose, respectively, and gained weight during the study. Deaths occurred between days 2 and 7 post-dose. Necropsy findings for seven of the rats that died prior to scheduled sacrifice in dose groups 6.3 g/kg and above included lobes of lung partially consolidated, fibrous tissue encasing heart and lungs, severely reddened gastric mucosa, and/or pyloric and intestinal mucosa reddened. One of the surviving female rats in the 5.0 g/kg dose group had all lobes of the right lung partially consolidated. No necropsy findings were noted for any other rats that survived until study termination.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2C

Remarks: Reliable with restrictions; comparable to guideline study with acceptable restrictions.

**References**

Consumer Product Testing. 1992. Initial Submission: Letter from Rhone-Poulenc Inc. to US EPA regarding toxicity tests of cocodiethanolamide with attachments and cover letter dated 101692. EPA Doc. No. 88-920009652, Microfiche No. OTS0571309.

**Other**

Last changed: June 12, 2002

Order number for sorting: 109

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Ethomeen T/12 (CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.) |
| Purity: | 95% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Acute Oral Toxicity, Up and Down Method |
| Type: | $LD_{50}$ |
| GLP: | No |
| Year: | 1984 |
| Species/Strain: | Rat/HC/CFY (Sprague-Dawley) |
| Sex: | Male and female |
| No. of animals per sex per dose: | See Remarks below |
| Vehicle: | 1% Methyl cellulose |
| Route of administration: | Oral gavage |
| Remarks: | One male and one female were administered a single dose of the test substance via a syringe and plastic catheter at the estimated $LD_{50}$. All subsequent decisions on dose levels were taken considering each sex individually. If an animal died or was considered moribund the next animal of that sex was dosed at a lower level. If the animal did not die the next animal was dosed at a higher level. The decision for the next dose level was not taken until at least the day after the previous dose had been given. Following are the dose levels administered for each sex:<br>Males: 1.0, 1.26, 1.6, 2.0, 2.5, 4.0 and 5.0 g/kg<br>Females: 0.8, 1. 0, 1.26, 1.6, 2.0, 2.5, 4.0 and 5.0 g/kg<br>The test substance was prepared as various w/v suspensions in the vehicle and administered at a volume not exceeding 10.0 ml/kg. Rats were in the weight range of 81-132 g and were approximately four to six weeks of age. All rats were acclimated to the laboratory for a minimum period of five days prior to the start of the study. Food was available *ad libitum*, except for overnight prior to administration and approximately four hours post dose. Water was available *ad libitum*. Temperature and humidity were monitored during the study. Rats were observed for signs of toxicity soon after dosing; then at frequent intervals on day 1 (day of dosing). Subsequent observations were made twice daily. Rats were observed for seven days following test substance administration. Individual body weights were recorded |

on days 1, 8 and at death. A necropsy was performed on all rats. The $LD_{50}$ values were estimated by probit analysis, using a slope estimated from background data. Approximate confidence intervals (95% level) were derived by adding and subtracting 1.96 times the standard error of the (log.) $LD_{50}$ estimate.

**Results**

Value: Male $LD_{50}$ = 1.5 g/kg
(95% confidence interval = 1.1 to 2.0 g/kg)
Female $LD_{50}$ = 1.2 g/kg
(95% confidence interval = 0.9 to 1.6 g/kg)

Number of deaths:
Males: 1.0 g/kg = 0/2
1.26 g/kg = 0/3
1.6 g/kg = 2/2
2.0, 2.5, 4.0 and 5.0 g/kg = 1/1
Females: 0.8 g/kg = 0/1
1.0 g/kg = 0/3
1.26 g/kg = 1/1
1.6 and 2.0 g/kg = 2/2
2.5, 4.0 and 5.0 g/kg = 1/1

Remarks: Piloerection and hunched posture were observed shortly after dosing in all treated animals. These signs were accompanied by pallor of the extremities, lethargy and abnormal gait in the majority of rats in all treatment groups. Incidences of ptosis, diarrhea and increase salivation were seen at dose levels of 1.0 g/kg and above. These signs were accompanied by a decreased respiratory rate in rats dosed at 1.26 g/kg and above. Deaths occurred amongst rats treated at 1.26 g/kg and above from within two and four days of dosing. All surviving rats appeared to recover between days 5 and 8, and gained weight over the observation period. Piloerection was still observed in one male rat dosed at 1.26 g/kg and one female rat dosed at 1.0 g/kg on day 8. This finding was not considered to be of toxicological importance and the observation period was not extended. Necropsy findings in the majority of rats that died prior to scheduled sacrifice included hemorrhage or congestion of the lungs. These findings were usually accompanied by pallor of the liver, kidneys and spleen. Congestion of the blood vessels of the stomach was observed in one female rat treated at 1.6 g/kg and congestion of the blood vessels of the intestine in one female rat treated at 5.0 g/kg. All rats that died showed a loss in body weight. No necropsy findings were noted in rats that survived the

observation period.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B

Remarks: Reliable without restriction; comparable to guideline study.

**References**

Kynoch, S. R. 1984. Acute Oral Toxicity to Rats of Ethomeen T/12. Report No. 84119D/AKZ 163/AC-3. Huntingdon Research Centre Plc., Huntingdon, Cambridgeshire, U.K.

**Other**

Last changed: June 13, 2002

Order number for sorting: 112

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Amines, tallow alkyl ethoxylates, 2EO (CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline No. 401, Acute Oral Toxicity |
| Type: | $LD_{50}$ |
| GLP: | Yes |
| Year: | 1989 |
| Species/Strain: | Rat/Sprague-Dawley |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Arachis oil B.P. |
| Route of administration: | Oral gavage |
| Remarks: | Ten rats (five males and five females) were administered a single dose of the test substance in Arachis oil B.P. by oral gavage at a concentration of 2000 mg/kg. At study initiation males and females weighed 131-145 g and 120-142 g, respectively. Rats were observed for signs of toxicity one and four hours post dose and subsequently once daily for 14 days. Individual body weights were recorded on the day of treatment and on days 7 and 14. A gross necropsy was performed on all rats. Temperature and humidity were monitored throughout the study. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ > 2000 mg/kg |
| Number of deaths: | 0/10 |
| Remarks: | Hunched posture and piloerection were observed in all rats one hour post dose. All rats appeared normal within four hours post dose. All rats showed body weight gain over the 14-day observation period. No necropsy findings were noted in any rat. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1A |
| Remarks: | Reliable without restriction; guideline study. |

**References**

Jones, J.R. 1991. Cesio Study: Fatty Amines and Derivatives. Acute Oral Toxicity Studies in the Rat. Safepharm Laboratories Limited, Derby, U.K.

**Other**

| | |
|---|---|
| Last changed: | June 10, 2002 |
| Order number for sorting: | 113 |
| Remarks: | |

### 5.1.2 ACUTE INHALATION TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Armeen C (CAS RN 61788-46-3; Amines, coco alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | EPA TSCA, Federal Register 44: No. 145, 1979 |
| Type: | Range finding |
| GLP: | No |
| Year: | 1975 |
| Species/Strain: | Rat/Sprague-Dawley |
| Sex: | Male |
| No. of animals per sex per dose: | 10 |
| Vehicle: | Air |
| Route of administration: | Inhalation (whole-body) |
| Remarks: | The object of this study was to determine the minimum lethal level of the test substance vapor when administered to albino rats via inhalation for one hour. Groups of ten male rats, initially weighing between 180 and 200 grams, were exposed to the test substance at mean analytical concentrations of 0.063 and 0.099 mg/l for one hour. Food and water were withheld during exposure. Chamber concentrations were monitored during the entire one-hour exposure period at a rate of 0.52 l/min. Rats were observed for mortality and signs of toxicity and/or abnormal behavior throughout the exposure and daily for 14 days after the termination of exposure. Body weights were recorded prior to exposure (day 1) and on day 14. All surviving rats were subjected to a gross necropsy, and the following tissues excised and preserved in 10% neutral buffer formalin: brain, liver, kidney, heart, pancreas, stomach, lungs, spleen and testes. The tissues from the animals in the 0.099 mg/l group were examined under a light microscope by a veterinarian. |

**Results**

| | |
|---|---|
| Value: | One hour $LC_{50}$ > 0.099 mg/l |
| Number of deaths: | 0.063 mg/l = 0/10<br>0.099 mg/l = 0/10 |
| Remarks: | After five minutes of exposure several rats in the 0.063 mg/l dose group were preening and inactive. All animals were hypoactive after ten minutes. After 40 minutes, several animals exhibited a slight irritation around the muzzle. This latter condition, as well as |

hypoactivity in all rats, continued for the remainder of the exposure period. After ten minutes of exposure all rats in the 0.099 mg/l dose group were hypoactive. After 30 minutes, several animals showed signs of irritation, were preening, and exhibited a nasal discharge. At the end of the one-hour exposure, all rats showed mild to severe irritation around the muzzle and had reddish areas of discoloration on the fur. All rats in both groups exhibited normal appearance and behavior throughout the 14-day postexposure observation period. A mean body weight gain in both dose groups was noted at the end of the observation period. No necropsy findings were noted in any rats from both dose groups. Microscopic evaluation of selected tissues from the rats in the 0.099 mg/l dose group included minimal to slight peribronchial lymphoid hyperplasia present in the lung, as well as minimal focal interstitial nephritis in seven of the ten rats, but these findings were believed not to reveal compound-related histomorphologic alterations. All other tissues were within normal histologic limits.

**Conclusions**

Remarks: The inhalation exposure of male albino rats to the test substance up to 0.1 mg/l for one hour would not appear to be toxic since no rats died and no serious pharmacotoxic signs were indicated. The effects observed were all reversed within 24 hours (Author of report).
The acute inhalation $LC_{50}$ was not provided. This study is included to provide additional information on the acute inhalation toxicity of this test substance. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2D

Remarks: Reliable with restrictions; exposure period was one hour.

**References**

Coate, W. B. 1975. Range Finding Acute Inhalation Toxicity Study in Albino Rats. Armeen C and Armeen T. Project No. M931-100. Hazleton Laboratories America, Inc., Vienna, VA, USA.

**Other**

| | |
|---|---|
| Last changed: | July 24, 2002 |
| Order number for sorting: | 95 |
| Remarks: | |

### 5.1.2 ACUTE INHALATION TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Bis-2-hydroxylethyl-tallow amine<br>(CAS RN 61791-44-4;<br>Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | EPA TSCA, Federal Register 44: No. 145, 1979 |
| Type: | Acute inhalation - aerosol |
| GLP: | Yes |
| Year: | 1983 |
| Species/Strain: | Rat/Sprague-Dawley |
| Sex: | Male and female |
| No. of animals per sex per dose: | 5 |
| Vehicle: | Preheated, dry, filtered air |
| Route of administration: | Inhalation (whole-body) |
| Remarks: | Four groups of ten rats (five males and five females) were exposed (whole-body) for at least four hours to a test atmosphere generated from heated air (Group A, control), heated test substance (Group B), polypropylene (Group C) or 75% test substance/25% polypropylene powder (Group D). Conditions were adjusted so that each test group was exposed to a test atmosphere containing the appropriate test substance at an average nominal concentration of 0.6 to 0.8 mg/l. Prior to test substance exposure, rats were acclimated to the laboratory environment for a minimum of five days. Food and water were available *ad libitum*, except during exposure. Chamber conditions including test atmosphere temperature and relative humidity, test atmosphere oxygen content, aerosol concentration, particle size distribution of the aerosol, and condition of the animals were periodically monitored during exposure. Rats were observed for signs of toxicity once per hour while in the chamber and twice daily during the 14-day observation period. Body weights were recorded prior to exposure (day 1) and on days 3, 4, 5, 8 and 15. All rats were subjected to a gross necropsy, and the following tissues excised and preserved in 10% neutral buffer formalin: whole head with nasal passages; lungs with trachea and mainstem bronchi; liver; kidneys; and gross lesions. |

**Results**

| | |
|---|---|
| Value: | $LC_{50}$ cannot be adequately defined |
| Number of deaths: | Control group (Group A) = 0/10<br>Test substance group (Group B) = 0/10<br>Polypropylene (Group C)= 0/10<br>75% test substance/25% polypropylene powder (Group D) = 10/10 |
| Remarks: | Average nominal concentrations for Groups B, C and D were 0.6, 0.7 and 0.8 mg/l, respectively. Actual aerosol concentrations (time weighted average), as measured by gravimetric analyses, were 0.1, 0.7 and 0.4 mg/l for Groups B, C and D, respectively. Nominal concentration and particle size analysis data indicated that the test atmosphere concentration of polypropylene was lower during Group D than during Group C exposure. Furthermore, analytical chemistry data suggested that the Group D test atmosphere was composed predominately of the test substance and that test substance levels were slightly higher during Group D than Group B exposure. Therefore, it is possible that the mortality that occurred in Group D may have been related to increased test substance exposure. However, because of the small magnitude of the difference in calculated test substance concentrations between Group B and Group D test atmospheres, the possibility of additive or synergistic toxicity (test substance and polypropylene) must be considered. No clinical observations were noted in Group A rats. Slight, transient nasal discharge was present in all rats in Groups B, C and D, but persisted beyond day 1 in Group D rats only. Pale appearance, lethargy and shallow, rapid breathing also were observed in Group D rats prior to death. Decreased individual body weight was observed in males and females in Groups B, C and D. Necropsy findings in Group D rats included nasal discharge (four males and one female), hydrothorax (three males) and discoloration of organs including lungs, liver, lymph nodes and thymus (four males and two females). There were no necropsy findings in any other group. |

**Conclusions**

| | |
|---|---|
| Remarks: | The $LC_{50}$ has not been adequately characterized because of the potential for inaccurate exposure; however, this study provides additional information on the acute inhalation toxicity of the test substance. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1A |
| Remarks: | Reliable without restriction; guideline study. |

**References**

Confidential. 1983. Acute Inhalation Toxicity of Polypropylene and 75%/25% Polypropylene Powder in Sprague-Dawley Rats. EPA Doc. No. 88-8300529, Microfiche No. OTS0503339.

**Other**

| | |
|---|---|
| Last changed: | June 12, 2002 |
| Order number for sorting: | 114 |
| Remarks: | |

### 5.1.3 ACUTE DERMAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Amine KK (CAS RN 61788-46-3; Amines, coco alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated. |
| Type: | $LD_{50}$ |
| GLP: | No |
| Year: | 1985 |
| Species/Strain: | Rat/Sprague-Dawley |
| Sex: | Male and female |
| No. of animals per sex per dose: | 2 |
| Vehicle: | Distilled water (used only in the 2000 mg/kg dose group) |
| Route of administration: | Dermal |
| Remarks: | Four animals per group were treated with a single application of the test substance at doses of 500 or 2000 mg/kg. The 500 mg/kg dose group received the neat test substance at a dose volume of 0.63 ml/kg and the 2000 mg/kg dose group received the test substance in distilled water (40% w/v) at a dose volume of 5.0 ml/kg. The animals were approximately 6 to 8 weeks of age and weighed 200 to 245 g at the start of the study. Each treatment site remained occluded for the entire 24-hour exposure period. At the end of the exposure period the dose site was washed with warm (30 to 40°C) water to remove any residual test substance. During the 14-day post exposure observation period, animals were observed at least twice daily and clinical observations were recorded. The treated skin was examined daily for signs of dermal irritation with erythema and edema scores recorded at each observation. Body weights were obtained on days 1, 4, 8 and 15. A post-mortem examination was performed on all animals on day 15. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ |
| Number of deaths: | No animals died. |
| Remarks: | Shortly after dosing, rats at 2000 mg/kg showed hunched posture, abnormal gait, lethargy and decreases respiration. Observation of the treated skin revealed edema until Day 4 or 5, scabs from days 4 to 5 and |

necrosis of the skin at 500 mg/kg. Treated animals initially lost body weight followed by recovery and normal weight gain. Necropsy findings included slight bruising in the subcutaneous tissue of one male and one female at 500 mg/kg; scab formation with or without ulceration in all rats in the 2000 mg/kg group and minimal congestion of the stomach in one female in the 2000 mg/kg group.

**Conclusions**

Remarks: The study provides evidence of irritation of the test material. Since the alkyl amines are not water soluble, it is possible that the 2000 mg/kg dose did not adequately represent exposure to this dose. The study provides limited information on acute dermal toxicity. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2D

Remarks: Reliable with restrictions; the study provides limited information on the acute dermal toxicity.

**References**

Kynoch, S.R. 1985. Acute Dermal Toxicity to Rats of Amine KK. HRC Report No. 851001D/KND 10/AC. Huntingdon Research Centre. Huntingdon, England

**Other available reports**

**Other**

Last changed: August 15, 2002

Order number for sorting: 95a

Remarks:

### 5.1.3 ACUTE DERMAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | ADMA 2 (CAS RN 112-18-5; N,N-Dimethyl-1-dodecanamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated. |
| Type: | $LD_{50}$ |
| GLP: | Not stated. |
| Year: | 1979 |
| Species/Strain: | Rabbit/New Zealand White |
| Sex: | Male and female |
| No. of animals per sex per dose: | 4 rabbits per group, the ratio of males and females was not stated. |
| Vehicle: | None |
| Route of administration: | Dermal |
| Remarks: | Twelve male and four female rabbits were approximately 9 weeks old and weighed 2.0 to 3.0 kg at study initiation. Immediately prior to dosing the fur was clipped from the abdomen of the animals. Abrasions were made in one half of the rabbits. The abrasions extended the length of the exposure site, scratched the stratum corneum but did not reach the derma or produce bleeding. Four rabbits per dose group were dosed at 20.0, 10.2, 5.20 and 2.68 g/kg. The test material was applied once dermally to the prepared site under a gauze patch and occluded. The test material was kept in contact with the skin for 24 hours, at which time the wrapping was removed. The exposure site was wiped, but not washed, to remove excess material. Dermal reactions were scored at 24 hours by the Draize scoring system. The rabbits were observed daily for 14 days for signs of toxicity, pharmacological effects and mortality. Body weights were recorded pretest and in the survivors at 14 days. All animals that died during the study and all surviving animals in the 2.68 g/kg group were examined for gross pathology. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ approximately 5.0 g/kg |
| Number of deaths: | 20.0 g/kg = 4/4<br>10.2 g/kg = 4/4<br>5.20 g/kg = 1/4<br>2.68 g/kg = 2/4 |
| Remarks: | Deaths occurred at all dose levels. All animals in the 10.2 and 20.0 g/kg group died. Significant predeath toxic signs included lethargy, ptosis, anorexia, adipsia, diarrhea, mucus in feces and ataxia. Toxic signs noted in the surviving animals in the 2.68 and 5.20 g/kg groups included lethargy and diarrhea and mucus in stool, ataxia, ptosis, and yellow nasal discharge. Additional signs of toxicity observed in the 5.20 g/kg surviving animals included isolated instances of vocalization post dose, blood-shot eyes and difficulty in mobility of rear legs, possibly due to severe skin reaction. Dermal reactions were moderate to severe at all dose levels. Minimal weight gains or weight loss were noted in all surviving animals. Necropsy observations revealed dilated hearts and gastrointestinal irregularities. |

**Conclusions**

| | |
|---|---|
| Remarks: | The test material is not toxic as defined in 16 CFR 1500.3, nor is it a Class B Poison as defined in 49 CFR 173.343 (Author of report)<br>The acute dermal $LD_{50}$ has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2A |
| Remarks: | Reliable with restrictions; acceptable, well-documented publication/study report which meets basic scientific principles. |

**References**

Test for Acute Dermal/$LD_{50}$ in Albino Rabbits with ADMA 2. 1979. Project Number: MB 79-3571. MB Research Laboratories, Inc. Spinnerstown, PA, USA.

**Other available reports**

**Other**

| | |
|---|---|
| Last changed: | June 6, 2002 |
| Order number for sorting: | 123c |
| Remarks: | |

### 5.1.3 ACUTE DERMAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Armeen DM16D (CAS RN 112-69-6; 1-Hexadecanamine, N,N-dimethyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Range-finding $LD_{50}$ |
| GLP: | No |
| Year: | 1957 |
| Species/Strain: | New Zealand White rabbit |
| Sex: | Not stated |
| No. of animals per sex per dose: | 4 (sex not stated) |
| Vehicle: | None |
| Route of administration: | Dermal |
| Remarks: | Groups of four rabbits were administered a single dose of the test substance dermally at concentrations of 4.0, 6.0 or 8.0 ml/kg. The test substance was administered undiluted. The hair on the backs of young, adult rabbits, averaging 2.5 kg in body weight, was clipped twenty-four hours prior to test substance administration. The test substance was applied to the back of each rabbit and gently, but thoroughly, rubbed into the exposure site and the site occluded with impervious plastic sheeting for 24 hours. Rabbits were observed for signs of toxicity for 14 days following removal of the plastic sheeting and excess test substance. A necropsy was performed on all rabbits. The method of Litchfield and Wilcoxon was used to determine the range-finding acute percutaneous mean lethal dose together with the $LD_{0.01}$ and $LD_{99.99}$ |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = 4.29 ml/kg<br>(95% confidence limits = 3.01 to 6.10 ml/kg |
| Number of deaths: | 4.0 ml/kg = 2/4<br>6.0 ml/kg = 3/4<br>8.0 ml/kg = 4/4 |
| Remarks: | $LD_{0.01}$ = 1.63 ml/kg<br>$LD_{99.99}$ = 11.25 ml/kg<br>No signs of toxicity were observed in the rabbits during the first six hours following test substance administration. Rabbits in all dose groups showed signs of generalized weakness and lassitude, and did |

not eat or drink 24 hours post dose. Between 24 and 48 hours post dose, the rabbits in the 8.0 ml/kg dose group became extremely weak, lethargic and in a moribund state. These rabbits died within the next few hours. Rabbits in the 4.0 and 6.0 ml/kg dose groups showed signs of increasing listlessness and extreme inactivity, with deaths occurring between four and five days post dose. Rabbits in the 4.0 and 6.0 ml/kg dose groups that survived until study termination eventually showed signs of recovery, although all lost considerable weight and hair regrowth was not observed. The skin at the application site in all dose groups showed signs of slight transient erythema, and appeared dried, leathery and wrinkly, which was most pronounced in animals in the 8.0 ml/kg dose group. There were no significant necropsy findings in any rabbit.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B

Remarks: Reliable without restriction; comparable to guideline study.

**References**

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

**Other**

Last changed: June 13, 2002

Order number for sorting: 3

Remarks:

### 5.1.3 ACUTE DERMAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Armeen DM18D (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Range-finding $LD_{50}$ |
| GLP: | No |
| Year: | 1957 |
| Species/Strain: | New Zealand White rabbit |
| Sex: | Not stated |
| No. of animals per sex per dose: | 4 (sex not stated) |
| Vehicle: | None |
| Route of administration: | Dermal |
| Remarks: | Groups of four rabbits were administered a single dose of the test substance dermally at concentrations of 4.0, 6.0 or 8.0 ml/kg. The test substance was administered undiluted. The hair on the backs of young, adult rabbits, averaging 2.5 kg in body weight, was clipped twenty-four hours prior to test substance administration. The test substance was applied to the back of each rabbit and the site occluded with impervious plastic sheeting for 24 hours. Rabbits were observed for signs of toxicity for 14 days following removal of the plastic sheeting and excess test substance. A necropsy was performed on all rabbits. The method of Litchfield and Wilcoxon was used to determine the range-finding acute percutaneous mean lethal dose together with the $LD_{0.01}$ and $LD_{99.99}$ |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = 4.29 ml/kg<br>(95% confidence limits = 3.01 to 6.10 ml/kg |
| Number of deaths: | 4.0 ml/kg = 2/4<br>6.0 ml/kg = 3/4<br>8.0 ml/kg = 4/4 |
| Remarks: | $LD_{0.01}$ = 1.63 ml/kg<br>$LD_{99.99}$ = 11.25 ml/kg<br>No signs of toxicity were observed in the rabbits during the first six hours following test substance administration. Signs of mild to moderate erythema and slight drying and wrinkling at the application site were observed 24 hours post dose. Rabbits in all dose |

groups were markedly inactive, and did not eat or drink. Between 24 and 48 hours post dose, the rabbits in the 8.0 ml/kg dose group died. Rabbits in the 4.0 and 6.0 ml/kg dose groups showed signs of increasing listlessness and extreme inactivity, with deaths occurring between three and four days post dose. Rabbits in the 4.0 and 6.0 ml/kg dose groups that survived until study termination eventually showed signs of recovery, although all lost considerable weight and hair regrowth was not observed. A slight injection of the blood vessels directly underneath the skin of the application sites was the only necropsy finding.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B

Remarks: Reliable without restriction; comparable to guideline study.

**References**

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

**Other**

Last changed: June 13, 2002

Order number for sorting: 37

Remarks:

### 5.1.3 ACUTE DERMAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Armeen DMCD (CAS RN 61788-93-0; Amines, coco alkyldimethyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Range-finding $LD_{50}$ |
| GLP: | No |
| Year: | 1957 |
| Species/Strain: | New Zealand White rabbit |
| Sex: | Not stated |
| No. of animals per sex per dose: | 4 (sex not stated) |
| Vehicle: | None |
| Route of administration: | Dermal |
| Remarks: | Groups of four rabbits were administered a single dose of the test substance dermally at concentrations of 4.0, 6.0 or 8.0 ml/kg. The test substance was administered undiluted. The hair on the backs of young, adult rabbits, averaging 2.5 kg in body weight, was clipped twenty-four hours prior to test substance administration. The test substance was applied to the back of each rabbit and gently, but thoroughly, rubbed into the exposure site and the site occluded with impervious plastic sheeting for 24 hours. Rabbits were observed for signs of toxicity for 14 days following removal of the plastic sheeting and excess test substance. A necropsy was performed on all rabbits. The method of Litchfield and Wilcoxon was used to determine the range-finding acute percutaneous mean lethal dose together with the $LD_{0.01}$ and $LD_{99.99}$ |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = 4.29 ml/kg<br>(95% confidence limits = 3.01 to 6.10 ml/kg |
| Number of deaths: | 4.0 ml/kg = 2/4<br>6.0 ml/kg = 3/4<br>8.0 ml/kg = 4/4 |
| Remarks: | $LD_{0.01}$ = 1.63 ml/kg<br>$LD_{99.99}$ = 11.25 ml/kg (As stated in report; appears inaccurate.<br>Subdermal hemorrhages were noted at the application sites within the first six hours following test substance administration. No other reactions were observed at |

this time. Rabbits in all dose groups were listless and inactive and the skin at the dose site was acutely inflamed 24 hours after dose administration, with subdermal hemorrhages present (most severe in the 8.0 ml/kg dose group). During the next 24 hours the rabbits in the 8.0 ml/kg dose group became moribund (pronounced weakness and inactivity) and died. Deaths that occurred in the 4.0 and 6.0 ml/kg groups three to four days post dose. The observations of these animals preceding death were similar to those animals that died in the 8.0 ml/kg dose group. Necropsy of the dead rabbits in all dose groups revealed diffuse subdermal hemorrhages about the entire trunk of the animals, ventral as well as dorsal, which extended well beyond the limits of the application sites. The skin at the dose site was indurated and leathery. Sloughing had begun prior to death and loss of sensitivity at the application site had been noted among the animals. All other organs and tissues appeared normal. The three surviving animals lost weight during the study and did not show any regrowth of hair at the application site; at the end of the 14-day observation period, they were still underweight.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B

Remarks: Reliable without restriction; comparable to guideline study.

**References**

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

**Other**

Last changed: June 13, 2002

Order number for sorting: 228f

Remarks:

### 5.1.3 ACUTE DERMAL TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Armeen DMSD (CAS RN 61788-91-8; Amines, dimethylsoya alkyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Range-finding $LD_{50}$ |
| GLP: | No |
| Year: | 1957 |
| Species/Strain: | New Zealand White rabbit |
| Sex: | Not stated |
| No. of animals per sex per dose: | 4 (sex not stated) |
| Vehicle: | None |
| Route of administration: | Dermal |
| Remarks: | Groups of four rabbits were administered a single dose of the test substance dermally at concentrations of 2.0, 4.0 or 8.0 ml/kg. The test substance was administered undiluted. The hair on the backs of young, adult rabbits, averaging 2.5 kg in body weight, was clipped twenty-four hours prior to test substance administration. The test substance was applied to the back of each rabbit and the site occluded with impervious plastic sheeting for 24 hours. Rabbits were observed for signs of toxicity for 14 days following removal of the plastic sheeting and excess test substance. A necropsy was performed on all rabbits. The method of Litchfield and Wilcoxon was used to determine the range-finding acute percutaneous mean lethal dose together with the $LD_{0.01}$ and $LD_{99.99}$ |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ = 3.0 ml/kg<br>(95% confidence limits = 1.96 to 4.57 ml/kg |
| Number of deaths: | 2.0 ml/kg = 0/4<br>4.0 ml/kg = 3/4<br>8.0 ml/kg = 4/4 |
| Remarks: | $LD_{0.01}$ = 0.93 ml/kg<br>$LD_{99.99}$ = 9.50 ml/kg<br>No signs of toxicity were observed in the rabbits during the first six hours following test substance administration. Rabbits in all dose groups showed signs of generalized weakness and lassitude, and did not eat or drink 24 hours post dose. Rabbits in the 4.0 |

and 8.0 ml/kg dose groups that died prior to scheduled sacrifice did so within three to five days post dose. Rabbits in the 2.0 and 4.0 ml/kg dose groups that survived until study termination eventually showed signs of recovery, although all lost considerable weight and hair regrowth was not observed. The skin at the application site of rabbits in all dose groups showed signs of moderate erythema and edema at the time of removal of the plastic sheeting and persisted for several days. There were no significant necropsy findings in any rabbit.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B

Remarks: Reliable without restriction; comparable to guideline study.

**References**

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

**Other**

Last changed: June 13, 2002

Order number for sorting: 104

Remarks:

## 5.4 REPEATED DOSE TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Octadecylamine (CAS RN 124-30-1) |
| Purity: | Commercial grade containing 20% hexadeclamine |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Test type: | Oral |
| GLP: | No |
| Year: | 1957 |
| Species: | Rat |
| Strain: | Sprague Dawley |
| Route of administration: | Oral (feed) |
| Duration of test: | Two years |
| Doses/concentration levels: | 20, 100, 200 and 500 ppm |
| Sex: | Male and female |
| Exposure period: | Two years |
| Frequency of treatment: | *ad libitum* |
| Control group and treatment: | Yes; untreated diet |
| Postexposure observation period: | None |
| Statistical methods: | Not stated |
| Remarks: | Five groups of 24 weanling rats (12 males and 12 females) were fed diets containing the test substance at concentrations of 0, 20, 100, 200 and 500 ppm daily for two years. Diets contained Purina Laboratory Chow supplemented with cod liver oil. The test substance was added to experimental diets as solutions in corn oil. A record was kept of food consumed by each animal. Individual body weights were determined at weekly intervals throughout the study. Complete blood counts, including red cell count, white cell count, hemoglobin concentration and differential white cell count, were carried out at varying intervals throughout the study on rats picked at random from all groups. These tests were conducted after 4, 8, 13, 16, 20, 25, 28, 43, 55, 66, 86 and 96 weeks of feeding. Organs and tissues of 30 rats fed 20, 100, 200 and 500 ppm of the test substance were examined. There were five to seven rats in each group. The organs examined microscopically consisted of the heart, lungs, liver, spleen, pancreas, kidneys, gastrointestinal tract, lymph nodes, brain, pituitary, adrenals and bone marrow. [The publication of this report (Deichmann, W.B., et.al. 1957, Arch. Ind. Health 18:483-487.) indicates that the ovaries and testes were also examined.] |

**Results**

| | |
|---|---|
| NOAEL (NOEL) | NOEL = 500 ppm |
| LOAEL (LOEL) | Not stated |
| Actual dose received: | Not stated |
| Toxic response/effects: | Described below |
| Statistical results: | Described below |
| Remarks: | There were no significant differences between the rats fed the test substance and the controls in either the percentage of deaths or the mean survival time throughout the two years. In both control and treated rats there was a higher than expected rate of mortality due to acute respiratory infections. There was no significant difference between the average diet consumption of the male and female rats fed the test substance and the control rats. There were no treatment-related effects on body weight gains or growth curves in any treatment group when compared to the controls. There was no discernable effect of the test substance on hemoglobin. There was a slight, but significant, decrease in the number of red blood cells in all rats in the treatment and control groups. This change was combined with an upward trend in the total number of white blood cells and total neutrophil counts. These effects probably were a reflection of the prevalence of respiratory disease in the experimental colony. There was no significant pathologic difference in organs examined between the control group and the treatment groups. Lesions encountered in all experimental and the control groups included pyelonephritis, hyaline casts in the renal tubules, occasional renal abscesses, and bronchitis or pneumonia. One rat in the control group showed a mild endocarditis and valvulitis; one rat in the 100 ppm dose group developed a brain abscess, and one rat receiving 500 ppm of the test substance showed histocytic hyperplasia of the mesenteric lymph node. The changes were not considered significant or treatment-related. Results were confirmed with a supplemental study reported in 1962 (article/report no. 66). |

**Conclusions**

| | |
|---|---|
| Remarks: | The test substance produced no toxic effects when fed to rats in the diet up to concentrations of 500 ppm for two years. No significant pathological changes were observed during the microscopic examination of the tissues of these rats. (Author of report) |

Although the study does not meet typical standards (primarily since the high dose group showed no effects) it provides a NOAEL of 50 mg/kg/day for chronic exposure. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2A

Remarks: Reliable with restrictions; acceptable, well-documented study report which meets basic scientific principles.

**References**

Deichmann, W. B. 1957. The Chronic Toxicity of Octadecylamine. Department of Pharmacology, School of Medicine, University of Miami, Coral Gables, FL, USA.

and

Deichmann, W.B., J.L. Radomski, W.E. McDonald, R.L. Kascht and R.L. Erdmann. 1957. The Chronic Toxicity of Octadecylamine. Arch. Ind. Health 18:483-487.

**Other**

Last changed: July 18, 2002

Order number for sorting: 63

Remarks:

## 5.4 REPEATED DOSE TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Octadecylamine (CAS RN 124-30-1) |
| Purity: | Contained 20% hexadeclamine |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not sated |
| Test type: | Oral |
| GLP: | No |
| Year: | 1961 |
| Species: | Rat |
| Strain: | Holzman Sprague Dawley |
| Route of administration: | Oral (feed) |
| Duration of test: | Two years |
| Doses/concentration levels: | 200 and 500 ppm |
| Sex: | Male and female |
| Exposure period: | Two years |
| Frequency of treatment: | *ad libitum* |
| Control group and treatment: | Yes; untreated diet |
| Post exposure observation period: | None |
| Statistical methods: | Not stated |
| Remarks: | This supplemental study was conducted in order to confirm the results of a two-year chronic study conducted in 1957 (article/report no. 63). Groups of 20 weanling rats (10 males and 10 females) were fed diets containing the test substance at concentrations of 0, 200 and 500 ppm daily for two years. Diets contained Purina Laboratory Chow supplemented with dried meat meal and cod liver oil, and corn oil. Test substance was added to experimental diets. A record was kept of food consumed by each animal. Individual body weights were determined at monthly intervals. All surviving animals were sacrificed after two years of treatment and postmortem examinations were performed. Organ weights were determined for the heart, liver, spleen, kidneys and testes. Micropathologic examinations were conducted on tissues of the heart, lungs, liver, spleen, kidneys, stomach, small and large intestine, lymph nodes, and gonads of seven rats from each group. Reproductive organs were examined, meeting the requirements for SIDS/HPV reproductive screening. |

**Results**

| | |
|---|---|
| NOAEL (NOEL) | NOEL = 500 ppm |
| LOAEL (LOEL) | Not stated |
| Actual dose received: | Not determined |
| Toxic response/effects: | Described below |
| Statistical results: | Described below |
| Remarks: | There were no significant differences observed between the rats fed the test substance and the controls in regard to: mean daily food consumption, mean weight gain and mean survival. Pathologic changes were observed to the same extent in both control and experimental rats. They included chronic murine pneumonia with the associated changes in other organs such as an occasional myocarditis, hepatitis, or nephritis; lesions of chronic arteriolar nephrosclerosis with resulting tubular atrophy and fibrosis; and panarteritis of the mesenteric arteries. No lesions were seen, either grossly or microscopically, which could be considered as having been caused by the long-term feeding of the test substance. These results confirmed the conclusions of the previous experiment. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2D |
| Remarks: | Reliable with restrictions; supplemental work done in support of previous study. |

References

W. E. MacDonald, W. B. Deichmann, J. L. Radomski and B. S. Ausin. 1962. The Chronic Toxicity of Octadecylamine in the Rat – A Supplemental Report. Toxicol Appl. Pharmacol. 4:610-612.

