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26 May 2008

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

PDN 2287

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, Water, Heritage and the Arts.

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)
Infineum Australia Pty Ltd (ABN 24 084 881 863)
Level 2, 6 Riverside Quay
Southbank, VIC 3006

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: Chemical name, other names, CAS number, molecular formula, structural formula, molecular weight, analytical data, degree of purity, hazardous impurities, non-hazardous impurities, introduction volume and details of use.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Dissociation constant and adsorption/desorption.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
United States of America, Canada and Europe.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
PDN 2287
Will be imported as part of the products such as Infineum T4705 and Infineum T4569 (< 10% notified chemical)

MOLECULAR WEIGHT
< 1000 $g.mol^{-1}$.

ANALYTICAL DATA
Reference IR, NMR and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY Not applicable as the notified chemical is a complex mixture.

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Brown viscous liquid

Property	Value	Data Source/Justification
Pour point	27 ± 3°C	Measured
Boiling Point	> 205°C	The test material starts to decompose at 205°C without boiling.
Density	1030 kg/m^3 at 21°C	Measured
Vapour Pressure	2×10^{-6} kPa at 25°C	Measured

Water Solubility	Approximately 0.5 mg/L at 21ºC	Measured
Hydrolysis as a Function of pH	Not determined.	Data for hydrolysis as a function of pH has been waived due to the low water solubility (~0.5mg/L) of the amalgamation. Based on the functional groups, the notified substance is not expected to hydrolyse readily in the environment.
Partition Coefficient (n-octanol/water)	log Pow > 6.5.at 20ºC	Estimated
Adsorption/Desorption	Not determined.	A suitable method could not be found to determine the adsorption/desorption coefficient given it being a complex mixture of compounds.
Dissociation Constant	Not determined.	Unable to determine due to complexity of the mixture of the notified substance and the poor water solubility.
Flash Point	Closed cup: 135ºC at 96.7 kPa Open cup: 183ºC at 96.9 kPa Fire point: 187ºC at 96.9 kPa	Measured
Pyrophoric properties	Non-pyrophoric	Measured
Flammabillity (contact with water)	Non-Flammable	Measured
Autoignition Temperature	270 ± 5ºC	Measured
Explosive Properties	Not explosive	Measured

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, please refer to Appendix A. In the toxicity studies conducted on the notified chemical the pH was determined to 2.0.

Reactivity

Expected to be stable under normal conditions. The test material starts to decompose at 205ºC.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will not be manufactured in Australia. The notified chemical will be imported as a component of a lubricant additive package at a concentration of < 10%. The lubricant additive package (Infineum T4569) will be imported in 205 L steel drums or bulk vessels.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	30-100	30-100	30-100	30-100	30-100

PORT OF ENTRY

Primarily through Melbourne and Brisbane with the possibility of Sydney and Fremantle also being used.

IDENTITY OF MANUFACTURER/RECIPIENTS

The imported lubricant additive package containing notified chemical will be sold to formulators of transmission fluids throughout Australia.

TRANSPORTATION AND PACKAGING

The lubricant additive package containing the notified chemical will be delivered by road to the lubricant blending plant. The finished lubricant will be packaged in containers that are generally between 1 L and 200 L.

USE

The notified chemical is an anti-wear additive for use in transmission fluids at a concentration of < 1%.

OPERATION DESCRIPTION

Reformulation

The lubricant additive package containing the notified chemical will be transported from the port to the customer's lubricant blending plants. At the lubricant blending plant the lubricant additive package containing < 10% of the notified chemical will be reformulated with mineral oil and other additives, typically in batches of between 5000 to 20000 L, to produce the finished transmission fluid. The notified chemical will be present in the transmission fluid at concentrations of < 1% by weight.

