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2 August 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Setalux 7204

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Akzo Nobel Pty Ltd (ABN: 59 000 119 424)
115 Hyde Road,
Yeronga QLD 4104

Nuplex Industries (Aust.) Pty Ltd (ABN: 25 000 045 572)
49-61 Stephen Road
Botany NSW 2019

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: [*List]*
Chemical Name, CAS Number, Structural Formula, Molecular Formula, Hazardous and Non-Hazardous Impurities, Degree of Purity, Import Volumes, Concentration.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Netherlands (1996)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Setalux 7204

OTHER NAME(S)
Acetotacetate resin

ANALYTICAL DATA

METHOD	UV-Visible and IR spectroscopy, ^{1}H NMR and LC-MS-MS spectrometry
Remarks	Reference spectra were consistent with the proposed structure. The purity and identity of impurities were determined by the above methods.
TEST FACILITY	NOTOX (1996)

3. COMPOSITION

DEGREE OF PURITY
>70%

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Yellow viscous liquid

Property	Value	Data Source/Justification
Freezing Point	<-81°C	Measured
Boiling Point	Decomposed above 253°C, boiling not observed at up to 320°C	Measured
Density	1130 kg/m^3 at room temperature	Measured
Vapour Pressure	2.72 ± 0.03 Pa at 20°C	Measured
Water Solubility	30 g/L at 20°C	Measured
Surface Tension	56.5 mN/m at 20°C	Measured
Hydrolysis as a Function of pH	$T_{1/2}$ >1 year at 25ºC at pH 4 $T_{1/2}$ ≥2007 h at 25ºC at pH 7 $T_{1/2}$ 302 h at 25ºC at pH 8 $T_{1/2}$ <1 day at 25ºC at pH 9	Measured
Partition Coefficient (n-octanol/water)	log Pow = 0.8 at 19.5°C	Measured
Adsorption/Desorption	Not determined	It was not possible to perform the test using the HPLC method. Based on high water solubility and low partition coefficient, the notified chemical is not expected to bind strongly to soil or sediments.
Dissociation Constant	Not determined	The notified chemical does not contain dissociable groups.
Particle Size	Not determined	The notified chemical is a liquid.
Flash Point	132°C at 101.2 kPa	Measured
Flammability	Is not expected to be flammable.	Expert statement
Autoignition Temperature	351°C	Measured
Explosive Properties	Not predicted to be explosive	Expert Statement

Discussion of Observed Effects

For full details of the physical-chemical properties tests please refer to Appendix A.

Reactivity

The notified chemical is classified as a C2 combustible liquid. The notified chemcial is expected to be stable under normal conditions of use.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

The notified chemical will be imported as a component of a finished product (a primer) at a concentration of < 5%.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<5	<5	<5	<5	10-50

PORT OF ENTRY

Queensland

IDENTITY OF MANUFACTURER/RECIPIENTS

Akzo Nobel Pty Ltd, 115 Hyde Road, Yeronga, QLD.

TRANSPORTATION AND PACKAGING

The primer coating containing the notified chemical will be imported in 1L, 3L, 3.75L steel cans or 205L steel drums. From the dockside, the primer will be off-loaded and shipped by road transport to Akzo Nobel Pty Ltd warehouse in Queensland.

USE
The notified chemical will be used as a component (at < 5%) of surface coatings for the marine vessels.

OPERATION DESCRIPTION
The notified chemical is not manufactured or reformulated in Australia.

End-Use
At the end use application sites, the primer containing the notified chemical (<5%) will be mixed with a hardener (2:1 primer:hardener) before being applied to marine vessels above the waterline (interior and exterior application may occur) by spray painting only. The notified chemical will be present in the final surface coating at a concentration of <2.5%

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure assessment

6.1.1. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Warehousing	10	1-2 hr	200 days/year
Unloading and preparation of mixture	1-2	1 hr	24 days/year
Cleaning equipment	500	10 mins	200days/year
Spray painting	500	10-45 mins	200 days/year

Exposure Details
Transport and Storage
During transport and warehousing, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached.

End-use
At the end-use sites, the primer containing < 5% of the notified chemical will be decanted and mixed with another paint component (a hardener) by operators and thinned to the appropriate viscosity with another additive and subsequently applied to marine vessels by sprayers. Dermal and accidental ocular exposure may occur during any of these processes, and inhalation or ingestion exposure may also occur during spray application. In some applications spray booths may be temporarily erected, otherwise only natural ventilation will be available at the end-use sites. For spray application the estimated reasonable worst-case and typical case dermal exposure is 250 mg and 62.5 mg respectively using measured data for the exposure scenario 'spray painting (large areas)' (European Commission, 2003) and assuming the notified chemical is present at a concentration of 2.5%. Therefore, for a 70 kg worker and a 100% dermal absorption factor, reasonable worst-case and typical case dermal exposure is estimated to be 3.6 mg/kg bw/day and 0.89 mg/kg bw/day, respectively.

Operators will wear personal protective equipment (PPE) such as chemical resistant gloves, coveralls and goggles and appropriate respirators as required and recommended in the MSDS. Maintenance workers at the end-use sites will repair and clean equipment such as spray guns and will wear similar PPE as the operators. The use of such controls will minimise exposure to the notified chemical.