**Other**

| | |
|---|---|
| Last changed: | July 18, 2002 |
| Order number for sorting: | 66 |
| Remarks: | |

## 5.4 REPEATED DOSE TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Octadecylamine (CAS RN 124-30-1) |
| Purity: | Commercial grade containing 20% hexadeclamine |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Test type: | Oral |
| GLP: | No |
| Year: | 1957 |
| Species: | Dog |
| Strain: | Mongrel |
| Route of administration: | Oral (capsule) |
| Duration of test: | One year |
| Doses/concentration levels: | 0.6, 3.0 and 15.0 mg/kg/day |
| Sex: | Male and female |
| Exposure period: | One year |
| Frequency of treatment: | Once daily, 5 days/week |
| Control group and treatment: | Yes; does not specify if controls received capsules of corn oil only or if they were untreated. |
| Postexposure observation period: | None |
| Statistical methods: | Not stated |
| Remarks: | Groups of three dogs received the test substance via capsule in corn oil solution at concentrations of 0.6, 3.0 and 15.0 mg/kg once a day, five days per week for one year. The per kilogram dose was adjusted based on the most recent body weight. The sexes were divided as evenly as the odd number of dogs in a group permitted. Dogs were wormed prior to testing and fed once a day during the study. The dogs were fed once per day and dog biscuits were available *ad libitum.* Individual body weights were determined once a month throughout the study. Complete blood counts were taken on all dogs at the start of the experiment and 1, 2, 3, 6, 8, 11 and 12 months thereafter. Organs and tissues from all dogs were examined. The organs examined microscopically consisted of the heart, lungs, liver, spleen, pancreas, kidneys, gastrointestinal tract, pancreas, lymph nodes, brain, pituitary, adrenals, ovary/testis, and bone marrow. Reproductive organs were examined, meeting the requirements for SIDS/HPV reproductive screening. |

**Results**

| | |
|---|---|
| NOAEL (NOEL) | NOEL = 3.0 mg/kg day |
| LOAEL (LOEL) | LOEL = 15.0 mg/kg |
| Actual dose received: | 0.6, 3.0 and 15.0 mg/kg/day |
| Toxic response/effects: | Described below |
| Statistical results: | Described below |
| Remarks: | One dog treated with 15.0 mg/kg of the test substance died after 22 weeks of treatment. During the last three weeks of life, signs of anorexia were observed, and bloody diarrhea during the last three days was observed. The dog did not exhibit a severe loss in weight. It was proposed that the dog was suffering from gastroenteric irritation. All other dogs appeared in good health at the end of the study. The average weight gain of the dogs in the 15 mg/kg dose group was less than the weight gain of the controls and the dogs fed lower levels of the test substance. The average weight gain of the dogs in the 0.6 and 3.0 mg/kg dose groups was essentially the same as that of the control group. No significant hematological effects considered to be treatment-related were observed. Microscopic examination of the organs found no definite lesion of the intestinal tract. However, in two dogs treated with 15.0 mg/kg/day of the test substance, the tips of the villi of the small intestinal mucosa were pale staining. This appeared in the superficial substantia propria. No foam cells or deposits of lipid material were identified although the intestines of these dogs had a different appearance from the intestines of the other dogs. This suggested the possibility of some absorption of a non-staining material into the small intestine mucosa. Also, in both of these dogs, the sinuses of the mesenteric lymph nodes were filled with pale “foamy” histiocytes. There was, however, no granuloma formation, and no necrosis or giant cell reaction occurred. No other changes in other organs considered to be treatment-related were observed. |

**Conclusions**

| | |
|---|---|
| Remarks: | It was concluded that the test substance is likely to be toxic if ingested at 15 mg/kg/day for one year. (Author of report)<br>The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2A |
| Remarks: | Reliable with restrictions; acceptable, well-documented study report which meets basic scientific principles. |

**References**

Deichmann, W. B. 1957. The Chronic Toxicity of Octadecylamine. Department of Pharmacology, School of Medicine, University of Miami, Coral Gables, FL, USA.

**Other**

| | |
|---|---|
| Last changed: | July 18, 2002 |
| Order number for sorting: | 63 |
| Remarks: | |

## 5.4 REPEATED DOSE TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Genamin TA 100 D(CAS RN 61790-33-8; Amines, tallow alkyl) |
| Purity: | >96% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD Guideline 407 "Repeated Dose Oral Toxicity – Rodent: 28-day or 14-day Study" |
| Test type: | Oral |
| GLP: | Yes |
| Year: | 1995 |
| Species: | Rat |
| Strain: | Sprague Dawley |
| Route of administration: | Oral gavage |
| Duration of test: | 28 days |
| Doses/concentration levels: | 0, 12.5, 50 and 150 mg/kg |
| Sex: | Male and female |
| Exposure period: | 28 days |
| Frequency of treatment: | Daily |
| Control group and treatment: | Yes; concurrent vehicle |
| Post exposure observation period: | None |
| Statistical methods: | Bartlett's test, ANOVA, Dunnet's test, Kruskal-Wallis and Mann Whitney's "U" test |
| Remarks: | Five male and five female rats per group were dosed for a period of 28 days to the test substance at concentrations of 0, 12.5, 50 and 150 mg/kg. At the start of dosing, the animals were approximately 7 weeks of age and weighed 214 to 240 g (males) and 157 to 182 g (females). Animals were observed for clinical signs daily and mortality twice daily. Body weights were obtained on Day 0 and weekly thereafter. Food consumption was measured weekly. Ophthalmoscopic examination was performed prior to study start and during week 4. Behavioral effects including, flexion reflex, grasping reflex, righting reflex, placing reactions, equilibrium tests, corneal reflex, pupillary reflex, auditory startle, toe spreading and head shaking, were measured during week 4. Hematology/biochemistry evaluation of the blood (according to OECD 407) was obtained for Day 29. Urinalysis was also evaluated on Day 29 (on Day 28, animals received 10 ml/kg tap water over a 16 hour period as per OECD 407). Organ weights were |

obtained for the following tissues: testes, epididymides, spleen, liver, kidneys, adrenals, heart, thymus, brain and pituitary. Macroscopic evaluation was performed according to OECD 407. The following tissues were examined microscopically from the animal in the control and high dose groups: urinary bladder, prostate, testes, epididymides, uterus, ovaries, spleen, stomach, intestine, lymph nodes (mesenteric and mandibular), liver, kidneys, adrenals, sternum (with bone marrow), heart, thymus, lungs, trachea, thyroids, brain, pituitary, skeletal muscle, sciatic nerve, spinal cord, gross lesions. From the mid and low dose groups the following tissues were examined microscopically: liver, spleen, mesenteric lymph nodes, thymus, lungs, adrenals, duodenum, jejunum and ileum and gross lesions. Dose formulations were analyzed for accuracy of preparation by HPLC/UV in weeks 1 and 3. Twenty-four hour stability analysis was performed on the 1 and 36 mg/ml dose formulations.

**Results**

NOAEL (NOEL) 12.5 mg/kg
LOAEL (LOEL) 50 mg/kg
Actual dose received: Not stated
Toxic response/effects: Described below
Statistical results: Significant decrease of body weights on Days 14 and 28, of body weight gain at 50 and 150 mg/kg. Most effects reported for hematology and clinical chemistry reached the level of significance.
Remarks: Dose concentrations were within 90 to 110% of nominal. Dose preparations were stable of the 24 hour period (>96% of initial concentration).

| Mortality | | |
|---|---|---|
| **Dose group (mg/kg)** | **Male** | **Female** |
| 12.5 | 0/5 | 0/5 |
| 50 | 0/5 | 1/5 (wk 2) |
| 150 | 2/5 (wks 2 and 3) | 3/5 (wks 3 and 4) |

Clinical signs: Salivation was observed in all animals at 50 and 150 mg/kg, and piloerection was observed at 50 mg/kg (females only) and at 150 mg/kg (all animals). Hunched posture, fur loss, soft stool, dyspnea were reported among high dose animals.

Body weight: Decreased in males at 50 mg/kg on Day 28 and in both sexes at 150 mg/kg on Days 14 to 28.
Body weight gain: At 50 mg/kg decreased in males on Days 21-28 and on Days 0-7 in females. At 150 mg/kg, decreased in males Day 7-14 and 21-28 and females Day 0-7.
Food consumption: Decreased at 50 and 150 mg/kg
Ophthalmoscopic examination: no treatment related effects.
Hematology: At 150 mg/kg, RBC increased in both sexes; white blood cells increased in males (more neutrophils and less lymphocytes compared to control values); MCV decreased in both sexes; platelets increased in both sexes; and prothrombine time increased in males. At 50 mg/kg, white blood cells increased in males (more neutrophils and less lymphocytes compared to control values); MCV decreased in both sexes; platelets increased in females; and prothrombine time increased in males. At 12.5 mg/kg, MCV decreased in females.
Clinical chemistry: At 150 mg/kg bw, ASAT and ALAT increased in both sexes and gamma glutamyl transpeptidase increased in females; ratio albumin/globulin decreased in both sexes; creatinine, total protein and cholesterol decreased in females; glucose and bilirubin decreased in males; and blood urea nitrogen increased in males. At 50 mg/kg, ALAT increased in both sexes; total protein and ratio albumin/globulin decreased in females; and potassium and bilirubin decreased in males. At 12.5 mg/kg, ALAT increased in males; and potassium and bilirubin decreased in males. Effects on ALAT, total protein and albumin/globulin ratio showed a relationship with dose.
Urinalysis: No treatment related effects.
Organ weights: At 150 mg/kg, absolute liver, kidney, heart and thymus weight were decreased in males and females (heart and thymus only); relative weight of brain and adrenals was increased in both sexes; testes and epididymides weight (rel.) was increased; rel. liver weight was increased in both sexes and relative kidney weight was increased in females only. At 50 mg/kg, absolute liver and kidney weight was decreased in males; and relative kidney weight was increased in females. The decrease in liver, kidney and heart weight was related to dose. The relative increase of brain weight was related to dose.

Gross pathology: At 150 mg/kg, dilation of the intestine and the stomach; congestion of the lungs; emaciation and increased size of lymph nodes noted in both sexes. At 50 mg/kg, dilation of the intestine in both sexes; congestion of the lungs and increased size of lymph nodes in females. Incidental in the highest dose levels; fur loss, dark areas on the lungs, increased size of the adrenals, and/or decreased size of the thymus.
Histopathology: At 150 mg/kg, histiocytosis (with vacuolization of histiocytes) of the lamina propria of the small intestine and mucosal hyperplasia in both sexes; decreased vacuolization of liver cells; necrosis with lymphocyte infiltration in the liver of both sexes; inflammation of the lungs (increased number of leukocytes) in females; histiocytosis (with vacuolization of histiocytes) of the lymph nodes in both sexes; depletion of lymphocytes in the thymus in both sexes; and spleen atrophy with leukocyte infiltration in both sexes. At 50 mg/kg, histiocytosis (with vacuolization of histiocytes) and mucosal hyperplasia in the small intestine in both sexes; liver necrosis in females; bronchial histiocytosis, fibrosis and inflammation in females; histiocytosis (with vacuolization of histiocytes) of the lymph nodes in both sexes; and depletion of lymphocytes in the thymus in both sexes. At 12.5 mg/kg, histiocytosis (with vacuolization of histiocytes) of the intestines in both sexes; and histiocytosis (with vacuolization of hystocytes) of the lymph nodes in both sexes. A relationship with dose was established for the effects on lymph nodes and thymus.
The NOEL of 12.5 mg/kg was based on the local effects on gastro-intestinal tract and lungs (related to the irritating properties of the test substance), body weight loss and the presence of liver effects (both histopathological and biochemical) at the two highest dose levels. Other effects seen were related to the poor condition of the animals.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1 |
| Remarks: | Reliable without restriction |

**References**

Oberto, G. 2000. Genamin TA100 "4-Week Toxicity Study in Rats by Oral Route". APAG, Instituto di Ricerche Biomediche "Antoine Marxer" RBM S.p.A.

**Other**

| | |
|---|---|
| Last changed: | August 8, 2002 |
| Order number for sorting: | 221a |
| Remarks: | |

## 5.4 REPEATED DOSE TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Oleylamine (9-octadecenylamine, (Z)-; (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | 89.11% and 90.4% (two samples received) |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | EPA TSCA, Health Effects Test Guideline and Pesticide Assessment Guidelines – Subdivision F – Hazard Evaluation |
| Test type: | Dermal |
| GLP: | Yes |
| Year: | 1985 |
| Species: | Rat |
| Strain: | Sprague Dawley |
| Route of administration: | Dermal |
| Duration of test: | 14 days |
| Doses/concentration levels: | 0.5, 1.5 and 3.0% v/v |
| Sex: | Male and female |
| Exposure period: | 10 days |
| Frequency of treatment: | Two 5-day dosing periods with intermediate 2-day non-dosing period |
| Control group and treatment: | Yes; mineral oil |
| Post exposure observation period: | None |
| Statistical methods: | Non-parametric analysis of variance; post hoc Wilcoxon's 2-sample test |
| Remarks: | Based on the results of a pilot study, groups of young adult rats (4 males and 4 females) were treated dermally with the test substance at concentrations of 0, 0.5, 1.5 and 3.0%. Rats were treated for two five-day dosing periods with an intermediate two-day non-dosing period in order to more closely reproduce conditions of human exposure to the test substance. The first day of dosing was designated as Day 1. Due to excessive tissue destruction indicated by sloughing, scores of moderate to severe erythema, scabbing, hardening of the skin, and sensitivity to touch, the dosing at the intermediate and high dose levels (1.5 and 3.0%) was discontinued on Day 9. These animals were subsequently sacrificed on Day 10.<br>At initiation of dosing the rats' body weights ranged from 205.7 to 321.3 g. Rats were acclimated to the laboratory for seven days prior to test substance application. Water and food were provided *ad libitum*. |

Approximately 24 hours prior to test substance application, the fur was clipped from the dorsal area of each animal. Shaving was repeated one week later. The test substance was applied at a volume dosage of 5 ml/kg. The application site was covered by a porous gauze dressing that was held in place with tape, and covered with a taped elastic bandage. Each day, wrappings were removed approximately six hours after test substance application and the test sites were washed with warm water to remove excess test substance. Observations of signs of toxicity were made once each day. Body weights were recorded during acclimation, weekly during the study and at sacrifice. Food consumption was recorded weekly during the study. Morbidity/mortality checks were made twice each day. The skin of each rat was examined prior to test substance administration on days 2, 4, 6, 8, 10, 12 and 14 for signs of erythema and edema. No animals died on study therefore, no necropsies were performed. Animals were killed and discarded three days following the completion of dosing.

**Results**

| | |
|---|---|
| NOAEL (NOEL) | Not defined |
| LOAEL (LOEL) | Not defined |
| Actual dose received: | Not stated |
| Toxic response/effects: | Described below |
| Statistical results: | Described below |
| Remarks: | All rats survived until scheduled sacrifice. Concentrations of 1.5 and 3.0% produced moderate to severe irritation (erythema scores 2-4), which in some instances progressed to hardening and sloughing of the skin. A number of rats were sensitive to touch. In the 0.5% group, erythema scores of 1 to 2 were observed, indicating mild to moderate irritation, and flaking of the outer layers of the epidermis was observed. An increased sensitivity in females to the irritant effects of the test substance as compared to males was observed. In the control group, one male showed an erythema score of 1 at one observation. All rats in the 1.5 and 3.0% v/v groups were sacrificed on day 9 of the study due to the irritant/corrosive effects of the test substance. No other treatment-related irritant effects or clinical signs were observed. A significant treatment-related effect on body weight was observed for males at day 7. Individual group comparisons |

revealed that body weights in both the 1.5 and 3.0% groups were significantly lower than controls. Females in the 3.0% group showed a mean weight loss during the first week of the study, although this finding was not significant. Food consumption during the first week of study was reduced significantly in the 1.5% group males when expressed as total food consumed. No significant difference was noted when expressed on a per weight basis.

**Conclusions**

Remarks: This endpoint has not been adequately characterized; however, the study provides additional data on the toxicity of repeated dermal dosing, including severe irritation, of this test substance at concentrations of 0.5, 1.5 and 3.0%. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2C

Remarks: Reliable with restrictions; comparable to guideline study with acceptable restrictions.

**References**

Chem MFGS Assn. 1985. 14-Day Dermal Toxicity Range-Finding Study of Oleylamine in Rats (Final Report) with cover letter dated 041185. EPA Doc. No. 40-8584196, Microfiche No. OTS0525400.

**Other**

Last changed: July 17, 2002

Order number for sorting: 18

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

| | |
|---|---|
| Identity: | Amine fluorides 335/242 [Hetaflur; CAS RN 3151-59-5; and 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6] |
| Purity: | Not stated |
| Remarks: | Description is a brown premix, containing approximately 5% compound (amine fluorides 335/242) |

### Method

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| Test type: | Oral |
| GLP: | No |
| Year: | 1973-1975 |
| Species: | Rat |
| Strain: | Long-Evans |
| Route of administration: | Oral feed |
| Duration of test: | 24 months |
| Doses/concentration levels: | 1.2, 6.0 and 30.0 mg/kg/day |
| Sex: | Male and female |
| Exposure period: | 24 months |
| Frequency of treatment: | Continuous |
| Control group and treatment: | Yes, laboratory diet alone |
| Postexposure observation period: | None |
| Statistical methods: | Yes |
| Remarks: | Seventy rats/sex/group were administered the test substance prepared in laboratory diet at doses of 1.2, 6.0 and 30.0 mg/kg/day for 24 months. Males (104 – 159 g) and females (98 – 148 g) of weanling age when received were used on study. The diet without test substance was administered to two control groups (70 rats/sex/group). Diets were prepared weekly and adjusted to the most recent body weight and food consumption data. Animals were observed daily for physical appearance, signs of local or systemic toxicity, pharmacologic effects or mortality. Observations for tissue masses were performed weekly. Eye examinations were performed pretest, and at months 3, 6, 12, 18 and 24. Body weights were measured once during pretest, weekly during treatment and at study termination, after fasting. Food consumption was recorded once during pretest and weekly during treatment. Compound consumption was calculated from food consumption data. Hematology (at 3, 6, 12, 18, 19 and 24 months), clinical chemistry |

(at 6, 12 and 24 months) and urinalysis (at 6, 12 and 24 months) were evaluated from 10 control animals/sex (5 from each control group) and from 10 treated animals/sex/group. A gross necropsy was performed on all animals. From those animals that died prior to study termination, any tissue masses present or organs abnormal in size were weighed. Adrenals, kidneys and liver were weighed. From 5 control animals/sex/group and 10 animals/sex in the 30 mg/kg treatment group, the following tissues were fixed and examined histopathologically at 6 and 24 months: adrenals, bone, bone marrow, brain, eye, heart, intestine, kidneys, liver, lung, lymph node, mammary gland, ovaries, pancreas, pituitary, prostate, skeletal muscle, stomach, testes, thyroid, tongue, urinary bladder, uterus and gross lesions. For 10 animals/sex in the 1.2 and 6.0 mg/kg treatment groups, the liver, kidney and/or mesenteric lymph nodes were fixed and examined histopathologically at 6 and 24 months.

**Results**

| | |
|---|---|
| NOAEL (NOEL): | NOEL = 6.0 mg/kg |
| LOAEL (LOEL): | Not stated |
| Actual dose received: | Males: 0.98 to 1.36, 5.6 to 8.49 and 25.28 to 33.99 mg/kg/day<br>Females: 0.75 to 1.38, 3.72 to 6.90 and 17.46 to 37.14 mg/kg/day |
| Toxic response/effects: | Described below |
| Statistical results: | 30 mg/kg group compared to controls: Significantly lower body weights for males and females throughout treatment except for 1 or 2 weeks. Significant reductions in food consumption periodically throughout the treatment period for both males and females. Decreased clinical chemistry values: serum glutamic pyruvic transaminase (female 12 mo.), alkaline phosphatase (female 24 mo., also in 6.0 mg/kg group), total protein (female 24 mo.), calcium (male 6 mo., female 12 mo.), cholesterol (male 12 mo.), triglycerides (male 12 mo., female 24 mo.). Absolute liver and kidney weights significantly reduced, and adrenal weights relative to body weight significantly increased in males at 6 months. Absolute liver weight significantly reduced and relative kidney weight significantly increased in females at 6 months. Relative liver weight in males at 24 months significantly increased.<br>No treatment-related significant differences from |

control group were noted in the 6.0 and 1.2 mg/kg groups.

Remarks: Compound intake was generally within 15% of the desired dose level throughout the study. Mortality rates were comparable among all treated and control groups. Effects noted in the 30 mg/kg group, when compared to controls, included consistently lower body weights and lower cholesterol and triglyceride levels in the males at 12 months and lower triglyceride levels in the females at 24 months. The nature of histologic changes observed in the intestinal mucosa suggest a possible malabsorption of lipids, which may have been responsible for the reduction in serum triglyceride levels. Ankylosis was observed in a few animals in all compound-treated groups. Evaluations of mortality, tissue masses, ocular changes, food and compound consumption, hematology, urine and organ/body weight ratios revealed no effects at any dose level considered to be of toxicologic significance. Histopathological examination revealed enlarged mesenteric lymph nodes and yellow discoloration of the small intestine. The incidence appeared to be dependent on dose level of the test substance. Histologically, the gross manifestations in these two organs were adjudged to be the result of reticuloendothelial (RE) cell hypertrophy and/or hyperplasia. Although foreign material was not detected in the RE cells, these gross and microscopic changes were considered to represent a phagocytic response to the compound at a site of absorption as well as by the lymphatic system related to this site. Many of the lymph nodes examined histologically also had sinusoidal dilation with congestion and fibroplasia. These latter changes were considered indicative of a chronic lymphadenopathy and representative of an exacerbation of the lymph node response to the compound after 2 years of continued administration. RE cell changes of the mesenteric lymph nodes were observed after 6 months of test substance administration, but there was no evidence of chronic, irreversible change at that time. Reproductive organs were examined, meeting the requirements for SIDS/HPV reproductive screening.

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2A |
| Remarks: | Reliable with restrictions; acceptable, well-documented study report which meets basic scientific principles. |

**References**

Killeen, J.C. and W.R. Rapp. 1975. A Two Year Oral Toxicity Study of Amine Fluorides 335/242 in Rats. Project No. 72R-816. Bio/dynamics Inc.

**Other**

| | |
|---|---|
| Last changed: | November 19, 2002 |
| Order number for sorting: | 74 |
| Remarks: | |

## 5.4 REPEATED DOSE TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Amine fluorides 335/242<br>[Hetaflur; CAS RN 3151-59-5; and 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6] |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Not stated |
| Test type: | Oral |
| GLP: | No |
| Year: | 1975 |
| Species: | Dog |
| Strain: | |
| Route of administration: | Oral gavage |
| Duration of test: | 2 years |
| Doses/concentration levels: | 1.2, 6.0 and 12.0 mg/kg/day |
| Sex: | Male and female |
| Exposure period: | 2 years |
| Frequency of treatment: | Once daily |
| Control group and treatment: | Yes, not stated |
| Postexposure observation period: | None |
| Statistical methods: | Body weights, hematology and clinical chemistry parameters were analyzed using F-test and Student's t-test.<br>Organ weights and organ to body weight ratios were analyzed using Dunnett's test. |
| Remarks: | Six Beagle dogs/sex/group were administered the test substance orally at doses of 1.2, 6.0 and 12.0 mg/kg/day for 2 years. The highest dose initially was 30.0 mg/kg (for the first five weeks of the study). Dosing at 12.0 mg/kg was initiated at the eighth week, following one week of nondosing and one week of dosing with a placebo (vehicle) in an attempt to decondition dogs from salivating in anticipation of dosing. Males (8.7 – 11.8 kg) and females (7.2 – 12.2 kg) 5 to 6 months old when received were used on study. The test substance was suspended in 0.25% Methocel 90® HG Premium 15000 CPS and these suspensions were prepared weekly. A group of 6 dogs/sex also was used as a control. Animals were acclimated to the testing facility for approximately seven weeks prior to test substance administration. Animals were observed daily for physical appearance, signs of local or systemic toxicity, pharmacologic |

effects or mortality. Eye examinations were performed pretest, and at months 6, 12 and 24. Body weights were measured pretest, weekly during treatment and at study termination, after fasting. Food consumption was estimated visually at pretest and 4 times weekly thereafter. Hematology, clinical chemistry and urinalysis were evaluated twice pretest, and at months 1, 3, 6, 9, 12, 20 and/or 24 for all animals. A necropsy was performed on all animals. An interim necropsy was performed at 6 months on 16 animals (2/sex/group). From all animals, adrenals, kidneys, thyroid and liver were weighed. Also, the following tissues were fixed and examined histopathologically: adrenals, bone, bone marrow, brain, eye, gall bladder, heart, intestine, kidneys, liver, lungs, lymph nodes, mammary gland, peripheral nerve, ovaries, pancreas, parathyroid, pituitary, prostate, salivary, gland, skeletal muscle, spleen, stomach, testes, thyroid, urinary bladder, uterus, gross lesions and tissue masses.

**Results**

| | |
|---|---|
| NOAEL (NOEL): | NOEL = 6.0 mg/kg/day |
| LOAEL (LOEL): | LOEL = 12.0 mg/kg/day |
| Actual dose received: | 1.2, 6.0 and 12.0 mg/kg/day |
| Toxic response/effects: | Described below |
| Statistical results: | Statistically significant differences were noted in some of the hematology and clinical chemistry parameters. However, they were transient and/or did not occur in a dose-related pattern. |
| Remarks: | Two accidental deaths occurred during the study; one mid-dose male and one high-dose male. The death of the mid-dose male resulted from complications arising from the accidental fracture of the os penis and the death of the high-dose male was attributed to an intratracheal dosing accident. There were no effects of the test substance evident at dose levels of 1.2, 6.0 and 12.0 mg/kg/day. At the original high-dose level of 30.0 mg/kg/day (administered for the first 5 weeks of the test), a decrease in body weight and food consumption was evident with slight decreases in the mean serum total protein and glucose values recorded at one month in the males. This dose level also resulted in excessive salivation before and after dosing, and increased incidences of diarrhea and emesis in both sexes. These effects disappeared after the high-dose was reduced from 30.0 to 12.0 mg/kg/day. No differences from the control group in mortality, |

ophthalmology, hematology, urinalysis, absolute or relative (to body weight) organ weight or pathology data were considered related to administration of the test substance. Total protein levels were consistently lower than controls in the high-dose females throughout the two years of the test. Reproductive organs were examined, meeting the requirements for SIDS/HPV reproductive screening.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2A

Remarks: Reliable with restrictions; acceptable, well-documented study report which meets basic scientific principles.

**References**

Killeen, J.C. and W.R. Rapp. 1975. A Chronic Oral Toxicity Study of Amine Fluorides 335/242 in Dogs. Project No. 72R-815. Bio/dynamics Inc.

**Other**

Last changed: November 19, 2002

Order number for sorting: 75

Remarks:

## 5.4 REPEATED DOSE TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | N-methyl-N-octadecyl-1-octadecanamine (CAS RN 4088-22-6; 1-Octadecanamine, N-methyl-N-octadecyl) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Test type: | Oral |
| GLP: | No |
| Year: | 1981 |
| Species: | Rat |
| Strain: | CD Sprague Dawley |
| Route of administration: | Oral (feed) |
| Duration of test: | 13 weeks |
| Doses/concentration levels: | 0, 0.15, 0.5 and 1.5% w/w (through week 4); 0, 0.15, 0.4 and 1.0% w/w (through week 13) |
| Sex: | Male and female |
| Exposure period: | 13 weeks |
| Frequency of treatment: | *ad libitum* |
| Control group and treatment: | Yes; untreated diet |
| Post exposure observation period: | None |
| Statistical methods: | Group mean values and standard deviations, where appropriate; analysis of variance, Student's t-test; and $\log_{10}$ transformed data |
| Remarks: | Groups of 40 rats (20 male and 20 female) were fed diets containing the test substance at concentrations of 0.15, 0.5 and 1.5% w/w daily. Due to marked depression of body weight gain at the highest concentration, from week 5 until termination (week 13) the dietary concentrations were changed to 0.15, 0.4 and 1.0% w/w daily (approximately 130, 375 and 1000 mg/kg/day). Diets were prepared at the laboratory and contained basic rat diet and corn oil or corn oil/test substance mixtures. Stability of the test substance in the diet was not performed. Water was available *ad libitum*. Rats were acclimated to the laboratory for 21 days prior to test substance administration. All rats were examined once daily for signs of ill-health, overt toxicity or behavioral changes. Individual body weights were recorded prior to treatment on the first day of the study, at weekly intervals throughout the study and at necropsy. Food consumption was measured weekly |

throughout the study. The blood samples obtained from all rats during week 12 were evaluated for the following: hemoglobin concentration, mean cell volume, red blood cell count and derived indices (packed cell volume, mean cell hemoglobin and mean cell hemoglobin concentration), and total and differential white blood cell count. A necropsy was conducted on all rats. The following organs were weighed: adrenals, heart, kidneys, liver, lung, and ovaries/testes. Samples of the following tissues and organs were fixed: adrenals, aorta, bone marrow smear, bladder, brain, cecum, colon, duodenum, epididymides, gross lesions, heart, ileum, jejunum, kidneys, liver, lungs, mandibular salivary gland and lymph node, esophagus, ovary/testis, pancreas, pituitary, psoas muscle, sciatic nerve, seminal vesicle, skin, spleen, stomach, thymus, tongue, trachea and uterus/prostrate. All tissues from the 0 and 1.5 (1.0)% dose groups were stained and examined microscopically. Subsequently sections of jejunum, mesenteric lymph nodes and ovaries from rats in the remaining two groups were prepared and examined.

**Results**

NOAEL (NOEL) None determined due to foamy macrophage accumulation in multiple organs and enlarged lymph nodes found in the 0.15 % group.

LOAEL (LOEL) 0.15%

Actual dose received:

| ***Mean Test Substance Intake (mg/kg/day) for Weeks 1-13*** | | | |
|---|---|---|---|
| **Dose group:** | **0.15%** | **0.5 (0.4)%** | **1.0 (1.5)%** |
| Males | 117 | 343 | 936 |
| Females | 139 | 406 | 1076 |

Toxic response/effects: Described below

Statistical results: Described below

Remarks: All rats survived the treatment period. Alopecia was observed in 12 male and 13 female rats in the high dose group. The overall body weight gains for rats in the mid and high dose groups were significantly lower than the controls ($p \leq 0.01$). There also was a significant decrease in overall body weight gain in females in the low dose group. Food consumption in the high dose group was moderately lower (20 to 25%) than the controls and there were slight reductions

(approximately 10%) in the mid dose group. Food conversion efficiencies of the high dose group were markedly lower than the controls throughout the study. Significant increases in total leukocyte count in all treated groups was observed when compared to the controls. Also, there were significant reductions in hemoglobin concentration in all treated groups and significant reductions in packed cell volume in the medium and high dose groups. The absolute weights of most weighed organs were lower in the high dose group male and female rats and in the mid dose group males than in the controls. Relative weights of the liver, testes, kidneys and lungs were higher in treated rats than the controls. Accumulation of histiocytes with foamy cytoplasm were found in the lamina propria of the jejunum, in the mesenteric lymph nodes, and to a lesser extent in other tissues. Focal degenerative changes were found in some of the histiocyte aggregates in the mesenteric lymph node of high dose rats, and a few animals had peritonitis. This histiocytosis was present in all treated groups and was sufficiently marked even in the low dose group rats to cause a visible enlargement of the mesenteric node at necropsy, thereby precluding this as the "no-effect" level. Effects in organs remote from the gastrointestinal tract and associated tissues were foamy interstitial cells (undetermined origin) in the ovary and alopecia in the skin. The ovarian changes were detected in all treated groups, but alopecia was restricted largely to rats in the high dose group. The histiocytosis in the jejunum and mesenteric lymph nodes indicated uptake of dietary lipid material by the local reticuloendothelial system, and the changes in the ovary and skin suggested possible systemic disturbances in lipid metabolism. Reproductive organs were examined, meeting the requirements of SIDS/HPV reproductive screening.

**Conclusions**

Remarks: The study fulfills the requirement of the HPV screening program although a NOAEL was not determined. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1B |
| Remarks: | Reliable without restriction; Comparable to guideline study. |

**References**

Procter & Gamble Co. 1981. Initial Submission: 13 Week Oral (Dietary Administration) Toxicity Study of N-methyl-n-octadecyl-1-octadecanamine in Rats with cover letter dated 081292. EPA Doc. No. 88-9200007039, Microfiche No. OTS0537649.

**Other**

| | |
|---|---|
| Last changed: | June 14, 2002 |
| Order number for sorting: | 76 |
| Remarks: | |

## 5.4 REPEATED DOSE TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Ethomeen T/12 (CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Test type: | Oral |
| GLP: | No |
| Year: | 1965 |
| Species: | Rat |
| Strain: | SPF Wistar |
| Route of administration: | Oral (feed) |
| Duration of test: | 90 days |
| Doses/concentration levels: | 0, 170, 500, 1500 and 4500 ppm |
| Sex: | Male and female |
| Exposure period: | 90 days |
| Frequency of treatment: | *ad libitum* |
| Control group and treatment: | Yes; concurrent, untreated diet |
| Post exposure observation period: | None |
| Statistical methods: | None |
| Remarks: | Groups of 25 young adult male and female rats were fed diets containing the test substance at concentrations of 0, 170, 500 and 1500 ppm (approximately 15, 50 and 150 mg/kg/day). A group of ten male and ten female rats were fed a diet containing test substance at a concentration of 4500 ppm. In addition, a further group of seven male and seven female rats were fed a diet containing 4500 ppm of the test substance and killed at intervals up to six weeks from the beginning of the experiment. Tissues from these animals were examined for sudanophilic material. Diets were prepared at the laboratory and contained powdered stock diet, malt extract and corn. Test substance was added to experimental diets via corn oil, in which it was dissolved by gentle heating at 40°C. The ingredients were mixed mechanically and water added to produce a dough, which was then formed into pellets and dried at a temperature of not more than 40°C. Food and water were available *ad libitum*. Body weights were recorded at study initiation and weekly during the treatment period. Hemoglobin concentrations, packed-cell volumes, white-cell counts |

and differential white-cell counts were measured prior to treatment and immediately prior to sacrifice at the end of the 90-day test period. These hematologic parameters were evaluated on individual samples from five male and five female rats from each group except that blood was examined from all animals fed diet containing 4500 ppm of the test substance. At the time of sacrifice, the liver, heart, lung, adrenals, kidneys and spleen were weighed and organ/body weight ratios calculated from random selection of animals in each group. Tissues and organs from the remaining animals were fixed and examined microscopically. The following tissues and organs were examined: liver, kidney, spleen, heart, lung, adrenals, gonads, thymus, thyroid, pancreas, stomach, duodenum, jejunum, ileum, caecum, colon, salivary gland, mesenteric lymph nodes, spinal cord and brain (cerebrum, cerebellum and medulla).

