

# Environmental Protection Agency Federal Register

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Wednesday  
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Part III

## Environmental Protection Agency

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Thirteenth Report of the Interagency  
Testing Committee to the Administrator;  
Receipt of Report and Request for  
Comments Regarding Priority List of  
Chemicals



## ENVIRONMENTAL PROTECTION AGENCY

[OPTS-41013 TSH-FRL #2484-7]

### Thirteenth Report of the Interagency Testing Committee to the Administrator; Receipt of Report and Request for Comments Regarding Priority List of Chemicals

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Interagency Testing Committee (ITC), established under section 4(e) of the Toxic Substances Control Act (TSCA), transmitted its Thirteenth Report to the Administrator of EPA on November 8, 1983. This report, which revises and updates the Committee's priority list of chemicals, adds four designated chemicals to the list for priority consideration by EPA in the promulgation of test rules under section 4(a) of the Act. The new chemicals are 2-(2-butoxyethoxy)ethyl acetate, ethylene bis(oxyethylene) diacetate, 1,2,3,4,7,7-hexachloronorborene, and oleylamine. The Thirteenth Report is included in this notice. The Agency invites interested persons to submit written comments on the Report, and to attend Focus Meetings to help narrow and focus the issues raised by the ITC's recommendations. Members of the public are also invited to inform EPA if they wish to be notified of subsequent public meetings on these chemicals. EPA also notes the removal of 19 chemicals from the priority list because EPA has responded to the ITC's prior recommendations for testing of the chemicals.

**DATES:** Written comments should be submitted by January 13, 1984. Focus Meetings will be held on January 16 and 17, 1984.

**ADDRESSES:** Send written submissions to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St., SW., Washington, D.C. 20460. Submissions should bear the document control number (OPTS-41012).

The public record supporting this action, including comments, is available for public inspection in Rm. E-107 at the address noted above from 8:00 a.m. to 4:00 p.m. Monday through Friday, except legal holidays. Focus Meetings will be held at Waterside Mall, in Rm. 3906, 401 M St., SW., Washington, D.C. Persons planning to attend any one of the Focus Meetings and/or seeking to be informed of subsequent public meetings on these

chemicals, should notify the TSCA Assistance Office at the address listed below. To insure seating accommodations at the Focus Meeting, persons interested in attending are asked to notify EPA at least 2 weeks ahead of the scheduled dates.

**FOR FURTHER INFORMATION CONTACT:** Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460, Toll Free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator-202-554-1404).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 4(a) of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) authorizes the Administrator of EPA to promulgate regulations requiring testing of chemical substances and mixtures in order to develop data relevant to determining the risks that such chemical substances and mixtures may present to health and the environment.

Section 4(e) of TSCA established an Interagency Testing Committee to make recommendations to the Administrator of EPA of chemical substances and mixtures to be given priority consideration in proposing test rules under section 4(a). Section 4(e) directs the Committee to revise its list of recommendations at least every 6 months as it determines to be necessary. The ITC may "designate" up to 50 substances and mixtures at any one time for priority consideration by the Agency. For such designations, the Agency must within 12 months either initiate rulemaking or issue in the **Federal Register** its reasons for not requiring testing. The ITC's Thirteenth Report was received by the Administrator on November 8, 1983, and follows this Notice. The report designates four substances for priority consideration and response by EPA within 12 months.

##### II. Written and Oral Comments and Public Meetings

EPA invites interested persons to submit detailed comments on the ITC's new recommendations. The Agency is interested in receiving information concerning additional or ongoing health and safety studies on the subject chemicals as well as information relating to the human and environmental exposure to these chemicals. A notice is published elsewhere in today's **Federal Register** adding the four substances designated in the ITC's Thirteenth

Report to the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716). The section 8(d) rule requires the reporting of unpublished health and safety studies on the listed chemicals. These four chemicals will also be added to the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712) published elsewhere in this issue. The section 8(a) rule requires the reporting of production volume, use, exposure, and release information on the listed chemicals.

Focus Meetings will be held to discuss relevant issues pertaining to the chemicals and to narrow the range of issues/effects which will be the focus of the Agency's subsequent activities in responding to the ITC recommendations. The Focus Meetings will be held January 16 and 17, 1984, at Waterside Mall, 401 M St., SW., Washington, D.C., Rm. S-355. These meetings are intended to supplement and expand upon written comments submitted in response to this notice. The schedule for the Focus Meetings is as follows: January 16, 9:30 a.m.—ethylene bis(oxyethylene) diacetate, and 1:00 p.m.—2-(2-butoxyethoxy)ethyl acetate; and January 17, 9:30 a.m.—1,2,3,4,7,7-hexachloronorborene, and 1:00 p.m.—oleylamine. Persons wishing to attend one or more of these meetings should call the TSCA Assistance Office at the toll free number listed above at least 2 weeks in advance.

After consideration of the data pertaining to each chemical, and any additional information provided in the written comments and the Focus Meetings, EPA will hold public meetings on each chemical after preliminary decisions have been made on the types of testing that are needed. These meetings will be several months in the future, but separate notice of these meetings will not be published at that time. Therefore, anyone wishing to attend these later meetings should contact EPA now at the address given for the TSCA Assistance Office in order to be notified in advance of the public meetings.

All written submissions should bear the identifying docket number (OPTS-41012).

##### III. Status of List

In addition to adding the 4 designations to the priority list, the ITC's Thirteenth Report notes the removal of 8 chemicals from the list since the last ITC report because EPA has responded to the Committee's prior recommendations for testing of the chemicals. Subsequent to the ITC's preparation of its Thirteenth Report,



EPA responded to the ITC's recommendations for 11 additional chemicals. The 19 chemicals removed and the dates of publication in the Federal Register of EPA's responses to the ITC for these chemicals are: Biphenyl, May 23, 1983 (48 FR 23080); cresols, July 11, 1983 (48 FR 31812); ethyltoluene (mixed isomers), May 23, 1983 (48 FR 23088); formamide, May 23, 1983 (48 FR 23098); mesityl oxide, July 5, 1983 (48 FR 30699); 4,4'-methylenedianiline, July 11, 1983 (48 FR 31806); and 1,2,4-trimethylbenzene, May 23, 1983 (48 FR 23088); other trimethylbenzene isomers, May 23, 1983 (48 FR 23088); seven alkyltin compounds, November 8, 1983 (48 FR 51361); bis(2-ethylhexyl) terephthalate, November 14, 1983 (48 FR 51845); 1,3-dioxolane, November 14, 1983 (48 FR 51839); 4-(1,1,3,3-tetramethylbutyl)phenol, November 15, 1983 (48 FR 51971); and tris(2-ethylhexyl)trimellitate, November 14, 1983 (48 FR 51842). The current list contains 20 designated substances or groups of substances and one recommended group of substances.

(Sec. 4, Pub. L. 94-469, 90 Stat. 203; (15 U.S.C. 2601))

Dated: November 25, 1983.

