

APPENDIX 2

**SUMMARY OF NOTIFICATION DOSSIER OF A NEW
CHEMICAL SUBSTANCE**

*In accordance with Directive 79/831/EEC
(Article 9)*

O.J. L 259, volume 22, 15 October 1979

1. Details of the Notification

Member State of notification:

Notification number:

Name of the substance (Trade name or other identification name if the trade name is not available):

Date of notification:

**This substance has already been notified under No.
(Lead number first, followed by all previous notification numbers):**

2. Notifier/Manufacturer/Importer

NOTIFIER (Name and address):

Domestic manufacturer Importer

**In case of import:
Manufacturer (Name and address)**

3. Name to be Included in ELINCS

The view of the authority with regard to the publication of the trade name/IUPAC name is as follows:

Non-Dangerous Substances

Dangerous Substances

The IUPAC name
and trade name (A)

The IUPAC name
and trade name (D)

Only the trade name for
a period of years
(maximum 3) (B)

Only the trade
name until such
time as the substance
is added to Annex 1
of the Directive (E)

The trade name only
for an indefinite
period for reasons of
commercial secrecy (C)

4. Classification and Labelling

Lead competent authorities should state their formal proposal for classification and labelling with justification (where necessary)

Classification

- | | |
|--|---|
| <input type="checkbox"/> very toxic | <input type="checkbox"/> highly flammable |
| <input type="checkbox"/> toxic | <input type="checkbox"/> flammable |
| <input type="checkbox"/> harmful | <input type="checkbox"/> carcinogenic |
| <input type="checkbox"/> corrosive | <input type="checkbox"/> teratogenic |
| <input type="checkbox"/> irritant | <input type="checkbox"/> mutagenic |
| <input type="checkbox"/> explosive | <input type="checkbox"/> or otherwise dangerous to man or the environment |
| <input type="checkbox"/> oxidising | <input type="checkbox"/> not classified |
| <input type="checkbox"/> extremely flammable | |

Labelling

Symbol(s) and indication of danger(s) (in accordance with Annex II of Directive 67/548/EEC)

Risk phrases (in accordance with Annex III of Directive 67/548/EEC)

Safety phrases (in accordance with Annex IV of Directive 67/548/EEC)

5. Comments/Observations of the Competent Authority concerning the Notification
(including the competent authority's acceptance of, or comments on the
notifier's proposed classification and labelling (page 52)).

6. *The following summary of the notification of a new chemical substance is transmitted to the Commission of the European Communities in accordance with Article 9 of Directive 79/831/EEC by
(member state)*

There are ... annexes attached to this summary notification. They are numbered in accordance with the corresponding entry number in this summary. The items which the notifier wishes to have considered as confidential and have been accepted as confidential by the competent Authority are properly marked in this summary.

The competent Authority accepts the reasons given by the notifier for not supplying certain information in accordance with the preamble to Annex VII of Directive 79/831/EEC (comments are given where necessary).

Signature:

Name and position of the
responsible Official(s):

Signature:

Name and position of the
responsible Official(s):

**SUMMARY NOTIFICATION DOSSIER
FOR SUBSTANCES NOTIFIED IN CONFORMITY WITH
ARTICLE 6.1 OF DIRECTIVE 79/831/EEC ON THE
CLASSIFICATION, PACKAGING AND LABELLING OF
DANGEROUS SUBSTANCES**

This summary notification dossier is divided into four sections.

- A. Technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment;*
- B. Declaration concerning the unfavourable effects of the substance in terms of the various uses envisaged;*
- C. Proposed classification and labelling of the substance in accordance with the directive;*
- D. Proposals for any recommended precautions relating to the safe use of the substance.*

When information is confidential, tick appropriate block. Where this block is absent or hatched, confidentiality cannot be claimed for the corresponding data.

1.1 Name

001

1.1.1 Names in the IUPAC nomenclature

Confidential

English	

1.1.2 Other names

- Trade name(s) (or other public identifier(s)):	///
	///
	///
- Other names:	

1.1.3 CAS number (if available, otherwise enter "Not yet allocated")

--	--

1.2. Empirical and structural formula

empirical formula (according to the Hill system, and the CAS system; if different from Hill)	
Hill:	
CAS:	
structural formula (if this formula cannot be given, please comment)	

A: IDENTITY OF THE SUBSTANCE

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003

1.3.5 Spectral data

Confidential

UV/visible spectrum: (Annex ...)