**Results**

| | |
|---|---|
| NOAEL (NOEL) | NOEL = 500 ppm (approximately 50 mg/kg/day) |
| LOAEL (LOEL) | LOEL = 1500 ppm |
| Actual dose received: | Not determined |
| Toxic response/effects: | Described below |
| Statistical results: | None |
| Remarks: | No unscheduled deaths occurred and males and females responded similarly. Rats fed diet containing 4500 ppm of the test substance lost hair and generally were lethargic throughout the study. No clinical observations were noted in rats at any other dietary level. Body weight gain was inhibited at the 4500 ppm dietary level and partly inhibited in the 1500 ppm dietary level. There was no apparent affect on body weight for rats in the 1500 ppm or 700 ppm groups. The palatability of the diet was decreased by the addition of 4500 and 1500 ppm of the test substance. No definite hematological abnormality was detected at any dose level of the test substance. No significant differences were seen between test and control group organ weights. Gross macroscopic observations at necropsy were seen only in the 4500 ppm group and comprised of yellow coloration of the stomach and bowel contents, and thickening and yellow coloration of the mucosa of the small intestine and the regional mesenteric nodes. Microscopic findings, which were documented in rats treated at dietary levels of 1500 and 4500 ppm, were confined to the small intestine and |

regional mesenteric nodes. All rats in the 4500 ppm group showed engorgement of the villi and lamina propria of the small intestine with swollen foamy macrophages. Similar macrophages occasionally were seen to a lesser degree in Peyer's patches and in the regional lymph nodes. Changes were most pronounced in the jejunum and upper ileum but were detected throughout the small intestine. The macrophages were sudanophilic and were presumed to contain deposits of the test substance. Similar findings were present to a lesser degree in 31 of the 40 rats fed 1500 ppm of the test substance. No findings were noted at any other dietary level. Reproductive organs were examined, meeting the requirements of SIDS/HPV reproductive screening.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B

Remarks: Reliable without restriction; comparable to guideline study.

**References**

Goater, T. O., D. Griffiths and T. F. McElligott. 1965. Ninety-Day Oral Toxicity of Ethomeen T/12 - Albino Rats. Report No. IHR/173. Industrial Hygiene Research Laboratories, Macclesfield, Cheshire.

**Other available reports**

Goater, T.O., D. Griffiths, T.F. McElligott and A.A.B. Swan. 1970. Summary of Toxicology Data - Acute Oral Toxicity and Short-Term Feeding Studies on Polyoxyethylene Tallow Amine in Rats and Dogs. Food & Cosmetics Toxicol. 8:249-252.

**Other**

Last changed: June 7, 2002

Order number for sorting: 115 and 134d

Remarks:

## 5.4 REPEATED DOSE TOXICITY

**Test Substance**

| | |
|---|---|
| Identity: | Ethomeen T/12 (Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.; CAS RN 61791-44-4) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Test type: | Oral |
| GLP: | No |
| Year: | 1965 |
| Species: | Dog |
| Strain: | Beagle |
| Route of administration: | Oral (feed) |
| Duration of test: | 90 days |
| Doses/concentration levels: | 0, 13, 40 and 120 mg/kg |
| Sex: | Male and female |
| Exposure period: | 90 days |
| Frequency of treatment: | *ad libitum* |
| Control group and treatment: | Yes; concurrent, untreated diet |
| Post exposure observation period: | None |
| Statistical methods: | None |
| Remarks: | Groups of four male and female dogs were fed diets containing the test substance at concentrations to yield doses of 0, 13, 40 and 120 mg/kg. Diets were prepared at the laboratory and contained a meat preparation, dry pelleted diet and corn oil. Test substance was added to experimental diets. The main meal was offered to each dog daily at noon and a dog biscuit was offered late each afternoon. Water was available *ad libitum*. Body weights were recorded at study initiation and weekly during the treatment period. Hemoglobin concentrations, packed-cell volumes, white-cell counts and differential white-cell counts were measured in all animals prior to treatment and immediately prior to sacrifice. Blood urea, serum alkaline phosphatate, liver function and urine analysis also were tested. At the end of the test period, dogs were sacrificed, and the following organ weights were recorded: heart, liver, kidneys, adrenals, spleen, thyroid, testes, epididymes, brain and pituitary. For microscopic examination, representative sections were taken from the following organs: brain (cerebrum, cerebellum and medulla), spinal cord, pituitary, submaxillary gland, thyroid, |

thymus, heart, lung, aorta, stomach, duodenum, jejunum, ileum, colon, liver, spleen, kidney, bladder, adrenal, ovary and uterus or testes and epididymis, and sciatic nerve.

**Results**

| | |
|---|---|
| NOAEL (NOEL) | NOEL = 13 mg/kg/day |
| LOAEL (LOEL) | LOEL = 50 mg/kg/day |
| Actual dose received: | Not determined |
| Toxic response/effects: | Described below |
| Statistical results: | None |
| Remarks: | No deaths occurred in any group. Dogs given the dietary concentration of 120 mg/kg/day frequently vomited the meal, despite attempts to condition the dogs to the meal either by gradual dose increment or by offering the food in small quantities throughout the day. Treatment in this group was terminated after five to six weeks due to the general poor health of these dogs and the loss of approximately 20% of their initial body weight. Dogs in the 40 mg/kg dose group vomited sporadically and showed signs of anorexia daily. On occasion dogs refused part of the meal when offered. However, no specific signs were observed other than subdued physical activity with the occasional vomiting. A decrease in body weight was observed in male dogs in this dose group at study termination. Vomiting did not occur in dogs given 13 mg/kg of the test substance or in the control group, and no clinical signs were observed in the dogs in either group. Dogs in both of these groups showed increases in body weight at study termination. At week 5, hematology results revealed a degree of simple hypochromic anemia in females in the 120 mg/kg dose group. Clinical blood chemistry showed a slight elevation in the blood urea and serum alkaline phosphate levels at week 6 in male dogs treated with 120 mg/kg of the test substance. In addition, the liver function test showed some retention of bromsulphalein in male dogs fed 120 mg/kg of the test substance. There were no urine analysis findings. No gross pathological variations or gross lesions were observed in the any dogs that were considered to be treatment-related. Histologic evaluations revealed an increase in the incidence of foamy macrophages in the small intestine and regional lymph nodes of dogs in the 40 and 120 mg/kg/day groups. The incidence of these foamy macrophages in the 13-mg/kg/day group was |

comparable with the control group suggesting that the increased incidence at higher dose levels was an accentuation of a normal response. Reproductive organs were examined, meeting the requirements for SIDS/HPV reproductive screening.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B

Remarks: Reliable without restriction; comparable to guideline study.

**References**

Goater, T. O., D. Griffiths and T. F. McElligott. 1965. Ninety-Day Oral Toxicity of Ethomeen T/12 – Beagle Dogs. Report No. IHR/175. Industrial Hygiene Research Laboratories, Macclesfield, Cheshire.

**Other available reports**

Goater, T.O., D. Griffiths, T.F. McElliogott and A.A.B. Swan. 1970. Summary of Toxicology Data - Acute Oral Toxicity and Short-Term Feeding Studies on Polyoxyethylene Tallow Amine in Rats and Dogs. Food & Cosmetics Toxicol. 8:249-252.

**Other**

Last changed: June 10, 2002

Order number for sorting: 116 and 134d

Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | PA-17 (CAS RN 68511-40-0; 1-Propanamine, 3-(tridecyloxy)-, branched) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Plate incorporation method described by: Ames, B. N., J. McCann and E. Yamasaki. 1975. Methods for detecting carcinogens and mutagens with the *Salmonella*/mammalian microsome mutagenicity test. *Mutation Res*. **31**:347-364; and updated by Maron, D. M. and Ames, B. N. 1983. Revised methods for the *Salmonella* mutagenicity test. *Mutation Res*. **113**:173-215. |
| Type: | Reverse mutation assay |
| System of testing: | Bacterial |
| GLP: | Yes |
| Year: | 1994 |
| Species/Strain: | *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538. |
| Metabolic activation: | With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from Sprague-Dawley rats |
| Concentrations tested: | 0.33, 1.0, 3.3, 10, 33 and 100 µg per plate. |
| Statistical methods: | Not stated |
| Remarks: | A dose-range finding study indicated that a maximum of 100 µg per plate be used for the mutagenicity assay, the maximum dose tested was 5000 µg per plate and results indicated no precipitate but toxicity was observed. The test substance was diluted in 100% ethanol, which was also used as the vehicle control. 2-Aminoanthracene (1.0 µg/plate) was the positive control for all tester strains with S-9 activation. The positive controls utilized without S-9 activation were as follows: 2-nitrofluorene (1.0 µg/plate, TA98 and TA 1538); sodium azide (1.0 µg/plate, TA 100 and TA 1535); and 9-aminoacridine (75 µg/plate, TA 1537). The positive control, vehicle control and all test substance doses were plated in triplicate. The S-9 homogenate and mix was prepared at the testing facility. The S-9 mix was prepared immediately before use. The S-9 mix, tester strain and vehicle, test article, or positive control were added to molten selective top agar. After vortexing, the mixture was overlaid onto the surface of 25 ml of minimal bottom agar. After |

solidification, the plates were inverted and incubated for 48-72 hours at 37±2°C.

**Results**

| | |
|---|---|
| Result: | The test substance showed no evidence of mutagenic activity when tested in this bacterial system with and without activation. |
| Cytotoxic concentration: | ≥ 100 µg per plate with S-9 activation<br>≥ 33 µg per plate without S-9 activation |
| Genotoxic effects: | Negative with and without S-9 activation |
| Statistical results: | Not stated |
| Remarks: | None |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1B |
| Remarks: | Reliable without restrictions; comparable to guideline study. |

**References**

San, R. H. C. and M. L. Klug. 1994. *Salmonella* Plate Incorporation Mutagenicity Assay (Ames Test). Report No. G94AV84.501. Microbiological Associates, Inc., USA.

**Other available reports**

**Other**

| | |
|---|---|
| Last changed: | July 15, 2002 |
| Order number for sorting: | 140 |
| Remarks: | |

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | Hexadecylamine (CAS RN 143-27-1) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Reverse mutation assay |
| System of testing: | Bacterial |
| GLP: | Not stated |
| Year: | 1983 |
| Species/Strain: | *Salmonella typhimurium* strains TA 97, TA 98, TA 100 and TA 1535 |
| Metabolic activation: | With and without S-9 activation; S-9 mix obtained by 9000 x g liver of Aroclor 1254-induced male Sprague Dawley rats and Syrian hamsters |
| Concentrations tested: | 0.3, 1.0, 3.0, 10.0, 33.0, 66.0 and 100.00 µg/plate |
| Statistical methods: | Not stated |
| Remarks: | A preincubation modification of the *Salmonella* test was used; the test substance was incubated with the tester strain, in either a 10% S-9 plus cofactor mix or buffer, for 20 minutes at 37°C prior to the addition of soft agar and plating on minimal agar plates for detection of induced mutation. The test substance was tested, in triplicate, at seven doses, along with positive and solvent (water) controls in the absence of exogenous metabolic activation, in the presence of rat liver S-9, and in the presence of hamster liver S-9. For those tests that yielded an equivocal response, the entire test was repeated with 30% S-9 at least one week after the initial test. A positive response was defined as a reproducible, dose-relate increase in histidine-independent (revertant) colonies. An equivocal response was either a non-dose-related increase or a response that was not reproducible |

**Results**

| | |
|---|---|
| Result: | The test substance showed no evidence of mutagenic activity when tested in this bacterial system with and without metabolic activation. |
| Cytotoxic concentration: | Not stated |
| Genotoxic effects: | Negative with and without activation |
| Statistical results: | Not stated |
| Remarks: | |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1D |
| Remarks: | Reliable without restriction; older study, prior to guideline development. |

**References**

Akzo Chemie America. 1984. Letter from Akzo Chemie America to US EPA regarding Oleylamine test results with attachment. EPA Doc. No. 40-8484007, Microfiche No. OTS0526846.

**Other**

| | |
|---|---|
| Last changed: | July 18, 2002 |
| Order number for sorting: | 73a |
| Remarks: | |

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | Hexadecylamine (CAS RN 143-27-1) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Reverse mutation assay |
| System of testing: | Bacterial |
| GLP: | Not stated |
| Year: | 1988 |
| Species/Strain: | *Salmonella typhimurium* strains TA 97, TA 98, TA 100 and TA 1535 |
| Metabolic activation: | With and without metabolic activation; Aroclor-induced liver homogenate from rats and hamsters |
| Concentrations tested: | 0.3 to 100µg per plate |
| Statistical methods: | Not stated |
| Remarks: | Preincubation test |

**Results**

| | |
|---|---|
| Result: | The test substance showed no evidence of mutagenic activity when tested in this bacterial system. |
| Cytotoxic concentration: | Not stated |
| Genotoxic effects: | Negative with and without activation |
| Statistical results: | Not stated |
| Remarks: | |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2D |
| Remarks: | Reliable with restrictions; data from summary document; acceptable because data consistent with other data in subcategory. |

**References**

Zeiger, E., B. Anderson, S. Haworth, T. Lawlor and K. Mortelmans. 1988. *Salmonella* Mutagenicity Tests: IV. Results from the Testing of 300 Chemicals. Supplement 12. Environ. Mol. Mutagen. 11:1-158. As cited in German Chemical Society. 1994. Primary Fatty Amines. GDCh-Advisory Committee on Existing Chemicals of Environmental Relevance (BUA). BUA Report 177; December. S. Hirzel, Wissenschaftliche Verlagsgesellschaft Stuttga.

**Other available reports**

**Other**

| | |
|---|---|
| Last changed: | June 5, 2002 |
| Order number for sorting: | 73b |
| Remarks: | |

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | 1-Octadecyl amine (CAS RN 124-30-1) |
| Purity: | 90% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Reverse mutation assay |
| System of testing: | Bacterial |
| GLP: | Not stated |
| Year: | 1988 |
| Species/Strain: | *Salmonella typhimurium* strains TA 97, TA 98, TA 100 and TA 1535 |
| Metabolic activation: | With and without metabolic activation; Aroclor-induced liver homogenate from rats and hamsters both at 10% and 30%. |
| Concentrations tested: | 0, 100, 333, 1000, 3333 and 6666 µg per plate |
| Statistical methods: | Not stated |
| Remarks: | Preincubation test. Each test was run in triplicate. The vehicle used was water, which was also used as the negative control. The following positive control groups were included with activation: sodium azide (TA100 and TA1535), 9-aminoacridine (TA97) and 4-nitro-o-phenolenediamine. 2-aminoanthracene was used as the positive control for all strains without activation. The criteria used for positive results was a dose-related increase in the number of revertant colonies. |

**Results**

| | |
|---|---|
| Result: | The test substance showed no evidence of mutagenic activity when tested in this bacterial system. |
| Cytotoxic concentration: | Not stated |
| Genotoxic effects: | Negative with and without activation |
| Statistical results: | Not stated |
| Remarks: | In the test using 10% rat S-9, precipitate was observed at the 333 µg/plate dosage level. In the test using 10% hamster S-9, precipitate was observed at the 1000 µg/plate dosage level. This would implicate that only 100 and 333 µg/plate concentrations could be evaluated for these tests. For all other tests no presence of precipitate was reported; therefore, overall validity of the results for the remaining tests is not affected. All positive controls exhibited sufficient mutant colonies. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2A |
| Remarks: | Reliable with restrictions; acceptable, well-documented publication/study report which meets basic scientific principles. |

**References**

Zeiger, E., B. Anderson, S. Haworth, T. Lawlor and K. Mortelmans. 1988. *Salmonella* Mutagenicity Tests: IV. Results from the Testing of 300 Chemicals. Supplement 12. Environ. Mol. Mutagen. 11:1-158.

**Other available reports**

**Other**

| | |
|---|---|
| Last changed: | June 5, 2002 |
| Order number for sorting: | 40d |
| Remarks: | |

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | 1-Octadecyl amine (CAS RN 124-30-1) |
| Purity: | ca. 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Method described by Green, M.H.L. and W.J. Muriel: Mutagen testing using $trp^+$ reversion in Escherichia coli, Mutation Res. 38 (1976) 3-32. |
| Type: | Ames test |
| System of testing: | Bacterial |
| GLP: | Yes |
| Year: | 1988 |
| Species/Strain: | *Salmonella typhimurium*/strains TA 100, TA 1535, TA 1537, TA 1538, TA 98<br>*Escherichia coli*/ strain WP2uvrA |
| Metabolic activation: | With and without metabolic activation; S-9 mix prepared from liver homogenate of Aroclor 1254-induced male Sprague Dawley rats |
| Concentrations tested: | Experiment 1: 0, 4, 20, 100, 500, 2500, 10000 µg/plate<br>Experiment 2: 0, 4, 20, 100, 500, 2500 and 5000 µg/plate |
| Statistical methods: | Not stated |
| Remarks: | Toxicity tests were performed prior to the mutagenicity test. Liver homogenate fraction and S-9 mix were prepared at the laboratory. On the day of the experiment the test substance was dissolved in ethanol at appropriate concentrations. Two independent experiments were performed. Positive and negative controls were run with each experiment. The positive controls without metabolic activation were: Sodium azide (TA100, TA1535), 9-aminoacridine (TA 1537), 2-nitrofluorene (TA98, TA1538) and N-methyl-N-nitro-N-nitrosoguanidine (WP2uvrA). The positive controls with metabolic activation were: benzo[a]pyrene and 2-aminoanthacene (all strains). The negative control was exposed to the solvent, ethanol. After mixing the agar, nutrient broth culture of the bacterial tester strain, test compound solution, S-9 mix (for tests with activation) or buffer (for tests without activation), the liquid was poured into a petri dish with minimal agar and incubated for 48 to 72 hours at 37°C in the dark. |

**Results**

| | |
|---|---|
| Result: | The test substance showed no evidence of mutagenic activity when tested in these bacterial systems. |
| Cytotoxic concentration: | 100 µg/plate |
| Genotoxic effects: | Negative with and without activation |
| Statistical results: | Not stated |
| Remarks: | Visible precipitation of the test compound on the plates was observed at 500 µg/plate and higher. Therefore, only the 4, 20 and 100 µg/plate concentration s were considered valid for interpretation. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1D |
| Remarks: | Reliable without restrictions; only two dose levels were used to evaluate mutagenicity since cytotoxicity was observed at 100 µg/plate. Guideline studies need at least five concentrations evaluated. However, the highest nontoxic concentrations were negative thus providing a negative assay. |

**References**

Müller, W. 1988. Genamin 18 R 100 D, Study of the Mutagenic Potential in Strains of *Salmonella typhimurium* (Ames test) and *Escherichia coli*. Report No. 88.0407. 01, Hoechst AG, ATA, TH-TVS.

**Other available reports**

**Other**

| | |
|---|---|
| Last changed: | August 12, 2002 |
| Order number for sorting: | 40c |
| Remarks: | |

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | Octadecylamine (CAS RN 124-30-1) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Reverse mutation assay |
| System of testing: | Bacterial |
| GLP: | Not stated |
| Year: | 1983 |
| Species/Strain: | *Salmonella typhimurium* strains TA 97, TA 98, TA 100 and TA 1535 |
| Metabolic activation: | With and without S-9 activation; S-9 mix obtained by 9000 x g liver of Aroclor 1254-induced male Sprague Dawley rats and Syrian hamsters |
| Concentrations tested: | 100, 333, 1000, 3333 and 6666 µg/ plate |
| Statistical methods: | Not stated |
| Remarks: | A preincubation modification of the *Salmonella* test was used; the test substance was incubated with the tester strain, in either a 10% S-9 plus cofactor mix or buffer, for 20 minutes at 37°C prior to the addition of soft agar and plating on minimal agar plates for detection of induced mutation. The test substance was tested, in triplicate, at five doses, along with positive and solvent (water) controls in the absence of exogenous metabolic activation, in the presence of rat liver S-9, and in the presence of hamster liver S-9. For those tests that yielded an equivocal response the entire test was repeated with 30% S-9 at least one week after the initial test. A positive response was defined as a reproducible, dose-relate increase in histidine-independent (revertant) colonies. An equivocal response was either a non-dose-related increase or a response that was not reproducible. |

**Results**

| | |
|---|---|
| Result: | The test substance showed no evidence of mutagenic activity when tested in this bacterial system with and without metabolic activation. |
| Cytotoxic concentration: | Not stated |
| Genotoxic effects: | Negative with and without activation |
| Statistical results: | Not stated |
| Remarks: | |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1D |
| Remarks: | Reliable without restriction; older study, prior to guideline development. |

**References**

Akzo Chemie America. 1984. Letter from Akzo Chemie America to US EPA Regarding Oleylamine Test Results with Attachment. EPA Doc. No. 40-8484007, Microfiche No. OTS0526846.

**Other**

| | |
|---|---|
| Last changed: | July 18, 2002 |
| Order number for sorting: | 73 |
| Remarks: | |

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | Genamin C 100 D (CAS RN 61788-46-3; Coco alkyl amine) |
| Purity: | ca. 100% dist. |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Ames et al. 1973. Proc. Nat. Acad. Sci. USA 70. 2281-2285. and Ames et al. 1975. Mutation Res. 21. 347-364. |
| Type: | Reverse mutation assay |
| System of testing: | Bacterial |
| GLP: | Yes |
| Year: | 1988 |
| Species/Strain: | *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538 and *Escherichia coli* strain WP2uvrA |
| Metabolic activation: | With and without metabolic activation |
| Concentrations tested: | 0.16, 0.8, 4, 20, 100, 500, 2500 and 10000µg per plate |
| Statistical methods: | Not stated |
| Remarks: | Three replicates were run at each dose level. The compound was dissolved in 100 µl acetone. Positive and negative controls were run with each experiment. The positive controls without metabolic activation were: Sodium azide (TA100, TA1535), 9-aminoacridine (TA 1537), 2-nitrofluorene (TA98, TA1538) and N-methyl-N-nitro-N-nitrosoguanidine (WP2uvrA). The positive controls with metabolic activation were: benzo[a]pyrene and 2-aminoanthacene. The negative controls were exposed to the vehicle, acetone. The direct plate assay procedure was employed. Independent repeat assays were run. |

**Results**

| | |
|---|---|
| Result: | The test substance showed no evidence of mutagenic activity when tested in this bacterial system. Precipitation was observed at 500 µg/plate and above. |
| Cytotoxic concentration: | Cytotoxic effects were observed at concentrations above 20 µg per plate with *Salmonella typhimurium* and at concentrations above 100 µg per plate with *Escherichia coli* |
| Genotoxic effects: | Negative with and without metabolic activation |
| Statistical results: | Not stated |

Remarks: With cytotoxicity observed at 20 µg/plate and above, only three dose levels were left to evaluate mutagenicity.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1D

Remarks: Reliable without restriction; comparable to guideline study. According to the guideline (OECD 471, 1997) at least 5 concentrations should be evaluated; however, the three highest non-toxic concentrations were negative thus providing for a negative assay.

**References**

Müller, W. 1988. Genamin CC 100 D. Study of the Mutagenic Potential in Strains of *Salmonella typhimurium* (Ames Test) and *Escherichia coli*. Report No. 88.0193. Hoechst AG, Pharma Research Toxicology and Pathology, Frankfurt/Main, 30 S.

**Other available reports**

**Other**

Last changed: June 5, 2002

Order number for sorting: 79b

Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | Tallow alkyl amine (CAS RN 61790-33-8) |
| Purity: | >99% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Reverse mutation assay |
| System of testing: | Bacterial |
| GLP: | Yes |
| Year: | 1988 |
| Species/Strain: | *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538 and *Escherichia coli* strain WP2uvrA |
| Metabolic activation: | With and without metabolic activation |
| Concentrations tested: | 0.16 to 10000 µg per plate |
| Statistical methods: | Not stated |
| Remarks: | The S9 mix was prepared from Aroclor 1254 induced rats. Compound was dissolved in 100 µl ethanol. Dosing was performed as follows: 0, 016 µg/plate (exp. 2 –S9), 0.8 µg/plate (exp. 2) 4, 20, 100, 500 and 2500 µg/plate (exp. 1, exp. 2 +S9) and 10000 µg/plate (exp. 1). Three replicates were run per concentration. The following positive controls were used without metabolic activation: Sodium azide (TA100, TA1535), 9-aminoacridine (TA1537), 2-nitrofluorene (TA98, TA1538), N-methyl-N-nitro-N-nitrosoguanidine (WU2uvrA). The following positive controls were used without metabolic activation: benzo[a]pyrene and 2-aminoantracene. A vehicle (ethanol) negative control was also included. The direct plate assay was employed for this test. |

**Results**

| | |
|---|---|
| Result: | The test substance showed no evidence of mutagenic activity when tested in this bacterial system. Cytotoxicity and precipitation were observed at 20 µg/plate, meaning that only 2 or 3 concentrations of the test substance were left to evaluate the mutagenicity. |
| Cytotoxic concentration: | 20 µg/plate with and without activation |
| Genotoxic effects: | Negative with and without activation |
| Statistical results: | Not stated |
| Remarks: | None |

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1D

Remarks: Reliable without restriction; comparable to guideline study. According to guideline OECD 471, at least 5 concentrations should have been evaluated; however, the three highest non-toxic concentrations were negative thus providing for a negative assay.

**References**

Hoechst AG. 1988. Genamin TA 100 D, Study of the Mutagenic Potential in Strains of *Salmonella typhimurium* (Ames Test) and *Escherichia coli*. (Unveröffentlichte Untersuchung, Bericht Nr. 88.0411). Hoechst AG, Pharma Research Toxicology and Pathology, Frankfurt/Main, 30 S.

**Other available reports**

**Other**

Last changed: August 9, 2002

Order number for sorting: 1 and 223

Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | ODA-FG-11-27-87 (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Reverse mutation assay |
| System of testing: | Bacterial |
| GLP: | Yes |
| Year: | 1985 |
| Species/Strain: | *Salmonella typhimurium* strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100 |
| Metabolic activation: | With and without S-9 activation; S-9 mix obtained from the liver of Aroclor 1254-induced rats |
| Concentrations tested: | 100, 50, 25, 10 and 2 µg per plate with activation; 15, 10, 5, 1 and 0.2 µg per plate without activation |
| Statistical methods: | None performed |
| Remarks: | Test substance was diluted in acetone, which was also used as the negative control. All positive controls, solvent controls and test substance doses were plated in triplicate. The S-9 homogenate and mix was prepared at the testing facility. The S-9 mix was prepared immediately before use. The initial toxicity assay indicated the following concentrations be used for the mutagenicity testing: 200, 100, 50, 10 and 2 µg per plate with activation, and 20, 10, 5, 1 and 0.2 µg per plate without activation. The results of this assay were more toxic than predicted so another assay was run with the following concentrations: 100, 50, 25, 10 and 2 µg per plate with activation, and 15, 10, 5, 1 and 0.2 µg per plate without activation. |

**Results**

| | |
|---|---|
| Result: | The test substance did not induce reverse mutations in the tested strains of *Salmonella typhimurium* in the presence or absence of S-9 activation. |
| Cytotoxic concentration: | 100 µg/plate with activation, 15 µg/plate without activation |
| Genotoxic effects: | Negative; with and without activation |
| Statistical results: | None |
| Remarks: | |

**Conclusions**

Remarks: The results indicated that under the conditions of this study the test article did not cause a positive response on any of the tester strains with or without metabolic activation by Aroclor-induced rat liver microsomes. (Author of report)
The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B
Remarks: Reliable without restriction; comparable to guideline study.

**References**

Haworth, S. R. 1985. *Salmonella*/Mammalian-Microsome Plate Incorporation Mutagenicity Assay (Ames Test.). Report No. T2693.501. Microbiological Associates, Inc., Bethesda, MD, USA. Submitted to EPA by Chem. Manuf. Assoc. as EPA Doc. No. 40-8584197.

**Other**

Last changed: July 17, 2002
Order number for sorting: 19
Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | (Z)-9-Octadecenylamine (CAS RN 112-90-3) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Based on published methodologies: Machanoff, R. *et al.*, 1981, Quantitative analysis of cytotoxicity and mutagenicity of benza(a)pyrene in mammalian cells (CHO/HGPRT), Chem. Biol. Interactions 34:1-10 and O'Neill, J. P. *et al.*, 1977, A quantitative assay of mutation induction at the hypoxanthineguanine phosphoribosyl transferase locus in Chinese hamster ovary cells (CHO/HGPRT system): Development and definition of the system, Mutat. Res. 45:91-101. |
| Type: | Mammalian cell forward mutation assay (HGPRT gene mutation) |
| System of testing: | Nonbacterial |
| GLP: | Not stated |
| Year: | 1984-1985 |
| Species/Strain: | Chinese hamster ovary cells |
| Metabolic activation: | With and without S-9 activation; S-9 mix obtained from the liver of Aroclor 1254-induced male Fischer 344 rats |
| Concentrations tested: | First assay:<br>0.1, 0.5, 1.0, 1.5 and 2.0 nl/ml (absence of S-9)<br>5.0, 6.0, 7.0, 8.0 and 9.0 nl/ml (presence of S-9)<br>Second assay (two independent parallel experiments were performed):<br>1.0, 1.5, 2.0, 2.25 and 2.5 nl/ml (absence of S-9)<br>7.0, 8.0, 9.0, 9.5 and 10.0 nl/ml (presence of S-9) |
| Statistical methods: | Not stated |
| Remarks: | Two preliminary toxicity tests were performed to determine dose levels in the gene mutation assay. The high dose level in the gene mutation assay was selected to produce a cell survival rate of 10 to 30% of control values, when possible. The lowest dose level was to be non-toxic.<br>Exponentially growing CHO-$K_1$-$BH_4$ cells were plated in F12FBS5 at a density of 5 x $10^5$ cells/25 $cm^2$ flask and were incubated at 37 ± 1°C in a humidified atmosphere of 5% $CO_2$ in air for 18-24 hours. Duplicate cultures per treatment condition were used for the mutation assay. The solvent for the test substance was DMSO. Cells were exposed to the concentrations listed above for five hours at 37 ± 1°C. |

The pH of the media was monitored, and no adjustment was required. After the treatment period, all media were aspirated, the cells washed with HBSS and cultured in F12FBS5 for an additional 18-24 hours at 37 ± 1°C. At this time the cells were subcultured to assess cytotoxicity and to initiate the phenotypic expression period. EMS was used as the positive control in the assay conducted in the absence of S-9 at a concentration of 0.2 µl/ml. BaP was used as the positive control in the assay conducted in the presence of S-9 at a concentration of 4.0 µg/ml. The solvent vehicle for the test substance (DMSO) was used as the solvent control at the same concentration as that found in the test substance-treated groups. Growth medium was used in the untreated (negative) control. The assay was considered positive in the event a dose-dependent increase in mutation frequency was observed with one or more of the four concentrations tested inducing a mutation frequency that is at least twice that of the solvent control. The assay was considered suspect if there was no dose response but one or more doses induced a mutation frequency that was at least twice that of the solvent control. The assay was considered negative if none of the doses tested induced a mutation frequency that was at least twice that of the solvent control.

**Results**

| | |
|---|---|
| Result: | The test substance showed no evidence of mutagenic activity when tested in this mammalian cell gene mutation assay. |
| Cytotoxic concentration: | 2.5 nl/ml in the absence of metabolic activation<br>10.0 nl/ml in the presence of metabolic activation |
| Genotoxic effects: | Negative with and without metabolic activation |
| Statistical results: | Described below |
| Remarks: | In the absence of S-9, relative to the solvent control, survival (relative cloning efficiency) was 102, 101, 74, 67 and 62% at 0.1, 0.5, 1.0, 1.5 and 2.0 nl/ml, respectively, for the first assay; was 98, 101 and 65% at 1.0, 1.5 and 2.0 nl/ml, respectively, in the first parallel experiment of the second assay; and was 107, 126 and 58% at 1.0, 1.5 and 2.0 nl/ml, respectively, in the second parallel experiment of the second assay. The higher dose levels, 2.25 and 2.5 nl/ml in the absence of S-9, were too toxic to clone. In the initial assay, the highest dose tested (2 nl/ml without S-9 and 9 nl/ml with S-9) induced more than a two-fold |

increase in the number of mutants. In the repeat assay with two independent parallel experiments, the test substance did not induce significant mutation frequencies compared to the solvent or the untreated controls, even at concurrent toxicity lower than the first assay. A high mutant frequency at a single dose that was observed in the first assay, was not reproduced in either the second or third experiment; therefore, the high mutant frequency at this single point was considered an anomaly.

**Conclusions**

Remarks: The test substance should be considered negative in the CHO/HGPRT mutation assay in the presence and absence of S-9 (Author of report).
The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B
Remarks: Reliable without restriction; comparable to guideline study.

**References**

Yang, L. L. 1985. CHO/HGPRT Mutation Assay in the Presence and Absence of Exogenous Metabolic Activation. Study No. T2693.332001. Microbiological Associates Inc., Bethesda, MD, USA.

**Other**

Last changed: July 17, 2002
Order number for sorting: 20
Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | Oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Based on procedure described by Clive, D and J. F. S. Spector, 1975, Laboratory procedure for assessing specific locus mutations at the TK locus in cultured L5178Y TK+/- mouse lymphoma cells, Mutat. Res. 31:17-29. |
| Type: | Mammalian cell forward mutation assay |
| System of testing: | Nonbacterial |
| GLP: | Yes |
| Year: | 1989 |
| Species/Strain: | L5178Y TK+/- mouse lymphoma cells |
| Metabolic activation: | With and without S-9 activation; S-9 mix obtained from the liver of Aroclor-induced rats |
| Concentrations tested: | 1st Initial assay:<br>0.13 to 0.32 nl/ml (absence of S-9)<br>1.3 to 10.0 nl/ml (presence of S-9)<br><br>2nd Initial assay:<br>0.13 to 1.8 nl/ml (absence of S-9)<br>1.3 to 13.0 nl/ml (presence of S-9)<br>Confirmatory assay:<br>0.2 to 1.0 nl/ml (absence of S-9)<br>1.5 to 11.0 nl/ml (presence of S-9) |
| Statistical methods: | Not stated |
| Remarks: | Single cultures per dose were used for the initial assays. For the initial assays the test substance was diluted and serial eighth log dilutions were carried out, which produced 16 dose levels for both activated and non activated portions of the assays. In the confirmatory assay, using duplicate cultures at each dose, the test substance was diluted and serially diluted, producing eight doses each for the activated and non-activated portions of the assay. Two controls received the solvent, acetone, only and the positive controls were treated with EMS (non-activated) and 7,12-DMBA (activated). The following criteria were used when evaluating the results: 1) a result was positive if there was a positive dose response and one or more of the three highest doses in the 10% or |

greater total growth range exhibited a mutant frequency that was two-fold greater than the background level, the first and confirmatory assays must both demonstrate a positive response to call the test substance a positive mutagen; 2) a result was equivocal if there was no dose response but any one or more of the three highest doses with 10% or greater total growth exhibited a two-fold increase in mutant frequency over background, or if there was a dose response but no culture exhibited a two-fold increase in mutant frequency over background, if an assay produces a positive response and the confirmatory assay produced an equivocal or negative response, then the results for the test substance were classified as equivocal; and 3) a result was negative if there was no dose response in cultures with 10% or greater total growth and none of these test cultures exhibited a two-fold or greater increase in mutant frequency over background, both assays must demonstrate a negative response for the test substance to be considered negative.