Don R. Clay,

Acting Assistant Administrator for Pesticides and Toxic Substances.

### Thirteenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency

#### Summary

Section 4 of the Toxic Substances Control Act of 1976 (TSCA, Pub. L. 94-469) provides for the testing of chemicals in commerce that may present an unreasonable risk of injury to health or the environment. It also provides for the establishment of a Committee, composed of representatives from eight designated Federal agencies, to recommend chemical substances and mixtures (chemicals) to which the Administrator of the U.S. Environmental Protection Agency (EPA) should give priority consideration for the promulgation of testing rules.

Section 4(e)(1)(A) of TSCA directs the Committee to recommend to the EPA Administrator chemicals to which the Administrator should give priority consideration for the promulgation of testing rules pursuant to section 4(a). The Committee is required to designate those chemicals, from among its recommendations, to which the Administrator should respond within 12 months by either initiating a rulemaking proceeding under section 4(a) or publishing the Administrator's reason

for not initiating such a proceeding. Every 6 months, the Committee makes those revisions in the TSCA section 4(e) Priority List that it determines to be necessary and transmits them to the EPA Administrator.

As a result of its deliberations, the Committee is revising the TSCA section 4(e) Priority List by the addition of 4 chemicals and is noting the removal of 8, as a result of responses by EPA.

The Priority List is divided into two parts: part A contains those recommended chemicals and groups designated for priority consideration and response by the EPA Administrator within 12 months, and part B contains chemicals and groups that have been recommended for priority consideration by EPA without being designated for response within 12 months. Although TSCA does not establish a deadline for EPA response to nondesignated chemicals and groups (part B of the Priority List), the Committee anticipates that the EPA Administrator will respond in a timely manner.

The entries being added to the Priority List are presented, together with the types of testing recommended, in the following Table 1:

Chemical/Group	Recommended studies
<b>A. Designated for response within 12 months:</b>	
2-(2-Butoxyethoxy)ethyl acetate (CAS No. 124-17-4).	Health Effects: Subchronic toxicity; toxicokinetic studies; reproductive effects.
Ethylene bis(oxyethylene) diacetate (CAS No. 111-21-7).	Health Effects: Subchronic toxicity; toxicokinetic studies; reproductive effects.
1, 2, 3, 4, 7, 7-Hexachloronorbomadiene (CAS No. 3389-71-7).	Health Effects: Subchronic tests, including neurotoxicity; biochemical effects, including enzyme-inducing capabilities.
Oleylamine (CAS No. 112-09-3).	Health Effects: Toxicokinetic studies; Genotoxicity and teratogenicity studies if percutaneous absorption is demonstrated.
<b>B. Recommended but not designated for response within 12 months:</b>	
None.....	

### TSCA Interagency Testing Committee

#### Statutory Member Agencies and Their Representatives

Council on Environmental Quality  
Thomas H. Magness, III, Member(1)  
Department of Commerce  
Bernard Greifer, Member  
Environmental Protection Agency  
Carl R. Morris, Member  
Arthur M. Stern, Alternate  
National Cancer Institute  
Elizabeth K. Weisburger, Member and  
Chairperson  
Richard Adamson, Alternate  
Jerrold Ward, Alternate

National Institute of Environmental Health Sciences  
Dorothy Canter, Member  
National Institute For Occupational Safety and Health  
Rodger L. Tatken, Member  
Richard J. Lewis, Sr., Alternate  
National Science Foundation  
Winston C. Nottingham, Member and  
Vice Chairperson  
Occupational Safety and Health Administration  
Ralph Yodaiken, Member(2)

#### Liaison Agencies and Their Representatives

Consumer Product Safety Commission  
Arthur Gregory  
Lakshmi Mishra  
Department of Agriculture  
Homer E. Fairchild  
Richard M. Parry, Jr.(3)  
Department of Defense  
Arthur H. McCreesh  
Department of the Interior  
Vyto A. Adomaitis(4)  
David R. Rosenberger(5)  
Food and Drug Administration  
Winston deMonsabert(6)  
Arnold Borsetti(7)  
Allen H. Heim  
National Toxicology Program  
Dorothy Canter

#### Committee Staff

Martin Greif, Executive Secretary  
Norma Williams, ITC Coordinator

#### Support Staff

Alan Carpien—Office of the General Counsel, EPA  
Stephen Ells—Office of Toxic Substances, EPA  
Vera W. Hudson—National Library of Medicine

#### Notes

- (1) Mr. Magness was appointed on July 27, 1983.
- (2) Dr. Yodaiken was appointed on July 11, 1983.
- (3) Dr. Parry was appointed on September 9, 1983.
- (4) Mr. Adomaitis was appointed on May 10, 1983.
- (5) Mr. Rosenberger was appointed on May 10, 1983.
- (6) Dr. deMonsabert retired from Federal Service on August 18, 1983.
- (7) Dr. Borsetti was appointed on August 18, 1983.

The Committee acknowledges and is grateful for the assistance and support given to it by the staffs of CRCS, Inc., and Dynamac Corporation (technical support prime and subcontractors) and personnel of the EPA Office of Toxic Substances.



## Chapter 1—Introduction

**1.1 Background.** The TSCA Interagency Testing Committee (Committee) was established under section 4(e) of the Toxic Substances Control Act of 1976 (TSCA, Pub. L. 94-469). The specific mandate of the Committee is to recommend to the Administrator of the U.S. Environmental Protection Agency (EPA) chemical substances and mixtures in commerce that should be given priority consideration for the promulgation of testing rules to determine their potential hazard to human health and/or the environment. TSCA specifies that the Committee's recommendations shall be in the form of a Priority List, which is to be published in the *Federal Register*. The Committee is directed by section 4(e)(1)(A) of TSCA to designate those chemicals on the Priority List to which the EPA Administrator should respond within 12 months by either initiating a rulemaking proceeding under section 4(a) or publishing the Administrator's reasons for not initiating such a proceeding.

Every 6 months, the Committee makes those revisions in the section 4(e) Priority List that it determines to be necessary and transmits them to the EPA Administrator.

The Committee is comprised of representatives from eight statutory member agencies, five liaison agencies, and one national program. The specific representatives and their affiliations are named in the front of this report. The Committee's chemical review procedures and prior recommendations are described in previous reports (Refs. 1 through 12).

**1.2 Committee's previous reports.** Twelve previous reports to the EPA Administrator have been issued by the Committee and published in the *Federal Register* (Refs. 1 through 12). Sixty-nine entries (chemicals and groups of chemicals) were recommended for priority consideration by the EPA Administrator and designated for response within 12 months. In addition, two groups were recommended without being so designated. Removal of thirty-five entries was noted in the previous reports.

**1.3 Committee's activities during this reporting period.** Between April 1, 1983 and September 30, 1983 the Committee continued to review chemicals from its third and fourth scoring exercises (see Ref. 1 for methodology). During this period, the Committee also completed the fifth round of scoring chemicals, and selected 82 additional chemicals for in-depth review.