IR Spectrum: (Annex ...)

NMR Spectrum: (Annex ...)

**Others (eg Mass spectrum)
(Annex ...)**

004

1.4 *Methods of detection and determination.*

A brief description of the methods used to detect and determine the substances detailed under 1.1.1, 1.3.1, 1.3.3 and 1.3.4 or the appropriate bibliographical references.

Confidential

<i>Substance(s) determined</i>	<i>Method</i>	<i>Confidential</i>

2.1 PROPOSED USES

005

2.1.1 Types of use

Confidential

<p>Use category:</p> <p>Desired effects:</p> <p>Detailed information on envisaged uses:</p>
--

Form in which the notifier intends to place the substance on the market

<p><input type="checkbox"/> substance as such <input type="checkbox"/> substance in a preparation</p> <p>Trade name of the preparation(s):</p> <p>Nature of the preparation(s) (granulate, paste.....):</p> <p>Estimated maximum content of the substance in the preparation(s):</p>
--

**2.1.2 Fields of application with approximate breakdown
(e.g. Industry, open system, 100%)**

<i>Industry, Closed Systems,</i>	<i>%</i>	
<i>Industry, Open Systems,</i>	<i>%</i>	
<i>Farmers and Skilled Trades, Closed Systems,</i>	<i>%</i>	
<i>Farmers and Skilled Trades, Open Systems,</i>	<i>%</i>	
<i>Public at large, Closed Systems,</i>	<i>%</i>	
<i>Public at large, Open Systems,</i>	<i>%</i>	

A2 INFORMATION ON THE SUBSTANCE

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007

**2.2 ESTIMATED PRODUCTION IN AND/OR IMPORTS TO THE MEMBER STATE FOR EACH USE
AND FOR EACH FIELD OF APPLICATION (in tonnes per calendar year)**

Confidential

2.2.1 PRODUCTION AND/OR IMPORTS

Production: Import:

2.2.1.1 For the balance of the calendar year of notification:

..... tonnes

**2.2.1.2 For the next three years, estimated production or
imports in tonnes per calendar year**

19 .. :

19 .. :

19 .. :

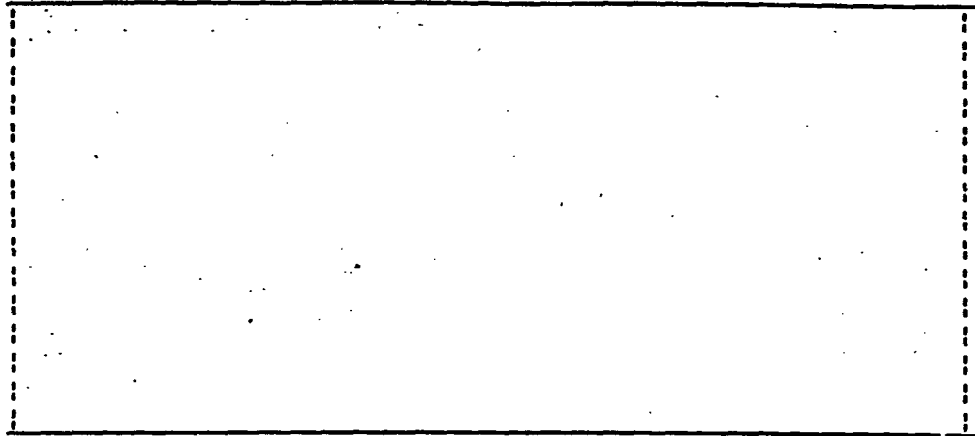
2.2.2 Production and/or imports broken down (in accordance with 2.1.1 and 2.1.2)

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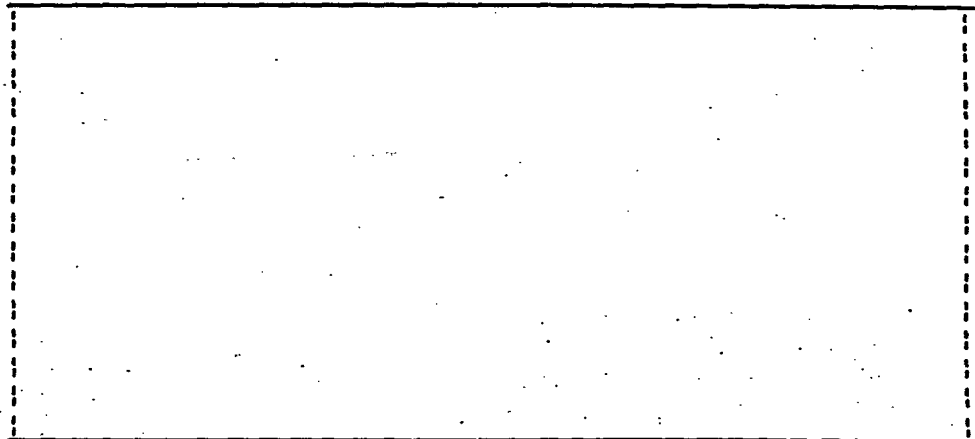
008