Overspray of the paint may result in dust containing the notified chemical being deposited on surfaces surrounding the spray area. Where possible the dust will be collected on drop cloths or tarpaulins and disposed of by waste contractors. Dust may also be generated as a result of sanding. Inhalation and dermal exposure to the dust may occur during these processes.

6.1.2. Public exposure

The notified chemical will not be sold to the public. The only likely exposure of the public would be in the event of an accident during transportation of the primer product containing the notified chemical. Although the public may make contact with the painted surfaces of marine vessels, no exposure is expected as the chemical is trapped within the paint matrix.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	oral LD50 > 2000 mg/kg bw low toxicity
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration study	genotoxic
Genotoxicity – in vivo mouse micronucleus assay	non genotoxic
Genotoxicity – in vivo mouse micronucleus assay	non genotoxic

Acute toxicity
The notified chemical is considered to be of low acute toxicity when administered orally or when applied to the skin.

Irritation and Sensitisation
Rabbit studies of eye and skin irritation found that the notified chemical is slightly irritating to both eyes and skin. There was no evidence of reactions indicative of skin sensitisation to the notified chemical when tested on Guinea pigs.

Repeated Dose Toxicity
Based on a 28-day subacute oral toxicity study in rats, the No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day based on the absence of adverse treatment related effects.

Mutagenicity
The notified chemical was found to be non-mutagenic in the Ames tests. The notified chemical was clastogenic in an *in vitro* chromosomal aberration test in cultured peripheral human lymphocytes cells. However the notified chemical was considered non-clastogenic in the *in vivo* mouse and rat micronucleus assay. It is therefore not considered to be genotoxic *in vivo*.

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Exposure and hence the risk of adverse effects is most likely during end-use spray application of the notified chemical via dermal exposure. In addition, there is the potential for inhalation / ingestion exposure during end-use by spray application of the coating or as a result of dust from overspray.

During the end-use processes the workers expected to have the highest potential for dermal exposure to the notified chemical are predicted to be those involved in spray painting. The dermal exposure for these workers is estimated to be 3.6 mg/kg bw/day and 0.89 mg/kg bw/day for the worst case and typical case respectively. A dermal NOAEL was not determined, however a NOAEL of 1000 mg/kg bw/day was established in a 28-day oral study in the rat. The use of this NOAEL results in a margin of exposure (MOE) of 769 for the worst case exposure and a MOE of 1124 for the typical case exposure. MOE greater than or equal to 100 are considered

acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data is acceptable for workers involved in spray painting application. The risk of inhalation exposure should be acceptable provided either appropriate engineering controls (temporary spray booth where possible) or PPE (eg respirator) are used when required. In addition, the notified chemical is manufactured and supplied in solution with other hazardous chemicals, and the precautions against exposure to these chemicals, may reduce exposure and risk from the notified chemical.

Due to the slight skin and eye irritancy potential of the notified chemical protective gloves and eyewear should be worn during processes when dermal and ocular exposure (i.e. during mixing of the resin) is possible.

Overall the risk to workers can be considered low given the low concentration of notified chemical in the end-use products and provided appropriate controls are in place at all workplaces where the notified chemical is used, especially where spray application occurs outside a booth.

6.3.2. Public health

The notified chemical is not a hazardous substance. The only likely exposure of the public would be in the event of an accident during transportation of the paint product containing the product. Although the public may make contact with the painted surfaces of marine vessels, no exposure is expected as the chemical is trapped within the paint matrix. Overall the risk to the public is considered to be low.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured or re-formulated in Australia. Thus there will be no environmental release associated with this process.

Release at the notifier's warehouse may result due to accidental spills. It is estimated that a maximum of 50 kg per year of notified chemical would be lost during spillage. Spills are contained and soaked up with inert absorbent material (sand, soil or vermiculite) and placed in a sealable container for appropriate disposal. Waste material is disposed of in accordance with government regulations.

RELEASE OF CHEMICAL FROM USE

Release of the notified chemical to the environment as a result of its use is expected to be minimal, unless an accidental spillage occurs. If accidental spillage occurs during normal operating procedures, it will be contained and soaked up with inert absorbent material (sand) and placed in a sealable container for disposal in accordance with government regulations.

The finished paint products will be packaged in 1 L, 3 L, 3.75 L steel cans or 205 L drums. The empty containers will be disposed of to landfill. The table below provides an estimate of the residue of the notified substance in the empty containers. On this basis the residues in the containers are expected to account for up to 2-5 % per year of the notified chemical.

Container size (L)	*Residual (%)*
1	5
3	3
3.75	3
200	2

The product will be applied using spray only for both interior and exterior surfaces but only above the water line. A loss of 20% of the ready-for-use material is achieved by the use of HVLP spray

guns and slightly higher loss with the more outdated high pressure guns when spray booths are used. The engineering controls for over-spray are typically spray booth filters and water scrubbers. The spray booth filters are usually renewed every 2-4 months. The overspray is collected via local exhaust extraction and scrubbers. The filters are removed and disposed off to landfill. This can be done privately or professionally depending on the repair shop management.