The Committee contacted 87 chemical manufacturers and trade associations to request information that would be of value in its deliberations. Seventy-one of those contacted provided unpublished information on current production, exposure, uses, and effects of chemicals under study by the Committee.

During this reporting period, the Committee evaluated 36 chemicals for priority consideration. Four chemicals were added to the section 4(e) Priority List, and 11 were deferred at this time. The remaining 21 chemicals are still under study.

**1.4 The TSCA section 4(e) Priority List.** Section 4(e)(1)(B) of TSCA directs the Committee to: " \* \* \* make such revisions in the [priority] list as it determines to be necessary and \* \* \* transmit them to the Administrator together with the Committee's reasons for the revisions." Under this authority, the Committee is revising the Priority List by adding four chemicals: 2-(2-butoxyethoxy)ethyl acetate; ethylene bis (oxyethylene) diacetate; 1,2,3,4,7,7-hexachloronorbomadiene; and oleylamine. All four chemicals are designated for response within twelve months. The testing recommended for these chemicals and the rationales for the recommendations are presented in Chapter 2 of this report.

Eight chemicals and groups of chemicals are being removed from the Priority List because the EPA Administrator has responded to the Committee's prior recommendations for testing these chemicals.

They are: biphenyl; cresols; ethyltoluene; formamide, mesityl oxide; 4,4'-methylenedianiline; 1,2,4-trimethylbenzene; and trimethylbenzenes.

With the 4 recommendations and 8 removals noted in this report, 32 entries

now appear on the section 4(e) Priority List. The Priority List is divided in the following Table 2 into two parts; namely, Table 2A, Chemicals and Groups of Chemicals Designated for Response Within 12 Months, and Table 2B, Other Recommended Chemicals and Groups.

TABLE 2.—THE TSCA SECTION 4(E) PRIORITY LIST NOVEMBER 1983

2A. Chemicals and Groups of Chemicals Designated for Response Within 12 Months

Entry	Date of designation
1. Alkyl epoxides.....	Oct. 1977.
2. Aniline and bromo- chloro- and/or nitroanilines.....	Apr. 1979.
3. Aryl phosphates.....	Apr. 1978.
4. Bis (2-ethylhexyl) terephthalate.....	Nov. 1982.
5. 2-(2-Butoxyethoxy) ethyl acetate.....	Nov. 1983.
6. Calcium naphthenate.....	May 1983.
7. Chlorinated benzenes, mono- and di-.....	Oct. 1977.
8. Chlorinated benzenes, tri-, tetra-, and penta-.....	Oct. 1978.
9. Cobalt naphthenate.....	May 1983.
10. Cyclohexanone.....	Apr. 1979.
11. Dibutyltin bis(isooctyl maleate).....	Nov. 1982.
12. Dibutyltin bis(isooctyl mercaptacetate).....	Do.
13. Dibutyltin bis(lauryl mercaptide).....	Do.
14. Dibutyltin dilaurate.....	Do.
15. 1,2-Dichloropropane.....	Oct. 1978.
16. Dimethyltin bis(isooctyl mercaptacetate).....	Nov. 1982.
17. 1,3-Dioxolane.....	Nov. 1982.
18. Ethylene bis(oxyethylene) diacetate.....	Nov. 1983.
19. Glycidol and its derivatives.....	Oct. 1978.
20. Halogenated alkyl epoxides.....	Apr. 1978.
21. 1,2,3,4,7,7-Hexachloronorbomadiene.....	Nov. 1983.
22. Hydroquinone.....	Nov. 1979.
23. Lead naphthenate.....	May 1983.
24. Methylolurea.....	Do.
25. Monobutyltin tris (isooctyl mercaptacetate).....	Nov. 1982.
26. Monomethyltin tris (isooctyl mercaptacetate).....	Do.
27. Oleylamine.....	Nov. 1983.
28. 2-Phenoxyethanol.....	May 1983.
29. Quinone.....	Nov. 1979.
30. 4-(1,1,3,3-Tetramethylbutyl) phenol.....	Nov. 1982.
31. Tris(2-ethylhexyl) trimellitate.....	Do.

2B. Other Recommended Chemicals and Groups of Chemicals

Entry	Date of recommendation
1. Carbofuran Intermediates.....	Nov. 1982.

To date, 43 chemicals and groups and groups of chemicals have been removed from the Priority List. The cumulative list is presented in the following Table 3.

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Table 3--Cumulative Removals from the TSCA Section 4(e) Priority List  
November 1983

EPA Responses to Committee Recommendations		
Chemical/Group	FEDERAL REGISTER	
	Citation	Publication Date
1. Acetonitrile	47 FR 58020-58023	Dec. 29, 1982
2. Acrylamide	48 FR 725-727	Jan. 6, 1983
3. Alkyl phthalates	46 FR 53775-53777	Oct. 30, 1981
4. Alkyltin compounds	46 FR 5456-5463	Feb. 5, 1982 <sup>1/</sup>
5. Antimony metal	48 FR 717-725	Jan. 6, 1983
6. Antimony sulfide	48 FR 717-725	Jan. 6, 1983
7. Antimony trioxide	48 FR 717-725	Jan. 6, 1983
8. Benzidine-based dyes	46 FR 55004-55006	Nov. 5, 1981
9. Benzyl butyl phthalate	46 FR 53775-53777	Oct. 30, 1981
10. Biphenyl	48 FR 23080-23086	May 23, 1983
11. Butyl glycolyl butyl phthalate	46 FR 54487	Nov. 2, 1981
12. Chlorendic acid	47 FR 44878-44879	Oct. 12, 1982
13. Chlorinated naphthalenes	46 FR 54491	Nov. 2, 1981
14. Chlorinated paraffins	47 FR 1017-1019	Jan. 8, 1982
15. Chlorobenzotrifluoride	47 FR 50555-50558	Nov. 8, 1982
16. Chloromethane	45 FR 48524-48564	July 18, 1980
17. 2-Chlorotoluene	47 FR 18172-18175	April 28, 1982
18. Cresols	48 FR 31812-31819	July 11, 1983
19. o-Dianisidine-based dyes	46 FR 55004-55006	Nov. 5, 1981
20. Dichloromethane	46 FR 30300-30320	June 5, 1981
21. Diethylenetriamine	47 FR 18386-18391	April 29, 1982

<sup>1/</sup>Removed by the Committee for reconsideration. Seven individual group members were subsequently designated in the 11th ITC Report (Ref. 11) for priority consideration.