2.3 Recommended methods and precautions concerning

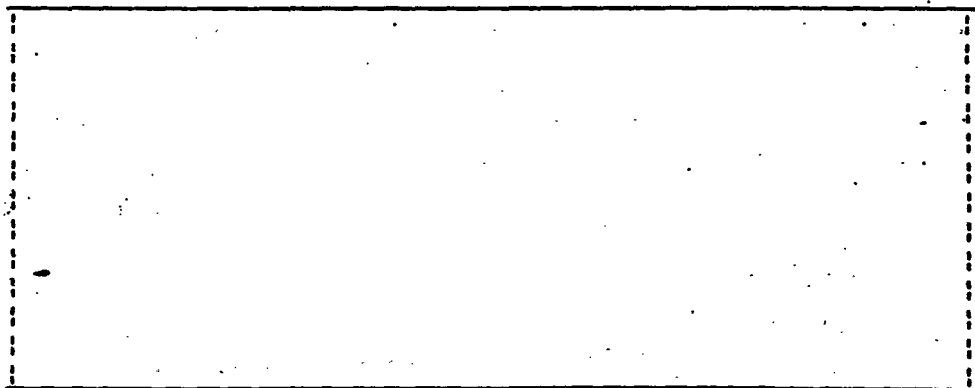
2.3.1 Handling



2.3.2 Storage



2.3.3. Transport (Including international and national code number for transport, eg UN, if available)



009

2.3.4. Fire (Including nature of combustion gases or pyrolysis)

<p>Recommended extinguishing agents:</p> <p>Products* arising from burning or pyrolysis:</p> <p>Protective equipment:</p>
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2.3.5 Other dangers, particularly reaction with water

<p>other dangers</p> <p>chemical reaction in combination with water</p>
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* Indicate if this information derives from tests carried out on the substance.

A2 INFORMATION ON THE SUBSTANCE

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011

2.6 Composition of the tested substance

Exact composition of the samples which were used to perform the tests in 3.1 to 5.3 (the purity must be within the ranges given in sections 1.3.1 - 1.3.4).

<i>Batch No.</i>	<i>Used for tests:</i>	<i>Composition (1.3)</i>

It is much to be preferred that all tests are conducted on the same batch. However, where several batches are used the appropriate batch number should be indicated for each test; where only one batch is described above it will be assumed unless indicated to the contrary that all tests were conducted on this batch.

2.4 Emergency measures in the case of accidental spillage

010

**2.5 Emergency measures in the case of injury to persons (e.g. poisoning)
(First-aid measures, recommended treatment)**

Eyes:
Skin:
Ingestion:
Inhalation:

A3. PHYSICO-CHEMICAL PROPERTIES

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012

3.0 Nature of the substance

<p>1. Colour</p>
<p>2. Physical state at 20°C and 101.3 kPa</p> <p><input type="checkbox"/> solid <input type="checkbox"/> liquid <input type="checkbox"/> gaseous</p>
<p>3. State (e.g. powder, viscous, crystalline, compact, particle size)</p> <p><i>(Where the particle size distribution has been determined, it should be given here and details of the test should be given under Item 3.14)</i></p>

3.1 Melting temperature/Freezing temperature

... °C
Method:
Body responsible for test:
Comments:

3.2 Boiling temperature

... °C at 101.3 kPa.
Method:
Body responsible for test:
Comments:

3.3 *Relative density*

013

20 D ₄
Method:
Body responsible for test:
Comments:

3.4 *Vapour pressure*

... Pa at ... °C ... Pa at ... °C ... Pa at ... °C (20 or 25°C) (estimated from data above)
Method:
Body responsible for test:
Comments:

3.5 Surface tension (of aqueous solution)

011

<i>mN/m at °C</i>	<i>Concentration mg/l</i>
<i>Method</i>	
<i>Body responsible for test:</i>	
<i>Comments:</i>	