Based on 30% (worst case) over-spray losses when spray booths are not used during application procedures and an annual import volume of up to 50 tonnes, it is expected that approximately 15 tonnes of notified chemical per annum would be lost via overspray. It is anticipated that the overspray will be collected on drop cloths or tarpaulins which are either incinerated or disposed of to landfill. Once the spraying is completed, the equipment is drained and cleaned using solvents and rags. This will be collected for disposal by a licensed contractor. Based on 1% losses from cleaning of equipment after application procedures, and an annual import volume of 50 tonnes, it is expected that approximately 500 kg of notified chemical per annum would be lost via cleaning of equipment.

The coated surface will be prepared to a profile that ensures good adhesion of the paint to the surface. Once cured, the coated surface will be overcoated, without sanding, with at least 300 microns dry, of other types of surface coatings ie fillers, primers and topcoats, totally encapsulating the material. As the product will be used above the waterlines the leaching of the notified chemical to the aquatic compartment is unlikely to occur. During maintenance work any cured coatings removed by sanding or other mechanical means are disposed of as prescribed for non-toxic cured paint remains to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Paint containers containing residues of the chemical will be disposed of by landfill. If incidental spillage occurs during normal operating procedures, it will be contained and soaked up with inert absorbent material (sand, soil or vermiculite) and placed in a sealable container for appropriate disposal. Wastes resulted from washings and overspray would be disposed of to landfill.

7.1.2 Environmental fate

The notified chemical is highly soluble in water and contains ester linkages that are expected to undergo hydrolysis under high pH conditions. On the basis of biodegradation study, it is not considered to be readily biodegradable. Given the low exposure to an aquatic compartment and a log Pow of 0.8, it is unlikely to bioaccumulate in aquatic organisms.

For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

The notified chemical will be used to coat substrates for manufacturing industry. The notified chemical will then be cured and will likely to be landfilled at the end of the coated substrates useful life. Approximately 20-30% will be wasted during coating operations as a result of overspray. This will be collected for disposal to landfill or be incinerated as cured waste by a licensed contractor. Under the proposed use pattern the exposure to the aquatic compartment is likely to be low. Therefore a PEC was not performed.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h EC50 >100 mg/L	Non-toxic
Daphnia Toxicity	48 h EC50 >100 mg/L	Non-toxic
Algal Toxicity	72 h ErC50 180 mg/L	Non-toxic
Inhibition of Bacterial Respiration	EC50 >100 mg/L	Non-toxic

On the basis of ecotoxicity data provided, the toxicological end point would be 72 h ErC50 of 180 mg/L for alga (see Appendix C for ecotox results).

7.2.1 Predicted No-Effect Concentration

The PNEC is 1.0 mg/L, using a safety factor of 100 since toxicity data are available for two trophic levels and the acute 48 h EC_{50} >100 mg/L for Daphnia.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
	100	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	
PNEC:	1.0	mg/L

7.3. Environmental risk assessment

The majority of the notified chemical will be cured on the coated substrates and thus minimal environmental exposure is likely to occur. The fate of the notified chemical will likely be a disposal to landfill with the cured products at the end of its useful lives.

Wastes generated during the coating process will either be landfilled or incinerated generating water vapour and carbon dioxide. The likely route of environmental exposure is from accidental spillage and washing of the equipment. Spillages are contained and likely to be disposed by landfill. The residues from the washings would be disposed of by a waste contractor. In landfill, the notified chemical is likely to be slowly degraded by the abiotic and biotic processes.

The very limited exposure of the notified chemical to the aquatic compartment due to its industrial settings and the non-toxicity demonstrated in aquatic organisms are unlikely to have an adverse effect in the aquatic compartment.

Given its limited environmental exposure, the notified chemical is unlikely to pose an environmental risk under the proposed use pattern.

8. CONCLUSIONS – SUMMARY OF RISK ASSESSMENT FOR THE ENVIRONMENT AND HUMAN HEALTH

8.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

8.2. Human health risk assessment

8.2.1. Occupational health and safety

Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable.

8.2.2. Public health

When used in the proposed manner the risk to the public is considered to be acceptable.

8.3. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

9. MATERIAL SAFETY DATA SHEET

The MSDS of the notified chemical and product containing the notified chemical provided by the notifier were reviewed by NICNAS and are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant. The MSDS were found to be in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003).

10. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in the product for use:
  - Isolation of spray working areas where possible

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in the product for use:
  - Avoid skin and eye contact;
  - Avoid breathing spray;
  - Application of the coating should be according to the NOHSC National Guidance for Spray Painting (1999).

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to notified chemical as introduced in the product for use:
  - Eye protection
  - Protective clothing;
  - Appropriate respiratory protection where there is potential exposure to spray or dust during end-use.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of by incineration or landfill.

Emergency procedures

- Dike the spill or place inert absorbent material onto spillage. Collect the material and place into a suitable container. Dispose of waste according to government regulations. Do not allow to enter drains or waterways.