Table 3--Cumulative Removals from the TSCA Section 4(e) Priority List (cont'd)  
November 1983

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EPA Responses to Committee Recommendations

Chemical/Group	FEDERAL REGISTER	
	Citation	Publication Date
22. Ethyltoluene	48 FR 23088-23095	May 23, 1983
23. Fluoroalkenes	46 FR 53704-53708	Oct. 30, 1981
24. Formamide	48 FR 23098-23102	May 23, 1983
25. Hexachloro-1,3-butadiene	47 FR 58029-58031	Dec. 29, 1982
26. Hexachlorocyclopentadiene	47 FR 58023-58025	Dec. 29, 1982
27. Hexachloroethane	47 FR 18175-18176	April 28, 1982
28. Isophorone	48 FR 727-730	Jan. 6, 1983
29. Mesityl oxide	48 FR 30700-30706	July 5, 1983
30. 4,4'-Methylenedianiline	48 FR 31806-31810	July 11, 1983
31. Methyl ethyl ketone	47 FR 58025-58029	Dec. 29, 1982
32. Methyl isobutyl ketone	47 FR 58025-58029	Dec. 29, 1982
33. Nitrobenzene	46 FR 30300-30320	June 5, 1981
34. Phenylenediamines	47 FR 973-983	Jan. 8, 1982
35. Polychlorinated terphenyls	46 FR 54482-54483	Nov. 2, 1981
36. Pyridine	47 FR 58031-58035	Dec. 29, 1982
37. o-Tolidine-based dyes	46 FR 55004-55006	Nov. 5, 1981
38. Toluene	47 FR 56391-56392	Dec. 16, 1982
39. 1,2,4-Trimethylbenzene	48 FR 23088-23095	May 23, 1983
40. Trimethylbenzenes	48 FR 23088-23095	May 23, 1983
41. 1,1,1-Trichloroethane	46 FR 30300-30320	June 5, 1981
42. Tris(2-chloroethyl)phosphite	47 FR 49466-49467	Nov. 1, 1982
43. Xylenes	47 FR 56392-56394	Dec. 16, 1982

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## References

- (1) Initial Report to the Administrator, Environmental Protection Agency, TSCA Interagency Testing Committee, October 1, 1977. Published in the *Federal Register* of Wednesday, October 12, 1977, 42 FR 55028-55080. Corrections published in the *Federal Register* of November 11, 1977, 42 FR 58777-58778. The report and supporting dossiers were also published by the Environmental Protection Agency, EPA 560-10-78/001, January 1978.
- (2) Second Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency, TSCA Interagency Testing Committee, April 1978. Published in the *Federal Register* of Wednesday, April 19, 1978, 43 FR 16684-16688. The report and supporting dossiers were also published by the Environmental Protection Agency, EPA 560-10-78/002, July 1978.
- (3) Third Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency, TSCA Interagency Testing Committee, October 1978. Published in the *Federal Register* of Monday, October 10, 1978, 43 FR 50630-50635. The report and supporting dossiers were also published by the Environmental Protection Agency, EPA 560-10-79/001, January 1979.
- (4) Fourth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency, TSCA Interagency Testing Committee, April 1979. Published in the *Federal Register* of Friday, June 1, 1979, 44 FR 31866-31889.
- (5) Fifth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency, TSCA Interagency Testing Committee, November 1979. Published in the *Federal Register* of Friday, December 7, 1979, 44 FR 70664-70674.
- (6) Sixth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency, TSCA Interagency Testing Committee, April 1980.

Published in the *Federal Register* of Wednesday, May 28, 1980, 45 FR 35897-35910.

(7) Seventh Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency, TSCA Interagency Testing Committee, October 1980. Published in the *Federal Register* of Tuesday, November 25, 1980, 45 FR 78432-78446.

(8) Eighth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency, TSCA Interagency Testing Committee, April 1981. Published in the *Federal Register* of Friday, May 22, 1981, 46 FR 28138-28144.

(9) Ninth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency, TSCA Interagency Testing Committee, October 1981. Published in the *Federal Register* of Friday, February 5, 1982, 47 FR 5458-5463.

(10) Tenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency, TSCA Interagency Testing Committee, April 1982. Published in the *Federal Register* of Tuesday, May 25, 1982, 47 FR 22585-22596.

(11) Eleventh Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency, TSCA Interagency Testing Committee, October 1982. Published in the *Federal Register* of Friday, December 3, 1982, 47 FR 54825-54844.

(12) Twelfth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency, TSCA Interagency Testing Committee, May 1983. Published in the *Federal Register* of Wednesday, June 1, 1983, 48 FR 24443-24452.

## Chapter 2—Recommendations of the Committee

2.1 *Chemicals recommended for priority consideration by the EPA Administrator.* As provided by section

4(e)(1)(B) of TSCA, the Committee is adding the following four chemical substances to the section 4(e) Priority List: 2-(2-butoxyethoxy)ethyl acetate; ethylene bis(oxyethylene) diacetate; 1,2,3,4,7,7-hexachloronorborene; and oleylamine. The recommendation of these chemicals is being made after considering the factors identified in section 4(e)(1)(A) and other available relevant information, as well as the professional judgment of Committee members.

The four recommendations designated for response by the EPA Administrator within 12 months and supporting rationales are presented in section 2.2 of this report.

2.2 *Chemicals designated for response within 12 months with supporting rationales.*

### 2.2.a Alkylxyethylene Acetates

*Summary of recommended studies.* It is recommended that ethylene bis(oxyethylene) diacetate and 2-(2-butoxyethoxy)ethyl acetate be tested for the following:

Health Effects:  
Subchronic toxicity  
Toxicokinetic studies  
Reproductive effects

### Physical and Chemical Information

Ethylene bis(oxyethylene) diacetate and 2-(2-butoxyethoxy)ethyl acetate react vigorously with oxidizing materials (Refs. 3 and 4, Eastman Kodak Co., 1978, 1981). Available physical and chemical information on the two compounds is given in the following Table 4.

TABLE 4.—PHYSICAL AND CHEMICAL PROPERTIES OF THE ALKYLXYETHYLENE ACETATES

Property	Ethylene bis(oxyethylene) diacetate <sup>a</sup>	2-(2-Butoxyethoxy) ethyl acetate <sup>b</sup>
CAS Number	111-21-7	124-17-4
Synonyms	Triethylene glycol diacetate; TGD; Ethanol, 2,2'-(1,2-ethanediylbis(oxy))bis-, diacetate (CA index name).	Diethyleneglycol monobutyl ether acetate; DGBA; Ethanol, 2-(2-butoxyethoxy)-, acetate (CA index name).
Structural Formula		
Empirical Formula	C <sub>12</sub> H <sub>18</sub> O <sub>6</sub>	C <sub>12</sub> H <sub>20</sub> O <sub>4</sub>
Molecular Weight	234	204
Melting Point	Not found	-32° C.
Boiling Point	296° C.	235° C.
Vapor Pressure	Not applicable (nonvolatile)	0.04 mmHg at 20° C.
Specific Gravity	1.123 at 15.6/15.6° C.	0.980 at 20/20° C.
Solubility in Water	Negligible	65 g/L at 20° C.
Log Octanol/Water Partition Coefficient	-0.1 <sup>c</sup>	2.0 <sup>c</sup>
Description of Chemical	Clear liquid; essentially odorless	Colorless liquid; faint, pleasant odor.