A typical reformulation process is likely to be as follows. The vessel containing the lubricant additive package will be connected by an operator to the blending tank via a transfer system. The lubricant additive package will then be pumped out of the vessel containing it into the blending tank. After the transfer is complete the transfer hoses and the vessel that contained the lubricant additive package are cleaned by flushing them through with mineral oil. The reformulation of the lubricant additive package with mineral oil and other additives to produce the finished transmission fluid is an automated process that takes place in a closed system. Quality control workers may take samples of products containing the notified chemical during the reformulation process. Repackaging of the finished lubricant into containers is carried out on an automated filling line and operator involvement will be limited to packaging the containers for further handling and distribution. The finished product is sold and transported in these containers to retail outlets, vehicle fleet operators and industrial users throughout Australia.

End use

The finished transmission fluid will be used by automotive mechanics, automobile manufacturing plants and the public. Used transmission fluid is drained out of the transmission and replaced with new fluid in a largely manual process. During vehicle manufacture, transmissions will be filled with fluid for the first time.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Dock workers	2/site	Incidental Exposure only	12
Transport	1-2/site	Incidental Exposure only	12
Reformulation workers	1-4/site	0.17	12
Maintanence workers	2/site	0.17	12
Quality control workers	2/site	0.17	12
End users	> 100	1-8	200

EXPOSURE DETAILS

Transport and dock workers will be exposed to the notified chemical only in the event of a spill due to an accident or leaking drum.

Reformulation

During reformulation, exposure to the lubricant additive package containing the notified chemical at a concentration of < 10% is possible during the connection and disconnection of the vessels containing it to the transfer hoses. Exposure will primarily be dermal although ocular exposure is also possible. Inhalation exposure is likely to be negligible due to the low vapour pressure of the notified chemical, its viscous nature and the automation of the formulation process. However, oil mists can be formed, especially if heating is part of the formulation process or if there are leaks under high pressure. Exposure is expected to be reduced by engineering controls such as flushing of the transfer hoses and containers with mineral oil and the use of PPE such as gloves, coveralls and safety glasses.

End use

Worker exposure to the notified chemical at concentrations of < 1% could occur during the changing of

transmission fluid by automotive mechanics. The main route of exposure is expected to be dermal, although ocular exposure to splashes is possible. Exposure may be reduced by the use of PPE such as gloves, coveralls and safety glasses and good hygiene practices.

6.1.2. Public exposure

Although the notified chemical will be present in transmission fluid public exposure to the notified chemical is expected to be minimal as the transmission fluid is sealed within the transmission casing. However, exposure may occur during the changing of transmission fluid in automobiles by the public, although this will only be on an infrequent basis. Exposure will primarily be dermal although ocular exposure is also possible. PPE is not expected to be worn by the public.

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	Low toxicity, oral LD50 >2000 mg/kg bw
Rat, acute dermal toxicity	Low toxicity LD50 >2000 mg/kg bw
Rabbit, skin irritation	Moderately irritating
Rabbit, eye irritation	Irritating
Guinea pig, skin sensitisation – adjuvant test	Evidence of sensitisation
Mouse, skin sensitisation – Local lymph node assay	Evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	LOAEL = 100 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	Non mutagenic
Genotoxicity – *in vitro* mammalian cell gene mutation test.	Non genotoxic
Genotoxicity – *in vitro* mammalian chromosome aberration test	Non genotoxic

Toxicokinetics, metabolism and distribution.

Based on the low molecular weight (< 1000 Da) and the lipophilicity of the notified chemical (water solubility 0.5 mg/l; log Pow > 6.5) dermal absorption may occur, but the transfer from the stratum corneum into the epidermis is expected to be slow. Penetration into the epidermis was shown to occur due to the skin sensitising potential of the notified chemical. In addition, dermal absorption may be enhanced due to the irritant nature of the notified chemical.

Acute toxicity.

The notified chemical is considered to be of low acute toxicity via the oral and dermal routes based on tests conducted in rats.

Irritation and Sensitisation.

Based on a test conducted in rabbits the notified chemical is considered to be moderately irritating to the skin and irritating to the eye. The pH of the notified chemical was found to be 2.0. The notified chemical was found to be a skin sensitiser, based on evidence of induction of a lymphocyte proliferative response in a local lymph node assay and evidence of sensitisation seen in a guinea pig maximisation test.