11. REGULATORY OBLIGATIONS

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act; if

- the function or use of the chemical has changed from being used as a component (<5%) of surface coatings for the marine vessels., or is likely to change significantly;
- the amount of chemical being introduced has increased from 50 tonne, or is likely to increase, significantly;
- if the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

APPENDIX A: PHYSICO-CHEMICAL PROPERTIES

Freezing Point <-81ºC

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Statement of GLP
During the cooling process, the test substance remained a viscous liquid without showing any indication of the freezing process.
TEST FACILITY NOTOX (1995a)

Boiling Point Not observed up to 370ºC, test substance decomposed > 253ºC

METHOD EEC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Statement of GLP
Determined by differential scanning calorimetry. During the test the sample lost 82% of its mass. After the experiment the sample was changed to dark brown.
The test substance is probably not stable at temperatures about 253ºC.
TEST FACILITY NOTOX (1995b)

Density 1130 kg/m^3 temperature unspecified

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Statement of GLP
Determined by pycnometer.
TEST FACILITY NOTOX (1996a)

Vapour Pressure 2.72 ± 0.03 Pa at 20ºC

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Statement of GLP
Determined using the static technique.
At the beginning of the test, the vapour pressure decreased after each measurement, due to the removal of volatile impurities.
TEST FACILITY NOTOX (1995c)

Water Solubility 30 g/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Statement of GLP
The test was performed in triplicate with approximately 4 g of the substance dissolved in 50 mL water. The content of the flask was stirred for 24, 48 or 72 h at 30ºC. After stirring, the flasks were re-equilibrated for 24 h at 20ºC. The concentration of the test substance was determined by HPLC.
TEST FACILITY NOTOX (1996b)

Surface Tension 56.6 mN/m at 20ºC

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Statement of GLP
The surface tension of the test substance at a concentration of 1.012 g/L was determined using ring tensiometer at 20ºC. The notified chemical is considered to be surface active.
TEST FACILITY NOTOX (1998a)

Hydrolysis as a Function of pH

METHOD EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ (days)*
4	25	>365
7	25	≥83.6
8	25	12.6
9	25	<1 day

Remarks Statement of GLP
The test substance is hydrolytically stable at pH 4 and hydrolytically unstable at pH 9. At pH 7 half-lives of 27.1 and 33.3 h were determined at 60 and 70ºC, respectively. At pH 8 half-lives were 3.83 and 1.38 h at the respective temperatures. From these values half-lives at 25ºC were calculated.
TEST FACILITY NOTOX (2000)

Partition Coefficient (n-octanol/water) log Pow = 0.5 at 20ºC

METHOD OECD TG 107 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Statement of GLP
The HPLC method was used for the determination of partition coefficient. On the basis of the retention times of the six references, the log Pow for the notified chemical was calculated.
TEST FACILITY NOTOX (1995d)

Adsorption/Desorption Not determined
SCREENING TEST
Remarks It was not possible to perform the test using the HPLC method. Based on high water solubility and low partition coefficient, the notified chemical is not expected to bind strongly to soil or sediments.
TEST FACILITY NOTOX (1998b)

Dissociation Constant Not determined

Remarks The notified chemical does not contain dissociable groups.

Particle Size Not applicable

Flash Point 132ºC at 101.2 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks Statement of GLP
Determined using the Pensky-Martens closed cup flash-point apparatus.
TEST FACILITY NOTOX (1994a)

Flammability Not flammable (expert statement)

METHOD EC Directive 92/69/EEC A.12 Flammability (Contact with Water).
EC Directive 92/69/EEC A.13 Pyrophoric properties of solids and liquids.
Remarks The notified chemical is considered incapable of igniting spontaneously at room temperature or to develop an amount of (flammable) gas in contact with water or damp air.
TEST FACILITY NOTOX (1996c)

Autoignition Temperature 350ºC

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).

Remarks	Statement of GLP
TEST FACILITY	NOTOX (1998c)

Explosive Properties Not explosive (expert statement)

METHOD	EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks	Statement of GLP The notified chemical does not contain structural moieties that are considered instable or highly energetic groups that might lead to an explosion.
TEST FACILITY	NOTOX (1998d)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/Wistar
Vehicle	Neat, administered as supplied.
Remarks - Method	Statement of GLP.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 males	2000	0/5
II	5 females	2000	0/5

LD50	>2000 mg/kg bw
Signs of Toxicity	All animals survived until scheduled necropsy. Slightly reduced bodyweight gain was noted in 3/5 females in the second week. Bodyweight gain for all other animals was considered normal.
Effects in Organs	A reduced size of the testes and epididymides was observed in 1/5 males. This finding was considered to be within the normal biological variation of animals of this strain and age.
Remarks - Results	None.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	NOTOX (1994b)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Wistar Crl:(WI) BR
Vehicle	None. Applied undiluted as supplied.
Type of dressing	Occlusive.
Remarks - Method	Statement of GLP.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 males	2000	0/5
II	5 females	2000	0/5

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Slightly yellow staining was observed in the treated area on the back of the animals (3/5 males and 2/5 females) during the study period (between days 2-13).
Signs of Toxicity - Systemic	Severe red staining of the neck was noted in all females from day 4 onwards. The red staining of the neck persisted at termination in one animal.