<sup>a</sup> Eastman Kodak Co., 1981 (unless otherwise noted).

<sup>b</sup> Eastman Kodak Co., 1978.

<sup>c</sup> Estimated (Ref. 10, Lyman et al., 1982).

## Rationale for Recommendations

I. *Exposure information—A.*  
*Production and use.* The public portion

of the TSCA Inventory (Ref. 7, EPA, 1982) lists the 1977 U.S. production of TGD as 1 million to 10 million pounds

and that DGBA as 0.1 million to 1 million pounds. These figures were reported as representing current



production (Ref. 5, Eastman Kodak Co., 1982).

TGD is used primarily as a plasticizer in bonding cellulose acetate in the manufacture of cigarette filter tips. DGBA is used primarily as a solvent in printing inks and in high-bake enamel coatings. It is also used as a coalescing aid in latex paints and as a selective solvent in industrial separations (Refs. 3 and 5, Eastman Kodak Co., 1978, 1982).

**B. Evidence for exposure.** According to a 1972-74 NIOSH survey, the estimated number of workers exposed to TGD and DGBA are 152 and 21,461, respectively (Ref. 12, NIOSH, 1982). Approximately 50 workers were potentially exposed to TGD and DGBA during manufacturing for 50 and 80 hours annually per worker, respectively (Ref. 5, Eastman Kodak Co., 1982). Consumers may be exposed repeatedly to TGD eluted from cigarette filter tips during smoking (Ref. 6, Eastman Kodak Co., 1983). The possibility of exposure to DGBA when using latex paints also exists.

**II. Chemical fate information—**No data were found; however, based upon their chemical structures both TGD and DGBA are expected to biodegrade readily in the environment. Neither chemical is expected to persist.

**III. Biological effects of concern to human health—A. Metabolism.** No information was found. However, by analogy with other acetate esters the compounds may undergo enzymatic hydrolysis to the free alcohols (Ref. 13, Sandmeyer and Kirwin, 1981). The hydrolysis product of TGD would likely be triethylene glycol, on which a metabolism study has been performed (Ref. 11, McKennis et al., 1962). The hydrolysis product of DGBA is more likely to be the monobutyl ether of diethylene glycol, or butyl carbitol. Oxidation of the hydrolysis products to alkyloxy acetic acids may also occur (Ref. 11, McKennis et al., 1962). These types of metabolites may also have testicular effects comparable to those of the glycol ethers (Ref. 8, Foster et al., 1983).

**B. Effects on enzymes and other biochemical systems.** No information was found.

**C. Carcinogenicity and mutagenicity.** No information was found.

**D. Short-term acute effects.**

Application of 500 mg of TGD to the skin of rabbits caused mild irritation; in guinea pigs, TGD also caused slight skin irritation but no sensitization.

Application of TGD to the eyes of rabbits led to slight irritation (Ref. 5,

Eastman Kodak Co., 1982). When 500 mg of DGBA was applied to the skin and eyes of rabbits, irritation was reported.

Additional acute toxicity information on the alkyloxyethylene acetates is summarized in the following Table 5.

Table 5 Acute toxicity of the alkyloxyethylene acetates in laboratory animals.

Animal	Route	Dose	Reference
<u>Triethylene glycol diacetate (TGD)</u>			
Mouse	Oral	LD <sub>50</sub> : > 3.2 g/kg	Ref. 5
Rat	Oral	LD <sub>50</sub> : 15.5 g/kg	Ref. 5
Rat	Inh	LD <sub>50</sub> : > 6.1 mg/L, 6 hours	Ref. 5
Guinea pig	Skin	LD <sub>50</sub> : > 20 ml/kg > (22-46 g/kg)	Ref. 5
<u>Diethylene glycol monobutyl ether acetate (DGBA)</u>			
Mouse	Oral	LD <sub>50</sub> : 6.6 ml/kg (6.5 g/kg)	Ref. 1
Rat	Oral	LD <sub>50</sub> : 7.1 ml/kg (7.0 g/kg)	Ref. 1
Rat	Oral	LD <sub>50</sub> : 11.9 g/kg <sup>a</sup>	Ref. 14
Rat	Inh	Concentrated vapor of unspecified concentration, for 8 hours <sup>b</sup>	Ref. 3
Guinea pig	Oral	LD <sub>50</sub> : 2.7 ml/kg (2.6 g/kg)	Ref. 1
Guinea pig	Oral	LD <sub>50</sub> : 2.3 g/kg <sup>a</sup>	Ref. 14
Rabbit	Oral	LD <sub>50</sub> : 2.6 ml/kg (2.5 g/kg)	Ref. 2
Rabbit	Oral	LD <sub>50</sub> : 2.8 ml/kg	Ref. 2
Rabbit	Skin	LD <sub>50</sub> : 5.8 ml/kg (5.7 g/kg)	Ref. 2
Rabbit	Skin	LD <sub>50</sub> : 5.5 ml/kg	Ref. 1
Rabbit	Skin	LD <sub>50</sub> : 14.8 ml/kg (14.5 g/kg)	Ref. 3

<sup>a</sup>Dissolved in 1% Tergitol®.

<sup>b</sup>One of six animals died.

**E. Long-term (subchronic/chronic) effects.** Rats fed diets containing 0.1 and 1 percent TGD for 90 days showed no changes from controls in food intake, weight gain, hematology, urine analysis, gross pathology, or clinical signs (Ref. 5, Eastman Kodak Co., 1982). Likewise, an inhalation study of rats exposed to TGD at 0.163 mg/L for 6 hours daily for 22 exposures over 29 days showed no changes or lesions indicative of a toxic response. No information was found on the chronic effects of the compound.

For DGBA, the 90-day cutaneous LD<sub>50</sub> in rabbits was on the order of 2-3 ml/kg. Skin application led to hematuria, hemolysis in the kidneys, and renal tubular degenerative changes (Refs. 2 and 1, Draize et al., 1944, 1948). No information was found on the chronic effects of the compound.

**F. Teratogenicity/embryotoxicity/fetotoxicity and reproductive effects.** No information was found. However, the hydrolysis product of DGBA, namely the monobutyl ether of diethylene glycol, had no appreciable effect on maternal



mortality or litter size in mice. An analog, the monobutyl ether of ethylene glycol, had a slight testicular effect in mice (Ref. 9, Hardin, 1983).

**G. Rationale for health effects recommendations.** Both TGD and DGBA have a relatively low toxicity, but DGBA may be absorbed through the skin, as shown by the appearance of hematuria, renal tubular changes, and other effects. The extent of enzymic hydrolysis of DGBA is now known; moreover, the first hydrolysis product would probably be a glycol ether, a product of concern because of the effects of certain of these compounds on the male reproductive system. Since both worker exposure and possible consumer exposure are involved, the toxicokinetics and biochemical disposition, as well as the reproductive effects, should be investigated. Additional subchronic toxicity studies in other species are needed to investigate the possible adverse effects on the renal system.