**Results**

Result: The test substance showed no evidence of mutagenic activity when tested in this mammalian cell gene mutation assay.

Cytotoxic concentration: Concentrations too toxic to clone:
1st Initial assay:
0.42 nl/ml (without S-9)
13.0 nl/ml (with S-9)
2nd Initial assay:
2.4 nl/ml (without S-9)
18.0 nl/ml (with S-9)
Confirmatory assay:
1.2 nl/ml (without S-9)
11.0 nl/ml (with S-9)

Genotoxic effects: Negative with and without metabolic activation

Statistical results: Described below

Remarks: 1st Initial assay: total growth from 75 to 99% and 6 to 106% were observed in non-activated and activated cultures, respectively.
2nd Initial assay: total growth from 3 to 110% and 13 to 107% were observed in non-activated and activated cultures, respectively.
Confirmatory assay: total growth from 6 to 109% and 2 to 115% were observed in non activated and activated cultures, respectively.

**Conclusions**

| | |
|---|---|
| Remarks: | Under the conditions of this test, Oleylamine was negative in both the presence and absence of exogenous metabolic activation (Author of report). The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1B |
| Remarks: | Reliable without restriction; comparable to guideline study. |

**References**

Harbell, J. W. 1989. L5178Y TK +/- Mouse Lymphoma Mutagenesis Assay with Confirmation. Study No. T8461.701020. Microbiological Associates Inc., Bethesda, MD, USA.

**Other**

| | |
|---|---|
| Last changed: | July 17, 2002 |
| Order number for sorting: | 24 |
| Remarks: | |

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | ODA-FG-11-27-84 (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Cytogenetic assay (chromosomal aberration) |
| System of testing: | Nonbacterial |
| GLP: | Yes |
| Year: | 1985 |
| Species/Strain: | Chinese hamster ovary cells (CHO) |
| Metabolic activation: | With and without S-9 activation; S-9 mix obtained from the liver of Aroclor 1254-induced male Sprague-Dawley rats |
| Concentrations tested: | 0.05, 0.15, 0.5, 1.5 and 5.0 nl/ml (absence of S-9)<br>0.2. 0.6, 2.0, 6.0 and 20.0 nl/ml (presence of S-9) |
| Statistical methods: | Chi-square analysis using a 2 x 2 contingency table |
| Remarks: | CHO cells were seeded in duplicate for each treatment condition at 6.0 x $10^5$ cells/25 $cm^2$ flask and were incubated at 37 ± 1°C in a humidified atmosphere of 5 ± 0.5% $CO_2$ in air for 18-24 hours. TEM was used as the positive control in the non-activation study at a concentration of 1 µg/ml. CP was used as the positive control in the S-9 activated study at a concentration of 50 µg/ml. The solvent vehicle, acetone, was used as the solvent control at the same concentration as that found in the test substance-treated groups. Growth medium was used in the untreated control. In the study without S-9 activation, duplicate cultures per treatment condition were exposed for 16 hours at 37 ± 1°C in a humidified atmosphere of 5 ± 0.5% $CO_2$ in air. At the end of the 16-hour period, flasks were harvested and cytotoxicity was estimated. Also at this time, medium was removed from a second set of duplicate flasks for each treatment condition, and the cells were washed and refed with complete medium containing 0.1 µg/ml of colcemid. In the study with S-9 activation, duplicate cultures per treatment condition were exposed for two hours at 37 ± 1°C in a humidified atmosphere of 5 ± 0.5% $CO_2$ in air. After the exposure period, the treatment medium was removed, the cells were washed with PBS, refed with complete medium |

and returned to the incubator for an additional 14 hours. At the end of the 14-hour period, flasks were harvested and cytotoxicity was estimated. Also at this time, colcemid was added to a second set of duplicate flasks for each treatment condition at a final concentration of 0.1 µg/ml. Two and ½ hours after the addition of colcemid, metaphase cells were harvested for both studies by mitotic shake-off. Slides were prepared from fixed cells and scored. One hundred cells were scored for each dose level. The following aberrations were scored: chromatid gaps and breaks, chromosome gaps and breaks, chromatid fragments, acentric fragments, dicentrics, rings, triradials, quadriradials, complex rearrangements, pulverized chromosomes and cells, endoreduplication, and severely damage cells (> 10 aberrations). The criteria for determination of a valid test included: 1) the number of cells with chromosome aberrations in the negative control must be in accordance with the historical data and 2) the number of cells with chromosome aberration in the positive control must be at least 25% of the cells scored. The four highest doses with scoreable metaphases were selected for evaluation of chromosome aberrations.

**Results**

| | |
|---|---|
| Result: | The test substance showed no evidence of mutagenic activity in the presence and absence of an S-9 metabolic activation system. |
| Cytotoxic concentration: | 5.0 nl/ml without S-9 (24% cell survival)<br>20 nl/ml with S-9 (24% cell survival) |
| Genotoxic effects: | Negative with and without metabolic activation |
| Statistical results: | Described below |
| Remarks: | In the absence of S-9 activation, relative to the solvent control, survival ranged from 24 to 111% and 24 to 133% in the presence of S-9 activation. At the time of harvest, the flasks receiving 5.0 nl/ml in the absence of S-9 appeared very toxic with few cells in metaphase. When slides were made of the mitotic shakeoff, few scoreable metaphases were observed in that treatment group; therefore this group was not evaluated for chromosome aberrations. In the absence of S-9, the frequency of cells with structural aberrations was not significantly increased above that of the solvent control (0.05) in all dose levels scored. The number of structural aberrations per cell in the treated groups ranged from 0 to 0.02, with a frequency of cells with |

structural aberrations from 0 to 1%. TEM induced 0.49 aberrations per cell and a frequency of cells with structural aberrations of 25%. In the presence of S-9, the frequency of cells with structural aberrations in the test substance-treated groups was not statistically increased above that of the solvent control and ranged from 0.01 to 0.03 with a frequency of cells with structural aberrations from 1 to 3%. CP induced 0.81 aberrations per cell and a frequency of cells with structural aberrations of 39%. The modal chromosome numbers of the negative and solvent controls as well as all test substance-treated groups was 19.

**Conclusions**

Remarks: Under the conditions of the assay described in this report, the test substance did not produce chromosome aberrations in CHO cells when tested in the presence and absence of an S-9 metabolic activation system (Author of report).
The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B
Remarks: Reliable without restriction; comparable to guideline study.

**References**

Putman, D. L. 1985. Chromosome Aberration Assay in Chinese Hamster Ovary (CHO) Cells. Study No. T2693.337010. Microbiological Associates Inc., Bethesda, MD, USA.

**Other**

Last changed: July 17, 2002
Order number for sorting: 25
Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | Farmin DM 40 (CAS RN 112-75-4<br>1-Tetradecanamine, N,N-dimethyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Procedures developed by: Ames, B. N., J. McCann and E. Yamasaki. 1975. Methods for detecting carcinogens and mutagens with the *Salmonella*/ mammalian microsome mutagenicity test. *Mutation Res*. **31**:347-364; and<br>Maron, D. M. and Ames, B. N. 1983. Revised methods for the *Salmonella* mutagenicity test. *Mutation Res*. **113**:173-215. |
| Type: | Reverse mutation assay (pour-plate assay) |
| System of testing: | Bacterial |
| GLP: | Yes |
| Year: | 1995-1996 |
| Species/Strain: | *Salmonella typhimurium* strains TA98, and TA100. |
| Metabolic activation: | With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from male CD rats was used as the metabolic activation system. |
| Concentrations tested: | 0.5, 1.6, 5.0, 15.8 and 50 µg per plate. |
| Statistical methods: | Not stated |
| Remarks: | Test substance was diluted in ethanol. The following positive control substances were included: sodium azide (2 µg/plate, TA 100, without S-9), 2-nitrofluorene (1 µg/plate, TA 98, without S-9) and Benzo[a]pyrene (5 µg/plate, TA 98 and TA 100, with S-9). The positive controls, solvent control and all test substance doses were plated in duplicate. The S-9 homogenate and mix was prepared at the testing facility. The S-9 mix was prepared immediately before use. The S-9 mix, tester strain and vehicle, test article, or positive control were added to molten selective top agar. After solidification, the plates were incubated for two days at 37°C. |

**Results**

| | |
|---|---|
| Result: | The test substance showed no evidence of mutagenic activity when tested in this bacterial system. |
| Cytotoxic concentration: | 50 µg per plate |
| Genotoxic effects: | Negative with and without activation |
| Statistical results: | Not stated |
| Remarks: | None |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has not been adequately characterized because only two tester strains were evaluated. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2D |
| Remarks: | Reliable with restrictions; well documented study report that meets basic scientific principles however, only two tester strains were evaluated. |

**References**

May, K. 1996. Farmin DM40: Preliminary Toxicity Screen: Assessment of Mutagenic Potential in Histidine Auxotrophs of *Salmonella typhimurium* (the Ames test). Report No. 96/KAS182/0143. Huntingdon Life Sciences Ltd., Eye, Suffolk England.

**Other**

| | |
|---|---|
| Last changed: | July 11, 2002 |
| Order number for sorting: | 257 |
| Remarks: | |

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | Farmin DM 60 (CAS RN 112-69-6<br>1-Hexadecanamine, N,N-dimethyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Procedures developed by: Ames, B. N., J. McCann and E. Yamasaki. 1975. Methods for detecting carcinogens and mutagens with the *Salmonella*/ mammalian microsome mutagenicity test. *Mutation Res*. **31**:347-364; and<br>Maron, D. M. and Ames, B. N. 1983. Revised methods for the *Salmonella* mutagenicity test. *Mutation Res*. **113**:173-215. |
| Type: | Reverse mutation assay (pour-plate assay) |
| System of testing: | Bacterial |
| GLP: | No |
| Year: | 1995-1996 |
| Species/Strain: | *Salmonella typhimurium* strains TA98, and TA100. |
| Metabolic activation: | With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from male CD rats was used as the metabolic activation system. |
| Concentrations tested: | 0.5, 1.6, 5.0, 15.8 and 50 µg per plate. |
| Statistical methods: | Not stated |
| Remarks: | Test substance was diluted in ethanol. The following positive control substances were included: sodium azide (2 µg/plate, TA 100, without S-9), 2-nitrofluorene (1 µg/plate, TA 98, without S-9) and Benzo[a]pyrene (5 µg/plate, TA 98 and TA 100, with S-9). The positive controls, solvent control and all test substance doses were plated in duplicate. The S-9 homogenate and mix was prepared at the testing facility. The S-9 mix was prepared immediately before use. The S-9 mix, tester strain and vehicle, test article, or positive control were added to molten selective top agar. After solidification, the plates were incubated for two days at 37°C. |

**Results**

| | |
|---|---|
| Result: | The test substance showed no evidence of mutagenic activity when tested in this bacterial system. |
| Cytotoxic concentration: | 50 µg per plate |
| Genotoxic effects: | Negative with and without activation |
| Statistical results: | Not stated |
| Remarks: | None |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has not been adequately characterized because only two tester strains were evaluated. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2D |
| Remarks: | Reliable with restrictions; well documented study report that meets basic scientific principles however, only two tester strains were evaluated. |

**References**

May, K. 1996. Farmin DM60: Preliminary Toxicity Screen: Assessment of Mutagenic Potential in Histidine Auxotrophs of *Salmonella typhimurium* (the Ames test). Report No. 96/KAS182/0143. Huntingdon Life Sciences Ltd., Eye, Suffolk England.

**Other**

| | |
|---|---|
| Last changed: | July 11, 2002 |
| Order number for sorting: | 4e |
| Remarks: | |

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | Farmin DM 80 (CAS RN 124-28-7<br>1-Octadecanamine, N,N-dimethyl) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Procedures developed by: Ames, B. N., J. McCann and E. Yamasaki. 1975. Methods for detecting carcinogens and mutagens with the *Salmonella*/ mammalian microsome mutagenicity test. *Mutation Res*. **31**:347-364; and<br>Maron, D. M. and Ames, B. N. 1983. Revised methods for the *Salmonella* mutagenicity test. *Mutation Res*. **113:**173-215. |
| Type: | Reverse mutation assay (pour-plate assay) |
| System of testing: | Bacterial |
| GLP: | No |
| Year: | 1995-1996 |
| Species/Strain: | *Salmonella typhimurium* strains TA98, and TA100. |
| Metabolic activation: | With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from male CD rats was used as the metabolic activation system. |
| Concentrations tested: | 0.5, 1.6, 5.0, 15.8 and 50 µg per plate. |
| Statistical methods: | Not stated |
| Remarks: | Test substance was diluted in ethanol. The following positive control substances were included: sodium azide (2 µg/plate, TA 100, without S-9), 2-nitrofluorene (1 µg/plate, TA 98, without S-9) and benzo[a]pyrene (5 µg/plate, TA 98 and TA 100, with S-9). The positive controls, solvent control and all test substance doses were plated in duplicate. The S-9 homogenate and mix was prepared at the testing facility. The S-9 mix was prepared immediately before use. The S-9 mix, tester strain and vehicle, test article, or positive control were added to molten selective top agar. After solidification, the plates were incubated for two days at 37°C. |

**Results**

| | |
|---|---|
| Result: | The test substance showed no evidence of mutagenic activity when tested in this bacterial system. |
| Cytotoxic concentration: | 50 µg per plate |
| Genotoxic effects: | Negative with and without activation |
| Statistical results: | Not stated |
| Remarks: | None |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has not been adequately characterized because only two tester strains were evaluated. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2D |
| Remarks: | Reliable with restrictions; well documented study report that meets basic scientific principles however, only two tester strains were evaluated. |

**References**

May, K. 1996. Farmin DM80: Preliminary Toxicity Screen: Assessment of Mutagenic Potential in Histidine Auxotrophs of *Salmonella typhimurium* (the Ames test). Report No. 96/KAS182/0143. Huntingdon Life Sciences Ltd., Eye, Suffolk England.

**Other**

| | |
|---|---|
| Last changed: | July 11, 2002 |
| Order number for sorting: | 38h |
| Remarks: | |

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | Genamin SH 301 (CAS RN 4088-22-6; 1-Octadecanamine, N-methyl-N-octadecyl) |
| Purity: | ca. 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | Procedures developed by: Ames, B. N., W. W. Durston, E. Yamasaki and F. D. Lee. 1973. Carcinogens are mutagens. A simple test system combining liver homogenate for activation and bacteria for detection. *Proc. Nat. Acad. Sci.* USA **70**:2281-2285;<br>Ames, B. N., J. McCann and E. Yamasaki. 1975. Methods for detecting carcinogens and mutagens with *Salmonella*/mammalian-microsome mutagenicity test. *Mutation Res*. **31**:347-364; and<br>Green, M.H.L and W.J. Muriel. 1976. Mutagen testing using trp+ reversion in *Escherichia coli*. *Mutation Res.* **38**:3-32. |
| Type: | Mutagenicity assay (Ames Test) |
| System of testing: | Bacterial |
| GLP: | Yes |
| Year: | 1988 |
| Species/Strain: | *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 and *Escherichia coli* WP2uvrA |
| Metabolic activation: | With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from male Sprague-Dawley rats was used as the metabolic activation system. |
| Concentrations tested: | 5000, 2500, 500, 100, 20, and 4 µg per plate |
| Statistical methods: | Not stated |
| Remarks: | Test substance was diluted in DMSO, which was also used as the vehicle control. The following substances were used as positive controls in tests without activation: sodium azide (TA 100, TA 1535); 9-aminoacridine (TA 1537); 2-nitrofluorene (TA 98, TA 1538); and N-methyl-N-nitro-N-nitrosoguanidine (WP2uvrA). Benzo[a]pyrene and 2-aminoanthracene were used as the positive controls in tests with activation for all *Salmonella* and *Escherichia coli* tester strains. The positive controls, vehicle control and all test substance doses were plated in triplicate. The S-9 homogenate and mix were prepared at the testing facility. The S-9 mix was prepared |

immediately before use. The S-9 mix, tester strain and vehicle, test article, or positive control were added to molten selective top agar. The top agar was prepared with histidine-biotin solution for the *Salmonella* strains and with tryptophan for *E. coli*. After solidification, the plates were incubated for 48-72 hours at 37°C in the dark.

**Results**

| | |
|---|---|
| Result: | The test substance showed no evidence of toxicity or mutagenic activity when tested in this bacterial system. |
| Cytotoxic concentration: | No cytotoxicity was observed at concentrations up to and including 5000 µg per plate |
| Genotoxic effects: | Negative with and without activation |
| Statistical results: | Not stated |
| Remarks: | None |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1B |
| Remarks: | Reliable without restrictions; comparable to guideline study. |

**References**

Müller, W. 1988. Genamin SH 301 – Study of the Mutagenic Potential in Strains of *Salmonella typhimurium* (Ames Test) and *Escheria coli*. Report No. 88.0293. Pharma Research Toxicology and Pathology, Frankfurt, Germany

**Other**

| | |
|---|---|
| Last changed: | July 12, 2002 |
| Order number for sorting: | 77b |
| Remarks: | |

## 5.5 GENETIC TOXICITY *IN VITRO*

**Test Substance**

| | |
|---|---|
| Identity: | DA-1618 [CAS RN 52898-18-7; 1,3-Propanediamine, N-(3-(dodecyloxy)propyl)-] |
| Purity: | Not stated |
| Remarks: | Report does not mention a chemical name, just the trade name. |

**Method**

| | |
|---|---|
| Method/Guideline followed: | OECD Guideline No. 471/472 |
| Type: | Reverse mutation assay |
| System of testing: | Bacterial |
| GLP: | Yes |
| Year: | 1999 |
| Species/Strain: | *Salmonella typhimurium* TA98, TA100, TA1535 and TA1537; and *Escherichia coli* WP2*uvr*A |
| Metabolic activation: | With and without S-9 activation; S-9 mix obtained from the liver of Arochlor 1254-induced rats; S-9 mix prepared in-house |
| Concentrations tested: | 333, 100, 33.3, 10.0, 3.33 and 1.0 µg per plate in the presence of S-9 mix and<br>100, 33.3, 10.0, 3.33, 1.0 and 0.333 µg per plate in the absence of S-9 mix |
| Statistical methods: | None |
| Remarks: | The doses tested in the mutagenicity assay were selected based on the results of a dose range-finding study using tester stains TA100 and WP2uvrA and ten doses of the test substance ranging from 5000 to 6.67 µg per plate, one plate per dose, both in the presence and absence of S-9 mix. The S-9 homogenate was purchased from Molecular Toxicology, Inc. The S-9 mix was prepared immediately prior to its use. The assay was conducted with a minimum of six doses of test substance in both the presence and absence of S-9 mix along with concurrent vehicle and positive controls using three plates per dose. The results of the initial mutagenicity assay were confirmed in an independent experiment. |

**Results**

| | |
|---|---|
| Result: | DA-1618 did not cause a positive increase in the mean number of revertants per plate with any of the tester stains either in the presence or absence of microsomal enzymes prepared from Aroclor-induced rat liver (S-9). In the confirmatory assay, all data were acceptable and a 2.4-fold increase in the mean number of |

revertants per plate was observed with tester strain TA98 in the absence of S-9 mix. No increases in the mean number of revertants per plate were observed with any of the remaining tester strain/activation condition combinations. TA98 was retested in the absence of S-9mix at doses of 60.0, 30.0, 20.0, 15.0, 10.0, 5.0, 2.0, 1.25, 0.5 and 0.1 µg in order to clarify the dose-responsiveness of the increase. In this retest, all data were acceptable and no positive increase in the mean number of revertants per plate was observed with tester strain TA98 in the absence of S-9 mix.

Cytotoxic concentration: 333 µg per plate and above in the presence of S-9 mix and 66.7 µg per plate and above in the absence of S-9 mix

Genotoxic effects: Negative with and without activation

Statistical results: None

Remarks:

**Conclusions**

Remarks: DA-1618 is not mutagenic in this bacterial test system. (Author of the study report) The endpoint has been adequately characterized by this study. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A

Remarks: Reliable without restriction; guideline study.

**References**

Lawlor, T. E. 1999. (Draft report) Mutagenicity Test with DA-1618 in the *Salmonella-Escherichia coli*/Mammalian/Microsome Reverse Mutation Assay with a Confirmatory Assay. Study No. 20557-Q-409OECD. Covance Laboratories Inc.

**Other**

Last changed: July 19, 2002

Order number for sorting: 166

Remarks:

## 5.6 GENETIC TOXICITY *IN VIVO*

**Test Substance**

| | |
|---|---|
| Identity: | Tallow alkyl amine (CAS RN 61790-33-8) |
| Purity: | 98.7% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | OECD Guideline 474, Genetic Toxicology: Micronucleus Test. |
| Type: | Micronucleus assay |
| GLP: | Yes |
| Year: | 1981 |
| Species: | Rat |
| Strain: | Sprague-Dawley |
| Sex: | Male and female |
| Route of administration: | Oral gavage |
| Doses/concentration levels: | Single dose/2000 mg/kg |
| Exposure period: | Single administration |
| Statistical methods: | Mann-Whitney |
| Remarks: | Groups of rats (five males and five females) were administered a single dose of the test substance in sesame oil by oral gavage. Two additional groups of rats (five males and five females/group) were used as the vehicle control and positive control. The vehicle control group received sesame oil by gavage. The positive control, cyclophosphamide, was injected IP. The following criteria were examined: 1) mortality and/or clinical signs; 2) number of micronucleated cells/2000 erythrocytes; and 3) ratio of polychromatic to normochromatic erythrocytes (PCE/NCE) by counting a total of 1000 PCE. |

**Results**

| | |
|---|---|
| Genotoxic effects: | Negative |
| NOAEL (NOEL): | Not determined |
| Statistical results: | Described below |
| Remarks: | One male died at 48-hours. Clinical signs observed in test substance-treated rats included piloerection, shallow breathing, hunched posture and hypoactivity.. The results of this assay indicate that under the conditions of this study, the test substance did not induce chromosomal aberrations in bone marrow cells of male and female rats. The positive control elicited the expected response. |

At 24-hours: 1.1 (1.2 controls)
At 48-hours: 1.2 (1.2 controls)
Genotoxic effects at 2000 mg/kg:
Mean number of micronucleated cells/2000 cells
At 24-hours: 1.3
At 48-hours: 1.6

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study.

**References**

Fassio, F. 2000. Micronucleus Test in Rat Bone Marrow Cells Treated by Oral Route. APAG, Instituto di Richerche Biomediche, "Antoine Marxer" RBM S.p.A.

**Other**

Last changed: June 26, 2002
Order number for sorting: 225a
Remarks:

## 5.6 GENETIC TOXICITY *IN VIVO*

**Test Substance**

| | |
|---|---|
| Identity: | Oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine,) |
| Purity: | 90% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | TSCA test guidelines for cytogenetic tests (40 CFR 798.5385) and the final test rule (40 CFR 799.3157) |
| Type: | Cytogenetics assay |
| GLP: | Yes |
| Year: | 1989 |
| Species: | Mouse |
| Strain: | ICR |
| Sex: | Male and female |
| Route of administration: | Oral gavage |
| Doses/concentration levels: | 500, 2500 and 5000 mg/kg |
| Exposure period: | Single administration |
| Statistical methods: | Fisher's exact test and Cochran-Armitage trend test for dose response. |
| Remarks: | Groups of mice (five males and five females) were administered a single dose of the test substance in corn oil by oral gavage at concentrations of 500, 2500 or 5000 mg/kg at a constant volume of 10 ml/kg. Two additional groups of mice (five males and five females) were used as the vehicle control and positive control. The vehicle control group received corn oil by gavage at 10 mg/kg. The positive control, triethylenemelamine (TEM), was injected IP at a dose level of 0.5 mg/kg. Body weights were taken immediately prior to dosing and at sacrifice. Clinical observations were made prior to sacrifice. Colchicine, used to arrest dividing cells at metaphase, was administered IP at 1 mg/kg to all mice two to four hours prior to scheduled sacrifice. Bone marrow cells, arrested in metaphase and collected 6, 12 and 24 hours after treatment, were examined microscopically for structural chromosome aberrations. The following criteria were used when evaluating the results: 1) the test substance was considered to induce a positive response when the number of aberrant cells was significantly increased in a dose-responsive manner relative to the vehicle control; 2) a significant increase at the high dose only with no dose-response was considered suspect; and 3) a significant increase at one |

dose other than the high dose with no dose-response was considered equivocal.
A range-finding study was conducted with five treatment levels, 763, 1221, 1953, 3125, and 5000 mg/kg. Each group consisted of five male and five female mice.

**Results**

| Male mice | Mean Aberrations/Cell | | |
|---|---|---|---|
| **Dose group** | **6 hours** | **12 hours** | **24 hours** |
| Vehicle control | 0 | 0 | 0.004 |
| 500 mg/kg | 0 | 0 | 0 |
| 2500 mg/kg | 0 | 0 | 0 |
| 5000 mg/kg | 0.004 | 0.008 | 0 |
| TEM | -- | 0.436 | -- |

| Female mice | Mean Aberrations/Cell | | |
|---|---|---|---|
| **Dose group** | **6 hours** | **12 hours** | **24 hours** |
| Vehicle control | 0.004 | 0.004 | 0 |
| 500 mg/kg | 0 | 0 | 0 |
| 2500 mg/kg | 0.004 | 0 | 0 |
| 5000 mg/kg | 0.004 | 0 | 0.004 |
| TEM | -- | 0.34 | -- |

Genotoxic effects: Negative
NOAEL (NOEL): Not determined
Statistical results: Described below
Remarks: One female in the 2500 mg/kg dose group died prematurely. No significant reduction in the rate of body weight gain was observed. Clinical signs observed in test substance-treated mice included diarrhea, piloerection, lethargy, crusty eyes and irregular breathing. No statistically significant increases in percentage of aberrant cells were observed in the test substance-treated groups, regardless of dose or bone marrow harvest time. The results of this assay indicate that under the conditions of this study, the test substance did not induce chromosomal aberrations in bone marrow cells of male and female mice.
The results of the dose range-finding study: One female in each of the following groups died prematurely: 5000, 3125 and 1221 mg/kg

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A

Remarks: Reliable without restriction; guideline study.

**References**

Microbiological Associates, Inc. 1989. Oleylamine: Acute *in vivo* Cytogenetics Assay in Mice (Final Report) with cover letter dated 112789. EPA Doc. No. 40-8984323, Microfiche No. OTS0525407.

**Other**

Last changed: July 17, 2002

Order number for sorting: 26

Remarks:

## 5.6 GENETIC TOXICITY *IN VIVO*

**Test Substance**

| | |
|---|---|
| Identity: | Genamin LA 302 D (CAS RN 112-18-5; N,N-Dimethyl-1-dodecanamine) |
| Purity: | 100% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | Mammalian Erythrocyte Micronucleus Test (OECD guideline 474), US EPA OPPTS 870.5395 and EEC Directive 92/69, L383 A, Annex B. |
| Type: | Mouse micronucleus assay |
| GLP: | Yes |
| Year: | 1999 |
| Species: | Mouse |
| Strain: | HsdWin:NMRI |
| Sex: | Male and female |
| Route of administration: | Oral gavage |
| Doses/concentration levels: | 0, 120, 400 and 1200 mg/kg bodyweight |
| Exposure period: | Doses given twice at an interval of 24 hours |
| Statistical methods: | One sided Wilcoxon Test |
| Remarks: | Groups of mice (five males and five females) were given two doses of the test substance in sesame oil by oral gavage at concentrations of 120, 400 and 1200 mg/kg at 24 hour intervals. Two additional groups of mice (five males and five females) were used as the vehicle control and positive control. The positive control, Endoxan® (cyclophosphamide dissolved in distilled water), was administered as a single oral dose at 50 mg/kg. All doses were administered at a constant volume of 10 ml/kg. Body weights were taken at the start of the study. Clinical observations were made following dosing. Bone marrow cells collected 24 hours after dose administration were examined microscopically for structural chromosome aberrations. Prior to study initiation, a dose range-finding toxicity study was conducted at dose levels of 1000, 1200, 1500 and 2000 mg/kg with three mice per sex per group. |

**Results**

| Dose group | PCE/NCE ratio | | Mutagenic Index |
|---|---|---|---|
| | Male | Female | Sexes Combined |
| Vehicle control | 0.53 | 0.46 | 1.0 |
| 120 mg/kg | 0.51 | 0.52 | 1.5 |
| 400 mg/kg | 0.48 | 0.50 | 1.3 |
| 1200 mg/kg | 0.38 | 0.37 | 1.8 |
| Positive control | 0.34 | 0.42 | 35.6 |

Genotoxic effects: Negative
NOAEL (NOEL): Not determined
Statistical results: Described below
Remarks: Six out of ten mice in the 1200 mg/kg dose group died prematurely. The animals were replaced and the new animals survived after treatment. Clinical signs of toxicity observed in test substance-treated mice included diarrhea, decreased motor activity, palpebral fissure narrow, uncoordinated movements, stupor, tonic convulsions, and prone position. All animals were free of clinical signs of toxicity 24 hours after treatment. No statistically significant increases in percentage of micronucleated polychromatic erythrocytes were observed in the test substance-treated groups. The results of this assay indicate that under the conditions of this study, the test substance did not induce a substantial increase of micronucleated polychromatic erythrocytes in bone marrow cells of male and female mice and is not mutagenic in the micronucleus test.
The results of the dose range-finding study: At 2000 and 1500 mg/kg doses, 3/3 males and 3/3 females died. At 1000 mg/kg dose, no animals died and at 1200 mg/kg dose, 1/3 males and 0/3 females died.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study.

**References**

Stammberger, I. 1999. Genamin LA 302 D. Mammalian Erythrocyte Micronucleus Test in Male and Female NMRI Mice. Report No. 99.0074. Hoechst Marion Roussel Deutschland GmbH, Drug Innovation & Approval, Department of Toxicology/Pathology, Frankfurt, Germany.

**Other**

| | |
|---|---|
| Last changed: | June 19, 2002 |
| Order number for sorting: | 124i |
| Remarks: | |

## 5.8 TOXICITY TO REPRODUCTION

**Test Substance**

| | |
|---|---|
| Identity: | Genamin TA 100 (CAS RN 61790-33-8; Amines, tallow alkyl) |
| Purity: | >96% |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | OECD 421: Reproduction/Developmental Toxicity Screening Test |
| Type | One generation |
| GLP: | Yes |
| Year: | 2000 |
| Species: | Rat |
| Strain: | Sprague Dawley Crl:CD(SD)BR |
| Route of administration: | Oral gavage |
| Doses/concentration levels: | 0, 12.5, 50 and 150 mg/kg |
| Vehicle | Sesame oil |
| Sex: | 10 male and 10 female per group |
| Exposure period: | Male rats from 14 days prior to mating until end of mating period for a maximum of 28 days.<br>Female rats from 14 days prior to mating throughout mating, during pregnancy up until day 3 of lactation (approximately 54 days). |
| Premating exposure period: | 14 days for males and females |
| Frequency of treatment: | Once daily |
| Control group and treatment: | Yes; concurrent, treated with vehicle (sesame oil) |
| Duration of test: | 14 days prior to mating until day 3 of lactation |
| Statistical methods: | Chi-square test, Fisher's exact test, Trend test, Bartlett's test, ANOVA, Dunnett's test, Kruskal-Wallis test, Mann-Whitney "U" test |
| Remarks: | Ten male and ten female rats per group received the test substance by oral administration at dose levels of 0 (vehicle control), 12.5, 50 or 150 mg/kg/day at a constant dose volume of 10 ml/kg. At study initiation, animals were approximately 10 weeks of age, males weighed 303 to 347g and females weighed 233 to 275 g. Animals were observed daily for clinical signs, behavior and mortality. Body weights and food consumption were recorded weekly for males. Body weights and food consumption were recorded weekly during premating for females and on gestation days 0, 7, 14 and 20 and during lactation on day 0 (parturition) and day 4. Females were examined three times daily for parturition. Maternal behavior was also evaluated. Histology was carried out on gross lesions, ovaries, |

uteri, testes, epididymides, and accessory sex organs of the control and high dose group animals. Additional sections of testes of final sacrificed animals of the control and high dose groups were stained with PAS-hematoxylin to allow spermatogenesis to be classified into 14 stages.
Parameters assessed for F1 generation:
Number of live and stillbirths were recorded. Pups were observed daily (from birth to day 4) for survival and clinical observations and weighed on days 0 and day 4. Sex and external abnormalities were noted on day 0. A necropsy was performed on all pups that died.
Dose formulations were analyzed by HPLC/UV on the first and last week of treatment of the females.

**Results**

| | |
|---|---|
| Maternal toxicity NOAEL: | 12.5 mg/kg/day |
| Offspring NOEL: | 12.5 mg/kg/day |
| Actual dose received: | 92 to 111% of nominal doses. |
| F0 Parental data: | Mortality – 1/10 females (gavage error); 1/10 females (day 13) and 1/10 males (day 24) at 50 mg/kg; and 5/10 females and 5/10 males at 150 mg/kg (days 9-25). Salivation, hunched posture, incidental soft stool and piloerection were observed in the 150 mg/kg group and salivation was observed in the 50 mg/kg group. A dose related decrease in premating body weight gains was observed in all animals in the 50 and 150 mg/kg dose groups. A dose related decrease in gestational body weights was observed for females in the 12.5 (body weight gain), 50 and 150 mg/kg dose groups. Lactation body weights were also decreased in females in the 12.5 and 50 mg/kg dose groups. Food consumption was decreased in all animals at 50 and 150 mg/kg. This decrease was dose-related only in the males. Females in the 50 and 150 mg/kg dose groups had decreased food consumption from gestation days 0 to 14. Food consumption was also decreased in the females in the 12.5 and 50 mg/kg dose groups during lactation. Mating index was 100% (9/9), 90% (9/10), 100%(9/9) and 43% 3/7 in the 0, 12.5, 50 and 150 mg/kg dose groups, and the fertility index in these respective groups was 100% (9/9), 89% (8/9), 78% (7/9) and 33% (1/3). Precoital interval was 2.3, 3.9, 2.7 and 13.5 days in the 0, 12.5, 50 and 150 mg/kg dose groups, respectively. Implantation loss was increased (100% loss) at the 150 mg/kg group. |

| | |
|---|---|
| | Duration of gestation was 22 days for females in all groups but the 150 mg/kg dose group. Gross necropsy observations for the animals that died included dilation and/or congestion of the gastrointestinal tract and congestion of the lungs. There were no macroscopic findings noted in the surviving animals. Statistically significant changes in the weight of the epididymides (decrease in absolute weight and increase in weight relative to body weight) and an increase in relative testes weight were noted 150 mg/kg dose group males. Tubular degeneration in the testes with decreased spermatogenesis in one male was noted in the males in the 150 mg/kg dose group. Atrophia of corpora lutea was observed in eight of ten females in the 150 mg/kg dose group. |
| Fetal data: | There were no litters in the 150 mg/kg dose group. There were no treatment-related effects on the sex ratio, viability index, survival or visible abnormalities. Body weights of the pups were decreased at 50 mg/kg. |
| Statistical results: | Effects reported were in almost all cases statistically significant in at least one sex. |
| Remarks: | NOAEL for parental toxicity = 12.5 mg/kg (author)<br>NOAEL for fertility = 50 mg/kg<br>NOAEL for effects on offspring = 12.5 mg/kg (author) |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1 |
| Remarks: | Reliable without restriction |

**References**

Bussi, R. 2000. Genamin TA100: Reproduction/Developmental Toxicity Screening Test in Rats by Oral Route. APAG, Instituto di Ricerche Biomediche "Antoine Marxer" RBM S.p.A.