Effects in Organs	None.
Remarks - Results	Decreased bodyweight was observed in 2 female rats at day 8, but gained weight by Day 15. One female rat had decreased bodyweight gain in the first week but normal weight gain by the termination of this study. All other bodyweight changes were considered normal.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	NOTOX (1998e)

B.3. Acute toxicity – inhalation

REMARKS	Not Determined

B.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 male
Vehicle	None. Applied undiluted as supplied.
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	Statement of GLP.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	1	< 24 hours	0
Oedema	0	0	0	0	-	-

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	Very slight erythema was noted in 2/3 animals at the 1 hour observation period but had resolved by 24 hours. Yellow staining of the skin was observed in all 3 animals immediately after the treatment period and 2/3 animals at the 1 hour observation but disappeared by 24 hours..
CONCLUSION	The notified chemical is slightly irritating to the skin.
TEST FACILITY	NOTOX (1995e)

B.5. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Observation Period	72 hours
Remarks - Method	Statement of GLP. Fluorescein application to the eye 24 hours after instillation was used to define the epithelial damage.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.3	0.3	1.0	2	< 72 hours	0
Conjunctiva: chemosis	0	0	0	1	< 24 hours	0
Conjunctiva: discharge	0	0	0	1	< 24 hours	0
Corneal opacity	0	0	0	0	-	-
Iridial inflammation	0	0	0	0	-	-

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results

Instillation of the test item resulted in mild effects of the conjunctivae that consisted of redness, chemosis and discharge that had resolved within 48 hours in two animals and within 72 hours in the third animal.
No corneal epithelial damage or effects of the iris were observed in any of the animals.

CONCLUSION

The notified chemical is slightly irritating to the eye.

TEST FACILITY

NOTOX (1995f)

B.6. Skin sensitisation

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 406 Skin Sensitisation - <Guinea Pig Maximisation Test>.
EC Directive 96/54/EC B.6 Skin Sensitisation - < Guinea Pig Maximisation Test >.

Species/Strain

Guinea pig/Dunkin Hartley Crl: (HA)BR

PRELIMINARY STUDY

Maximum Non-irritating Concentration: 5% intradermal, 100% topical
intradermal: 100%, 50% (in corn oil), 25% (in corn oil), 5% (in corn oil)
irritation observed at 25, 50 and 100%
topical: 100%, 50% (in corn oil), 25% (in corn oil), 5% (in corn oil)
no irritation observed at any dose tested

MAIN STUDY

Number of Animals

Test Group: 10 females/dose Control Group: 5 females/dose

INDUCTION PHASE

Induction Concentration:
intradermal:
Freund's complete adjuvant
10% (in corn oil)
20% (in corn oil with and without Freund's complete adjuvant)
topical:
100%

Signs of Irritation

Intradermal: The intradermal injections with Freund's Complete Adjuvant (with and without notified chemical) caused irritation in all animals. Slight to mild erythema was observed in 9/10 test animals and 5/5 control animals and moderate to severe erythema was observed in 1/10 test animals.

Topical: Slight erythema was observed in 6/10 test animals and 3/5 control animals, severe erythema to slight eschar formation was observed in 4/10 test animals and 2/5 control animals following topical application with the notified chemical, as supplied. Slight oedema was observed in 1/10 test animals and 2/5 control animals.

CHALLENGE PHASE

1st challenge

topical: 100%, 50% (in corn oil) and 25% (in corn oil)

Remarks - Method	Statement of GLP. As no skin irritation was observed in the pretest the epidermal application site was pretreated with 10% sodium lauryl sulphate 24 hours prior to epidermal induction.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100	0/10	0/10	-	-
	50	2/10	1/10	-	-
	25	0/10	0/10	-	-
	0	0/10	0/10	-	-
*Control Group**	0	0/4	0/4	-	-

*One control animal was found dead on Day 16.

Remarks - Results	One control animal was found dead on day 16. Necropsy revealed dark red appearance of the lungs indicating acute pneumonia. Since no mortality occurred and no symptoms of systemic toxicity were observed in other test anmials, it was considered that the study outcome was not adversely affected. Two skin reactions consisting of grade 1 were observed in test animals at 24 hours in response to 50% notified chemical which persisted in one animal at the 48 hour observation. These reactions were considered to be non-specific signs of irritation since no skin reactions were seen in response to the undiluted notified chemical in these animals. There were no reactions observed in the control animals.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	NOTOX (1995g)

B.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Wistar Crl:(WI) BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7/7 days per week Post-exposure observation period: 0
Vehicle	Propylene glycol
Remarks - Method	Statement of GLP. A preliminary 5 day repeat dose oral toxicity study was conducted at 50, 200 and 1000 mg/kg bw/day (3/sex) to determine the highest dose level tolerable for the 28 day study. This study indicated 1000 mg/kg bw/day was acceptable as the highest dosage. Deviations from current protocol include: 1. No post-exposure observation period 2. No urinalysis performed

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*

I (control)	5/sex	0	0/10
II (low dose)	5/sex	50	0/10
III (mid dose)	5/sex	200	0/10
IV (high dose)	5/sex	1000	0/10

Mortality and Time to Death
All animals survived until scheduled necropsy.

Clinical Observations
The clinical symptoms observed mainly in treated animals include: increased salivation, scabs, colour staining of the neck and and/or back, alopecia. These findings are considered to be attributed to the unpalatability of the test substance and are therefore not of toxicological significance.

Food Consumption: No significant findings.