3.6 Water solubility

<i>mg/l at °C at pH ...(if available)</i>
<i>Method:</i>
<i>Analytical method:</i>
<i>Body responsible for test:</i>
<i>Comments:</i>

A3 PHYSICO-CHEMICAL PROPERTIES

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015

3.7 Fat solubility

... mg/100 g solvent at ... °C
Method:
Analytical method:
Body responsible for test:
Comments:

3.8 Partition coefficient n-octanol/water

log Pow = at ... °C
Method:
Analytical method:
Body responsible for test:
Comments:

016

3.9 Flash point

... °C; open cup <input type="checkbox"/> ; closed cup <input type="checkbox"/>
Method (Including reference to the specific procedure used)
Body responsible for test:
Comments:

018

3.11 Explosive properties (within the meaning of the definition given in article 2 (2) (a))

explosive under influence of a flame:	<input type="checkbox"/> yes	<input type="checkbox"/> no
more sensitive to shocks than m-dinitrobenzene:	<input type="checkbox"/> yes	<input type="checkbox"/> no
more sensitive to friction than m-dinitrobenzene:	<input type="checkbox"/> yes	<input type="checkbox"/> no
Method:		
Body responsible for test:		
Comments:		

3.12 Auto-flammability

- Self ignition temperature on heating °C (Test Method A15 / A16 of Annex V)
Method (including reference to the specific procedure used in the case of method A15)
Body responsible for test:
Comments:

3.13 Oxidizing properties (within the meaning of the definition given in article 2 (2) (b)) 019

<p>oxidizing <input type="checkbox"/> <input type="checkbox"/> organic peroxide <input type="checkbox"/> yes no</p> <p>max. burning rate of test mixture : mm/s</p> <p>max. burning rate of reference mixture : mm/s</p>
<p>Method</p>
<p>Body responsible for test:</p>
<p>Comments:</p>

3.14 Any additional physico-chemical properties, where available

<p>(minimum information: Property; Result; Test Method; Body responsible for the test; Comments)</p>
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A4 TOXICOLOGICAL STUDIES

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020

4.1 Acute toxicity

4.1.1 Administered orally

On the basis of the test results given below and in conformity with the criteria given in annex VI of the Directive, the substance should be:

- classified as very toxic
- classified as toxic
- classified as harmful
- not classified

Lethal test yes no

LD₅₀: mg/kg

95% confidence limits:

Slope of the dose-mortality curve:

Species/strain:

Vehicle:

Results:

	dose	number of animals	number of deaths
♂			
♀			

A4 TOXICOLOGICAL STUDIES

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021

4.1.1. Administered orally (continued)

Signs of toxicity related to dose level used, time of onset and duration

Effects in organs (related to dose level):

4.1.1 Administered orally (continued)

022

Method:
Body responsible for test:
Comments:

4.1.2 Administered by Inhalation

023

On the basis of the test results given below and in conformity with the criteria given in annex VI of the Directive, the substance should be:

- classified as very toxic
- classified as toxic
- classified as harmful
- not classified

Limit test yes no

LC50: mg/l

95% confidence limits:

Slope of the concentration-mortality curve:

Species/strain:

Exposure period: hours

Method of exposure:

Physical form of substance gas liq. aerosol solid aerosol

Mass median aerodynamic diameter (for liquid and solid aerosols):

Vehicle:

Results:

	concentration	number of animals	number of deaths
♂			
♀			

A4 TOXICOLOGICAL STUDIES

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024

4.1.2 Administered by Inhalation (continued)

Signs of toxicity related to concentration, time of onset and duration

Effects in organs (related to concentration):

Method:

A4 TOXICOLOGICAL STUDIES

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025

4.1.2 Administered by Inhalation (continued)

<p>Body responsible for test:</p>
<p>Comments:</p>

026

4.1.3 Administered cutaneously

On the basis of the test results given below and in conformity with the criteria given in annex VI of the Directive, the substance should be:

classified as very toxic

classified as toxic

classified as harmful

not classified

Limit test yes no

LD₅₀: mg/kg

95% confidence limits:

Slope of the dose-mortality curve:

Species/strain:

Exposure period: hours

Type of dressing:

occlusive semi-occlusive

Vehicle:

Results:

	dose	number of animals	number of deaths
♂			
♀			

4.1.3 Administered cutaneously (continued)

027

**Signs of toxicity related to dose level used,
time of onset and duration:**

a) local:

b) systemic:

Effects in organs (related to dose level):

A4 TOXICOLOGICAL STUDIES

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028-

4.1.3 Administered cutaneously (continued)

Method:
Body responsible for test:
Comments:

A4 TOXICOLOGICAL STUDIES

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029

4.1.5 Skin irritation

On the basis of the test results given below and in conformity with the criteria given in Annex VI of the Directive the substance should be:

classified as corrosive

classified as irritant

not classified

Species/strain:

Number of animals:

Duration of exposure: hours

Amount of substance:

Type of dressing: occlusive semi-occlusive

Vehicle:

Reversibility of any observed effect:

 Changes fully reversible within ... days

 Changes not fully reversible within an observation period of ... days

Overall results:

if 3 animals or less	* mean score animal n°			maximum duration value of any effect	Maximum value at the end of the observation period
	1	2	3		
erythema/eschar					
oedema					
* calculated on the basis of the scores at 24, 48, 72 h for each animal					
if > 3 animals	** mean score			maximum duration value of any effect	Maximum value at the end of the observation period
erythema/eschar					
oedema					
** calculated on the basis of the scores at 24, 48, 72 h for all animals.					

030

4.1.5 Skin Irritation (continued)

Other observations:
Method:
Body responsible for test:
Comments:

A4 TOXICOLOGICAL STUDIES

031

4.1.6 Eye Irritation

On the basis of the test results given below and in conformity with the criteria given in Annex VI of the Directive the substance should be:

classified as irritant

not classified

Species/strain:

Number of animals:

Nature and amount of substance:

Reversibility of any observed effects:

Changes fully reversible within ... days

Changes not fully reversible within an observation period of ... days

Overall results:

if 3 animals or less	* mean score animal n°			maximum duration value of any effect	maximum value at the end of the observation period
	1	2	3		
conjunctiva/redness					
conjunctiva/chemosis					
cornea					
iris					

* calculated on the basis of the scores at 24, 48, 72 h for each animal

if > 3 animals	** mean score			maximum duration value of any effect	Maximum value at the end of the observation period
conjunctiva/redness					
conjunctiva/chemosis					
cornea					
iris					

** calculated on the basis of the scores at 24, 48, 72 h for all animals

4.1.6 Eye Irritation (continued)

032

Other observations:
Method:
Body responsible for test:
Comments:

A4 TOXICOLOGICAL STUDIES

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033

4.1.7 Skin sensitization

On the basis of the test results given below and in conformity with the criteria given in Annex VI of the Directive the substance should be

classified as Irritant

not classified

Species/strain:

Number of animals in test group:

Number of animals in negative control group:

Maximum concentration not giving rise to irritating effects in the preliminary test :

Concentrations of test material and vehicle used at each stage of induction :

a)

b)

Concentrations of test material and vehicle used at each challenge :

a)

b)

Signs of Irritation during induction:

Results:

	Challenge concentrations of test substance (a,b,etc. If more than 1 concentration)	Number of animals showing skin reactions after			
		1st challenge		2nd challenge	
		24 hr	48 hr	24 hr	48 hr
Test group	a)				
	b)				
Negative control group	a)				
	b)				

Number of animals showing evidence of sensitization at each challenge concentration:

4.1.7 Skin sensitization (continued)

034

Other observations:
Method (type of test):
Body responsible for test:
Comments:

A4 TOXICOLOGICAL STUDIES

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035

4.2.1 Subacute toxicity (28-day-test)

On the basis of the test results given below and in conformity with the criteria given in Annex VI of the Directive the substance should be

classified as toxic

classified as harmful

not classified

Limit test yes no

Dose or concentration at which no toxic effects were observed:
 mg/kg/day
 mg/l/...h/day

Species/strain:

Route of administration:

Method of administration or of exposure:

Vehicle:

Mass median aerodynamic diameter (for liquid and solid aerosols):

Duration of exposure per day (inhalation or dermal) : hours

Dosing regime (5 or 7 days/week):

Number of animals, doses (concentrations) and group numbers:

	Number of animals	Dose or concentration	Group number
♂			1
			2
			3
			4
			5
			6
♀			1
			2
			3
			4
			5
			6

AP2-40

4.2.1 Subacute toxicity (28 days) (continued)

036

Results (in relation to dose levels/concentrations):

1) Clinical observations:

2) Laboratory findings:

3) Effects in organs:

A4 TOXICOLOGICAL STUDIES

-37-

037

4.2.1 Subacute toxicity (28-day-test) (continued)

<p><i>Dose or concentration at which no effect was observed (if available) :</i> mg/kg/day mg/l/...h/day</p>
<p><i>Method:</i></p>
<p><i>Body responsible for test:</i></p>
<p><i>Comments:</i></p>

4.4 TOXICOLOGICAL STUDIES

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4.3 Mutagenicity

038

4.3.1 Bacteriological test

Type of bacteria/strain:

**Concentration range in the main test -
with metabolic activation:**

without metabolic activation:

Concentration of test substance observed to be toxic to bacteria

a) In a preliminary test: with metabolic activation:

without metabolic activation:

b) In the main test: with metabolic activation:

without metabolic activation:

Solvent:

Concentration of the test substance resulting in precipitation:

Metabolic activation system:

Observations:

Result:	+	-
With metabolic activation	<input type="checkbox"/>	<input type="checkbox"/>
Without metabolic activation	<input type="checkbox"/>	<input type="checkbox"/>

4.3.1 Bacteriological test (continued)

039

Method (type of test):
Body responsible for the test:
Comments:

4.3.2 Non-bacteriological test In vitro

Type of cell used:
Concentration range in the main test - with metabolic activation:
without metabolic activation:
Concentrations producing toxicity:
a) In a preliminary test: with metabolic activation:
without metabolic activation:
b) In the main test : with metabolic activation:
without metabolic activation:
Vehicle:
Exposure period: with metabolic activation:
without metabolic activation:
Fixation time:
Metabolic activation system:

4.3.2 Non-bacteriological test In vitro (continued)

040

Observations:		
Result:	+	-
With metabolic activation	<input type="checkbox"/>	<input type="checkbox"/>
Without metabolic activation	<input type="checkbox"/>	<input type="checkbox"/>
Method (type of test)		
Body responsible for the test:		
Comments:		

4.3.3 Non-bacteriological test In vivo

Species/strain:
Dose levels:
Doses producing toxicity:
Number of animals at each dose level for each sacrifice time:
Route of administration:
Vehicle:
Sacrifice times (in hours):

5.1 Effects on organisms

042

5.1.1 Acute toxicity for fish

Values in mg l⁻¹

LC50	24h	48h	72h	96h

No observed effect concentration at 96h mg/l

Species:

static test semi-static test flow-through test

% loss in concentration of the test substance over test period:

Identity and concentration of any auxiliary solvent or details of any other method used for dispersal:

Water hardness:

Method (type of test):

Body responsible for the test:

Comments:

AD **ECOTOXICOLOGICAL STUDIES**

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043

5.1.2 Acute toxicity for daphnia

Conc. in mg l⁻¹

EC50	24h	48h

No observed effect concentration after 48h mg/l

Species: *Daphnia magna* *Daphnia pulex*

% loss in concentration over test period:

Identity and concentration of any auxiliary solvent or details of any other method used for dispersal:

Water hardness:

Method (type of test):

Body responsible for the test:

Comments:

5.2 Degradation

5.2.0 Inhibition of microbial activity (if available)

<p>Type of test: aerobic <input type="checkbox"/></p> <p> anaerobic <input type="checkbox"/></p> <p>Duration of test : hours</p> <p>IC₅₀ at hours = mg/l</p> <p>No observed effect concentration at hours = mg/l</p>
<p>Method (type of test):</p>
<p>Body responsible for the test:</p>
<p>Comments:</p>

045

5.2.1 Biodegradability

5.2.1.1 Ready biodegradability

..... % degradation

Classification: readily biodegradable yes no

Reference substance:

Experimental Values			
test substance		reference substance	
day	%	day	%

Degradation curve:

Biodegradability (%)

100 -
90 -
80 -
70 -
60 -
50 -
40 -
30 -
20 -
10 -
0 -

.5 10 15 20 25 30

time (days)

AP2-50

5.2.1.1 Ready Biodegradability (continued)

046

Method (type of test):
Body responsible for the test:
Comments:

047

5.2.1.2 BOD/COD

<i>BOD (5 days)</i>	<i>g/g</i>
<i>COD</i>	<i>g/g</i>
<i>BOD/COD :</i>	
<i>Method (type of test):</i>	
<i>Body responsible for the test:</i>	
<i>Comments:</i>	