**Other available reports**

**Other**

| | |
|---|---|
| Last changed: | August 12, 2002 |
| Order number for sorting: | 225b |
| Remarks: | |

## 5.8 TOXICITY TO REPRODUCTION

**Test Substance**

| | |
|---|---|
| Identity: | Amine fluorides 335/242<br>[Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6] |
| Purity: | Amine fluoride 335 = 6.2%<br>Amine fluoride 242 = 7.0% |
| Remarks: | 1:1 mixture of each amine fluoride |

**Method**

| | |
|---|---|
| Method/guideline followed: | Segment I (Study of Fertility and General Reproductive Performance), Guidelines for Reproduction Studies for Safety Evaluation of Drugs for Human Use, U. S. Food and Drug Administration, 1966. |
| Type: | Oral |
| GLP: | Not stated |
| Year: | 1973 |
| Species: | Rat |
| Strain: | Long-Evans |
| Route of Administration: | Oral gavage |
| Doses/concentration levels: | 0, 1.2, 6.0 and 30.0 mg/kg/day |
| Sex: | Male and female |
| Control group and treatment: | Yes, 0.25% methylcellulose at 10 ml/kg/day |
| Frequency of treatment: | Once daily |
| Duration of test: | Treatment began for males and females at least 60 and 15 days, respectively, prior to and throughout mating of the $F_0$ generation, and continued for females during gestation and lactation for one litter. |
| Premating exposure period for males: | At least 60 days prior to mating |
| Premating exposure period for females: | At least 15 days prior to mating |
| Statistical methods: | Comparisons between control and test groups were made where applicable by the Chi-square method or the t-test, including Cochran's adjustment if the variances were significantly different (F-test) |
| Remarks: | Ten males and 20 females per group were exposed to the test substance by gavage at dose levels of 1.2, 6.0 and 30.0 mg/kg/day at a dose volume of 10 ml/kg/day in a vehicle of 0.25% methylcellulose for a prebreed period of 60 and 15 days, respectively. A control group with the same number of animals was treated with the vehicle only. Following the prebreed exposure period, one male and two females within |

each dose group were caged together until a sign of mating was observed, for a maximum 23-day mating period. Exposure to the test substance or vehicle continued through mating for males and females, and continued through gestation and lactation for females. Body weights were collected weekly for males. Body weights for females were collected weekly prior to evidence of mating, daily during gestation and on days 0 through 7, 14 and 21 of lactation. Physical observations were conducted daily for signs of pharmacologic or toxicologic effects, and mortality. Estrous cycle observations were performed beginning at study initiation and continuing until mating was observed or 23 days of cohabitation had been completed.

A gross necropsy was conducted on animals sacrificed at scheduled termination, on moribund animals, and on spontaneous deaths. The uterine contents were examined and implantation sites were counted for females that died prior to scheduled sacrifice. On gestation day 13 every other mated female in each group was sacrificed, and examined for evidence and status of embryos. An examination of the uterus, including the number and location of resorptions, embryos and implantation sites, and ovaries, including the number of corpora lutea, was conducted. Males were sacrificed after pregnancy was assured (by the presence of offspring) for at least two-thirds of the dams. The testes and epididymides were fixed in buffered neutral formalin.

The remaining females were allowed to deliver and lactate. Pups were examined for general condition and counted daily. They were checked for the presence of milk daily, until no longer discernible because of fur growth. Pups also were sexed and weighed individually on lactation days 0, 4 and 21. Pups that died prior to scheduled sacrifice were weighed, and examined externally and internally for malformations. The remaining dams and all surviving pups were sacrificed and necropsied on lactation day 21. The implantation scars of the dams were counted and the pups were weighed, examined externally and internally (for visceral gross pathology), and sexed internally.

**Results**

| | |
|---|---|
| NOAEL: | Parental NOAEL = 6.0 mg/kg/day<br>Offspring NOAEL = 30.0 mg/kg/day |
| Actual dose received: | 1.2, 6.0 and 30.0 mg/kg/day |
| $F_0$ and $F_1$ data: | One female in the high dose group died during the first week of premating. This death was not attributed to the administration of the test substance. There were no adverse effects that could be attributed to the test substance as evidenced in evaluations of female body weights and weight gains, adult mortality, mating performances, estrous cycles, pregnancy rates, lengths of gestation, intrauterine deaths, implantation efficiencies, numbers of implantations or litter size. A statistically significant decrease in mean body weight gain was observed in males for the high dose group when compared to the control group. No test substance-related gross pathology was observed in the males or females that were sacrificed or died spontaneously. |
| Offspring toxicity: | Evaluations of offspring viability, litter survival, offspring weight, sex ratio, and incidence of malformations showed no adverse effects attributable to administration of the test substance. Examination of the skeletons of pups dying prior to weaning revealed no malformations that could be attributed to administration of the test substance. |
| Statistical results: | Described above |
| Remarks: | |

**Conclusions:**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability: | 1A |
| Remarks: | Reliable without restriction; guideline study. |

**References**

Smith, J.M. 1973. A Segment I Rat Fertility Study of Amine Fluoride 335/242. Project Number 72R-817. Bio/dynamics Inc., East Millstone, NJ, USA.

**Other available reports:**

**Other**

| | |
|---|---|
| Last changed: | November 19, 2002 |
| Order number for sorting: | 27a |
| Remarks: | |

## 5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

**Test Substance**

| | |
|---|---|
| Identity: | Oleylamine (9-Octadecenylamine, (Z)-; (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/guideline followed: | US EPA TSCA 40 CFR Part 798.4700 |
| GLP: | Yes |
| Year: | 1989 |
| Species: | Rat |
| Strain: | Sprague Dawley Crl:COBS®CD®BR®VAF/PLUS® |
| Route of administration: | Oral gavage |
| Doses/concentration levels: | 0, 10, 40 and 80 mg/kg |
| Sex: | Female |
| Exposure period: | Days 6 through 15 of gestation |
| Frequency of treatment: | Daily |
| Control group and treatment: | Yes, 5 ml/kg corn oil |
| Duration of test: | Days 0 through 15 or 0 through 20 of gestation |
| Statistical methods: | Two-tailed tests, one-way analysis of variance, Dunnett's Test, Chi-Square Test, Mann-Whitney U-Test, Fisher's Exact Test |
| Remarks: | Groups of 28 mated female rats, 14 weeks old and weighing 229 to 316 g, were administered the test substance at dose levels of 10, 40 and 80 mg/kg/day at a dose volume of 5 ml/kg. The control rats received corn oil at an equivalent volume. All rats were administered the test substance and/or vehicle for ten consecutive days, from GD 6 through GD 15. The rats were observed daily, and individual body weights and food consumption were taken on GDs 0, 6, 9, 12, 16 and 20. Evidence of mating was determined by the presence of a copulatory plug in the vagina or a sperm positive vaginal smear and was considered day 0 of gestation. Two rats in each group were sacrificed after treatment on GD 15. The gastrointestinal tract was examined for signs of irritation. Cesarean sections were performed for the remaining rats on GD 20 and included a maternal necropsy examination. Individual gravid uterine weights were recorded. The fetuses were individually weighed, sexed and examined for external abnormalities. Fetuses were subsequently processed and examined for visceral and skeletal abnormalities. |

*Range-finding study:* A range-finding study was conducted prior to this study to provide information concerning the effects of Oleylamine when administered orally to pregnant rats on gestation day (GD) 6 through 15 to aid in dose level selection for the definitive developmental toxicity study. The test substance was administered at dose levels of 5, 50, 100, 150 and 250 mg/kg/day in corn oil at a dose volume of 5 ml/kg. A control group received corn oil at 5 ml/kg. Each group consisted of eight mated females. Two females from each group were sacrificed on GD 15 and examined for signs of gastrointestinal irritation. The study parameters evaluated in the range-finding study were identical to the definitive study except that at necropsy, the fetuses were examined externally and then discarded without further evaluation.

**Results**

| | |
|---|---|
| Maternal toxicity NOEL: | 10 mg/kg/day |
| Developmental toxicity NOEL: | 80 mg/kg/day |
| Actual dose received: | 10, 40 and 80 mg/kg |
| Maternal and fetal data: | All rats survive to scheduled sacrifice. Clinical signs of toxicity were observed at the 40 and 80 mg/kg/day dose levels. In the 40 and 80 mg/kg/day dose groups, the most notable clinical findings included rales, salivation, soft stools, diarrhea, few feces, abnormal colored feces, fecal and/or urine stain, and unkempt appearance. Clinical signs observed only in the 80 mg/kg/day dose group included emaciation, rough coat and dark red material around the eyes, nose and/or mouth. Significant post dose observations included salivation in the 40 and 80 mg/kg/day dose groups and rales in the 80 mg/kg/day dose group. Dose-dependent body weight losses or reduced weight gain, along with a corresponding reduction in food consumption occurred during the treatment period at the 40 and 80 mg/kg/day dose levels. Gross necropsy evaluation of the gastrointestinal tracts from females sacrificed on GD 15 revealed no irritative effects. No treatment-related changes were apparent at any level tested concerning necropsy observations, cesarean section data or fetal external, visceral or skeletal examinations. |
| Statistical results: | Described above |
| Remarks: | Range-finding study results: Treatment-related deaths occurred in the 100, 150 and 250 mg/kg/day dose groups. Outward clinical signs of toxicity occurred at |

dose levels of 50 mg/kg/day and higher. The findings were primarily related to changes in the amount, color and consistency of the feces. Other clinical signs included emaciation, unkempt appearance, dark red material around the eyes, nose and/or mouth and reddish colored vaginal discharge and/or urogenital staining. Post dose observations also revealed transient toxic signs including salivation, tremors, gasping, scratching at the cage floor and dragging chin on the cage floor. Body weight losses or reduced weight gain also occurred at dose levels from 50 mg/kg/day and higher throughout the treatment period. After treatment, weight gain was observed in all dose groups except the 150 mg/kg/day group. Necropsy findings of animals that did not survive to scheduled sacrifice included enlarged and/or dark red adrenals and dark red foci in the stomach mucosa. No other signs of gastrointestinal irritation were noted at the GD 15 sacrifice; however, dark red and enlarged adrenals were observed in the 100, 150 and 250 mg/kg/day groups. All of the females sacrificed on GD 20 were normal internally. The mean post-implantation loss was increased and the mean fetal weight was reduced at the 150 and 250 mg/kg/day group.

**Conclusions**

Remarks: Oral administration of 40 and 80 mg/kg/day of Oleylamine to pregnant CD® rats induced dose dependent maternal toxicity exhibited by adverse clinical signs, body weight losses and reduced food consumption. Oleylamine was neither developmentally toxic nor teratogenic at dosages up to 80 mg/kg/day. (Author of report)
The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study.

**References**

Mercieca, M. D. 1989. Teratology Study in Rats with Oleylamine. Study No. 3205.9. Springborn Laboratories Inc., Spencerville, OH, USA.
and
Mercieca, M. D. 1989. Range-Finding Teratology Study in Rats with Oleylamine. Study No. 3205.8. Springborn Laboratories Inc., Spencerville, OH, USA.

**Other**

| | |
|---|---|
| Last changed: | July 17, 2002 |
| Order number for sorting: | 29a |
| Remarks: | |

## 5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

**Test Substance**

| | |
|---|---|
| Identity: | Oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine) |
| Purity: | Not stated |
| Remarks: | |

**Method**

| | |
|---|---|
| Method/Guideline followed: | U.S. EPA TSCA 40 CFR 798.4700 |
| GLP: | Yes |
| Year: | 1989 |
| Species: | Rabbits |
| Strain: | New Zealand White |
| Route of administration: | Oral gavage |
| Doses/concentration levels: | 0, 3, 10 and 30 mg/kg/day |
| Sex: | Female |
| Exposure period: | Days 6 through 18 of gestation |
| Frequency of treatment: | Daily |
| Control group and treatment: | Yes (concurrent, dosed with corn oil at a dose volume of 0.5 ml/kg) |
| Duration of test: | Days 0 through 29 of gestation |
| Statistical methods: | Continuous data evaluated used a one-way ANOVA. If significant, group comparisons were performed using Dunnett's test. Count data analyzed using Chi-Square test for fetal sex ratios, Mann-Whitney U-Test for resorptions, and a Fisher's Exact test for the number of fetal variations and malformations. The doe or litter were considered the experimental unit of measure. |
| Remarks: | The test substance, in the vehicle corn oil, was administered orally to 3 groups of artificially inseminated female rabbits (22 rabbits/group). The vehicle alone was administered orally to one group of 22 rabbits. Animals were treated at dose levels of 0, 3, 10 and 30 mg/kg/day at a dose volume of 0.5 ml/kg. Animals were administered the test substance or vehicle for 13 consecutive days, from gestation day (GD) 6 through GD 18. Dose solutions were prepared daily. Animals were observed daily, and individual body weights and food consumption were measured on GD 0, 6, 9, 12, 15, 19, 24 and 29. Two animals from each group were sacrificed after treatment on GD 18. Fecal samples were collected from these animals to determine the proportion of gram positive to gram negative organisms in the microflora. The gastrointestinal tract also was examined for signs of |

irritation. Cesarean sections were performed on the surviving animals on GD 29 and included a maternal necropsy examination. Individual gravid uterine weights were recorded. The fetuses were individually weighed, sexed and examined for external abnormalities. Fetuses subsequently were processed and examined for visceral and skeletal abnormalities.
*Range-finding study:* A range-finding study was conducted prior to this study to provide information concerning the effects of Oleylamine when administered orally to pregnant rabbits on gestation day (GD) 6 through 18 to aid in dose level selection for the definitive developmental toxicity study. The test substance was administered at dose levels of 5, 25, 50, 100 and 150 mg/kg/day in corn oil at a dose volume of 5 ml/kg. A control group received corn oil at 5 ml/kg. Each group consisted of seven mated female rabbits. The study parameters evaluated in the range-finding study were identical to the definitive study except that at necropsy, the fetuses were examined externally and then discarded without further evaluation.

**Results**

| | |
|---|---|
| Maternal toxicity NOEL: | 3 mg/kg/day |
| Developmental toxicity NOEL: | 30 mg/kg/day |
| Actual dose received: | 0, 3, 10 and 30 mg/kg/day |
| Maternal data: | Two females died in the 30 mg/kg/day group. Clinical signs of toxicity and irritation of the lips and chin were observed in animals dosed at 10 and 30 mg/kg/day. Salient clinical signs at 10 and 30 mg/kg/day included labored breathing and rales. Animals at 30 mg/kg/day were also emaciated. Dose-dependent body weight losses or reduced weight gain, along with a corresponding reduction in food consumption occurred during the treatment period in animals dosed at 10 and 30 mg/kg/day. Gross necropsy evaluation of the gastrointestinal tracts from females sacrificed on GD 18 revealed no signs of gastrointestinal irritation. No treatment-related changes were apparent at any level tested concerning necropsy observations or cesarean section data. |
| Fetal data: | The mean fetal weight of the 30 mg/kg/day group was slightly lower than the control group; however not statistically significant. A similar lower mean occurred in the 3 mg/kg/day but not at 10 mg/kg/day, where the mean fetal weight was comparable to the control value. This lack of a dose response in addition |

to the variability of the fetal weights suggests that the apparent lower mean in the 30 mg/kg/day group was not related to treatment. No treatment-related changes were apparent at any level tested concerning fetal morphological examinations.

Statistical results: Mean maternal body weights were significantly reduced in the 30 mg/kg/day group on GD 19. Mean maternal body weight gains were significantly reduced in the 30 mg/kg/day group for all intervals throughout the treatment period (GD 6-19). A significant increase in weight gain was observed in this group from GD 19 to 24 indicating a recovery from the affects of the test substance. Both absolute and relative food consumption were significantly reduced in the 30 mg/kg/day group as compared to control for the entire treatment interval (GD 6-19) and the entire gestation interval (GD 0-29).

Remarks: R*ange-finding study results:* Treatment-related moralities occurred in the 50, 100 and 150 mg/kg/day groups. Two females in the 50 mg/kg/day group died and all females in the 100 and 150 mg/kg/day group died prior to study termination. One female aborted at the 50 mg/kg/day dose level. Clinical signs of toxicity were observed at all dose levels tested and included rales, labored breathing, emaciation, changes in the amount and consistency of feces, no urine and fecal stain. In addition, irritation of the lips and chin characterized by swollen, raised white areas progressing to scab-like lesions and sloughing of the tissue, were observed in animals dosed at 25, 50, 100 and 150 mg/kg/day. Various signs were also observed following dosing including salivation, labored breathing, gasping, cyanosis, rales and decreased activity. Body weight losses occurred during the treatment period in animals dosed at 25 mg/kg/day and above. Necropsy findings for the animals that died were indicative of an irritative effect on the epithelial lining of the stomach. Pale yellow, cheesy material was found in the trachea in one animal each in the 5, 25 and 50 mg/kg/day groups during the day 18 sacrifice. The proportion of gram negative to gram positive bacteria appeared to be consistent at 24 and 48 hours in the treated groups and the control groups. The females sacrificed for cesarean section were internally normal. The mean post implantation loss was increased at the 50 mg/kg/day dose level. No other changes were observed in the cesarean section data.

One fetus in the 25 mg/kg/day group had an omphalocele. All other fetuses were normal externally.

**Conclusions**

Remarks: Oleylamine was neither developmentally toxic nor teratogenic at dose levels of 3, 10 and 30 mg/kg/day. (Author of the study report)
The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A
Remarks: Reliable without restriction; guideline study.

**References**

Mercieca, M. D. 1989. Teratology Study in Rabbits with Oleylamine. Study No. 3205.11. Springborn Life Sciences, Inc., USA.
and
Mercieca, M. D. 1989. Range-Finding Teratology Study in Rabbits with Oleylamine. Study No. 3205.10. Springborn Life Sciences, Inc., USA.

**Other**

Last changed: July 17, 2002
Order number for sorting: 29c
Remarks:

## 5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

**Test Substance**

| | |
|---|---|
| Identity: | Amine fluorides 335/242<br>[Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6] |
| Purity: | Not provided in this report; however, the following information was provided in a Segment I study performed at this laboratory in the same time frame by the same author:<br>Amine fluoride 335 = 6.2%<br>Amine fluoride 242 = 7.0% |
| Remarks: | 1:1 mixture of each amine fluoride |

**Method**

| | |
|---|---|
| Method/guideline followed: | Segment II (Teratology Study), Guidelines for Reproduction Studies for Safety Evaluation of Drugs for Human Use, U. S. Food and Drug Administration, 1966 |
| GLP: | No |
| Year: | 1973 |
| Species: | Rat |
| Strain: | Long-Evans |
| Route of administration: | Oral gavage |
| Doses/concentration levels: | 1.2, 6.0 and 30.0 mg/kg |
| Sex: | Female |
| Exposure period: | Days 6 through 15 of gestation |
| Frequency of treatment: | Daily |
| Control group and treatment: | Yes, 0.25% methylcellulose |
| Duration of test: | Days 0 through 21 of gestation |
| Statistical methods: | Comparisons between control and test groups were made where applicable by the Chi-square method or the t-test, including Cochran's adjustment if the variances were significantly different (F-test). |
| Remarks: | Twenty mated female rats/group were exposed to the test substance by oral gavage at dose levels of 1.2, 6.0 and 30.0 mg/kg/day at a dose volume of 10 ml/kg/day in a vehicle of 0.25% methylcellulose from day 6 through day 15 of gestation. A control group of 20 animals was treated with the vehicle only. Body weights were taken on gestation days 0, 6 through 15 (daily) and 21. Physical observations were conducted daily for signs of pharmacologic or toxicologic effects, and mortality. A gross necropsy was conducted on animals sacrificed at scheduled termination, on moribund animals, and on spontaneous deaths. Dams that aborted or delivered early were sacrificed on the |

day clear signs of abortion or early delivery were observed, and the reproductive system was examined. Fetuses less than 19 days old were fixed in buffered neutral formalin and those 19 days or older were cleared and stained. All surviving dams were sacrificed at study termination on gestation day 21. An examination of the uterus, including the number and location of live and dead fetuses, early and late resorptions, and implantation sites, and ovaries, including the number of corpora lutea, was conducted. At sacrifice all fetuses were identified, weighed, crown-rump distance measured and examined externally for malformations, and the external sex was determined. In approximately two-thirds of the fetuses, gross dissection and examination of viscera, and internal sex determination were conducted as well as an examination of the skeleton for anomalies and ossification variations after clearing and alizarin red staining of the fetuses. The remaining one-third of the fetuses were fixed with Bouin's and examined for neural and visceral defects after being serially sectioned by the Wilson slicing technique. Additionally, sex was determined internally.

**Results**

| | |
|---|---|
| Maternal toxicity NOEL: | 30.0 mg/kg/day |
| Developmental toxicity NOEL: | Not determined. Study repeated. |
| Actual dose received: | 1.2, 6.0 and 30.0 mg/kg/day |
| Maternal data: | There were 16, 16, 16 and 20 pregnant animals in the control, 1.2, 6.0 and 30.0 mg/kg dose groups, respectively. There were no adverse effects upon maternal body weight, pregnancy rate, mortality, early deliveries or abortions, implantation efficiency, or resorptions. |
| Fetal data: | There were no dead fetuses in any group. There were no adverse effects upon fetal size or fetal sex. There was no biologic or toxicologic significance attached to the incidence of ossification variations observed in this study. The incidence of malformed fetuses was 0, 0.6, 0.5 and 3.1% in the control, low, mid and high dose groups, respectively. The malformations observed in this study had been reported to occur spontaneously in control animals of other studies; however, because of the zero incidence of malformations in the control group of this study, it could not be concluded that there was no contributory effect of the test substance. |
| Statistical results: | Described above |

| | |
|---|---|
| Remarks: | Because of the observation of sporadic malformations in the treatment groups and absence of these malformations in the control group of this study, which had been observed in control animals of other studies, this study was repeated using the exact methods of this study and was identified by Bio/dynamics project number 73R-880 (see following robust summary). |

**Conclusions**

| | |
|---|---|
| Remarks: | The study was repeated due to equivocal results. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1A |
| Remarks: | Reliable without restriction; guideline study. |

**References**

Smith, J.M. 1973. A Segment II Rat Teratology Study of Amine Fluoride 335/242. Project Number 72R-820. Bio/dynamics Inc., East Millstone, NJ, USA.

**Other available reports**

**Other**

| | |
|---|---|
| Last changed: | November 19, 2002 |
| Order number for sorting: | 178/195 |
| Remarks: | |

## 5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

**Test Substance**

| | |
|---|---|
| Identity: | Amine fluorides 335/242<br>[Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6] |
| Purity: | Not provided in this report; however, the following information was provided in a Segment I study performed at this laboratory in the same time frame by the same author:<br>Amine fluoride 335 = 6.2%<br>Amine fluoride 242 = 7.0% |
| Remarks: | 1:1 mixture of each amine fluoride |

**Method**

| | |
|---|---|
| Method/guideline followed: | Segment II (Teratological Study), Guidelines for Reproduction Studies for Safety Evaluation of Drugs for Human Use, U. S. Food and Drug Administration, 1966 |
| GLP: | No |
| Year: | 1973 |
| Species: | Rat |
| Strain: | Long-Evans |
| Route of administration: | Oral gavage |
| Doses/concentration levels: | 1.2, 6.0 and 30.0 mg/kg |
| Sex: | Female |
| Exposure period: | Days 6 through 15 of gestation |
| Frequency of treatment: | Daily |
| Control group and treatment: | Yes, 0.25% methylcellulose |
| Duration of test: | Days 0 through 21 of gestation |
| Statistical methods: | Comparisons between control and test groups were made where applicable by the Chi-square method or the t-test, including Cochran's adjustment if the variances were significantly different (F-test). |
| Remarks: | To clarify the results of a previously reported study (Bio/dynamics project number 72R-820) in which sporadic malformations were observed, the test substance was administered under identical conditions. Twenty mated female rats/group were exposed to the test substance by oral gavage at dose levels of 1.2, 6.0 and 30.0 mg/kg/day at a dose volume of 10 ml/kg/day in a vehicle of 0.25% methylcellulose from day 6 through day 15 of gestation. A control group of 20 animals was treated with the vehicle only. Body weights were taken on gestation days 0, 6 through 15 (daily) and 21. Physical observations were conducted daily for signs of pharmacologic or toxicologic effects, |

and mortality. A gross necropsy was conducted on animals sacrificed at scheduled termination, on moribund animals, and on spontaneous deaths. Dams that aborted or delivered early were sacrificed on the day clear signs of abortion or early delivery were observed, and the reproductive system was examined. Fetuses less than 19 days old were fixed in buffered neutral formalin and those 19 days or older were cleared and stained. All surviving dams were sacrificed at study termination on gestation day 21. An examination of the uterus, including the number and location of live and dead fetuses, early and late resorptions, and implantation sites, and ovaries, including the number of corpora lutea, was conducted. At sacrifice all fetuses were identified, weighed, crown-rump distance measured and examined externally for malformations, and the external sex was determined. In approximately two-thirds of the fetuses gross dissection and examination of viscera, and internal sex determination were conducted as well as an examination of the skeleton for anomalies and ossification variations after clearing and alizarin red staining of the fetuses. The remaining one-third of the fetuses were fixed with Bouin's and examined for neural and visceral defects after being serially sectioned by the Wilson slicing technique. Additionally, sex was determined internally.

**Results**

| | |
|---|---|
| Maternal toxicity NOAEL: | 6.0 mg/kg/day |
| Developmental toxicity NOAEL: | 30.0 mg/kg/day |
| Actual dose received: | 1.2, 6.0 and 30.0 mg/kg/day |
| Maternal data: | There were 19, 18, 18 and 17 pregnant animals in the control, 1.2, 6.0 and 30.0 mg/kg dose groups, respectively. One dam died on gestation day 10, but the death was not considered test substance-related as it was the result of a dosing accident. A statistically significant decrease in the mean weight gains of the high dose group dams was observed when compared to the control group. There were no adverse effects upon pregnancy rate, mortality, early deliveries, implantation efficiency, or resorptions. |
| Fetal data: | There were no dead fetuses in any group. There were no adverse effects upon fetal size or fetal sex. The incidences of delay in ossification were almost identical for control and test groups. |
| Statistical results: | Described above |

| | |
|---|---|
| Remarks: | In the absence of any malformed fetuses in the high dose group, the test substance was considered to be nonteratogenic when administered to rats under the conditions of this study. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1A |
| Remarks: | Reliable without restriction; guideline study. |

**References**

Smith, J.M. 1973. Segment II Rat Teratology Study of Amine Fluoride 335/242. Project Number 73R-880. Bio/dynamics Inc., East Millstone, NJ, USA.

**Other available reports**

**Other**

| | |
|---|---|
| Last changed: | November 19, 2002 |
| Order number for sorting: | 179/196 |
| Remarks: | |

## 5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

**Test Substance**

| | |
|---|---|
| Identity: | Amine fluorides 335/242<br>[Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6] |
| Purity: | Not provided in this report; however, the following information was provided in a Segment I study performed at this laboratory in the same time frame by the same author:<br>Amine fluoride 335 = 6.2%<br>Amine fluoride 242 = 7.0% |
| Remarks: | 1:1 mixture of each amine fluoride |

**Method**

| | |
|---|---|
| Method/guideline followed: | Segment II (Teratology Study), Guidelines for Reproduction Studies for Safety Evaluation of Drugs for Human Use, U. S. Food and Drug Administration, 1966 |
| GLP: | No |
| Year: | 1973 |
| Species: | Rabbit |
| Strain: | New Zealand White |
| Route of administration: | Oral gavage |
| Doses/concentration levels: | 1.2, 6.0 and 30.0 mg/kg |
| Sex: | Female |
| Exposure period: | Days 7 through 19 of gestation |
| Frequency of treatment: | Daily |
| Control group and treatment: | Yes, 0.25% methylcellulose |
| Duration of test: | Days 0 through 30 of gestation |
| Statistical methods: | Comparisons between control and test groups were made where applicable by the Chi-square method or the t-test, including Cochran's adjustment if the variances were significantly different (F-test). |
| Remarks: | Fourteen, 19 and 18 mated female rabbits were exposed to the test substance by oral gavage at dose levels of 1.2, 6.0 and 30.0 mg/kg/day, respectively, at a dose volume of 1 ml/kg/day in a vehicle of 0.25% methylcellulose from days 7 through day 19 of gestation. A control group with 17 animals was treated with the vehicle only. Body weights were taken on gestation days 0, 7, 10, 13, 16, 19, 24 and 30. Physical observations were conducted daily for signs of pharmacologic or toxicologic effects, and mortality. A gross necropsy was conducted on animals sacrificed at scheduled termination, on moribund animals, and on spontaneous deaths. Dams that aborted or delivered |

early were sacrificed on the day clear signs of abortion or early delivery were observed, and the reproductive system was examined. Fetuses less than 28 days old were fixed in buffered neutral formalin and those 28 days or older were cleared and stained. All surviving dams were sacrificed at study termination on gestation day 30. An examination of the uterus, including the number and location of live and dead fetuses, early and late resorptions, and implantation sites, and ovaries, including the number of corpora lutea, was conducted. At sacrifice, fetuses were identified, weighed, crown-rump distance measured and examined externally for defects. Gross dissection and examination of viscera, and internal sex determination also were conducted on each fetus. Finally, an examination of the skeleton for anomalies and ossification variations was conducted after clearing and alizarin red staining of the fetuses.

**Results**

Maternal toxicity NOEL: Not determined. The LOAEL = 1.2 mg/kg/day

Developmental toxicity NOEL: 30 mg/kg/day

Actual dose received: 1.2, 6.0 and 30.0 mg/kg/day

Maternal data: There were 12, 11, 13 and 13 pregnant animals in the control, 1.2, 6.0 and 30.0 mg/kg dose groups, respectively. A statistically significant decrease in maternal body weight gain in the low dose group was observed. In addition, increased maternal mortality in the mid and high dose groups was observed. Six females (three mid dose and three high dose) died between gestation days 12 and 24. Of those animals that died, one high dose and two mid dose does were pregnant. One high and two mid dose does had lesions compatible with those of toxemia (one mid dose death was considered related to pneumonia, the other two deaths being of an unknown origin); and one high dose doe had acute pneumonia. The post mortem condition of the other high-dose doe precluded a meaningful evaluation. The cause of death of the other mid dose doe was unknown. Effects described above were attributed to a secondary toxemia resulting from the antibacterial properties of the amine fluorides against Gram-positive bacteria followed by an overgrowth of Gram-negative bacteria. The incidences of resorptions in all treatment groups were substantially greater when comparisons were made to the control group incidence. This increase in resorptions was statistically significant in the high dose group only (25 resorbed of the total

103 fetuses). The cause of the increases in the number of resorptions could not be determined Due to the increases in mortality and secondary toxemia of the does. There were no adverse effects upon pregnancy rate, or incidences of early deliveries and abortions that could be attributed to the administration of the test substance.

Fetal data: There were no dead fetuses in any group. Four fetuses (two low dose, one mid dose and one high dose) were observed to be malformed. This low incidence was not considered to express evidence of a teratogenic effect resulting from the administration of the test substance. There were no adverse effects upon fetal size, fetal sex or ossification variations that could be attributed to the administration of the test substance.

Statistical results: Described above

Remarks:

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A

Remarks: Reliable without restriction; guideline study.

**References**

Smith, J.M. 1973. Amine Fluoride 335/242 Segment II Rabbit Teratology Study. Project Number 72R-818. Bio/dynamics Inc., East Millstone, NJ, USA.

**Other available reports**

**Other**

Last changed: November 19, 2002

Order number for sorting: 177/194

Remarks:

## 5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

**Test Substance**

| | |
|---|---|
| Identity: | Amine fluorides 335/242<br>[Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6] |
| Purity: | Not provided in this report; however, the following information was provided in a Segment I study performed at this laboratory in the same time frame by the same author:<br>Amine fluoride 335 = 6.2%<br>Amine fluoride 242 = 7.0% |
| Remarks: | 1:1 mixture of each amine fluoride |

**Method**

| | |
|---|---|
| Method/guideline followed: | Segment III (Perinatal and Postnatal Study), Guidelines for Reproduction Studies for Safety Evaluation of Drugs for Human Use, U. S. Food and Drug Administration, 1966 |
| GLP: | No |
| Year: | 1973 |
| Species: | Rat |
| Strain: | Long-Evans |
| Route of administration: | Oral gavage |
| Doses/concentration levels: | 1.2, 6.0 and 30.0 mg/kg |
| Sex: | Female |
| Exposure period: | Day 15 of gestation through Day 21 of lactation |
| Frequency of treatment: | Daily |
| Control group and treatment: | Yes, 0.25% methylcellulose |
| Duration of test: | Day 0 of gestation through Day 21 of lactation |
| Statistical methods: | Comparisons between control and test groups were made where applicable by the Chi-square method or the t-test, including Cochran's adjustment if the variances were significantly different (F-test). |
| Remarks: | Female rats were administered the test substance by oral gavage at dose levels of 1.2, 6.0 and 30.0 mg/kg/day at a dose volume of 10 ml/kg/day in a vehicle of 0.25% methylcellulose from day 15 of gestation through day 21 of lactation. A control group was treated with the vehicle only. The 0 (control), 1.2 and 6.0 mg/kg/day groups each contained 20 mated female rats and the 30.0 mg/kg/day group contained 22 mated female rats. Body weights were obtained during gestation on days 0 and 7, and daily from day 15 through the end of the gestation period. During lactation, body weights were obtained on days 0 through 7 (daily), 14 and 21. Physical observations |

were conducted daily for signs of pharmacologic or toxicologic effects, and mortality. A gross necropsy was conducted on animals sacrificed at scheduled termination, on moribund animals, and on spontaneous deaths. Toward the end of gestation dams were provided with nesting material and examined daily for signs of parturition. The uterine contents were examined and implantation sites were counted for females that died during gestation, prior to scheduled sacrifice. Pups were examined for general condition and counted daily. They were checked for the presence of milk daily, until no longer discernible because of fur growth. Pups also were sexed and weighed individually on lactation days 0, 4 and 21. Pups that died prior to scheduled sacrifice were weighed, and examined externally. They were examined internally for sex determination and for the presence of milk in the stomach. Finally, they were preserved for studies of skeletal anomalies. If the entire litter died prior to lactation day 21, the dam was sacrificed, the mammary tissue was saved in buffered neutral formalin, and implantation scars were counted. If dams died prior to lactation day 21, the mammary tissue was saved in buffered neutral formalin, and implantation scars were counted. Surviving pups were sacrificed, and the same procedures were used for dead pups. The remaining dams and all surviving pups were sacrificed and necropsied on lactation day 21. The implantation scars of the dams were counted and the pups were individually weighed, examined externally and internally (for visceral gross pathology), and sexed internally.