Body Weight: No significant findings.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Clinical Chemistry
Decreases (not significant) in alanine aminotransferase levels for males (7%, 4% and 10% for groups II, III and IV respectively) and in females (20% and 15% for groups II and III respectively) were observed. Decreases (not significant) in aspartate aminotransferase levels for males (14%, 17% and 11% for groups II, III and IV respectively) and in females (5% for group III) were observed. Alkaline phosphatase levels were increased in group II males (6%, not significant) and decreased in group IV males (6%, not significant) and in females in groups II, III and IV increases were observed (5%, 13% and 20%, respectively, not significant).

Inorganic phosphate was significantly decreased in group III males (9%, $p<0.05$) only there were no significant changes observed in females however some fluctuations in groups II, III and IV were respectively, a decrease of 11% an increase of 4% and a decrease of 4%.

In group III females an increase in urea (24%, not significant) was observed. A significant increase in creatinine was observed in group III females (38%, $p<0.01$) however this change was not does-related.

There were no other significant findings.

Haematology
No significant findings.

Urinalysis
Not performed.

Effects in Organs
No significant findings regarding body weight or relative body weight to organ weight in males in any dose group were observed.

A decrease in absolute liver weight was observed in treated females group II (13%, not significant). The relative liver weight was also statistically significantly decreased group II females (13%, $p<0.05$). However no dose response relationship was observed. No macroscopic or microscopic effects were observed in the liver. In group III females the absolute thymus weight was significantly increased (32%, $p<0.05$) along with the relative thymus weight in group III females (29%, $p<0.05$). Again, no dose response relationship was observed and no macroscopic or microscopic histopathology of the thymus was noted.

All other macroscopic or microscopic effects observed were considered incidental and not of toxicological significance.

Remarks – Results
No deaths were noted through out the treatment period and no dose or treatment-related changes were noted in clinical signs, body weight, haematology, blood biochemistry, organ weight, macroscopic and microscopic observations.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day in this study, based on the effects observed in this study.

TEST FACILITY NOTOX (1998f)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 100-5000 µg/plate b) Without metabolic activation: 100-5000 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	Statement of GLP. The preliminary toxicity test (3-5000 µg/plate) was carried out with strains *S. typhimurium* TA100 with and without metabolic activation. Deviations from current protocol: 1. No strain used to detect cross-linking mutagens (absence of *S. typhimurium* TA102 or *E. coli* WP uvrA *E. coli* WP uvrA (pKM101)

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 3330	≥ 3330	> 5000	Negative
Test 2	-	≥ 5000	> 5000	Negative
Present				
Test 1	> 5000	> 5000	> 5000	Negative
Test 2	-	> 5000	> 5000	Negative

Remarks - Results The notified chemical did not induce gene mutations in the strains of *S. typhimurium* either with or without metabolic activation. Positive controls confirmed the sensitivity of the test system.

CONCLUSION The notified chemical was not mutagenic to *S. typhimurium* bacteria under the conditions of the test.

TEST FACILITY NOTOX (1995h)

B.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.

Species/Strain	Cultured peripheral human lymphocytes
Metabolic Activation System	Aroclor-1254 induced rat liver S9-mix

Vehicle	Dimethyl sulfoxide
Remarks - Method	Statement of GLP.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	33, 100*, 130*, 180*, 240, 333	24	24
Test 2	100, 130, 180*, 240	48	48
Test 3	33*, 100*, 130*, 180, 240, 333	24	24
Present			
Test 1	33, 100, 180, 333, 420*, 560*, 750*, 1000, 1300	3	24
Test 2	420, 560, 750*, 1000*	3	48
Test 3	420*, 560, 750*, 800, 850*, 900, 950, 1000	3	24

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 100	> 130	-	Positive
Test 2	> 100	> 180	-	Positive
Test 3	-	> 100	-	Positive
Present				
Test 1	> 333	> 750	-	Positive
Test 2	-	> 1000	-	Positive
Test 3	-	≥ 800	-	Positive

*Based on ≥50% decrease in mitotic index. The absence or presence of precipitation in the main study was not recorded.

Remarks - Results	Positive controls confirmed the sensitivity of the test system. Statistically significant increases in the percentage of aberrant cells above the vehicle control levels were recorded in the presence of metabolic activation and all concentrations of the notified chemical. A clear dose-response relationship was observed over the analysed concentrations. Statistically significant increases in the number of structural chromosome aberrations at all concentrations, except for the lowest dose in test 3, were observed in the absence of metabolic activation however there was no clear dose-response relationship.
CONCLUSION	The notified chemical was clastogenic to cultured peripheral human lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	NOTOX (1998g)

B.10. Genotoxicity – in vivo

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test. EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Rat/Wistar WI rats (SPF)
Route of Administration	Intravenous injection via the tail vein
Vehicle	None. Administered neat.
Remarks - Method	The doses in the main study were determined by a preliminary dose-range

finding study for two dose groups: Group I (500 mg/kg bw/day), 2/sex and Group II (350 mg/kg bw/day) 3/sex was performed. No significant differences between females and males was noted, hence only males were used in the main study.

No significant protocol deviations in the main study. However, due to the deaths observed 7/12 animals in the high dose level in experiment 1 prior to the sampling time a second experiment was conducted, experiment 2. Statement of GLP.