**IV. Exological effects—No ecological effects testing is recommended** because neither TGD nor DGBA is expected to be acutely toxic to aquatic organisms and because neither is expected to persist in the environment.

#### References

- (1) Draize JH, Alvarez E, Whitesell MF, Woodard G, Hagan EC, Nelson AA. 1948. Toxicological investigations of compounds proposed for use as insect repellents. *J. Pharmacol. Exp. Ther.* 98:26-39.
- (2) Draize JH, Woodard G, Calvery HO. 1944. Methods for the study of irritation and toxicity of substances applied topically to the skin and mucous membranes. *J. Pharmacol. Exp. Ther.* 82:377-390.
- (3) Eastman Kodak Co. 1978. Material Safety Data Sheet and Product Bulletin (Publication No. M-149B) on diethylene glycol monobutyl ether acetate.
- (4) Eastman Kodak Co. 1981. Material Safety Data Sheet on triethylene glycol diacetate.
- (5) Eastman Kodak Co. 1982. Unpublished information on triethylene glycol monobutyl ether acetate submitted to ITC by G.Y. Brokaw, Eastman Kodak Co. July 13, 1982.
- (6) Eastman Kodak Co. 1983. Unpublished information on potential consumer exposure to TGD submitted to ITC by G. Ford, Eastman Kodak Co. May 18, 1983.
- (7) EPA. 1982. Environmental Protection Agency. TSCA Chemical Substances Inventory (public portion). Washington, D.C.: Environmental Protection Agency.
- (8) Foster PMD, Creasy DM, Foster JR, Thomas LV, Cook MW, Gangolli SD. 1983. Testicular toxicity of ethylene glycol monomethyl and monethyl ethers in the rat. *Toxicol. Appl. Pharmacol.* 69:385-399.
- (9) Hardin BD. 1983. Reproductive toxicity of the glycol ethers. *Toxicol.* 27:91-102.
- (10) Lyman WJ, Reehl WF, Rosenblatt DH. 1982. Handbook of Chemical Property Estimation Methods. New York: McGraw-Hill Book Co., Chapters 1 and 7.
- (11) McKennis H Jr., Turner RA, Turnbull LB, Bowman ER, Muelder WW, Neidhardt MP, Hake CL, Henderson R, Nadev HG, Spencer S. 1982. The excretion and metabolism of triethylene glycol. *Toxicol. Appl. Pharmacol.* 4:411-431.
- (12) NIOSH. 1982. National Institute for Occupational Safety and Health. National Occupational Exposure Survey. Cincinnati: National Institute for Occupational Safety and Health.
- (13) Sandmeyer EE, Kirwin CJ Jr. 1981. Esters. In: Clayton GD, Clayton FE, eds. *Patty's Industrial Hygiene and Toxicology*, 3rd rev. ed. Vol. 2A:2259-2412.
- (14) Smyth HF Jr., Seaton J, Fischer L. 1941. The single dose toxicity of some glycols and derivatives. *J. Ind. Hyg. Toxicol.* 23:259-268.

**2.2.b 1,2,3,4,7,7-Hexachloronorbornadiene**

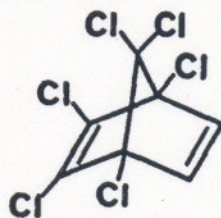
**Summary of recommended studies.** It is recommended that 1,2,3,4,7,7-hexachloronorbornadiene be tested for the following:

**Health Effects:**  
Subchronic tests, including neurotoxicity  
Biochemical effects, including enzyme-inducing capabilities

**Physical and Chemical Information**  
CAS Number: 3389-71-7.  
Synonyms:

Hexachloronorbornadiene;  
HEX-BCH;  
Hexachlorobicycloheptadiene;  
Bicyclo[2.2.1]hepta-2,5-diene, 1,2,3,4,7,7-hexachloro- (CA Index name)

Structural Formula:



Empirical Formula: C<sub>7</sub>H<sub>2</sub>Cl<sub>6</sub>  
Molecular Weight: 299  
Boiling Point: 118-120° C at 0.1 mmHg  
Vapor Pressure: 10<sup>-3</sup> mmHg at 25° C (estimated; Ref. 6, Lyman et al., 1982).  
Solubility in Water: 15 mg/L at 25° C (estimated; Ref. 6, Lyman et al., 1982).  
Solubility in Organic Solvents: Soluble in ether, ethanol, carbon tetrachloride, chloroform, DMSO.  
Log Octanol/Water Partition Coefficient: 5.28 (estimated; Ref. 9, Veith et al., 1979).

Description of Chemical: Oily liquid.

#### Rationale for Recommendations

##### I. Exposure information—A. Production and use.

Hexachloronorbornadiene is an intermediate in the manufacture of the pesticide endrin (Ref. 10, Velsicol, 1982). In recent years endrin has been produced in the U.S. in one plant only, which is in Memphis, Tennessee (Ref. 8, SRI, 1982). Based on the 1981 production volume of endrin of 2 million to 4 million pounds (Ref. 5, Glaze, 1982), it can be inferred that the production volume of hexachloronorbornadiene in 1981 was 1.5 million to 3 million pounds. However, the only manufacturer of the compound has reported that production was halted in 1982 (Ref. 11, Velsicol, 1983a).

##### B. Evidence for exposure.

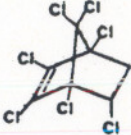
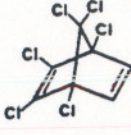
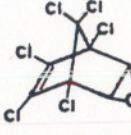
Hexachloronorbornadiene has been released to the environment through waste discharges from the Memphis, Tennessee manufacturing plant. Aqueous wastes have been treated by the Memphis municipal sewage treatment plant, then dumped into the Cypress Creek, which empties into the Mississippi River. The compound has been identified in the air within the treatment facility (Ref. 3, Elia et al., 1980), in the urine of the treatment plant workers, in the effluent of the treatment plant (Ref. 10, Velsicol, 1982), in the waters and sediment of the Mississippi River and tributaries (Ref. 1, Barthel et al., 1966), and in edible portions of fish caught in the Mississippi River (Ref. 14, Yurawecz and Roach, 1978). Solid wastes containing hexachloronorbornadiene most recently have been incinerated or buried in secure landfills (Ref. 10, Velsicol, 1982), but from 1964 to 1972 they were disposed of in surface landfills. The compound has been found in well water in the vicinity of these landfills (Ref. 2, Clark et al., 1981).

Although the manufacturer reports no current production, the compound is persistent, and leaching into surface and ground waters from waste residues of the compound may be expected to continue. Human exposure can occur as a result of drinking water or eating fish contaminated with the compound. Residues of the compound and its derivatives found in Mississippi River fish are listed in the following Table 6.

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Table 6--Residues of Hexachloronorbornadiene and Related Compounds  
in Mississippi River Fish (Adapted from Yurawecz and Roach (1978)).