**Results**

Maternal toxicity NOEL: 30.0 mg/kg/day

Developmental toxicity NOEL: 30.0 mg/kg/day

Actual dose received: 1.2, 6.0 and 30.0 mg/kg/day

Maternal data: There were 19, 19, 19 and 18 pregnant animals in the control, 1.2, 6.0 and 30.0 mg/kg dose groups, respectively. There were no adverse effects upon pregnancy rate, mortality, length of gestation, number of implantations, live-birth index, postnatal viability, offspring weights on lactation days 4 and 21, sex ratios, or soft-tissue malformations. There was a smaller maternal body weight gain during the period of lactation in the high dose group when compared to the controls, although this difference was not statistically

| | |
|---|---|
| | significant. |
| Fetal data: | There were no dead fetuses in any group. There were no adverse effects upon fetal size, fetal sex or ossification variations that could be attributed to the administration of the test substance. The mean offspring weights of all the test substance-treated groups were lower than the controls on lactation day 0, although this difference was not statistically significant, and were comparable thereafter. |
| Statistical results: | Described above |
| Remarks: | The administration of amine fluoride 335/242 was considered not to have a biologic or toxicologic effect in this study. |

**Conclusions**

| | |
|---|---|
| Remarks: | The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group) |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1A |
| Remarks: | Reliable without restriction; guideline study. |

**References**

Smith, J.M. 1973. A Segment III Perinatal and Postnatal Study of Amine Fluoride 335/242 in Rats. Project Number 72R-819. Bio/dynamics Inc., East Millstone, NJ, USA.

**Other available reports**

**Other**

| | |
|---|---|
| Last changed: | November 19, 2002 |
| Order number for sorting: | 176/197 |
| Remarks: | |

# Appendix B

# Robust Summaries for SAR Model Data

## Index of Robust Summaries for SAR Model Data
## ACC FND Panel - Amines Task Group

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## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Propanamine, 3-(isodecyloxy)- (CAS RN 30113-45-2)

| | |
|---|---|
| Melting Point (ºC) | 51 |
| Boiling Point (ºC) | 278 |
| Vapor Pressure (hPa) | 0.0035 |
| Partition Coefficient (log $K_w$) | 3.92 |
| Water Solubility (mg/l) | 165 |
| Photodegradation (cm3/molecule-sec) [$t_{1/2}$ (hr)] | 64 E-12 [2.0] |
| Hydrolysis [$t_{1/2}$ (hr)] | NC |
| Level III Fugacity (All input to water) | Air: <1%<br>Water: 90%<br>Soil: <1%<br>Sediment: 10% |
| Acute Fish Toxicity - 96-hour $LC_{50}$ (mg/l) | 126 – as cationic surfactant<br>3.50– as aliphatic amine |
| Acute Toxicity to Aquatic Invertebrates - 48-hour $EC_{50}$ (mg/l) | 7.9 – as cationic surfactant<br>0.33– as aliphatic amine |
| Toxicity to Aquatic Plants - 96-hour $EC_{50}$ (mg/l) | NC – as cationic surfactant<br>1.21– as aliphatic amine |

NC – Not calculated by Model

### Model Input/Output

```
SMILES : NCCCOCCCCCCCC(C)C
CHEM   : 1-Propanamine, 3-(isodecyloxy)-
CAS NUM: 030113-45-2
MOL FOR: C13 H29 N1 O1
MOL WT : 215.38
------------------------------ EPI SUMMARY (v3.05) --------------------------
 Physical Property Inputs:
    Water Solubility (mg/L):   ------
    Vapor Pressure (mm Hg) :   ------
    Henry LC (atm-m3/mole) :   ------
    Log Kow (octanol-water):   ------
    Boiling Point (deg C)  :   ------
    Melting Point (deg C)  :   ------

 Log Octanol-Water Partition Coef (SRC):
    Log Kow (KOWWIN v1.66 estimate) =  3.92

 Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):
    Boiling Pt (deg C):  278.48  (Adapted Stein & Brown method)
    Melting Pt (deg C):  51.27  (Mean or Weighted MP)
    VP(mm Hg,25 deg C):  0.00348  (Modified Grain method)

 Water Solubility Estimate from Log Kow (WSKOW v1.37):
    Water Solubility at 25 deg C (mg/L):  165.1
       log Kow used: 3.92 (estimated)
```

```
      no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):
   Class(es) found:
      Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
  Bond Method :   2.00E-006  atm-m3/mole
  Group Method:   4.99E-007  atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]:  5.973E-006 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):
   Linear Model         :   0.4515
   Non-Linear Model     :   0.0855
Expert Survey Biodegradation Results:
   Ultimate Survey Model:   2.7390  (weeks-months)
   Primary Survey Model :   3.5705  (days-weeks  )
Readily Biodegradable Probability (MITI Model):
   Linear Model         :   0.5504
   Non-Linear Model     :   0.5375

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:
  Hydroxyl Radicals Reaction:
     OVERALL OH Rate Constant =  63.5274 E-12 cm3/molecule-sec
     Half-Life =     0.168 Days (12-hr day; 1.5E6 OH/cm3)
     Half-Life =     2.020 Hrs
  Ozone Reaction:
     No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):
     Koc    :  1261
     Log Koc:  3.101

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
   Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):
   Log BCF =  2.322  (BCF = 209.9)
      log Kow used: 3.92 (estimated)

Volatilization from Water:
   Henry LC:  4.99E-007 atm-m3/mole  (estimated by Group SAR Method)
   Half-Life from Model River:       1723  hours   (71.81 days)
   Half-Life from Model Lake : 1.892E+004  hours   (788.5 days)

Removal In Wastewater Treatment:
   Total removal:              26.57  percent
   Total biodegradation:        0.29  percent
   Total sludge adsorption:    26.25  percent
   Total to Air:                0.02  percent

Level III Fugacity Model:
         Concentration   Half-Life    Emissions
           (percent)        (hr)       (kg/hr)
  Air       0.274           4.04         1000
  Water     28.7            900          1000
  Soil      67.7            900          1000
```

```
   Sediment  3.32            3.6e+003     0
     Persistence Time: 652 hr

-------------------------------------------------------------------------------

CHEM   : 30113452
CAS Num: 30113452
ChemID1:
ChemID2:
ChemID3:
WatDisp: 165.1 mg/L

Avg Length Carbon Chain: 9.00
```

**ECOSAR Class: Surfactants, Cationic (C < 16)**

| Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|
| Daphnid | acute | LC50 | 7.943 |
| Fish | acute | LC50 | 125.892 |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none
```

**ECOSAR v0.99f Class(es) Found**
**----------**
**Aliphatic Amines**

| ECOSAR Class | Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|---|
| Neutral Organic SAR (Baseline Toxicity) | : Fish | 14-day | LC50 | 6.150 |
| Aliphatic Amines | : Fish | 96-hr | LC50 | 3.503 |
| Aliphatic Amines | : Daphnid | 48-hr | LC50 | 0.331 |
| Aliphatic Amines | : Green Algae | 96-hr | EC50 | 1.213 |
| Aliphatic Amines | : Green Algae | 96-hr | ChV | 0.422 |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none

Level III Fugacity Model (Full-Output):
========================================
  Chem Name   : 1-Propanamine, 3-(isodecyloxy)-
```

```
Molecular Wt: 215.38
Henry's LC  : 4.99e-007 atm-m3/mole (Henrywin program)
Vapor Press : 0.00348 mm Hg  (Mpbpwin program)
Liquid VP   : 0.00633 mm Hg  (super-cooled)
Melting Pt  : 51.3 deg C (Mpbpwin program)
Log Kow     : 3.92  (Kowwin program)
Soil Koc    : 3.41e+003  (calc by model)

        Concentration   Half-Life    Emissions
          (percent)        (hr)       (kg/hr)
 Air       0.00242         4.04         0
 Water     89.6            900          1000
 Soil      0.0151          900          0
 Sediment  10.4            3.6e+003     0

           Fugacity    Reaction    Advection   Reaction    Advection
            (atm)      (kg/hr)      (kg/hr)    (percent)   (percent)
 Air       1.71e-014    2.58        0.15        0.258       0.015
 Water     6.4e-012     428         556         42.8        55.6
 Soil      1.47e-016    0.0722      0           0.00722     0
 Sediment  4.5e-012     12.4        1.29        1.24        0.129

 Persistence Time: 620 hr
 Reaction Time:    1.4e+003 hr
 Advection Time:   1.11e+003 hr
 Percent Reacted:  44.3
 Percent Advected: 55.7

 Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
    Air:      4.042
    Water:    900
    Soil:     900
    Sediment: 3600
      Biowin estimate: 2.739  (weeks-months)

 Advection Times (hr):
    Air:      100
    Water:    1000
    Sediment: 5e+004
```

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Propanamine, 3-(tridecyloxy)-, branched (CAS RN 68511-40-0)

| | |
|---|---|
| Melting Point (ºC) | 81 |
| Boiling Point (ºC) | 322 |
| Vapor Pressure (hPa) | 0.00017 |
| Partition Coefficient (log $K_w$) | 5.40 |
| Water Solubility (mg/l) | 5.38 |
| Photodegradation (cm3/molecule-sec) [$t_{1/2}$ (hr)] | 68 E-12 [1.9] |
| Hydrolysis [$t_{1/2}$ (hr)] | NC |
| Level III Fugacity (All input to water) | Air: <1%<br>Water: 26%<br>Soil: <1%<br>Sediment: 74% |
| Acute Fish Toxicity - 96-hour $LC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Acute Toxicity to Aquatic Invertebrates - 48-hour $EC_{50}$ (mg/l) | 3.24 – as cationic surfactant<br>0.05 – as aliphatic amine |
| Toxicity to Aquatic Plants - 96-hour $EC_{50}$ (mg/l) | NC – as cationic surfactant<br>0.33 – as aliphatic amine |

NC – Not calculated by Model
NTS – Model indicates "Not Toxic at Solubility"

### Model Input/Output

```
SMILES : NCCCOCCCCCCCCCCC(C)C
CHEM   : 1-Propanamine, 3-(tridecyloxy)-, branched
CAS NUM: 068511-40-0
MOL FOR: C16 H35 N1 O1
MOL WT : 257.46
------------------------------ EPI SUMMARY (v3.05) --------------------------
 Physical Property Inputs:
    Water Solubility (mg/L):   ------
    Vapor Pressure (mm Hg) :   ------
    Henry LC (atm-m3/mole) :   ------
    Log Kow (octanol-water):   ------
    Boiling Point (deg C)  :   ------
    Melting Point (deg C)  :   ------

 Log Octanol-Water Partition Coef (SRC):
    Log Kow (KOWWIN v1.66 estimate) =  5.40

 Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):
    Boiling Pt (deg C):  322.28  (Adapted Stein & Brown method)
    Melting Pt (deg C):  80.96  (Mean or Weighted MP)
    VP(mm Hg,25 deg C):  0.000174  (Modified Grain method)

 Water Solubility Estimate from Log Kow (WSKOW v1.37):
    Water Solubility at 25 deg C (mg/L):  5.377
```

```
      log Kow used: 5.40 (estimated)
      no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):
   Class(es) found:
      Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
  Bond Method :   4.68E-006  atm-m3/mole
  Group Method:   1.41E-006  atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]:  1.096E-005 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):
   Linear Model         :   0.4314
   Non-Linear Model     :   0.0489
Expert Survey Biodegradation Results:
   Ultimate Survey Model:   2.6460  (weeks-months)
   Primary Survey Model :   3.5098  (days-weeks  )
Readily Biodegradable Probability (MITI Model):
   Linear Model         :   0.5735
   Non-Linear Model     :   0.5557

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:
  Hydroxyl Radicals Reaction:
     OVERALL OH Rate Constant =  67.7665 E-12 cm3/molecule-sec
     Half-Life =     0.158 Days (12-hr day; 1.5E6 OH/cm3)
     Half-Life =     1.894 Hrs
  Ozone Reaction:
     No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):
     Koc    :  7909
     Log Koc:  3.898

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
   Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):
   Log BCF =  2.456  (BCF = 286)
      log Kow used: 5.40 (estimated)

Volatilization from Water:
   Henry LC:  1.41E-006 atm-m3/mole  (estimated by Group SAR Method)
   Half-Life from Model River:      667.9  hours   (27.83 days)
   Half-Life from Model Lake :       7421  hours   (309.2 days)

Removal In Wastewater Treatment:
   Total removal:              86.88  percent
   Total biodegradation:        0.74  percent
   Total sludge adsorption:    86.14  percent
   Total to Air:                0.01  percent

Level III Fugacity Model:
         Concentration   Half-Life    Emissions
           (percent)        (hr)       (kg/hr)
  Air       0.175           3.79         1000
  Water     14.3            900          1000
```

```
   Soil      44.6            900          1000
   Sediment  40.9            3.6e+003     0
     Persistence Time: 978 hr

CHEM   : 68511400
CAS Num: 68511400
ChemID1:
ChemID2:
ChemID3:
WatDisp: 5.377 mg/L

Avg Length Carbon Chain: 12.00
```

**ECOSAR Class: Surfactants, Cationic (C < 16)**

| Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|
| Daphnid | acute | LC50 | 3.236 |
| Fish | acute | LC50 | 9.772 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none
```

**ECOSAR v0.99f Class(es) Found**
**----------**
**Aliphatic Amines**

| ECOSAR Class | Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|---|
| Neutral Organic SAR (Baseline Toxicity) | : Fish | 14-day | LC50 | 0.378 |
| Aliphatic Amines | : Fish | 96-hr | LC50 | 0.473 * |
| Aliphatic Amines | : Daphnid | 48-hr | LC50 | 0.054 |
| Aliphatic Amines | : Green Algae | 96-hr | EC50 | 0.330 |
| Aliphatic Amines | : Green Algae | 96-hr | ChV | 0.161 |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none

Level III Fugacity Model (Full-Output):
========================================
  Chem Name   : 1-Propanamine, 3-(tridecyloxy)-, branched
  Molecular Wt: 257.46
  Henry's LC  : 1.41e-006 atm-m3/mole (Henrywin program)
  Vapor Press : 0.000174 mm Hg  (Mpbpwin program)
```

```
Liquid VP   : 0.000622 mm Hg  (super-cooled)
Melting Pt  : 81 deg C (Mpbpwin program)
Log Kow     : 5.4  (Kowwin program)
Soil Koc    : 1.03e+005  (calc by model)

        Concentration   Half-Life    Emissions
          (percent)        (hr)       (kg/hr)
 Air       0.00163         3.79         0
 Water     26              900          1000
 Soil      0.00374         900          0
 Sediment  74              3.6e+003     0

           Fugacity    Reaction    Advection   Reaction    Advection
            (atm)      (kg/hr)      (kg/hr)    (percent)   (percent)
 Air       2.5e-014     4.82        0.263       0.482       0.0263
 Water     9.82e-012    322         419         32.2        41.9
 Soil      7.42e-018    0.0464      0           0.00464     0
 Sediment  6.61e-012    230         23.9        23          2.39

 Persistence Time: 1.61e+003 hr
 Reaction Time:    2.9e+003 hr
 Advection Time:   3.64e+003 hr
 Percent Reacted:  55.7
 Percent Advected: 44.3

 Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
    Air:      3.787
    Water:    900
    Soil:     900
    Sediment: 3600
      Biowin estimate: 2.646  (weeks-months)

 Advection Times (hr):
    Air:      100
    Water:    1000
    Sediment: 5e+004
```

## SAR ROBUST SUMMARY

### Test Substance

Identity: Dodecylamine (CAS RN 124-22-1)

| | |
|---|---|
| Melting Point (ºC) | 28.3 |
| Boiling Point (ºC) | 259 |
| Vapor Pressure (hPa) | 0.0081 |
| Partition Coefficient (log $K_w$) | 4.76 |
| Water Solubility (mg/l) | 45.1 |
| Photodegradation (cm3/molecule-sec) [$t_{1/2}$ (hr)] | 46 E-12 [2.8] |
| Hydrolysis [$t_{1/2}$ (hr)] | NC |
| Level III Fugacity (All input to water) | Air < 1%<br>Water 75%<br>Soil < 1%<br>Sediment 25% |
| Acute Fish Toxicity - 96-hour $LC_{50}$ (mg/l) | 9.77 – as cationic surfactant<br>0.87 – as aliphatic amine |
| Acute Toxicity to Aquatic Invertebrates - 48-hour $EC_{50}$ (mg/l) | 3.24 – as cationic surfactant<br>0.09 – as aliphatic amine |
| Toxicity to Aquatic Plants - 96-hour $EC_{50}$ (mg/l) | NC – as cationic surfactant<br>0.45 – as aliphatic amine |

NC – Not calculated by Model

### Model Input/Output

```
SMILES : NCCCCCCCCCCCC
CHEM   : 1-Dodecanamine
CAS NUM: 000124-22-1
MOL FOR: C12 H27 N1
MOL WT : 185.36
------------------------------ EPI SUMMARY (v3.05) --------------------------
 Physical Property Inputs:
    Water Solubility (mg/L):   ------
    Vapor Pressure (mm Hg) :   ------
    Henry LC (atm-m3/mole) :   ------
    Log Kow (octanol-water):   ------
    Boiling Point (deg C)  :   ------
    Melting Point (deg C)  :   ------

 Log Octanol-Water Partition Coef (SRC):
    Log Kow (KOWWIN v1.66 estimate) =  4.76

 Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):
    Boiling Pt (deg C):  254.63  (Adapted Stein & Brown method)
    Melting Pt (deg C):  35.06  (Mean or Weighted MP)
    VP(mm Hg,25 deg C):  0.0156  (Modified Grain method)
    MP  (exp database):  28.3 deg C
    BP  (exp database):  259 deg C
    VP  (exp database):  8.05E-03 mm Hg at 25 deg C
```

```
Water Solubility Estimate from Log Kow (WSKOW v1.37):
   Water Solubility at 25 deg C (mg/L):  45.13
      log Kow used: 4.76 (estimated)
      no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):
   Class(es) found:
      Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
  Bond Method :   1.71E-004  atm-m3/mole
  Group Method:   2.74E-004  atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]:  8.431E-005 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):
   Linear Model         :   0.9216
   Non-Linear Model     :   0.9655
Expert Survey Biodegradation Results:
   Ultimate Survey Model:   3.1123  (weeks       )
   Primary Survey Model :   3.8927  (days        )
Readily Biodegradable Probability (MITI Model):
   Linear Model         :   0.7380
   Non-Linear Model     :   0.8367

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:
  Hydroxyl Radicals Reaction:
     OVERALL OH Rate Constant =  45.7176 E-12 cm3/molecule-sec
     Half-Life =     0.234 Days (12-hr day; 1.5E6 OH/cm3)
     Half-Life =     2.807 Hrs
  Ozone Reaction:
     No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):
     Koc    :  8125
     Log Koc:  3.910

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
   Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):
   Log BCF =  1.968  (BCF = 92.89)
      log Kow used: 4.76 (estimated)

Volatilization from Water:
   Henry LC:  0.000274 atm-m3/mole  (estimated by Group SAR Method)
   Half-Life from Model River:      4.298  hours
   Half-Life from Model Lake :      161.1  hours   (6.71 days)

Removal In Wastewater Treatment:
   Total removal:              70.40  percent
   Total biodegradation:        0.59  percent
   Total sludge adsorption:    66.52  percent
   Total to Air:                3.29  percent

Level III Fugacity Model:
         Concentration   Half-Life    Emissions
           (percent)        (hr)       (kg/hr)
```

```
   Air       1.16            5.62         1000
   Water     27.5            360          1000
   Soil      62.2            360          1000
   Sediment  9.17            1.44e+003    0
     Persistence Time: 278 hr



CHEM   : 124221
CAS Num: 124221
ChemID1:
ChemID2:
ChemID3:
WatDisp: 45.13 mg/L

Avg Length Carbon Chain: 12.00
```

**ECOSAR Class: Surfactants, Cationic (C < 16)**

| Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|
| Daphnid | acute | LC50 | 3.236 |
| Fish | acute | LC50 | 9.772 |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none
```

---

**ECOSAR v0.99f Class(es) Found**
**----------**
**Aliphatic Amines**

| ECOSAR Class | Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|---|
| Neutral Organic SAR (Baseline Toxicity) | : Fish | 14-day | LC50 | 0.982 |
| Aliphatic Amines | : Fish | 96-hr | LC50 | 0.874 |
| Aliphatic Amines | : Daphnid | 48-hr | LC50 | 0.092 |
| Aliphatic Amines | : Green Algae | 96-hr | EC50 | 0.451 |
| Aliphatic Amines | : Green Algae | 96-hr | ChV | 0.190 |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
```

```
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none

-----------------------------

Level III Fugacity Model (Full-Output):
=======================================
  Chem Name   : 1-Dodecanamine
  Molecular Wt: 185.36
  Henry's LC  : 0.000274 atm-m3/mole (Henrywin program)
  Vapor Press : 0.0156 mm Hg  (Mpbpwin program)
  Liquid VP   : 0.0196 mm Hg  (super-cooled)
  Melting Pt  : 35.1 deg C (Mpbpwin program)
  Log Kow     : 4.76  (Kowwin program)
  Soil Koc    : 2.36e+004  (calc by model)

          Concentration   Half-Life    Emissions
            (percent)        (hr)       (kg/hr)
   Air       0.709           5.62         0
   Water     74.5            360          1000
   Soil      0.0103          360          0
   Sediment  24.8            1.44e+003    0

             Fugacity    Reaction    Advection   Reaction    Advection
              (atm)      (kg/hr)      (kg/hr)    (percent)   (percent)
   Air       2.88e-012    269         21.8        26.9        2.18
   Water     1.63e-009    441         229         44.1        22.9
   Soil      4.59e-015    0.061       0           0.0061      0
   Sediment  4.98e-010    36.8        1.53        3.68        0.153

   Persistence Time: 308 hr
   Reaction Time:    412 hr
   Advection Time:   1.22e+003 hr
   Percent Reacted:  74.7
   Percent Advected: 25.3

   Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
      Air:      5.616
      Water:    360
      Soil:     360
      Sediment: 1440
        Biowin estimate: 3.112  (weeks       )

   Advection Times (hr):
      Air:      100
      Water:    1000
      Sediment: 5e+004
```

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Hexadecanamine (CAS RN 143-27-1)

| | |
|---|---|
| Melting Point (ºC) | 47 |
| Boiling Point (ºC) | 323 |
| Vapor Pressure (hPa) | 0.00013 |
| Partition Coefficient (log $K_w$) | 6.73 |
| Water Solubility (mg/l) | 0.48 |
| Photodegradation (cm3/molecule-sec) [$t_{1/2}$ (hr)] | 51 E-12 [2.5] |
| Hydrolysis [$t_{1/2}$ (hr)] | NC |
| Level III Fugacity (All input to water) | Air: <1%<br>Water: 13%<br>Soil: <1%<br>Sediment: 87% |
| Acute Fish Toxicity - 96-hour $LC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Acute Toxicity to Aquatic Invertebrates - 48-hour $EC_{50}$ (mg/l) | NTS – as cationic surfactant<br>0.008 – as aliphatic amine |
| Toxicity to Aquatic Plants - 96-hour $EC_{50}$ (mg/l) | NC – as cationic surfactant<br>NTS – as aliphatic amine |

NC – Not calculated by Model
NTS – Model indicates "Not Toxic at Solubility"

### Model Input/Output

```
SMILES : NCCCCCCCCCCCCCCCC
CHEM   : 1-Hexadecanamine
CAS NUM: 000143-27-1
MOL FOR: C16 H35 N1
MOL WT : 241.46
------------------------------ EPI SUMMARY (v3.05) --------------------------
 Physical Property Inputs:
    Water Solubility (mg/L):   ------
    Vapor Pressure (mm Hg) :   ------
    Henry LC (atm-m3/mole) :   ------
    Log Kow (octanol-water):   ------
    Boiling Point (deg C)  :   ------
    Melting Point (deg C)  :   ------

 Log Octanol-Water Partition Coef (SRC):
    Log Kow (KOWWIN v1.66 estimate) =  6.73

 Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):
    Boiling Pt (deg C):  316.42  (Adapted Stein & Brown method)
    Melting Pt (deg C):  75.64  (Mean or Weighted MP)
    VP(mm Hg,25 deg C):  0.000371  (Modified Grain method)
    MP  (exp database):  46.8 deg C
    BP  (exp database):  322.5 deg C
    VP  (exp database):  1.33E-04 mm Hg at 25 deg C
```

```
Water Solubility Estimate from Log Kow (WSKOW v1.37):
   Water Solubility at 25 deg C (mg/L):  0.4823
      log Kow used: 6.73 (estimated)
      no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):
   Class(es) found:
      Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
  Bond Method :   5.31E-004  atm-m3/mole
  Group Method:   1.09E-003  atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]:  2.444E-004 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):
   Linear Model         :   0.8949
   Non-Linear Model     :   0.9265
Expert Survey Biodegradation Results:
   Ultimate Survey Model:   2.9883  (weeks       )
   Primary Survey Model :   3.8117  (days        )
Readily Biodegradable Probability (MITI Model):
   Linear Model         :   0.7687
   Non-Linear Model     :   0.8497

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:
  Hydroxyl Radicals Reaction:
     OVERALL OH Rate Constant =  51.3698 E-12 cm3/molecule-sec
     Half-Life =     0.208 Days (12-hr day; 1.5E6 OH/cm3)
     Half-Life =     2.499 Hrs
  Ozone Reaction:
     No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):
     Koc    :  9.402E+004
     Log Koc:  4.973

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
   Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):
   Log BCF =  2.981  (BCF = 956.2)
      log Kow used: 6.73 (estimated)

Volatilization from Water:
   Henry LC:  0.00109 atm-m3/mole  (estimated by Group SAR Method)
   Half-Life from Model River:       2.42  hours
   Half-Life from Model Lake :      156.7  hours   (6.529 days)

Removal In Wastewater Treatment:
   Total removal:              93.71  percent
   Total biodegradation:        0.77  percent
   Total sludge adsorption:    92.77  percent
   Total to Air:                0.17  percent

Level III Fugacity Model:
         Concentration   Half-Life    Emissions
```

| | (percent) | (hr) | (kg/hr) |
|---|---|---|---|
| Air | 0.425 | 5 | 1000 |
| Water | 8.67 | 360 | 1000 |
| Soil | 30.8 | 360 | 1000 |
| Sediment | 60.1 | 1.44e+003 | 0 |

Persistence Time: 562 hr

CHEM : 143271
CAS Num: 143271
ChemID1:
ChemID2:
ChemID3:
WatDisp: 0.4823 mg/L

Avg Length Carbon Chain: 16.00

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

| Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|
| Fish | acute | LC50 | 2.239 * |
| Snail | acute | LC50 | 0.679 * |
| Daphnid | acute | LC50 | 1.585 * |

Note: * = asterick designates: Chemical may not be soluble enough to measure this predicted effect.
Fish and daphnid acute toxicity log Kow cutoff: none
Green algal EC50 toxicity log Kow cutoff: none
Chronic toxicity log Kow cutoff: none
MW cutoff: none

**ECOSAR v0.99f Class(es) Found**
**----------**
**Aliphatic Amines**

| ECOSAR Class | Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|---|
| Neutral Organic SAR (Baseline Toxicity) | Fish | 14-day | LC50 | 0.025 * |
| Aliphatic Amines | Fish | 96-hr | LC50 | 0.062 * |
| Aliphatic Amines | Daphnid | 48-hr | LC50 | 0.008 |
| Aliphatic Amines | Green Algae | 96-hr | EC50 | 0.082 * |
| Aliphatic Amines | Green Algae | 96-hr | ChV | 0.054 * |

Note: * = asterick designates: Chemical may not be soluble enough to measure this predicted effect.
Fish and daphnid acute toxicity log Kow cutoff: none
Green algal EC50 toxicity log Kow cutoff: none
Chronic toxicity log Kow cutoff: none
MW cutoff: none

```
Level III Fugacity Model (Full-Output):
========================================
  Chem Name   : 1-Hexadecanamine
  Molecular Wt: 241.46
  Henry's LC  : 0.00109 atm-m3/mole (Henrywin program)
  Vapor Press : 0.000371 mm Hg  (Mpbpwin program)
  Liquid VP   : 0.00118 mm Hg  (super-cooled)
  Melting Pt  : 75.6 deg C (Mpbpwin program)
  Log Kow     : 6.73  (Kowwin program)
  Soil Koc    : 2.2e+006  (calc by model)

          Concentration   Half-Life    Emissions
            (percent)        (hr)       (kg/hr)
   Air       0.0378          5            0
   Water     12.6            360          1000
   Soil      0.000802        360          0
   Sediment  87.4            1.44e+003    0

             Fugacity    Reaction    Advection   Reaction    Advection
              (atm)      (kg/hr)      (kg/hr)    (percent)   (percent)
   Air       4.43e-013    60.8        4.38        6.08        0.438
   Water     7.21e-010    281         146         28.1        14.6
   Soil      4.41e-017    0.0179      0           0.00179     0
   Sediment  2.16e-010    487         20.3        48.7        2.03

   Persistence Time: 1.16e+003 hr
   Reaction Time:    1.4e+003 hr
   Advection Time:   6.79e+003 hr
   Percent Reacted:  82.9
   Percent Advected: 17.1

   Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
      Air:      4.997
      Water:    360
      Soil:     360
      Sediment: 1440
        Biowin estimate: 2.988  (weeks       )

   Advection Times (hr):
      Air:      100
      Water:    1000
      Sediment: 5e+004
```

## SAR ROBUST SUMMARY

### Test Substance

Identity: Hydrogenated Tallow Alkyl Amines (CAS RN 61788-45-2)

| | |
|---|---|
| Melting Point (ºC) | 52.9 |
| Boiling Point (ºC) | 346.8 |
| Vapor Pressure (hPa) | 0.000087 |
| Partition Coefficient (log $K_w$) | 7.71 |
| Water Solubility (mg/l) | 0.049 |
| Photodegradation (cm3/molecule-sec) [$t_{1/2}$ (hr)] | 54 E-12 [2.4] |
| Hydrolysis [$t_{1/2}$ (hr)] | NC |
| Level III Fugacity (All input to water) | Air: <1%<br>Water: 10%<br>Soil: <1%<br>Sediment: 90% |
| Acute Fish Toxicity - 96-hour $LC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Acute Toxicity to Aquatic Invertebrates - 48-hour $EC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Toxicity to Aquatic Plants - 96-hour $EC_{50}$ (mg/l) | NC – as cationic surfactant<br>NTS – as aliphatic amine |

NC – Not calculated by Model
NTS – Model indicates "Not Toxic at Solubility"

### Model Input/Output

```
SMILES : CCCCCCCCCCCCCCCCCCN
CHEM   : HYDROGENATED TALLOW ALKYL AMINES
CAS NUM: 061788-45-2
MOL FOR: C18 H39 N1
MOL WT : 269.52
------------------------------ EPI SUMMARY (v3.05) --------------------------
 Physical Property Inputs:
    Water Solubility (mg/L):   ------
    Vapor Pressure (mm Hg) :   ------
    Henry LC (atm-m3/mole) :   ------
    Log Kow (octanol-water):   ------
    Boiling Point (deg C)  :   ------
    Melting Point (deg C)  :   ------

 Log Octanol-Water Partition Coef (SRC):
    Log Kow (KOWWIN v1.66 estimate) =  7.71

 Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):
    Boiling Pt (deg C):  341.88  (Adapted Stein & Brown method)
    Melting Pt (deg C):  94.34  (Mean or Weighted MP)
    VP(mm Hg,25 deg C):  8.7E-005  (Modified Grain method)
    MP  (exp database):  52.9 deg C
    BP  (exp database):  346.8 deg C
```

```
Water Solubility Estimate from Log Kow (WSKOW v1.37):
   Water Solubility at 25 deg C (mg/L):  0.04875
      log Kow used: 7.71 (estimated)
      no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):
   Class(es) found:
      Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
  Bond Method :   9.36E-004  atm-m3/mole
  Group Method:   2.18E-003  atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]:  6.329E-004 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):
   Linear Model         :   0.8815
   Non-Linear Model     :   0.8943
Expert Survey Biodegradation Results:
   Ultimate Survey Model:   2.9263  (weeks       )
   Primary Survey Model :   3.7712  (days        )
Readily Biodegradable Probability (MITI Model):
   Linear Model         :   0.7841
   Non-Linear Model     :   0.8559

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:
  Hydroxyl Radicals Reaction:
     OVERALL OH Rate Constant =  54.1959 E-12 cm3/molecule-sec
     Half-Life =     0.197 Days (12-hr day; 1.5E6 OH/cm3)
     Half-Life =     2.368 Hrs
  Ozone Reaction:
     No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):
     Koc    :  3.198E+005
     Log Koc:  5.505

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
   Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):
   Log BCF =  2.337  (BCF = 217.3)
      log Kow used: 7.71 (estimated)

Volatilization from Water:
   Henry LC:  0.00218 atm-m3/mole  (estimated by Group SAR Method)
   Half-Life from Model River:      2.116  hours
   Half-Life from Model Lake :      160.7  hours   (6.698 days)

Removal In Wastewater Treatment:
   Total removal:              94.00  percent
   Total biodegradation:        0.78  percent
   Total sludge adsorption:    93.19  percent
   Total to Air:                0.03  percent

Level III Fugacity Model:
         Concentration   Half-Life    Emissions
           (percent)        (hr)       (kg/hr)
```

```
   Air       0.35            4.74         1000
   Water     7.43            360          1000
   Soil      28.2            360          1000
   Sediment  64              1.44e+003    0
     Persistence Time: 614 hr

CHEM   : 61788452
CAS Num: 61788452
ChemID1:
ChemID2:
ChemID3:
WatDisp: 0.04875 mg/L

Avg Length Carbon Chain: 18.00
```

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

| Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|
| Fish | acute | LC50 | 2.489 * |
| Snail | acute | LC50 | 1.014 * |
| Daphnid | acute | LC50 | 2.692 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none
```

**ECOSAR v0.99f Class(es) Found**
**----------**
**Aliphatic Amines**

| ECOSAR Class | Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|---|
| Neutral Organic SAR (Baseline Toxicity) | : Fish | 14-day | LC50 | 0.004 * |
| Aliphatic Amines | : Fish | 96-hr | LC50 | 0.016 * |
| Aliphatic Amines | : Daphnid | 48-hr | LC50 | 0.003 * |
| Aliphatic Amines | : Green Algae | 96-hr | EC50 | 0.034 * |
| Aliphatic Amines | : Green Algae | 96-hr | ChV | 0.029 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none

Level III Fugacity Model (Full-Output):
========================================
  Chem Name   : HYDROGENATED TALLOW ALKYL AMINES
```

```
Molecular Wt: 269.52
Henry's LC  : 0.00218 atm-m3/mole (Henrywin program)
Vapor Press : 8.7e-005 mm Hg  (Mpbpwin program)
Liquid VP   : 0.000422 mm Hg  (super-cooled)
Melting Pt  : 94.3 deg C (Mpbpwin program)
Log Kow     : 7.71  (Kowwin program)
Soil Koc    : 2.1e+007  (calc by model)

        Concentration   Half-Life    Emissions
          (percent)        (hr)       (kg/hr)
 Air       0.00426         4.74         0
 Water     10.4            360          1000
 Soil      0.000169        360          0
 Sediment  89.6            1.44e+003    0

           Fugacity    Reaction    Advection   Reaction    Advection
            (atm)      (kg/hr)      (kg/hr)    (percent)   (percent)
 Air       5.07e-014    8.19        0.56        0.819       0.056
 Water     1.58e-010    263         137         26.3        13.7
 Soil      1.98e-018    0.00428     0           0.000428    0
 Sediment  4.72e-011    567         23.6        56.7        2.36

 Persistence Time: 1.32e+003 hr
 Reaction Time:    1.57e+003 hr
 Advection Time:   8.18e+003 hr
 Percent Reacted:  83.9
 Percent Advected: 16.1

 Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
    Air:      4.738
    Water:    360
    Soil:     360
    Sediment: 1440
      Biowin estimate: 2.926  (weeks       )

 Advection Times (hr):
    Air:      100
    Water:    1000
    Sediment: 5e+004
```