5.2.2 Hydrolysis as a function of pH

<i>pH</i>	<i>T in °C</i>	<i>k-value in s⁻¹</i>	<i>t_{1/2}-value in h.</i>
4.0			
7.0			
9.0			

048

5.2.2 Hydrolysis as function of pH (continued)

Method:
Body responsible for the test:
Comments:

**5.3 Any additional Ecotoxicological Tests, where available
(for example: bioconcentration factor
adsorption/desorption
photodegradation)**

Minimum Information: End point investigated; Description of the essential features of the test method; Results; Test procedure used; Body responsible for the test; Comments.
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A6 POSSIBILITY OF RENDERING THE SUBSTANCE HARMLESS

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049

6.1 For Industry/skilled trades

6.1.1 Possibility of recovery/recycling of the used substance

6.1.2 Possibility of neutralization (of any potentially hazardous effects)

6.1.3 Possibility of destruction (where special techniques are necessary please indicate)

Controlled discharge:

Incineration:

Water purification system:

Others:

050

6.2 For the public at large

6.2.1 Possibility of recovery/recycling of the used substance

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6.2.2 Possibility of neutralization (of any potentially hazardous effects)

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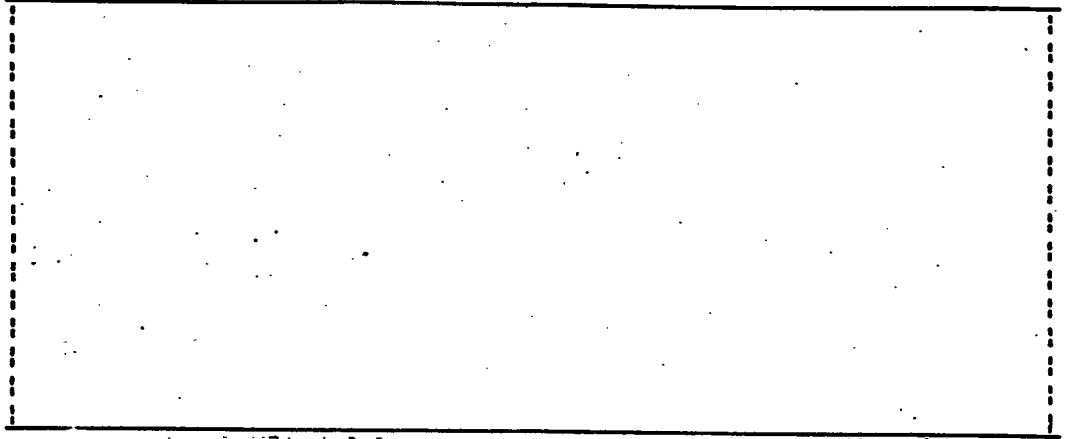
6.2.3 Possibility of destruction

Controlled discharge:
Incineration:
Water purification system:
Others:

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051

B *DECLARATION CONCERNING THE UNFAVOURABLE EFFECTS ON MAN AND THE ENVIRONMENT
FOR THE VARIOUS USES ENVISAGED*



**C PROPOSED CLASSIFICATION AND LABELLING OF THE SUBSTANCE IN ACCORDANCE WITH
DIRECTIVE 79/831/EEC FOLLOWING THE CRITERIA OF ANNEX VI PART II B**

Classification

- | | |
|--|--|
| <input type="checkbox"/> very toxic | <input type="checkbox"/> highly flammable |
| <input type="checkbox"/> toxic | <input type="checkbox"/> flammable |
| <input type="checkbox"/> harmful | <input type="checkbox"/> carcinogenic |
| <input type="checkbox"/> corrosive | <input type="checkbox"/> teratogenic |
| <input type="checkbox"/> irritant | <input type="checkbox"/> mutagenic |
| <input type="checkbox"/> explosive | <input type="checkbox"/> or otherwise dangerous to
man or the environment |
| <input type="checkbox"/> oxidising | <input type="checkbox"/> not classified |
| <input type="checkbox"/> extremely flammable | |

Labelling

**Symbol(s) and indication of danger(s) (In accordance with
Annex II of Directive 67/548/EEC)**

Risk phrases (In accordance with Annex III of Directive 67/548/EEC)

Safety phrases (In accordance with Annex IV of Directive 67/548/EEC)

053

**D PROPOSALS FOR ANY RECOMMENDED PRECAUTIONS RELATING TO THE SAFE USE OF THE
SUBSTANCE**