Repeated Dose Toxicity (sub acute).

In a 28 day study in rats effects indicative of gastric irritation were observed in all treated males, as well as females treated at 500 and 1000 mg/kg bw/day. In addition adverse effects (clinical signs, decreases in body weight/food consumption and white blood cell effects) were observed in the high dose group and were considered to be related to the irritant nature of the notified chemical. Increased clotting times were also observed in males treated at 500 and 1000 mg/kg bw/day. A NOAEL for males could not be determined, so the LOAEL was established as 100 mg/kg bw/day. The NOAEL for females was established as 100 mg/kg bw/day based on the absence of gastric irritation in the low dose females.

Mutagenicity and genotoxicity

The notified chemical was negative in an Ames test, an *in vitro* mammalian chromosome aberration test and an *in vitro* mammalian cell gene mutation test. The notified chemical is not considered to be mutagenic or genotoxic.

Classification
Based on the skin irritation, eye irritation, and skin sensitisation tests the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Occupational dermal and ocular exposure to the notified chemical for reformulation workers may occur during handling of the drums, connection of transfer lines, cleaning and maintenance of the equipment. Dermal and ocular exposure may also occur in the end use where transmission fluid (< 1% notified chemical) is changed by automotive mechanics.

Local effects
Although the notified chemical is considered to be an eye and skin irritant, the severity of these effects will be reduced due to the relatively low concentrations in the products. In addition the exposure is expected to be minimised due to the use of personal protective equipment in the case of reformulation workers. Therefore the risk of irritant effects after exposure to the notified chemical is not considered to be an unacceptable risk.

However the notified chemical was shown to have significant skin sensitising potential. Based on the concentrations in the products used there is higher risk of skin sensitisation for reformulation workers handling < 10% solutions. This risk can be minimised by the use of personal protective equipment and automated processes that avoid skin contact. For end-users the risk of skin sensitisation is reduced due to the lower concentrations (< 1%), however this risk cannot be completely ruled out for sensitive individuals.

Systemic effects
As only a LOAEL could be determined from the repeat dose oral study (due to the gastric irritation effects seen at all dose levels) a quantitative risk assessment has not been conducted for systemic effects of the notified chemical. However, due to the precautions required to prevent skin sensitisation, systemic exposure due to skin contact is expected to be minimal. Therefore the risk to workers would not be considered unacceptable.

6.3.2. Public health
Exposure to the notified chemical (< 1%) by the general public will be on an infrequent basis at relatively low concentrations. Therefore, although the risk of sensitisation in sensitive individuals cannot be completely ruled out, the risk to the public from exposure to the notified chemical would not be considered unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
Domestic manufacture of the notified substance is not expected, however, domestic reformulation is expected to occur by lubricant formulators. Therefore, environmental release is expected to be limited to accidental spills during transport and handling. During reformulation, any residual amount of notified substance in transport vessels or equipment will be recovered by using a sump system and recycled. However, if disposal is warranted, then it is expected that the formulated notified substance will be thermally decomposed to recover its calorific value.

RELEASE OF CHEMICAL FROM USE
As the end use of the new chemical is as a component of transmission fluids, environmental exposure will be minimal as it will be contained with the essentially closed system of an automotive transmission system. Apart from the filling operation, the chemical will be retained in a closed system and hence its use will not result in its wide distribution in the environment. Transmission fluids are not frequently changed and, in many cases, these lubricants are effective for the life of the machine.

RELEASE OF CHEMICAL FROM DISPOSAL
When the time comes for the lubricant to be removed from the automotive transmission, it is expected by

the notifier that this transmission fluid change will occur at an automotive garage and that such "used oil" would be properly disposed of according to local regulations.

7.1.2 Environmental fate

A single ready biodegradability study was performed on the notified substance, which demonstrated 28.4% degradation after twenty nine days. Based on this study, the notified substance can not be classified as readily biodegradable. For the details of the environmental fate study, please refer to Appendix C.