Year Collected	Species	Location <sup>b</sup>	Levels in Parts Per Million <sup>a</sup>		
			I	II	III
					
1974	Catfish	Baton Rouge, LA	1.2	0.44	0.23
1974	Carp	Baton Rouge, LA	1.1	0.20	0.25
1974	Gaspergoo <sup>c</sup>	Baton Rouge, LA	1.3	0.63	0.25
1974	Catfish	Geismar, LA	1.5	0.71	0.15
1974	Buffalo fish	Geismar, LA	0.19	0.17	0.10
1974	Gaspergoo <sup>c</sup>	Geismar, LA	0.21	0.03	0.05
1973	Carp	Memphis, TN	16.2	5.2	0.51
1973	Carp	Luling, LA	0.54	0.11	d
1974	Gaspergoo <sup>d</sup>	Plaquemine, LA	0.85	0.32	0.14

<sup>a</sup>In the edible portion of fish.

<sup>b</sup>All these sites are below Memphis, TN, where the manufacturing site is located. These compounds were not observed in fish from Cape Girardeau, MO, upstream from Memphis.

<sup>c</sup>Gaspareau, alewife (*Alosa pseudoharengus*)

<sup>d</sup>Observed but not quantitated.

I = 1,2,3,4,5-endo-7,8-heptachloro-2-norbornene

II = 1,2,3,4,7,7-Hexachloronorbornadiene (HEX-BCH)

III = 1,2,3,4,7,7-Hexachloro-5,6 endo-epoxy-2-norbornene



A bioconcentration factor of approximately 6,400 in fish was calculated by Spehar et al. (Ref. 7, 1979). Analyses of fish caught downstream from the location where hexachloronorbomadiene was produced showed they contained appreciable levels of the compound (Ref. 14, Yurawecz and Roach, 1978). Additional exposure may occur through eating food from areas treated with endrin since hexachloronorbomadiene may occur to a small but variable extent in endrin (Ref. 12, Velsicol, 1983b).

**II. Chemical fate information.** No specific information was found. Under ambient conditions in ground and surface waters the compound is not expected to be reactive and should persist. Due to its low vapor pressure and high octanol/water partition coefficient it is expected to partition into sediment and the fatty tissues of animals.

**III. Biological effects of concern to human health.—A. Metabolism.** No information was found.

**B. Effects on biochemical systems.** No information was found. By analogy with compounds of similar structure, (e.g., chlordane) hexachloronorbomadiene has a potential for microsomal enzyme induction (Ref. 4, Fouts, 1970; Ref. 13, Welch et al., 1971).

**C. Carcinogenicity/mutagenicity/teratogenicity and fetotoxicity.** No information was found.

**D. Short-term (acute) effects.** The acute oral LD<sub>50</sub> in male and female rats are 726 mg/kg and 825 mg/kg, respectively (Ref. 10, Velsicol, 1982). Tremors, ataxia, and increased respiratory rate were observed in the animals.

**E. Long-term (subchronic/chronic) effects.** No information was found.

**F. Rationale for health effects recommendations.** A potential exists for exposure to hexachloronorbomadiene through consumption of water and/or fish contaminated with the compound. Also, sewage treatment workers may be exposed to the compound.

Due to the lack of information on the compound, subchronic tests are recommended to better understand its health effects. Neurotoxicity is of particular concern because of the observed acute effects. Because of the potential of the compound for inducing enzymes, biochemical effects testing is recommended.

**IV. Ecological effects.** The environmental effects information found is sufficient to assess the ecological hazard of hexachloronorbomadiene. Additional tests for environmental effects are not needed.

## References

- (1) Barthel WF, Parsons DA, McDowell LL, Grissinger EH. 1966. Surface hydrology and pesticides. A preliminary report on the analysis of sediments from the lower Mississippi River. ASA special Publication No. 8. pp. 128-144.
- (2) Clark CS, Bjornson HS, Holland JW, Elia VJ, Majeti VA. 1981. Evaluation of the health risks associated with the treatment and disposal of municipal wastewater and sludge. EPA 600/1-80-030, PB81-175945, USEPA Cincinnati, OH. p. 227.
- (3) Elia VJ, Clark CS, Majeti VA, MacDonald T, Richdale N. 1980. Worker exposure to organic chemicals at an activated sludge wastewater treatment plant. EPA 600/9-80-028. NTIS No. PB 81-169884, pp. 265-272.
- (4) Fouts JR. 1970. Some effects of insecticides on hepatic microsomal enzymes in various animal species. Rev. Canad. Biol. 29:377-389.
- (5) Glaze M. 1982. Unpublished information on the U.S. production of endrin submitted to ITC by M. Glaze, U.S. EPA, Office of Pesticides and Toxic Substances. December 6, 1982.
- (6) Lyman JW, Reehl WF, Rosenblatt DH. 1982. Handbook of Chemical Property Estimation Methods. New York: McGraw-Hill Book Co., Chapters 1, 2, and 14.
- (7) Spehar RL, Veith GD, DeFoe DL, Bergstedt BU. 1979. Toxicity and bioaccumulation of hexachlorocyclopentadiene, hexachloronorbomadiene and heptachloronorbomene in larval and early juvenile fathead minnows, *Pimephales promelas*. Bull. Environ. Contam. Toxicol. 21:576-583.
- (8) SRI. 1982. Directory of Chemical Producers, USA, 1982. Stanford Research Institute, Menlo Park, CA: SRI International.
- (9) Veith GD, DeFoe DL, Bergstedt BV. 1979. Measuring and estimating bioconcentration factor of chemicals in fish. J. Fish. Res. Board Can. 36:1040-1048.
- (10) Velsicol. 1982. Unpublished information on the production, use, occupational exposure, and toxicity of hexachloronorbomadiene submitted to ITC by A. Levin, Velsicol Chemical Corp. April 23, 1982.
- (11) Velsicol. 1983a. Unpublished information provided by A. Levin, Velsicol Chemical Corp. August 24, 1983.
- (12) Velsicol. 1983b. Unpublished information provided by A. Levin, Velsicol Chemical Corp. August 16, 1983.
- (13) Welch RM, Levin W, Kuntzman R, Jacobson M, Conney AH. 1971. Effects of halogenated hydrocarbon insecticides on the metabolism and uterotrophic action of estrogens in mice. Toxicol. Appl. Pharmacol. 19:234-246.
- (14) Yurawecz MP, Roach JAG. 1978. Gas-liquid chromatographic determination of chlorinated norbornene derivatives in fish. J. Assoc. Off. Anal. Chem. 61(1):26-31.

## 2.2.c Oleylamine

**Summary of recommended studies.** It is recommended that oleylamine be tested for the following:

**Health Effects:**

Toxicokinetic studies

Genotoxicity and teratogenicity studies if percutaneous absorption is demonstrated

## Physical and Chemical Information

CAS Number: 112-90-3.