Experiment 1

Group	*Number and Sex of Animals per Sacrifice Time*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5 males	0	24
II (low dose)	5 males	87.5	24
III (mid dose)	5 males	175	24
IV (high dose)	12 males	350	24*, 48*
V (positive control, CP)	5 males	50	48

CP=cyclophosphamide. *7/12 deaths prior to sacrifice time

Experiment 2

Group	*Number and Sex of Animals per Sacrifice Time*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5 males	0	24
IV (high dose)	5 males	250	24,48
V (positive control, CP)	5 males	50	48

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity

No signs of toxicity were observed in animals in the vehicle control, positive control or low and mid dose groups.

In the high dose group in experiment 1 several signs of toxicity were noted that included: lethargy, ventro-lateral recumbency, quick breathing, rough coat and closed eyes. In the high dose group in experiment 1 animal died within one hour after dosing and was replaced by two additional treated animals, however within 17 hours after dosing six more animals died and the remaining animals were sacrificed fro humane reasons.

In the high dose group in experiment 2 the animals showed signs of toxicity including lethargy and ataxia immediately after dosing, however, all animals had recovered within ten minutes.

No statistically significant decrease in ratio of polychromatic (PCE)/normochromatic erythrocytes (NCE) was observed in any of the treated groups and therefore did not elicit any toxic effects on erythropoiesis.

Genotoxic Effects

The test substance did not induce a statistically significant increase in the frequency of micronucleated PCE over the levels observed in the vehicle control.

Remarks - Results

Positive controls confirmed the sensitivity of the test system.

CONCLUSION

The notified chemical was not clastogenic under the conditions of this in vivo erythrocyte micronucleus test.

TEST FACILITY

NOTOX (2002)

B.11. Genotoxicity – in vivo

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test. EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mice/ NMRI BR mice(SPF)
Route of Administration	Intraperitoneal injection
Vehicle	Corn oil
Remarks - Method	Statement of GLP. The doses in the main study were determined by a preliminary dose-range finding study for two dose groups: Group I (2000 mg/kg bw/day), 3/sex and Group II (1000 mg/kg bw/day) 3/sex was performed.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5/sex	0	24, 48
II (low dose)	5/sex	500	24, 48
III (mid dose)	5/sex	1000	24, 48
IV (high dose)	5/sex	2000	24, 48
V (positive control, CP)	5/sex	50	48

CP=cyclophosphamide.

RESULTS	
Doses Producing Toxicity	No signs of toxicity were observed in animals in the vehicle control, positive control or low dose groups. In the mid dose group one male animal had a rough coat immediately after dosing. No other animals in the mid dose group showed any signs of toxicity. In the high dose group one male animal died, five males and two females had a rough coat and all other animals appeared normal. Within 20 hours after dosing all male animals had a rough coat and one also had hunched posture. Six female animals had a rough coat and all other female animals appeared normal. Within 44 hours of dosing all male and female animals appeared normal. No statistically significant decrease in ratio of polychromatic (PCE)/normochromatic erythrocytes (NCE) was observed in any of the treated groups and therefore did not elicit any toxic effects on erythropoiesis.
Genotoxic Effects	The test substance did not induce a statistically significant increase in the frequency of micronucleated PCE over the levels observed in the vehicle control.
Remarks - Results	Positive controls confirmed the sensitivity of the test system.
CONCLUSION	The notified chemical was not clastogenic under the conditions of this in vivo erythrocyte micronucleus test.
TEST FACILITY	NOTOX (1998h)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

ENVIRONMENTAL FATE

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test. EEC directive 92/69, C.4C
Inoculum	Activated sludge freshly obtained from a municipal sewage treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	None
Remarks - Method	The test substance was tested in duplicate at 15 mg TOC/L. The test consists of inoculum blank, positive control containing sodium acetate as the reference substance at TOC =12 mg/L and the inoculum, and toxicity control containing test substance, reference substance and inoculum. The amount of CO_2 produced was determined by titration with HCl. Titrations were made on every second or third day during the first 10 days and thereafter at least every fifth day until the 28th day. The pH of the test suspension was measured and the theoretical CO_2 production was calculated from the molecular formula.

RESULTS

Test substance		*Sodium acetate*	
Day	*Mean % Degradation*	*Day*	*% Degradation*
2	0.5	2	16
7	32	7	54
14	52	14	80
19	62	19	86
23	67	23	88
29	72	29	94

Remarks - Results	The % biodegradation of the test substance was determined to be a mean of 72% by day 29. However, it did not meet the criterion for ready biodegradation as at least 60% degradation was not reached within 10 days of biodegradation exceeding 10%. The test substance was not inhibitory as >25% degradation occurred in 14 days in the toxicity control test. The reference substance was degraded 80% in 14 days and 94% by the end of the test and thus the test was validated.
CONCLUSION	The test substance is considered to be not readily biodegradable.
TEST FACILITY	NOTOX (1995i)

C.1.2. Bioaccumulation

No data were provided for bioaccumulation. However, on the basis of the log Kow of 0.8, the notified chemical is not likely to bioaccumulate.

ECOTOXICOLOGICAL INVESTIGATIONS

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - Static
Species	Carp (*Cyprinus carpio*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$mg $CaCO_3$/L
Analytical Monitoring	None
Remarks – Method	A limit test was performed in combination with the range-finding test. Three fish per concentration were exposed to concentration ranging from 0.1-10 mg/L, whereas seven fish were exposed to a concentration of 100 mg/L and a control. The effects of toxicity were observed at 2.5, 24, 48, 72 and 96 h following the start of exposure. A reference test was also performed with the reference substance pentachlorphenol. pH, oxygen concentration and temperature were measured during the test.