The notified substance has bioaccumulation potential based on its physico-chemical properties. However, the risk of bioaccumulation is mitigated by the negligible release to the environment.

7.1.3 Predicted Environmental Concentration (PEC)

As significant aquatic exposure is not expected to occur at any stage of the life of the notified substance, based on its proposed use pattern, a Predicted Environmental Concentration (PEC) has not been calculated.

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	LC50 >1000 mg/L WAF	Not harmful to fish
Daphnia Toxicity	EC50 = 56.7 mg/L WAF	Harmful to daphnids
Algal Toxicity	E_rC50 = 21.6 mg/L WAF	Harmful to algae

Adverse effects such as dark pigmentation were noticed on the fish tested in the 300 mg/L sample set throughout the duration of the test. Fish tested in the 1000 mg/L set were lethargic on day 1; however, they seemed to recover from days 2 to 4.

7.2.1 Predicted No-Effect Concentration

Using the most sensitive ecotoxicity endpoint, algae, the Predicted No-Effect Concentration for the notified substance has been calculated as follows:

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga).	21.6	mg/L
Assessment Factor	100	
PNEC:	216	µg/L

7.3. Environmental risk assessment

As a PEC has not been calculated, it is not possible to derive a risk quotient for the proposed use of the notified substance. However, as significant aquatic exposure to the notified substance is not expected at any stage in its lifecycle in Australia, the risk to the aquatic environment is considered acceptable.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

Xi: R38 Irritating to skin
Xi: R36 Irritating to eyes
Xi: R43 May cause sensitisation by skin contact

and

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Environment	Acute Cat. 3. Chronic Cat. 3.	Harmful to aquatic life. Harmful to aquatic life with long lasting effects
Skin irritation	Category 3	Causes mild skin irritation
Eye irritation	Category 2A	Causes serious eye irritation
Skin sensitisation	Category 1	May cause an allergic skin reaction

Human health risk assessment

Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unacceptable risk to public health.

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified substance is not considered to pose an unacceptable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classifications for the notified chemical:
  - Xi: R38 Irritating to skin
  - Xi: R36 Irritating to eyes
  - Xi: R43 May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 20%: Xi: R36, R38, R43
  - ≥ 1% < 20 %: Xi: R43

- The following safety phrases should appear on the MSDS and label for the product containing the notified polymer:
  - S24: Avoid contact with skin
  - S25: Avoid contact with eyes
  - S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
  - S36: Wear suitable protective clothing
  - S37: Wear suitable gloves

Health Surveillance

- As the notified chemical is a sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to products containing the notified chemical:
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to products containing the notified chemical:
  - Safety goggles or face shield
  - Impervious gloves
  - Protective clothing

  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.

- Sensitised workers should be advised not to further handle the notified polymer.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] 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 where possible, or to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
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 of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - If the notified chemical will be present at a concentration of ≥ 1% w/w in products available to the public.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from an anti-wear additive for use in transmission fluids at a concentration of < 1%, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 100 tonnes, 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.

Material Safety Data Sheet
The MSDS of products containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Pour point 27 ± 3°C

Method	ASTM D97-66
Remarks	No significant protocol deviations. GLP compliant.
Test Facility	Pharmaco (1995)

Boiling Point > 205°C

Method	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	The boiling point could not be determined due to the test samples decomposing. Decomposition started at 205°C and was indicated by a gradual darkening of the test sample, by 235°C the test sample had turned dark brown and heating was stopped. No significant protocol deviations. GLP compliant.
Test Facility	Pharmaco (1995)

Density 1030 kg/m^3 at 21°C

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	No significant protocol deviations. GLP compliant. The relative density was determined using a pyknometer.
Test Facility	Pharmaco (1995)

Vapour Pressure 2×10^{-6} kPa at 25°C

Method	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	No significant protocol deviations. GLP compliant. The vapour pressure was measured using a vapour pressure balance method.
Test Facility	University of Leeds (1995)