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Octadecanamine (CAS RN 124-30-1)

| | |
|---|---|
| Melting Point (ºC) | 52.9 |
| Boiling Point (ºC) | 346.8 |
| Vapor Pressure (hPa) | 0.000087 |
| Partition Coefficient (log $K_w$) | 7.71 |
| Water Solubility (mg/l) | 0.049 |
| Photodegradation (cm3/molecule-sec) [$t_{1/2}$ (hr)] | 54 E-12 [2.4] |
| Hydrolysis [$t_{1/2}$ (hr)] | NC |
| Level III Fugacity (All input to water) | Air: <1%<br>Water: 10%<br>Soil: <1%<br>Sediment: 90% |
| Acute Fish Toxicity - 96-hour $LC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Acute Toxicity to Aquatic Invertebrates - 48-hour $EC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Toxicity to Aquatic Plants - 96-hour $EC_{50}$ (mg/l) | NC – as cationic surfactant<br>NTS – as aliphatic amine |

NC – Not calculated by Model
NTS – Model indicates "Not Toxic at Solubility"

### Model Input/Output

```
SMILES : NCCCCCCCCCCCCCCCCCC
CHEM   : 1-Octadecanamine
CAS NUM: 000124-30-1
MOL FOR: C18 H39 N1
MOL WT : 269.52
------------------------------ EPI SUMMARY (v3.05) --------------------------
 Physical Property Inputs:
    Water Solubility (mg/L):   ------
    Vapor Pressure (mm Hg) :   ------
    Henry LC (atm-m3/mole) :   ------
    Log Kow (octanol-water):   ------
    Boiling Point (deg C)  :   ------
    Melting Point (deg C)  :   ------

 Log Octanol-Water Partition Coef (SRC):
    Log Kow (KOWWIN v1.66 estimate) =  7.71

 Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):
    Boiling Pt (deg C):  341.88  (Adapted Stein & Brown method)
    Melting Pt (deg C):  94.34  (Mean or Weighted MP)
    VP(mm Hg,25 deg C):  8.7E-005  (Modified Grain method)
    MP  (exp database):  52.9 deg C
    BP  (exp database):  346.8 deg C
```

```
Water Solubility Estimate from Log Kow (WSKOW v1.37):
   Water Solubility at 25 deg C (mg/L):  0.04875
      log Kow used: 7.71 (estimated)
      no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):
   Class(es) found:
      Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
  Bond Method :   9.36E-004  atm-m3/mole
  Group Method:   2.18E-003  atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]:  6.329E-004 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):
   Linear Model         :   0.8815
   Non-Linear Model     :   0.8943
Expert Survey Biodegradation Results:
   Ultimate Survey Model:   2.9263  (weeks       )
   Primary Survey Model :   3.7712  (days        )
Readily Biodegradable Probability (MITI Model):
   Linear Model         :   0.7841
   Non-Linear Model     :   0.8559

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:
  Hydroxyl Radicals Reaction:
     OVERALL OH Rate Constant =  54.1958 E-12 cm3/molecule-sec
     Half-Life =     0.197 Days (12-hr day; 1.5E6 OH/cm3)
     Half-Life =     2.368 Hrs
  Ozone Reaction:
     No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):
     Koc    :  3.198E+005
     Log Koc:  5.505

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
   Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):
   Log BCF =  2.337  (BCF = 217.3)
      log Kow used: 7.71 (estimated)

Volatilization from Water:
   Henry LC:  0.00218 atm-m3/mole  (estimated by Group SAR Method)
   Half-Life from Model River:      2.116  hours
   Half-Life from Model Lake :      160.7  hours   (6.698 days)

Removal In Wastewater Treatment:
   Total removal:              94.00  percent
   Total biodegradation:        0.78  percent
   Total sludge adsorption:    93.19  percent
   Total to Air:                0.03  percent

Level III Fugacity Model:
         Concentration   Half-Life    Emissions
           (percent)        (hr)       (kg/hr)
```

```
   Air       0.35            4.74         1000
   Water     7.43            360          1000
   Soil      28.2            360          1000
   Sediment  64              1.44e+003    0
     Persistence Time: 614 hr

CHEM   : 124301
CAS Num: 124301
ChemID1:
ChemID2:
ChemID3:
WatDisp: 0.04875 mg/L

Avg Length Carbon Chain: 18.00
```

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

| Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|
| Fish | acute | LC50 | 2.489 * |
| Snail | acute | LC50 | 1.014 * |
| Daphnid | acute | LC50 | 2.692 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none
```

**ECOSAR v0.99f Class(es) Found**
**----------**
**Aliphatic Amines**

| ECOSAR Class | Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|---|
| Neutral Organic SAR (Baseline Toxicity) | : Fish | 14-day | LC50 | 0.004 * |
| Aliphatic Amines | : Fish | 96-hr | LC50 | 0.016 * |
| Aliphatic Amines | : Daphnid | 48-hr | LC50 | 0.003 * |
| Aliphatic Amines | : Green Algae | 96-hr | EC50 | 0.034 * |
| Aliphatic Amines | : Green Algae | 96-hr | ChV | 0.029 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none
Level III Fugacity Model (Full-Output):
========================================
  Chem Name   : 1-Octadecanamine
  Molecular Wt: 269.52
```

```
Henry's LC  : 0.00218 atm-m3/mole (Henrywin program)
Vapor Press : 8.7e-005 mm Hg  (Mpbpwin program)
Liquid VP   : 0.000422 mm Hg  (super-cooled)
Melting Pt  : 94.3 deg C (Mpbpwin program)
Log Kow     : 7.71  (Kowwin program)
Soil Koc    : 2.1e+007  (calc by model)

        Concentration   Half-Life    Emissions
          (percent)        (hr)       (kg/hr)
 Air       0.00426         4.74         0
 Water     10.4            360          1000
 Soil      0.000169        360          0
 Sediment  89.6            1.44e+003    0

           Fugacity    Reaction    Advection   Reaction    Advection
            (atm)      (kg/hr)      (kg/hr)    (percent)   (percent)
 Air       5.07e-014    8.19        0.56        0.819       0.056
 Water     1.58e-010    263         137         26.3        13.7
 Soil      1.98e-018    0.00428     0           0.000428    0
 Sediment  4.72e-011    567         23.6        56.7        2.36

 Persistence Time: 1.32e+003 hr
 Reaction Time:    1.57e+003 hr
 Advection Time:   8.18e+003 hr
 Percent Reacted:  83.9
 Percent Advected: 16.1

 Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
    Air:      4.738
    Water:    360
    Soil:     360
    Sediment: 1440
      Biowin estimate: 2.926  (weeks       )

 Advection Times (hr):
    Air:      100
    Water:    1000
    Sediment: 5e+004
```

## SAR ROBUST SUMMARY

### Test Substance

Identity: 9-Octadecen-1-amine, (Z)- (CAS RN 112-90-3)

| | |
|---|---|
| Melting Point (ºC) | 93 |
| Boiling Point (ºC) | 346 |
| Vapor Pressure (hPa) | 0.000037 |
| Partition Coefficient (log $K_w$) | 7.50 |
| Water Solubility (mg/l) | 0.076 |
| Photodegradation (cm3/molecule-sec) [$t_{1/2}$ (hr)] | 107 E-12 [1.2] |
| Hydrolysis [$t_{1/2}$ (hr)] | NC |
| Level III Fugacity (All input to water) | Air: <1%<br>Water: 11%<br>Soil: <1%<br>Sediment: 89% |
| Acute Fish Toxicity - 96-hour $LC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Acute Toxicity to Aquatic Invertebrates - 48-hour $EC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Toxicity to Aquatic Plants - 96-hour $EC_{50}$ (mg/l) | NC – as cationic surfactant<br>NTS – as aliphatic amine |

NC – Not calculated by Model
NTS – Model indicates "Not Toxic at Solubility"

### Model Input/Output

```
SMILES : NCCCCCCCCC=CCCCCCCCC
CHEM   : 9-Octadecen-1-amine, (Z)-
CAS NUM: 000112-90-3
MOL FOR: C18 H37 N1
MOL WT : 267.50
------------------------------ EPI SUMMARY (v3.05) --------------------------
 Physical Property Inputs:
    Water Solubility (mg/L):   ------
    Vapor Pressure (mm Hg) :   ------
    Henry LC (atm-m3/mole) :   ------
    Log Kow (octanol-water):   ------
    Boiling Point (deg C)  :   ------
    Melting Point (deg C)  :   ------

 Log Octanol-Water Partition Coef (SRC):
    Log Kow (KOWWIN v1.66 estimate) =  7.50

 Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):
    Boiling Pt (deg C):  345.55  (Adapted Stein & Brown method)
    Melting Pt (deg C):  92.87  (Mean or Weighted MP)
    VP(mm Hg,25 deg C):  3.72E-005  (Modified Grain method)

 Water Solubility Estimate from Log Kow (WSKOW v1.37):
    Water Solubility at 25 deg C (mg/L):  0.07639
```

```
      log Kow used: 7.50 (estimated)
      no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):
   Class(es) found:
      Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
  Bond Method :   8.23E-004  atm-m3/mole
  Group Method:   5.73E-004  atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]:  1.714E-004 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):
   Linear Model         :   0.8825
   Non-Linear Model     :   0.8969
Expert Survey Biodegradation Results:
   Ultimate Survey Model:   2.9308  (weeks       )
   Primary Survey Model :   3.7741  (days        )
Readily Biodegradable Probability (MITI Model):
   Linear Model         :   0.7036
   Non-Linear Model     :   0.7384

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:
  Hydroxyl Radicals Reaction:
     OVERALL OH Rate Constant = 107.2413 E-12 cm3/molecule-sec [Cis-isomer]
     OVERALL OH Rate Constant = 114.8413 E-12 cm3/molecule-sec [Trans-isomer]
     Half-Life =    1.197 Hrs (12-hr day; 1.5E6 OH/cm3) [Cis-isomer]
     Half-Life =    1.118 Hrs (12-hr day; 1.5E6 OH/cm3) [Trans-isomer]
  Ozone Reaction:
     OVERALL Ozone Rate Constant =    13.000000 E-17 cm3/molecule-sec [Cis-]
     OVERALL Ozone Rate Constant =    20.000000 E-17 cm3/molecule-sec [Trans-]
     Half-Life =     2.116 Hrs (at 7E11 mol/cm3) [Cis-isomer]
     Half-Life =     1.375 Hrs (at 7E11 mol/cm3) [Trans-isomer]
  Reaction With Nitrate Radicals May Be Important!

Soil Adsorption Coefficient (PCKOCWIN v1.66):
     Koc    :  3.198E+005
     Log Koc:  5.505

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
   Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):
   Log BCF =  2.632  (BCF = 428.1)
      log Kow used: 7.50 (estimated)

Volatilization from Water:
   Henry LC:  0.000573 atm-m3/mole  (estimated by Group SAR Method)
   Half-Life from Model River:       3.34  hours
   Half-Life from Model Lake :      173.6  hours   (7.232 days)

Removal In Wastewater Treatment:
   Total removal:              93.98  percent
   Total biodegradation:        0.78  percent
   Total sludge adsorption:    93.18  percent
   Total to Air:                0.02  percent
```

Level III Fugacity Model:

| | Concentration (percent) | Half-Life (hr) | Emissions (kg/hr) |
|---|---|---|---|
| Air | 0.0882 | 1.12 | 1000 |
| Water | 7.55 | 360 | 1000 |
| Soil | 28.4 | 360 | 1000 |
| Sediment | 63.9 | 1.44e+003 | 0 |

Persistence Time: 609 hr

CHEM : 112903
CAS Num: 112903
ChemID1:
ChemID2:
ChemID3:
WatDisp: 0.07639 mg/L

Avg Length Carbon Chain: 18.00

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

| Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|
| Fish | acute | LC50 | 2.489 * |
| Snail | acute | LC50 | 1.014 * |
| Daphnid | acute | LC50 | 2.692 * |

Note: * = asterick designates: Chemical may not be soluble enough to measure this predicted effect.
Fish and daphnid acute toxicity log Kow cutoff: none
Green algal EC50 toxicity log Kow cutoff: none
Chronic toxicity log Kow cutoff: none
MW cutoff: none

**ECOSAR v0.99f Class(es) Found**
**----------**
**Aliphatic Amines**

| ECOSAR Class | Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|---|
| Neutral Organic SAR (Baseline Toxicity) | : Fish | 14-day | LC50 | 0.006 * |
| Aliphatic Amines | : Fish | 96-hr | LC50 | 0.022 * |
| Aliphatic Amines | : Daphnid | 48-hr | LC50 | 0.003 * |
| Aliphatic Amines | : Green Algae | 96-hr | EC50 | 0.042 * |
| Aliphatic Amines | : Green Algae | 96-hr | ChV | 0.033 * |

Note: * = asterick designates: Chemical may not be soluble enough to measure this predicted effect.
Fish and daphnid acute toxicity log Kow cutoff: none
Green algal EC50 toxicity log Kow cutoff: none
Chronic toxicity log Kow cutoff: none
MW cutoff: none

```
Level III Fugacity Model (Full-Output):
========================================
  Chem Name   : 9-Octadecen-1-amine, (Z)-
  Molecular Wt: 267.5
  Henry's LC  : 0.000573 atm-m3/mole (Henrywin program)
  Vapor Press : 3.72e-005 mm Hg  (Mpbpwin program)
  Liquid VP   : 0.000174 mm Hg  (super-cooled)
  Melting Pt  : 92.9 deg C (Mpbpwin program)
  Log Kow     : 7.5  (Kowwin program)
  Soil Koc    : 1.3e+007  (calc by model)

          Concentration   Half-Life    Emissions
            (percent)        (hr)       (kg/hr)
   Air       0.00134         1.12         0
   Water     10.6            360          1000
   Soil      0.000112        360          0
   Sediment  89.4            1.44e+003    0

             Fugacity    Reaction    Advection   Reaction    Advection
              (atm)      (kg/hr)      (kg/hr)    (percent)   (percent)
   Air       1.59e-014    10.8        0.175       1.08        0.0175
   Water     6.71e-011    266         138         26.6        13.8
   Soil      5.58e-019    0.00281     0           0.000281    0
   Sediment  2.01e-011    562         23.4        56.2        2.34

   Persistence Time: 1.31e+003 hr
   Reaction Time:    1.56e+003 hr
   Advection Time:   8.09e+003 hr
   Percent Reacted:  83.9
   Percent Advected: 16.1

   Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
      Air:      1.123
      Water:    360
      Soil:     360
      Sediment: 1440
        Biowin estimate: 2.931  (weeks       )

   Advection Times (hr):
      Air:      100
      Water:    1000
      Sediment: 5e+004
```

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Dodecanamine, N,N-dimethyl- (CAS RN 112-18-5)

| | |
|---|---|
| Melting Point (ºC) | 22 |
| Boiling Point (ºC) | 260 |
| Vapor Pressure (hPa) | 0.0159 |
| Partition Coefficient (log $K_w$) | 5.44 |
| Water Solubility (mg/l) | 8.58 |
| Photodegradation (cm3/molecule-sec) [$t_{1/2}$ (hr)] | 93 E-12 [1.4] |
| Hydrolysis [$t_{1/2}$ (hr)] | NC |
| Level III Fugacity (All input to water) | Air: <1%<br>Water: 42%<br>Soil: <1%<br>Sediment: 58% |
| Acute Fish Toxicity - 96-hour $LC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Acute Toxicity to Aquatic Invertebrates - 48-hour $EC_{50}$ (mg/l) | 3.24 – as cationic surfactant<br>0.04– as aliphatic amine |
| Toxicity to Aquatic Plants - 96-hour $EC_{50}$ (mg/l) | NC – as cationic surfactant<br>0.26– as aliphatic amine |

NC – Not calculated by Model
NTS – Model indicates "Not Toxic at Solubility"

### Model Input/Output

```
SMILES : N(CCCCCCCCCCCC)(C)C
CHEM   : 1-Dodecanamine, N,N-dimethyl-
CAS NUM: 000112-18-5
MOL FOR: C14 H31 N1
MOL WT : 213.41
------------------------------ EPI SUMMARY (v3.05) --------------------------
 Physical Property Inputs:
    Water Solubility (mg/L):   ------
    Vapor Pressure (mm Hg) :   ------
    Henry LC (atm-m3/mole) :   ------
    Log Kow (octanol-water):   ------
    Boiling Point (deg C)  :   ------
    Melting Point (deg C)  :   ------

 Log Octanol-Water Partition Coef (SRC):
    Log Kow (KOWWIN v1.66 estimate) =  5.44

 Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):
    Boiling Pt (deg C):  260.12  (Adapted Stein & Brown method)
    Melting Pt (deg C):  22.53  (Mean or Weighted MP)
    VP(mm Hg,25 deg C):  0.0159  (Mean VP of Antoine & Grain methods)
    MP  (exp database):  22 deg C
    BP  (exp database):  260 deg C
```

```
Water Solubility Estimate from Log Kow (WSKOW v1.37):
   Water Solubility at 25 deg C (mg/L):  8.575
      log Kow used: 5.44 (estimated)
      no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):
   Class(es) found:
      Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
  Bond Method :   8.24E-004  atm-m3/mole
  Group Method:   4.88E-003  atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]:  5.207E-004 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):
   Linear Model         :   0.5491
   Non-Linear Model     :   0.4011
Expert Survey Biodegradation Results:
   Ultimate Survey Model:   2.7711  (weeks       )
   Primary Survey Model :   3.5209  (days-weeks  )
Readily Biodegradable Probability (MITI Model):
   Linear Model         :   0.5372
   Non-Linear Model     :   0.5764

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:
  Hydroxyl Radicals Reaction:
     OVERALL OH Rate Constant =  93.2472 E-12 cm3/molecule-sec
     Half-Life =     0.115 Days (12-hr day; 1.5E6 OH/cm3)
     Half-Life =     1.376 Hrs
  Ozone Reaction:
     No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):
     Koc    :  1.308E+004
     Log Koc:  4.116

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
   Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):
   Log BCF =  2.489  (BCF = 308.6)
      log Kow used: 5.44 (estimated)

Volatilization from Water:
   Henry LC:  0.00488 atm-m3/mole  (estimated by Group SAR Method)
   Half-Life from Model River:      1.666  hours
   Half-Life from Model Lake :      140.7  hours   (5.861 days)

Removal In Wastewater Treatment:
   Total removal:              90.25  percent
   Total biodegradation:        0.61  percent
   Total sludge adsorption:    79.63  percent
   Total to Air:               10.01  percent

Level III Fugacity Model:
         Concentration   Half-Life    Emissions
           (percent)        (hr)       (kg/hr)
```

```
   Air       0.55            2.75         1000
   Water     18.8            360          1000
   Soil      54.7            360          1000
   Sediment  25.9            1.44e+003    0
     Persistence Time: 315 hr

CHEM   : 112185
CAS Num: 112185
ChemID1:
ChemID2:
ChemID3:
WatDisp: 8.575 mg/L

Avg Length Carbon Chain: 12.00
```

**ECOSAR Class: Surfactants, Cationic (C < 16)**

| Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|
| Daphnid | acute | LC50 | 3.236 |
| Fish | acute | LC50 | 9.772 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none
```

**ECOSAR v0.99f Class(es) Found**
**----------**
**Aliphatic Amines**

| ECOSAR Class | Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|---|
| Neutral Organic SAR (Baseline Toxicity) | : Fish | 14-day | LC50 | 0.289 |
| Aliphatic Amines | : Fish | 96-hr | LC50 | 0.370 * |
| Aliphatic Amines | : Daphnid | 48-hr | LC50 | 0.042 |
| Aliphatic Amines | : Green Algae | 96-hr | EC50 | 0.263 |
| Aliphatic Amines | : Green Algae | 96-hr | ChV | 0.130 |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none

Level III Fugacity Model (Full-Output):
========================================
  Chem Name   : 1-Dodecanamine, N,N-dimethyl-
  Molecular Wt: 213.41
```

```
Henry's LC  : 0.00488 atm-m3/mole (Henrywin program)
Vapor Press : 0.0159 mm Hg  (Mpbpwin program)
Log Kow     : 5.44  (Kowwin program)
Soil Koc    : 1.13e+005  (calc by model)

        Concentration   Half-Life    Emissions
          (percent)        (hr)       (kg/hr)
 Air       0.322           2.75         0
 Water     41.9            360          1000
 Soil      0.00332         360          0
 Sediment  57.8            1.44e+003    0

           Fugacity    Reaction    Advection   Reaction    Advection
            (atm)      (kg/hr)      (kg/hr)    (percent)   (percent)
 Air       1.56e-012    344         13.7        34.4        1.37
 Water     1.72e-008    342         178         34.2        17.8
 Soil      6.61e-015    0.0271      0           0.00271     0
 Sediment  5.17e-009    118         4.9         11.8        0.49

 Persistence Time: 424 hr
 Reaction Time:    528 hr
 Advection Time:   2.16e+003 hr
 Percent Reacted:  80.4
 Percent Advected: 19.6

 Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
    Air:      2.753
    Water:    360
    Soil:     360
    Sediment: 1440
      Biowin estimate: 2.771  (weeks       )

 Advection Times (hr):
    Air:      100
    Water:    1000
    Sediment: 5e+004
```

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Tetradecanamine, N,N-dimethyl- (CAS RN 112-75-4)

| | |
|---|---|
| Melting Point (ºC) | 43 |
| Boiling Point (ºC) | 292 |
| Vapor Pressure (hPa) | 0.0020 |
| Partition Coefficient (log $K_w$) | 6.42 |
| Water Solubility (mg/l) | 0.88 |
| Photodegradation (cm3/molecule-sec) [$t_{1/2}$ (hr)] | 96 E-12 [1.3] |
| Hydrolysis [$t_{1/2}$ (hr)] | NC |
| Level III Fugacity (All input to water) | Air: <1%<br>Water: 7%<br>Soil: <1%<br>Sediment: 93% |
| Acute Fish Toxicity - 96-hour $LC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Acute Toxicity to Aquatic Invertebrates - 48-hour $EC_{50}$ (mg/l) | NTS – as cationic surfactant<br>0.01– as aliphatic amine |
| Toxicity to Aquatic Plants - 96-hour $EC_{50}$ (mg/l) | NC – as cationic surfactant<br>NTS – as aliphatic amine |

NC – Not calculated by Model
NTS – Model indicates "Not Toxic at Solubility"

### Model Input/Output

```
SMILES : N(CCCCCCCCCCCCCC)(C)C
CHEM   : 1-Tetradecanamine, N,N-dimethyl-
CAS NUM: 000112-75-4
MOL FOR: C16 H35 N1
MOL WT : 241.46
------------------------------ EPI SUMMARY (v3.05) --------------------------
 Physical Property Inputs:
    Water Solubility (mg/L):   ------
    Vapor Pressure (mm Hg) :   ------
    Henry LC (atm-m3/mole) :   ------
    Log Kow (octanol-water):   ------
    Boiling Point (deg C)  :   ------
    Melting Point (deg C)  :   ------

 Log Octanol-Water Partition Coef (SRC):
    Log Kow (KOWWIN v1.66 estimate) =  6.42

 Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):
    Boiling Pt (deg C):  292.24  (Adapted Stein & Brown method)
    Melting Pt (deg C):  43.18  (Mean or Weighted MP)
    VP(mm Hg,25 deg C):  0.00201  (Modified Grain method)

 Water Solubility Estimate from Log Kow (WSKOW v1.37):
    Water Solubility at 25 deg C (mg/L):  0.8787
```

```
      log Kow used: 6.42 (estimated)
      no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):
   Class(es) found:
      Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
  Bond Method :   1.45E-003  atm-m3/mole
  Group Method:   9.74E-003  atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]:  7.268E-004 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):
   Linear Model         :   0.5358
   Non-Linear Model     :   0.3102
Expert Survey Biodegradation Results:
   Ultimate Survey Model:   2.7091  (weeks-months)
   Primary Survey Model :   3.4804  (days-weeks  )
Readily Biodegradable Probability (MITI Model):
   Linear Model         :   0.5526
   Non-Linear Model     :   0.5883

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:
  Hydroxyl Radicals Reaction:
     OVERALL OH Rate Constant =  96.0733 E-12 cm3/molecule-sec
     Half-Life =     0.111 Days (12-hr day; 1.5E6 OH/cm3)
     Half-Life =     1.336 Hrs
  Ozone Reaction:
     No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):
     Koc    :  4.448E+004
     Log Koc:  4.648

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
   Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):
   Log BCF =  2.746  (BCF = 556.7)
      log Kow used: 6.42 (estimated)

Volatilization from Water:
   Henry LC:  0.00974 atm-m3/mole  (estimated by Group SAR Method)
   Half-Life from Model River:      1.679  hours
   Half-Life from Model Lake :      148.6  hours   (6.192 days)

Removal In Wastewater Treatment:
   Total removal:              93.74  percent
   Total biodegradation:        0.74  percent
   Total sludge adsorption:    90.41  percent
   Total to Air:                2.59  percent

Level III Fugacity Model:
         Concentration   Half-Life    Emissions
           (percent)        (hr)       (kg/hr)
  Air       0.112           2.67         1000
  Water     4.85            900          1000
```

```
   Soil      33.6            900          1000
   Sediment  61.4            3.6e+003     0
     Persistence Time: 1.29e+003 hr
CHEM   : 112754
CAS Num: 112754
ChemID1:
ChemID2:
ChemID3:
WatDisp: 0.8787 mg/L

Avg Length Carbon Chain: 14.00
```

**ECOSAR Class: Surfactants, Cationic (C < 16)**

| Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|
| Daphnid | acute | LC50 | 1.778 * |
| Fish | acute | LC50 | 1.778 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none
```

**ECOSAR v0.99f Class(es) Found**
**----------**
**Aliphatic Amines**

| ECOSAR Class | Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|---|
| Neutral Organic SAR (Baseline Toxicity) | Fish | 14-day | LC50 | 0.046 * |
| Aliphatic Amines | Fish | 96-hr | LC50 | 0.099 * |
| Aliphatic Amines | Daphnid | 48-hr | LC50 | 0.013 |
| Aliphatic Amines | Green Algae | 96-hr | EC50 | 0.112 * |
| Aliphatic Amines | Green Algae | 96-hr | ChV | 0.069 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none

Level III Fugacity Model (Full-Output):
========================================
  Chem Name   : 1-Tetradecanamine, N,N-dimethyl-
  Molecular Wt: 241.46
  Henry's LC  : 0.00974 atm-m3/mole (Henrywin program)
  Vapor Press : 0.00201 mm Hg  (Mpbpwin program)
  Liquid VP   : 0.00304 mm Hg  (super-cooled)
```

```
Melting Pt  : 43.2 deg C (Mpbpwin program)
Log Kow     : 6.42  (Kowwin program)
Soil Koc    : 1.08e+006  (calc by model)

        Concentration   Half-Life    Emissions
          (percent)        (hr)       (kg/hr)
 Air       0.0241          2.67         0
 Water     7.32            900          1000
 Soil      0.000817        900          0
 Sediment  92.7            3.6e+003     0

           Fugacity    Reaction    Advection   Reaction    Advection
            (atm)      (kg/hr)      (kg/hr)    (percent)   (percent)
 Air       6.23e-013    160         6.16        16          0.616
 Water     1.37e-008    144         187         14.4        18.7
 Soil      1.81e-015    0.0161      0           0.00161     0
 Sediment  9.22e-009    456         47.3        45.6        4.73

 Persistence Time: 2.55e+003 hr
 Reaction Time:    3.36e+003 hr
 Advection Time:   1.06e+004 hr
 Percent Reacted:  75.9
 Percent Advected: 24.1

 Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
    Air:      2.671
    Water:    900
    Soil:     900
    Sediment: 3600
      Biowin estimate: 2.709  (weeks-months)

 Advection Times (hr):
    Air:      100
    Water:    1000
    Sediment: 5e+004
```

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Hexadecanamine, N,N-dimethyl- (CAS RN 112-69-6)

| | |
|---|---|
| Melting Point (ºC) | 63 |
| Boiling Point (ºC) | 321 |
| Vapor Pressure (hPa) | 0.00029 |
| Partition Coefficient (log $K_w$) | 7.41 |
| Water Solubility (mg/l) | 0.089 |
| Photodegradation (cm3/molecule-sec) [$t_{1/2}$ (hr)] | 99 E-12 [1.3] |
| Hydrolysis [$t_{1/2}$ (hr)] | NC |
| Level III Fugacity (All input to water) | Air: <1%<br>Water: 5%<br>Soil: <1%<br>Sediment: 95% |
| Acute Fish Toxicity - 96-hour $LC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Acute Toxicity to Aquatic Invertebrates - 48-hour $EC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Toxicity to Aquatic Plants - 96-hour $EC_{50}$ (mg/l) | NC – as cationic surfactant<br>NTS – as aliphatic amine |

NC – Not calculated by Model
NTS – Model indicates "Not Toxic at Solubility"

### Model Input/Output

```
SMILES : N(CCCCCCCCCCCCCCCC)(C)C
CHEM   : 1-Hexadecanamine, N,N-dimethyl-
CAS NUM: 000112-69-6
MOL FOR: C18 H39 N1
MOL WT : 269.52
------------------------------ EPI SUMMARY (v3.05) --------------------------
 Physical Property Inputs:
    Water Solubility (mg/L):   ------
    Vapor Pressure (mm Hg) :   ------
    Henry LC (atm-m3/mole) :   ------
    Log Kow (octanol-water):   ------
    Boiling Point (deg C)  :   ------
    Melting Point (deg C)  :   ------

 Log Octanol-Water Partition Coef (SRC):
    Log Kow (KOWWIN v1.66 estimate) =  7.41

 Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):
    Boiling Pt (deg C):  320.74  (Adapted Stein & Brown method)
    Melting Pt (deg C):  62.77  (Mean or Weighted MP)
    VP(mm Hg,25 deg C):  0.000286  (Modified Grain method)

 Water Solubility Estimate from Log Kow (WSKOW v1.37):
    Water Solubility at 25 deg C (mg/L):  0.08883
```

```
      log Kow used: 7.41 (estimated)
      no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):
   Class(es) found:
      Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
  Bond Method :   2.56E-003  atm-m3/mole
  Group Method:   1.94E-002  atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]:  1.142E-003 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):
   Linear Model         :   0.5224
   Non-Linear Model     :   0.2319
Expert Survey Biodegradation Results:
   Ultimate Survey Model:   2.6471  (weeks-months)
   Primary Survey Model :   3.4400  (days-weeks  )
Readily Biodegradable Probability (MITI Model):
   Linear Model         :   0.5680
   Non-Linear Model     :   0.6001

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:
  Hydroxyl Radicals Reaction:
     OVERALL OH Rate Constant =  98.8994 E-12 cm3/molecule-sec
     Half-Life =     0.108 Days (12-hr day; 1.5E6 OH/cm3)
     Half-Life =     1.298 Hrs
  Ozone Reaction:
     No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):
     Koc    :  1.513E+005
     Log Koc:  5.180

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
   Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):
   Log BCF =  2.755  (BCF = 568.9)
      log Kow used: 7.41 (estimated)

Volatilization from Water:
   Henry LC:  0.0194 atm-m3/mole  (estimated by Group SAR Method)
   Half-Life from Model River:      1.725  hours
   Half-Life from Model Lake :      156.5  hours   (6.52 days)

Removal In Wastewater Treatment:
   Total removal:              94.04  percent
   Total biodegradation:        0.77  percent
   Total sludge adsorption:    92.72  percent
   Total to Air:                0.56  percent

Level III Fugacity Model:
         Concentration   Half-Life    Emissions
           (percent)        (hr)       (kg/hr)
  Air       0.0794          2.6          1000
  Water     3.64            900          1000
```

```
   Soil      27.9            900          1000
   Sediment  68.4            3.6e+003     0
     Persistence Time: 1.55e+003 hr
CHEM   : 112696
CAS Num: 112696
ChemID1:
ChemID2:
ChemID3:
WatDisp: 0.08883 mg/L

Avg Length Carbon Chain: 0.00
```

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

| Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|
| Daphnid | acute | LC50 | 117.490 * |
| Fish | acute | LC50 | 2.69e+005 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none
```

**ECOSAR v0.99f Class(es) Found**
**----------**
**Aliphatic Amines**

| ECOSAR Class | Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|---|
| Neutral Organic SAR (Baseline Toxicity) | : Fish | 14-day | LC50 | 0.007 * |
| Aliphatic Amines | : Fish | 96-hr | LC50 | 0.026 * |
| Aliphatic Amines | : Daphnid | 48-hr | LC50 | 0.004 * |
| Aliphatic Amines | : Green Algae | 96-hr | EC50 | 0.046 * |
| Aliphatic Amines | : Green Algae | 96-hr | ChV | 0.036 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none

Level III Fugacity Model (Full-Output):
========================================
  Chem Name   : 1-Hexadecanamine, N,N-dimethyl-
  Molecular Wt: 269.52
  Henry's LC  : 0.0194 atm-m3/mole (Henrywin program)
  Vapor Press : 0.000286 mm Hg  (Mpbpwin program)
```

```
Liquid VP   : 0.000676 mm Hg  (super-cooled)
Melting Pt  : 62.8 deg C (Mpbpwin program)
Log Kow     : 7.41  (Kowwin program)
Soil Koc    : 1.05e+007  (calc by model)

        Concentration   Half-Life    Emissions
          (percent)        (hr)       (kg/hr)
 Air       0.00249         2.6          0
 Water     5.05            900          1000
 Soil      0.000174        900          0
 Sediment  94.9            3.6e+003     0

           Fugacity    Reaction    Advection   Reaction    Advection
            (atm)      (kg/hr)      (kg/hr)    (percent)   (percent)
 Air       7.56e-014    22.3        0.835       2.23        0.0835
 Water     3.37e-009    131         170         13.1        17
 Soil      9.24e-017    0.0045      0           0.00045     0
 Sediment  2.27e-009    613         63.7        61.3        6.37

 Persistence Time: 3.35e+003 hr
 Reaction Time:    4.38e+003 hr
 Advection Time:   1.43e+004 hr
 Percent Reacted:  76.6
 Percent Advected: 23.4

 Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
    Air:      2.597
    Water:    900
    Soil:     900
    Sediment: 3600
      Biowin estimate: 2.647  (weeks-months)

 Advection Times (hr):
    Air:      100
    Water:    1000
    Sediment: 5e+004
```

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Octadecanamine, N,N-dimethyl (CAS RN 124-28-7)

| | |
|---|---|
| Melting Point (ºC) | 22.9 |
| Boiling Point (ºC) | 346 |
| Vapor Pressure (hPa) | 0.00017 |
| Partition Coefficient (log $K_w$) | 8.39 |
| Water Solubility (mg/l) | 0.009 |
| Photodegradation (cm3/molecule-sec) [$t_{1/2}$ (hr)] | 102 E-12 [1.3] |
| Hydrolysis [$t_{1/2}$ (hr)] | NC |
| Level III Fugacity (All input to water) | Air < 1%<br>Water 5%<br>Soil < 1%<br>Sediment 95% |
| Acute Fish Toxicity - 96-hour $LC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Acute Toxicity to Aquatic Invertebrates - 48-hour $EC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Toxicity to Aquatic Plants - 96-hour $EC_{50}$ (mg/l) | NC – as cationic surfactant<br>NTS – as aliphatic amine |