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*Mortality*				
		2.5 h	*24 h*	*48 h*	*72 h*	*96 h*
Blank control	7	0	0	0	0	0
0.1	3	0	0	0	0	0
1.0	3	0	0	0	0	0
10	3	0	0	0	0	0
100	7	0	0	0	0	0

LC50	>100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	All final test solutions were clear and colourless without any test substance precipitate. pH, oxygen concentrations and temperatures were within acceptable range. No mortality or clinical effects were observed during the test period in any of the concentrations tested except for 100 mg/L after 48 h of exposure when fish were observed swimming slightly slower as compared to the control. TOC analysis showed that recoveries for organic carbon had been maintained at 80% of the initial concentration. The response of the fish to the reference substance is considered to be within acceptable range.
CONCLUSION	The test substance is considered to be non-toxic to fish.
TEST FACILITY	NOTOX (1998i)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks - Method	A limit test was performed in combination with the range-finding test. The test groups of 0.1, 1.0 and 10 mg/L consisted of one vessel per group containing 10 daphnids per vessel, whereas the 100 mg/L test group and the control consisted of 2 vessels containing 10 daphnids per vessel. Immobility was observed at 24 and 48 h. pH, oxygen concentration and

temperature were measured during the test. A reference test with potassium dichromate was performed to determine the sensitivity of the test.

RESULTS

Concentration mg/L *Nominal*	*Number of D. magna*	*Number Immobilised* *24 h*	*48 h*
Blank control	20	0	0
0.1	10	0	0
1.0	10	0	0
10	10	0	0
100	20	0	0

LC50	>100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	All final test solutions were clear and colourless without any test substance precipitate. pH, oxygen concentrations and temperatures were within acceptable range. No immobility of daphnia was observed up to the limit concentration of 100 mg/L during the test period. TOC analysis showed that recoveries for organic carbon had been maintained at 80% of the nominal concentration. The response of the fish to the reference substance is within acceptable range.

CONCLUSION The test substance is considered to be non-toxic to daphnia.

TEST FACILITY NOTOX (1998j)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	Freshwater alga (*Selenastrum capricornutum*)
Exposure Period	72 hours
Concentration Range	Nominal: 10. 18, 32, 56, 100 and 180 mg/L
Auxiliary Solvent	None
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks - Method	On the basis of the range finding test, a nominal concentration range of 10-180 mg/L was used for the definitive test. 3 replicates of each test concentration, 6 replicates of the control and 1 replicate of the highest concentration without the algae were conducted for an exposure period of 72 h under static condition. A reference test was performed on potassium dichromate to check the sensitivity of the system. Temperatures and pH were measured during the test. Cells were counted by microscope and cell densities were determined by spectrophotometric measurements. Calculations of the EC50 were based on linear regression analysis of the % of growth inhibition and the percentages of growth rate reduction.

RESULTS

Biomass		*Growth*	
EbC50 *mg/L at 72 h*	*NOEC* *mg/L*	*ErC50* *mg/L at 72 h*	*NOEC* *mg/L*
72 (CI: 50-105 mg/L)	32	180 (CI:130-230 mg/L)	32

Remarks - Results	Inhibition of cell growth increased with increasing concentration from 56

	mg/L upwards resulting in 86% inhibition at 180 mg/L. Growth rates from 56 to 180 mg/L were increasingly reduced. These observations were statistically significant at test concentration of ≥56 mg/L. The extent of reduction remained constant or increased slightly as exposure progressed. TOC analysis showed that recoveries of organic carbon were acceptable based on the nominal concentrations at the start of exposure. At 32 and 56 mg/L the TOC values had decreased by >20% at the end of the exposure, while they remained stable at 100 and 180 mg/L. The decreased in organic carbon was probably due to adsorption of the test substance to alga. The results of the reference substance indicate that the response of the test system is within acceptable range. pH and temperatures were within acceptable range during the test.
CONCLUSION	The test substance is considered to be non-toxic to alga.
TEST FACILITY	NOTOX (1998k)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 67/548/EEC Part C, Publication No. L133.
Inoculum	Activated sludge from municipal sewage treatment plant
Exposure Period	30 minutes
Concentration Range	Nominal: 100 mg/L
Remarks – Method	Nominal concentration of 100 mg/L in duplicate with contact time of 30 minutes and two controls used for each of the test were conducted. A reference test was performed using 3,5-dichlorophenol at nominal concentrations of 3.2, 10 and 32 mg/L. Temperature and pH were determined during the test.
RESULTS	
IC50	>100 mg/L
NOEC	100 mg/L
Remarks – Results	Preparation of the stock solution resulted in a clear yellow solution with a part of the test substance adsorbed to the glass of the preparation bottle. No significant inhibition in respiration rate of the sludge was observed at 100 mg/L. The respiration rate of the controls was within 15% of each other. The EC50 of the reference substance was 10 mg/L indicating the test was valid.
CONCLUSION	The test substance is considered to be non-toxic to micro-organisms.
TEST FACILITY	NOTOX (1998l)

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