Synonyms:

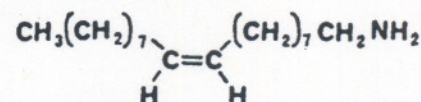
Armeen O®; Armeen OD®;

(Z)-9-Octadecenylamine;

9-Octadecen-1-amine, (Z)

(CA Index name)

Structural Formula:



Empirical Formula: C<sub>18</sub>H<sub>35</sub>N.

Molecular Weight: 267.

Melting Point: 20° C.

Boiling Point: 275-344° C.

Vapor Pressure: < 1 mmHg at 20° C.

Specific Gravity: 0.819 at 38° C.

Solubility in Water: Low.

Log Octanol/Water Partition

Coefficient: 7.5 (estimated; Ref. 5, Leo et al., 1971).

Description of Chemical: Yellow liquid with ammoniacal odor. Oleylamine in commerce is produced, not as a pure material, but as a mixture with other fatty materials; the oleylamine content is between 44 and 76 percent (Ref. 1, Armark Co., 1982).

## Rationale for Recommendations

**I. Exposure information.—A.**

**Production/use/disposal.** In 1977, between 0.2 million and 2 million pounds of oleylamine were reported to be produced in the United States (Ref. 3, EPA, 1982). The current domestic production of oleylamine is reported to be in the range of 4.5 million to 5.5 million pounds (Ref. 1, Armark Co., 1982).

Oleylamine is a surfactant used primarily as an additive in lubricating oils. The compound is also used as a gasoline additive (Ref. 1, Armark Co., 1982).

In a 1972-74 survey, NIOSH estimated that 3,073 workers are potentially exposed to oleylamine (Ref. 7, NIOSH, 1982). Although the manufacture of the compound is reported to be carried out in a closed system (Ref. 1, Armark Co., 1982), worker exposure is expected during transport of the compound, end-use processing, and use of lubricating oils (Ref. 1, Armark Co., 1982; Ref. 6, MacPherson, 1983).

**B. Evidence for exposure.** Worker exposure occasionally occurs during production (Ref. 6, MacPherson, 1983). The general procedure for protection is to wash the skin with 3 percent acetic



acid. However, when contact with oleylamine in oils occurs, this type of removal is not expected to be used.

Dermal uptake of oleylamine in mechanics was calculated to be about one milligram per day. This is based on these assumptions: that concentration in lubricating oils is 150 ppm, exposure time is one hour per day, exposed area is 100 cm<sup>2</sup>, and the permeability coefficient is 0.052 cm/hr (Ref. 4, ITC, 1983).

Environmental exposure varies with the method of disposal at the site. Some producers discharge into public treatment works. Others use settling ponds and filtration (Ref. 6, MacPherson, 1983).

**II. Chemical fate information—A. Transport.** No information on the transport of oleylamine was found. Because of its high estimated octanol/water partition coefficient, it is expected to sorb to soil and organic sediments.

**B. Persistence.** Abiotic degradation is not expected to occur. By analogy with other primary amines (Ref. 10, Yoshimura et al., 1980), oleylamine is expected to biodegrade readily.

**C. Summary.** Because oleylamine is expected to be biodegraded readily, no recommendations are made for chemical fate testing.

**III. Biological effects of concern to human health—A. Acute toxicity.** The single-dose intraperitoneal LD<sub>50</sub> of oleylamine in mice is 888.6 mg/kg (Ref. 9, Stratmann and Eifinger, 1980). In another study, mice received single oral doses of oleylamine. At a dose level of 800 mg/kg, no deaths were observed among five treated animals; at a dose level of 3,200 mg/kg, one death in five animals was observed (Ref. 2, Eifinger and Koehler, 1977).

**B. Teratogenicity/embryotoxicity.** Eifinger and Koehler (Ref. 2, 1977) studied the teratogenicity and embryotoxicity of oleylamine in mice. The test compound was administered orally in single doses (dose levels: 200, 800, 3,200 mg/kg) and intraperitoneally (dose levels: 200, 400, 800, 1,600 mg/kg) to pregnant mice on day 9 of gestation. Maternal toxicity (death) occurred following intraperitoneal administration at 800 and 1,600 mg/kg and oral administration at 3,200 mg/kg. Oleylamine was embryotoxic at all dose levels by both routes of administration and teratogenic by the intraperitoneal route at the higher dose levels.

**C. Toxicokinetic studies.** No information on absorption, distribution, excretion, or cellular toxicity of oleylamine was found. Because of the physical properties of oleylamine, particularly its high estimated octanol/water partition coefficient and relatively low molecular weight, the compound may be absorbed through the skin (Ref. 8, Scheuplein and Blank, 1971).

**D. Mutagenicity and carcinogenicity.** No information was found.

**E. Rationale for health effects recommendations.** There is potential for dermal exposure to oleylamine from various occupational uses. Since no data on dermal absorption of the compound were found, toxicokinetic testing, including study of percutaneous absorption, is recommended.

If the toxicokinetic studies demonstrate percutaneous absorption, short-term genotoxicity and teratogenicity tests should be conducted.

**IV. Ecological effects.** Although oleylamine is toxic to aquatic organisms, tests to quantify the toxic effect levels are not needed at this time. Based upon

the manufacturing process reported, substantial releases are unlikely. Although releases from use are likely to occur, such releases would be dispersed. The expected biodegradation of oleylamine further reduces the likelihood of substantial exposure to aquatic organisms.

#### References

- (1) Armak Co. 1982. Unpublished information on the production, use, occupational exposure, release, and toxicity of Z-9-octadecenylamine submitted to ITC by E. Bissinger, Armak Co. July 13, 1983.
- (2) Eifinger FF, Koehler F. 1977. Comparative teratological investigations with organic fluorine compounds, their bases, and amines. (In German). *Dtsch. Zahnärztl. Z.* 32:861-866.
- (3) EPA. 1982. TSCA Chemical Substances Inventory. Washington, DC: U.S. Environmental Protection Agency.
- (4) ITC. 1983. Updated production and toxicity information on (Z)-9-octadecenylamine, Information Review Addendum. September 16, 1983.
- (5) Leo AR, Hansch C, Elkins D. 1971. Partition coefficients and their uses. *Chem. Rev.* 71 (6):525-615.
- (6) MacPherson J. 1983. Unpublished information on oleylamine submitted to ITC by J. MacPherson. June 27, 1983.
- (7) NIOSH. 1982. National Institute for Occupational Safety and Health. National Occupation Exposure Survey. Cincinnati: National Institute for Occupational Safety and Health.
- (8) Scheuplein R, Blank IH. 1971. Permeability of the skin. *Physiol. Rev.* 51:782.
- (9) Stratmann KR, Eifinger FF. 1980. Embryotoxic baseline values of organic fluorides of their fluoride-free bases. (In German). *Dtsch. Zahnärztl. Z.* 35:1070-1072.
- (10) Yoshimura K, Machida S, Masuda F. 1980. Biodegradation of long chain alkylamines. *J. Am. Oil Chem. Soc.* (July): 238-241.

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