NC – Not calculated by Model
NTS – Model indicates "Not Toxic at Solubility"

### Model Input/Output

```
SMILES : N(CCCCCCCCCCCCCCCCCC)(C)C
CHEM   : 1-Octadecanamine, N,N-dimethyl-
CAS NUM: 000124-28-7
MOL FOR: C20 H43 N1
MOL WT : 297.57
------------------------------ EPI SUMMARY (v3.05) --------------------------
 Physical Property Inputs:
    Water Solubility (mg/L):   ------
    Vapor Pressure (mm Hg) :   ------
    Henry LC (atm-m3/mole) :   ------
    Log Kow (octanol-water):   ------
    Boiling Point (deg C)  :   ------
    Melting Point (deg C)  :   ------

 Log Octanol-Water Partition Coef (SRC):
    Log Kow (KOWWIN v1.66 estimate) =  8.39

 Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):
    Boiling Pt (deg C):  345.70  (Adapted Stein & Brown method)
    Melting Pt (deg C):  81.33  (Mean or Weighted MP)
    VP(mm Hg,25 deg C):  0.000167  (Modified Grain method)
    MP  (exp database):  22.89 deg C

 Water Solubility Estimate from Log Kow (WSKOW v1.37):
```

```
   Water Solubility at 25 deg C (mg/L):  0.008882
      log Kow used: 8.39 (estimated)
      no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):
   Class(es) found:
      Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
  Bond Method :   4.51E-003  atm-m3/mole
  Group Method:   3.88E-002  atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]:  7.362E-003 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):
   Linear Model         :   0.5090
   Non-Linear Model     :   0.1685
Expert Survey Biodegradation Results:
   Ultimate Survey Model:   2.5851  (weeks-months)
   Primary Survey Model :   3.3995  (days-weeks  )
Readily Biodegradable Probability (MITI Model):
   Linear Model         :   0.5833
   Non-Linear Model     :   0.6119

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:
  Hydroxyl Radicals Reaction:
     OVERALL OH Rate Constant = 101.7254 E-12 cm3/molecule-sec
     Half-Life =     0.105 Days (12-hr day; 1.5E6 OH/cm3)
     Half-Life =     1.262 Hrs
  Ozone Reaction:
     No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):
     Koc    :  5.147E+005
     Log Koc:  5.712

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
   Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):
   Log BCF =  1.409  (BCF = 25.67)
      log Kow used: 8.39 (estimated)

Volatilization from Water:
   Henry LC:  0.0388 atm-m3/mole  (estimated by Group SAR Method)
   Half-Life from Model River:      1.786  hours
   Half-Life from Model Lake :      164.1  hours   (6.839 days)

Removal In Wastewater Treatment:
   Total removal:              94.05  percent
   Total biodegradation:        0.78  percent
   Total sludge adsorption:    93.15  percent
   Total to Air:                0.12  percent

Level III Fugacity Model:
         Concentration   Half-Life    Emissions
           (percent)        (hr)       (kg/hr)
  Air       0.0738          2.52         1000
```

```
   Water     3.5             900          1000
   Soil      27.2            900          1000
   Sediment  69.2            3.6e+003     0
     Persistence Time: 1.59e+003 hr


--------------------------------------------------------------------------------

CHEM   : 124287
CAS Num: 124287
ChemID1:
ChemID2:
ChemID3:
WatDisp: 0.008882 mg/L

Avg Length Carbon Chain: 18.00
```

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

| Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|
| Fish | acute | LC50 | 2.489 * |
| Snail | acute | LC50 | 1.014 * |
| Daphnid | acute | LC50 | 2.692 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none


--------------------------------------------------------------------------------

ECOSAR Program (v0.99f) Results:
================================
SMILES : N(CCCCCCCCCCCCCCCCCC)(C)C
CHEM   : 1-Octadecanamine, N,N-dimethyl-
CAS Num:
ChemID1:
ChemID2:
ChemID3:
MOL FOR: C20 H43 N1
MOL WT : 297.57
Log Kow: 8.39  (KowWin estimate)
Melt Pt:
Wat Sol: 0.0004016 mg/L  (calculated)
```

**ECOSAR v0.99f Class(es) Found**
**----------**
**Aliphatic Amines**

| ECOSAR Class | Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|---|

```
==========================  ==================  ========  ======   ==========
Neutral Organic SAR        : Fish                14-day    LC50      0.00109 *
(Baseline Toxicity)

Aliphatic Amines           : Fish                96-hr     LC50        0.007 *
Aliphatic Amines           : Daphnid             48-hr     LC50      0.00112 *
Aliphatic Amines           : Green Algae         96-hr     EC50        0.019 *
Aliphatic Amines           : Green Algae         96-hr     ChV         0.019 *

 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none

--------------------------------------------------------------------------------

Level III Fugacity Model (Full-Output):
========================================
  Chem Name   : 1-Octadecanamine, N,N-dimethyl-
  Molecular Wt: 297.57
  Henry's LC  : 0.0388 atm-m3/mole (Henrywin program)
  Vapor Press : 0.000167 mm Hg  (Mpbpwin program)
  Liquid VP   : 0.000602 mm Hg  (super-cooled)
  Melting Pt  : 81.3 deg C (Mpbpwin program)
  Log Kow     : 8.39  (Kowwin program)
  Soil Koc    : 1.01e+008  (calc by model)

          Concentration   Half-Life    Emissions
            (percent)        (hr)       (kg/hr)
   Air       0.000256        2.52         0
   Water     4.82            900          1000
   Soil      1.93e-005       900          0
   Sediment  95.2            3.6e+003     0

             Fugacity    Reaction    Advection   Reaction    Advection
              (atm)      (kg/hr)      (kg/hr)    (percent)   (percent)
   Air       7.27e-015    2.44        0.0887      0.244       0.00887
   Water     6.63e-010    129         167         12.9        16.7
   Soil      2.01e-018    0.000517    0           5.17e-005   0
   Sediment  4.46e-010    636         66          63.6        6.6

   Persistence Time: 3.47e+003 hr
   Reaction Time:    4.52e+003 hr
   Advection Time:   1.49e+004 hr
   Percent Reacted:  76.7
   Percent Advected: 23.3

   Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
      Air:      2.522
      Water:    900
      Soil:     900
      Sediment: 3600
        Biowin estimate: 2.585  (weeks-months)

   Advection Times (hr):
```

```
Air:      100
Water:    1000
Sediment: 5e+004
```

## SAR ROBUST SUMMARY

### Test Substance

Identity: Octadecen-1-amine, N,N-dimethyl- (CAS RN 28061-69-0)

| | |
|---|---|
| Melting Point (ºC) | 80 |
| Boiling Point (ºC) | 345 |
| Vapor Pressure (hPa) | 0.000052 |
| Partition Coefficient (log $K_w$) | 8.25 |
| Water Solubility (mg/l) | 0.012 |
| Photodegradation (cm3/molecule-sec) [$t_{1/2}$ (hr)] | 126 E-12 [1.0 hr] |
| Hydrolysis [$t_{1/2}$ (hr)] | NC |
| Level III Fugacity (All input to water) | Air: <1%<br>Water: 5%<br>Soil: <1%<br>Sediment: 95% |
| Acute Fish Toxicity - 96-hour $LC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Acute Toxicity to Aquatic Invertebrates - 48-hour $EC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Toxicity to Aquatic Plants - 96-hour $EC_{50}$ (mg/l) | NC– as cationic surfactant<br>NTS – as aliphatic amine |

NC – Not calculated by Model
NTS – Model indicates "Not Toxic at Solubility"

### Model Input/Output

```
SMILES : C=CCCCCCCCCCCCCCCCCN(C)C
CHEM   : Octadecen-1-amine, N,N-dimethyl-
CAS NUM: 028061-69-0
MOL FOR: C20 H41 N1
MOL WT : 295.56
------------------------------ EPI SUMMARY (v3.05) --------------------------
 Physical Property Inputs:
    Water Solubility (mg/L):   ------
    Vapor Pressure (mm Hg) :   ------
    Henry LC (atm-m3/mole) :   ------
    Log Kow (octanol-water):   ------
    Boiling Point (deg C)  :   ------
    Melting Point (deg C)  :   ------

 Log Octanol-Water Partition Coef (SRC):
    Log Kow (KOWWIN v1.66 estimate) =  8.25

 Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):
    Boiling Pt (deg C):  344.76  (Adapted Stein & Brown method)
    Melting Pt (deg C):  80.18  (Mean or Weighted MP)
    VP(mm Hg,25 deg C):  5.23E-005  (Modified Grain method)

 Water Solubility Estimate from Log Kow (WSKOW v1.37):
    Water Solubility at 25 deg C (mg/L):  0.01193
```

```
      log Kow used: 8.25 (estimated)
      no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):
   Class(es) found:
      Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
  Bond Method :   3.36E-003  atm-m3/mole
  Group Method:   1.23E-002  atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]:  1.705E-003 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):
   Linear Model         :   0.4016
   Non-Linear Model     :   0.0320
Expert Survey Biodegradation Results:
   Ultimate Survey Model:   2.2912  (weeks-months)
   Primary Survey Model :   3.1333  (weeks       )
Readily Biodegradable Probability (MITI Model):
   Linear Model         :   0.5581
   Non-Linear Model     :   0.5374

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:
  Hydroxyl Radicals Reaction:
     OVERALL OH Rate Constant = 126.4451 E-12 cm3/molecule-sec
     Half-Life =     0.085 Days (12-hr day; 1.5E6 OH/cm3)
     Half-Life =     1.015 Hrs
  Ozone Reaction:
     OVERALL Ozone Rate Constant =     1.200000 E-17 cm3/molecule-sec
     Half-Life =     0.955 Days (at 7E11 mol/cm3)
     Half-Life =     22.920 Hrs

Soil Adsorption Coefficient (PCKOCWIN v1.66):
     Koc    :  5.147E+005
     Log Koc:  5.712

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
   Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):
   Log BCF =  1.596  (BCF = 39.47)
      log Kow used: 8.25 (estimated)

Volatilization from Water:
   Henry LC:  0.0123 atm-m3/mole  (estimated by Group SAR Method)
   Half-Life from Model River:      1.836  hours
   Half-Life from Model Lake :      164.2  hours   (6.841 days)

Removal In Wastewater Treatment:
   Total removal:              94.03  percent
   Total biodegradation:        0.78  percent
   Total sludge adsorption:    93.20  percent
   Total to Air:                0.05  percent

Level III Fugacity Model:
         Concentration   Half-Life    Emissions
           (percent)        (hr)       (kg/hr)
```

```
   Air       0.0551          1.86         1000
   Water     3.51            900          1000
   Soil      27.3            900          1000
   Sediment  69.2            3.6e+003     0
     Persistence Time: 1.59e+003 hr

CHEM   : 28061690
CAS Num: 28061690
ChemID1:
ChemID2:
ChemID3:
WatDisp: 0.01193 mg/L

Avg Length Carbon Chain: 18.00
```

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

| Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|
| Fish | acute | LC50 | 2.489 * |
| Snail | acute | LC50 | 1.014 * |
| Daphnid | acute | LC50 | 2.692 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none
```

**ECOSAR v0.99f Class(es) Found**
**----------**
**Aliphatic Amines**

| ECOSAR Class | Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|---|
| Neutral Organic SAR (Baseline Toxicity) | : Fish | 14-day | LC50 | 0.00143 * |
| Aliphatic Amines | : Fish | 96-hr | LC50 | 0.008 * |
| Aliphatic Amines | : Daphnid | 48-hr | LC50 | 0.00134 * |
| Aliphatic Amines | : Green Algae | 96-hr | EC50 | 0.022 * |
| Aliphatic Amines | : Green Algae | 96-hr | ChV | 0.021 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none

Level III Fugacity Model (Full-Output):
=======================================
```

```
Chem Name   : Octadecen-1-amine, N,N-dimethyl-
Molecular Wt: 295.56
Henry's LC  : 0.0123 atm-m3/mole (Henrywin program)
Vapor Press : 5.23e-005 mm Hg  (Mpbpwin program)
Liquid VP   : 0.000184 mm Hg  (super-cooled)
Melting Pt  : 80.2 deg C (Mpbpwin program)
Log Kow     : 8.25  (Kowwin program)
Soil Koc    : 7.29e+007  (calc by model)

        Concentration   Half-Life    Emissions
          (percent)        (hr)       (kg/hr)
 Air       0.00026         1.86         0
 Water     4.83            900          1000
 Soil      5.05e-005       900          0
 Sediment  95.2            3.6e+003     0

           Fugacity    Reaction    Advection   Reaction    Advection
            (atm)      (kg/hr)      (kg/hr)    (percent)   (percent)
 Air       7.4e-015     3.34        0.09        0.334       0.009
 Water     2.92e-010    129         167         12.9        16.7
 Soil      2.31e-018    0.00135     0           0.000135    0
 Sediment  1.96e-010    635         65.9        63.5        6.59

 Persistence Time: 3.46e+003 hr
 Reaction Time:    4.52e+003 hr
 Advection Time:   1.49e+004 hr
 Percent Reacted:  76.7
 Percent Advected: 23.3

 Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
    Air:      1.865
    Water:    900
    Soil:     900
    Sediment: 3600
      Biowin estimate: 2.291  (weeks-months)

 Advection Times (hr):
    Air:      100
    Water:    1000
    Sediment: 5e+004
```

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Octadecanamine, N-methyl-N-octadecyl- (CAS RN 4088-22-6)

| | |
|---|---|
| Melting Point (ºC) | 216 |
| Boiling Point (ºC) | 543 |
| Vapor Pressure (hPa) | $2.0 \times 10^{-11}$ |
| Partition Coefficient (log $K_w$) | 17 |
| Water Solubility (mg/l) | 2 E-11 |
| Photodegradation (cm3/molecule-sec) [$t_{1/2}$ (hr)] | 134 E-12 [1.0] |
| Hydrolysis [$t_{1/2}$ (hr)] | NC |
| Level III Fugacity (All input to water) | Air: <1%<br>Water: 5%<br>Soil: <1%<br>Sediment: 95% |
| Acute Fish Toxicity - 96-hour $LC_{50}$ (mg/l) | NTS - as cationic surfactant<br>NTS - as aliphatic amine |
| Acute Toxicity to Aquatic Invertebrates - 48-hour $EC_{50}$ (mg/l) | NTS - as cationic surfactant<br>NTS - as aliphatic amine |
| Toxicity to Aquatic Plants - 96-hour $EC_{50}$ (mg/l) | NC - as cationic surfactant<br>NTS - as aliphatic amine |

NC – Not calculated by Model
NTS – Model indicates "Not Toxic at Solubility"

### Model Input/Output

```
SMILES : N(CCCCCCCCCCCCCCCCCC)(CCCCCCCCCCCCCCCCCC)C
CHEM   : 1-Octadecanamine, N-methyl-N-octadecyl-
CAS NUM: 004088-22-6
MOL FOR: C37 H77 N1
MOL WT : 536.03
------------------------------ EPI SUMMARY (v3.05) --------------------------
 Physical Property Inputs:
    Water Solubility (mg/L):   ------
    Vapor Pressure (mm Hg) :   ------
    Henry LC (atm-m3/mole) :   ------
    Log Kow (octanol-water):   ------
    Boiling Point (deg C)  :   ------
    Melting Point (deg C)  :   ------

 Log Octanol-Water Partition Coef (SRC):
    Log Kow (KOWWIN v1.66 estimate) =  16.74

 Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):
    Boiling Pt (deg C):  542.96  (Adapted Stein & Brown method)
    Melting Pt (deg C):  215.91  (Mean or Weighted MP)
    VP(mm Hg,25 deg C):  2.04E-011  (Modified Grain method)

 Water Solubility Estimate from Log Kow (WSKOW v1.37):
    Water Solubility at 25 deg C (mg/L):  2.179e-011
```

```
      log Kow used: 16.74 (estimated)
      no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):
   Class(es) found:
      Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
  Bond Method :   5.58E-001  atm-m3/mole
  Group Method:   1.17E+001  atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]:  6.603E-001 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):
   Linear Model         :   0.5040
   Non-Linear Model     :   0.0415
Expert Survey Biodegradation Results:
   Ultimate Survey Model:   2.3565  (weeks-months)
   Primary Survey Model :   3.3245  (days-weeks  )
Readily Biodegradable Probability (MITI Model):
   Linear Model         :   0.7140
   Non-Linear Model     :   0.7053

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:
  Hydroxyl Radicals Reaction:
     OVERALL OH Rate Constant = 133.6565 E-12 cm3/molecule-sec
     Half-Life =     0.080 Days (12-hr day; 1.5E6 OH/cm3)
     Half-Life =     0.960 Hrs
  Ozone Reaction:
     No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):
     Koc    :  1E+010
     Log Koc:  10.251

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
   Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):
   Log BCF =  0.500  (BCF = 3.162)
      log Kow used: 16.74 (estimated)

Volatilization from Water:
   Henry LC:  11.7 atm-m3/mole  (estimated by Group SAR Method)
   Half-Life from Model River:      2.363  hours
   Half-Life from Model Lake :      219.9  hours   (9.163 days)

Removal In Wastewater Treatment:
   Total removal:              94.04  percent
   Total biodegradation:        0.78  percent
   Total sludge adsorption:    93.26  percent
   Total to Air:                0.00  percent

Level III Fugacity Model:
         Concentration   Half-Life    Emissions
           (percent)        (hr)       (kg/hr)
  Air       0.0509          1.92         1000
  Water     3.43            900          1000
```

```
   Soil      28.3            900          1000
   Sediment  68.2            3.6e+003     0
     Persistence Time: 1.63e+003 hr


CHEM   : 4088226
CAS Num: 4088226
ChemID1:
ChemID2:
ChemID3:
WatDisp: 2.2e-011 mg/L

Avg Length Carbon Chain: 18.00
```

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

| Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|
| Fish | acute | LC50 | 2.489 * |
| Snail | acute | LC50 | 1.014 * |
| Daphnid | acute | LC50 | 2.692 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none
```

---

**ECOSAR v0.99f Class(es) Found**
**---**
**Aliphatic Amines**

| ECOSAR Class | Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|---|
| Neutral Organic SAR (Baseline Toxicity) | Fish | 14-day | LC50 | 1.04e-010 * |
| Aliphatic Amines | Fish | 96-hr | LC50 | 5.44e-008 * |
| Aliphatic Amines | Daphnid | 48-hr | LC50 | 2.69e-008 * |
| Aliphatic Amines | Green Algae | 96-hr | EC50 | 8.24e-006 * |
| Aliphatic Amines | Green Algae | 96-hr | ChV | 5.48e-005 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none
```

---

```
Level III Fugacity Model (Full-Output):
========================================
  Chem Name   : 1-Octadecanamine, N-methyl-N-octadecyl-
  Molecular Wt: 536.03
  Henry's LC  : 11.7 atm-m3/mole (Henrywin program)
  Vapor Press : 2.04e-011 mm Hg  (Mpbpwin program)
  Liquid VP   : 1.58e-009 mm Hg  (super-cooled)
  Melting Pt  : 216 deg C (Mpbpwin program)
  Log Kow     : 16.7  (Kowwin program)
  Soil Koc    : 2.25e+016  (calc by model)

          Concentration   Half-Life    Emissions
            (percent)        (hr)       (kg/hr)
   Air       8.17e-013       1.92         0
   Water     4.79            900          1000
   Soil      2.86e-011       900          0
   Sediment  95.2            3.6e+003     0

             Fugacity    Reaction    Advection   Reaction    Advection
              (atm)      (kg/hr)      (kg/hr)    (percent)   (percent)
   Air       2.27e-026    1.03e-008   2.85e-010   1.03e-009   2.85e-011
   Water     4.98e-016    128         167         12.8        16.7
   Soil      2.23e-030    7.67e-010   0           7.67e-011   0
   Sediment  3.35e-016    638         66.3        63.8        6.63

   Persistence Time: 3.48e+003 hr
   Reaction Time:    4.54e+003 hr
   Advection Time:   1.49e+004 hr
   Percent Reacted:  76.7
   Percent Advected: 23.3

   Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
      Air:      1.921
      Water:    900
      Soil:     900
      Sediment: 3600
        Biowin estimate: 2.356  (weeks-months)

   Advection Times (hr):
      Air:      100
      Water:    1000
      Sediment: 5e+004
```

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched (CAS RN 68479-04-9)

| | |
|---|---|
| Melting Point (ºC) | 130 |
| Boiling Point (ºC) | 380 |
| Vapor Pressure (hPa) | $2.2 \times 10^{-6}$ |
| Partition Coefficient (log $K_w$) | 5.37 |
| Water Solubility (mg/l) | 2.64 |
| Photodegradation (cm3/molecule-sec) [$t_{1/2}$ (hr)] | 154 E-12 [0.8] |
| Hydrolysis [$t_{1/2}$ (hr)] | NC |
| Level III Fugacity (All input to water) | Air: <1%<br>Water: 27%<br>Soil: <1%<br>Sediment: 73% |
| Acute Fish Toxicity - 96-hour $LC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Acute Toxicity to Aquatic Invertebrates - 48-hour $EC_{50}$ (mg/l) | NTS – as cationic surfactant<br>0.07 – as aliphatic amine |
| Toxicity to Aquatic Plants - 96-hour $EC_{50}$ (mg/l) | NC – as cationic surfactant<br>0.42 – as aliphatic amine |

NC – Not calculated by Model
NTS – Model indicates "Not Toxic at Solubility"

### Model Input/Output

```
SMILES : NCCCNCCCOCCCCCCCCCCC(C)C
CHEM   : 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched
CAS NUM: 068479-04-9
MOL FOR: C19 H42 N2 O1
MOL WT : 314.56
------------------------------ EPI SUMMARY (v3.05) --------------------------
 Physical Property Inputs:
    Water Solubility (mg/L):   ------
    Vapor Pressure (mm Hg) :   ------
    Henry LC (atm-m3/mole) :   ------
    Log Kow (octanol-water):   ------
    Boiling Point (deg C)  :   ------
    Melting Point (deg C)  :   ------

 Log Octanol-Water Partition Coef (SRC):
    Log Kow (KOWWIN v1.66 estimate) =  5.37

 Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):
    Boiling Pt (deg C):  380.33  (Adapted Stein & Brown method)
    Melting Pt (deg C):  130.24  (Mean or Weighted MP)
    VP(mm Hg,25 deg C):  2.2E-006  (Modified Grain method)

 Water Solubility Estimate from Log Kow (WSKOW v1.37):
```

```
   Water Solubility at 25 deg C (mg/L):  2.639
      log Kow used: 5.37 (estimated)
      no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):
   Class(es) found:
      Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
  Bond Method :   1.86E-009  atm-m3/mole
  Group Method:   1.23E-010  atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]:  3.450E-007 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):
   Linear Model         :   0.5581
   Non-Linear Model     :   0.0649
Expert Survey Biodegradation Results:
   Ultimate Survey Model:   2.5442  (weeks-months)
   Primary Survey Model :   3.4707  (days-weeks  )
Readily Biodegradable Probability (MITI Model):
   Linear Model         :   0.5852
   Non-Linear Model     :   0.3964

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:
  Hydroxyl Radicals Reaction:
     OVERALL OH Rate Constant = 153.5476 E-12 cm3/molecule-sec
     Half-Life =     0.070 Days (12-hr day; 1.5E6 OH/cm3)
     Half-Life =     0.836 Hrs
  Ozone Reaction:
     No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):
     Koc    :  5.166E+004
     Log Koc:  4.713

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
   Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):
   Log BCF =  2.439  (BCF = 274.6)
      log Kow used: 5.37 (estimated)

Volatilization from Water:
   Henry LC:  1.23E-010 atm-m3/mole  (estimated by Group SAR Method)
   Half-Life from Model River: 8.442E+006  hours   (3.518E+005 days)
   Half-Life from Model Lake :  9.21E+007  hours   (3.837E+006 days)

Removal In Wastewater Treatment:
   Total removal:              86.41  percent
   Total biodegradation:        0.73  percent
   Total sludge adsorption:    85.67  percent
   Total to Air:                0.00  percent

Level III Fugacity Model:
         Concentration   Half-Life    Emissions
           (percent)        (hr)       (kg/hr)
  Air       0.00122         1.67         1000
```

```
   Water     11.2            900          1000
   Soil      58.5            900          1000
   Sediment  30.2            3.6e+003     0
     Persistence Time: 1.39e+003 hr
CHEM   : 68479049
CAS Num: 68479049
ChemID1:
ChemID2:
ChemID3:
WatDisp: 2.639 mg/L

Avg Length Carbon Chain: 12.00
```

**ECOSAR Class: Surfactants, Cationic (C < 16)**

| Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|
| Daphnid | acute | LC50 | 3.236 * |
| Fish | acute | LC50 | 9.772 * |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none
```

**ECOSAR v0.99f Class(es) Found**
**----------**
**Aliphatic Amines**

| ECOSAR Class | Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|---|
| Neutral Organic SAR (Baseline Toxicity) | Fish | 14-day | LC50 | 0.490 |
| Aliphatic Amines | Fish | 96-hr | LC50 | 0.604 * |
| Aliphatic Amines | Daphnid | 48-hr | LC50 | 0.069 |
| Aliphatic Amines | Green Algae | 96-hr | EC50 | 0.416 |
| Aliphatic Amines | Green Algae | 96-hr | ChV | 0.202 |

```
 Note:  * = asterick designates: Chemical may not be soluble
        enough to measure this predicted effect.
         Fish and daphnid acute toxicity log Kow cutoff: none
         Green algal EC50 toxicity log Kow cutoff: none
         Chronic toxicity log Kow cutoff: none
         MW cutoff: none

Level III Fugacity Model (Full-Output):
========================================
  Chem Name   : 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched
  Molecular Wt: 314.56
  Henry's LC  : 1.23e-010 atm-m3/mole (Henrywin program)
  Vapor Press : 2.2e-006 mm Hg  (Mpbpwin program)
```

```
Liquid VP   : 2.42e-005 mm Hg  (super-cooled)
Melting Pt  : 130 deg C (Mpbpwin program)
Log Kow     : 5.37  (Kowwin program)
Soil Koc    : 9.61e+004  (calc by model)

        Concentration   Half-Life    Emissions
          (percent)        (hr)       (kg/hr)
 Air       1.51e-009       1.67         0
 Water     27.1            900          1000
 Soil      3.37e-005       900          0
 Sediment  72.9            3.6e+003     0

           Fugacity    Reaction    Advection   Reaction    Advection
            (atm)      (kg/hr)      (kg/hr)    (percent)   (percent)
 Air       1.78e-020    9.85e-006   2.38e-007   9.85e-007   2.38e-008
 Water     7.22e-016    329         427         32.9        42.7
 Soil      5.01e-024    0.000409    0           4.09e-005   0
 Sediment  4.86e-016    221         23          22.1        2.3

 Persistence Time: 1.58e+003 hr
 Reaction Time:    2.86e+003 hr
 Advection Time:   3.5e+003 hr
 Percent Reacted:  55
 Percent Advected: 45

 Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
    Air:      1.672
    Water:    900
    Soil:     900
    Sediment: 3600
      Biowin estimate: 2.544  (weeks-months)

 Advection Times (hr):
    Air:      100
    Water:    1000
    Sediment: 5e+004
```

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1,3-Propanediamine, N-(9Z)-octadecenyl- (CAS RN 7173-62-8)

| | |
|---|---|
| Melting Point (ºC) | 142 |
| Boiling Point (ºC) | 402 |
| Vapor Pressure (hPa) | $4.9 \times 10^{-7}$ |
| Partition Coefficient (log $K_w$) | 7.47 |
| Water Solubility (mg/l) | 0.037 |
| Photodegradation (cm3/molecule-sec) [$t_{1/2}$ (hr)] | 193 E-12 [0.7] |
| Hydrolysis [$t_{1/2}$ (hr)] | NC |
| Level III Fugacity (All input to water) | Air: <1%<br>Water: 11%<br>Soil: <1%<br>Sediment: 89% |
| Acute Fish Toxicity - 96-hour $LC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Acute Toxicity to Aquatic Invertebrates - 48-hour $EC_{50}$ (mg/l) | NTS – as cationic surfactant<br>NTS – as aliphatic amine |
| Toxicity to Aquatic Plants - 96-hour $EC_{50}$ (mg/l) | NC – as cationic surfactant<br>NTS – as aliphatic amine |

NC – Not calculated by Model
NTS – Model indicates "Not Toxic at Solubility"

### Model Input/Output

```
SMILES : N(CCCCCCCCC=CCCCCCCCC)CCCN
CHEM   : 1,3-Propanediamine, N-9-octadecenyl-, (Z)-
CAS NUM: 007173-62-8
MOL FOR: C21 H44 N2
MOL WT : 324.60
----------------------------- EPI SUMMARY (v3.05) --------------------------
 Physical Property Inputs:
    Water Solubility (mg/L):   ------
    Vapor Pressure (mm Hg) :   ------
    Henry LC (atm-m3/mole) :   ------
    Log Kow (octanol-water):   ------
    Boiling Point (deg C)  :   ------
    Melting Point (deg C)  :   ------

 Log Octanol-Water Partition Coef (SRC):
    Log Kow (KOWWIN v1.66 estimate) =  7.47

 Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):
    Boiling Pt (deg C):  402.06  (Adapted Stein & Brown method)
    Melting Pt (deg C):  142.10  (Mean or Weighted MP)
    VP(mm Hg,25 deg C):  4.85E-007  (Modified Grain method)

 Water Solubility Estimate from Log Kow (WSKOW v1.37):
    Water Solubility at 25 deg C (mg/L):  0.03723
```

```
      log Kow used: 7.47 (estimated)
      no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):
   Class(es) found:
      Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
  Bond Method :   3.28E-007  atm-m3/mole
  Group Method:   4.99E-008  atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]:  5.564E-006 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):
   Linear Model         :   1.0091
   Non-Linear Model     :   0.9215
Expert Survey Biodegradation Results:
   Ultimate Survey Model:   2.8291  (weeks       )
   Primary Survey Model :   3.7351  (days-weeks  )
Readily Biodegradable Probability (MITI Model):
   Linear Model         :   0.7153
   Non-Linear Model     :   0.5970

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:
  Hydroxyl Radicals Reaction:
     OVERALL OH Rate Constant = 193.0224 E-12 cm3/molecule-sec [Cis-isomer]
     OVERALL OH Rate Constant = 200.6224 E-12 cm3/molecule-sec [Trans-isomer]
     Half-Life =    0.665 Hrs (12-hr day; 1.5E6 OH/cm3) [Cis-isomer]
     Half-Life =    0.640 Hrs (12-hr day; 1.5E6 OH/cm3) [Trans-isomer]
  Ozone Reaction:
     OVERALL Ozone Rate Constant =    13.000000 E-17 cm3/molecule-sec [Cis-]
     OVERALL Ozone Rate Constant =    20.000000 E-17 cm3/molecule-sec [Trans-]
     Half-Life =     2.116 Hrs (at 7E11 mol/cm3) [Cis-isomer]
     Half-Life =     1.375 Hrs (at 7E11 mol/cm3) [Trans-isomer]
  Reaction With Nitrate Radicals May Be Important!

Soil Adsorption Coefficient (PCKOCWIN v1.66):
     Koc    :  2.089E+006
     Log Koc:  6.320

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
   Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):
   Log BCF =  2.663  (BCF = 460.2)
      log Kow used: 7.47 (estimated)

Volatilization from Water:
   Henry LC:  4.99E-008 atm-m3/mole  (estimated by Group SAR Method)
   Half-Life from Model River: 2.114E+004  hours   (880.9 days)
   Half-Life from Model Lake : 2.308E+005  hours   (9616 days)

Removal In Wastewater Treatment:
   Total removal:              93.97  percent
   Total biodegradation:        0.78  percent
   Total sludge adsorption:    93.19  percent
   Total to Air:                0.00  percent
```

Level III Fugacity Model:

| | Concentration (percent) | Half-Life (hr) | Emissions (kg/hr) |
|---|---|---|---|
| Air | 0.0588 | 0.817 | 1000 |
| Water | 7.5 | 360 | 1000 |
| Soil | 29.1 | 360 | 1000 |
| Sediment | 63.3 | 1.44e+003 | 0 |

Persistence Time: 624 hr

CHEM : 7173628
CAS Num: 7173628
ChemID1:
ChemID2:
ChemID3:
WatDisp: 0.03723 mg/L

Avg Length Carbon Chain: 18.00

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

| Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|
| Fish | acute | LC50 | 2.489 * |
| Snail | acute | LC50 | 1.014 * |
| Daphnid | acute | LC50 | 2.692 * |

Note: * = asterick designates: Chemical may not be soluble enough to measure this predicted effect.
Fish and daphnid acute toxicity log Kow cutoff: none
Green algal EC50 toxicity log Kow cutoff: none
Chronic toxicity log Kow cutoff: none
MW cutoff: none

**ECOSAR v0.99f Class(es) Found**
**----------**
**Aliphatic Amines**

| ECOSAR Class | Organism | Duration | End Pt | Predicted mg/L (ppm) |
|---|---|---|---|---|
| Neutral Organic SAR (Baseline Toxicity) | Fish | 14-day | LC50 | 0.007 * |
| Aliphatic Amines | Fish | 96-hr | LC50 | 0.028 * |
| Aliphatic Amines | Daphnid | 48-hr | LC50 | 0.004 * |
| Aliphatic Amines | Green Algae | 96-hr | EC50 | 0.053 * |
| Aliphatic Amines | Green Algae | 96-hr | ChV | 0.041 * |

Note: * = asterick designates: Chemical may not be soluble enough to measure this predicted effect.
Fish and daphnid acute toxicity log Kow cutoff: none
Green algal EC50 toxicity log Kow cutoff: none
Chronic toxicity log Kow cutoff: none
MW cutoff: none

```
Level III Fugacity Model (Full-Output):
========================================
  Chem Name   : 1,3-Propanediamine, N-9-octadecenyl-, (Z)-
  Molecular Wt: 324.6
  Henry's LC  : 4.99e-008 atm-m3/mole (Henrywin program)
  Vapor Press : 4.85e-007 mm Hg  (Mpbpwin program)
  Liquid VP   : 6.98e-006 mm Hg  (super-cooled)
  Melting Pt  : 142 deg C (Mpbpwin program)
  Log Kow     : 7.47  (Kowwin program)
  Soil Koc    : 1.21e+007  (calc by model)

          Concentration   Half-Life    Emissions
            (percent)        (hr)       (kg/hr)
   Air       2.89e-007       0.817        0
   Water     10.6            360          1000
   Soil      6.61e-006       360          0
   Sediment  89.4            1.44e+003    0

             Fugacity    Reaction    Advection   Reaction    Advection
              (atm)      (kg/hr)      (kg/hr)    (percent)   (percent)
   Air       2.54e-018    0.00323     3.81e-005   0.000323    3.81e-006
   Water     5.21e-015    269         140         26.9        14
   Soil      2.57e-024    0.000168    0           1.68e-005   0
   Sediment  1.56e-015    568         23.6        56.8        2.36

   Persistence Time: 1.32e+003 hr
   Reaction Time:    1.58e+003 hr
   Advection Time:   8.08e+003 hr
   Percent Reacted:  83.7
   Percent Advected: 16.3

   Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
      Air:      0.8166
      Water:    360
      Soil:     360
      Sediment: 1440
        Biowin estimate: 2.829  (weeks       )

   Advection Times (hr):
      Air:      100
      Water:    1000
      Sediment: 5e+004
```