Water Solubility Approximately 0.5 mg/L at 21°C

Method	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Both the Flask Method and Turbidimetry were used. The flask method failed to produce an accurate result due to the inability of the notified chemical to form a solution even at low concentrations. Instead the turbidity was measured using a Jenway Model 6035 Turbidimeter. Logarithmic graphs of the mean turbidity verses concentration were plotted and a linear regression performed on each half of the curve, the intercept of the two curves was taken as the critical micelle concentration. It should be noted that the notified substance contains a complex mixture of components, which may be expected to have a range of water solubilities. GLP compliant.
Test Facility	Pharmaco (1995)

Partition Coefficient (n-octanol/water) log Pow >6.5 at 20°C (Estimated)

Remarks	As a preliminary estimation of the partition coefficient of the notified substance from individual n-octanol (>1.5 g/mL) and water solubility (0.5 mg/L) values indicated that the log P_{OW} value falls outside the range of the two different test methods for determination of partition coefficient (Flask/HPLC), no definitive test was performed. As noted above, the notified substance contains a complex mixture of components which may be expected to have a range of partition coefficients.
Test Facility	Pharmaco (1995)

Flash Point Closed cup: 135°C at 96.7 kPa
Open cup: 183°C at 96.9 kPa
Fire point: 187°C at 96.9 kPa

Method	BS6664 part 5 and BS2000 part 35.
Remarks	The flash and fire points were determined using a Pensky-Martens closed tester and a Pensky-Martens open tester that had been calibrated using n-hexadecane. No significant protocol deviations. GLP compliant.
Test Facility	Pharmaco (1995)

Flammability (Contact with Water) Non-Flammable

Method	In house observations
Remarks	The EC Directive 92/69/EEC A.12 Flammability (Contact with Water) test was considered inappropriate based on observations made during the relative density and water solubility tests. GLP compliant.
Test Facility	Pharmaco (1995)

Pyrophoric Properties of solids and liquids Non-pyrophoric

Method	EC Directive 92/69/EEC A.13 Pyrophoric Properties of Solids and Liquids
Remarks	The test material exhibited no pyrophoric properties during prolonged exposure to the air. No significant protocol deviations. GLP compliant.
Test Facility	Pharmaco (1995)

Autoignition Temperature 270 ± 5°C

Method	EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks	No significant protocol deviations. GLP compliant.
Test Facility	ZENECA (1995)

Explosive Properties Not explosive

Method	EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks	No significant protocol deviations. GLP compliant. No changes in the notified chemical were seen in the drop-weight test (mechanical sensitivity) and steel cartridge test (thermal sensitivity). The notified chemical was not tested in the friction mill as this test is only applicable for solids.
Test Facility	ZENECA (1995)

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/Crl:CDBR
Vehicle	Test substance administered as supplied
Remarks - Method	No significant protocol deviations.
RESULTS	
LD50	> 2000 mg/kg bw
Signs of Toxicity	Clinical signs of toxicity were prominent within the first 6 hours after administration of the test substance in 3/5 male and 3/5 female rats. Symptoms included oral discharge in 2 male and 2 females and soft stools were observed in 2 male and 1 female animals. Anogenital staining was observed in 3 female rats, with 1 female continuing to show staining at the Day 1 and 2 observation periods. There were no observable signs of toxicity in any animal after Day 2. All animals were free of abnormalities from Day 3 to the end of the observation period.
Effects in Organs	No adverse gross macroscopic changes were observed at terminal necropsy.
Remarks - Results	There were no deaths and no overt sign of systemic toxicity. All animals showed normal body weight gain throughout the study.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Exxon Biomedical Sciences Inc (1995a)

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	Rabbit/New Zealand White
Vehicle	Test substance administered as supplied
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.
RESULTS	
LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Well-defined to moderate erythema was present in 100% of animals tested throughout the entire study period, in particular on Day 7 and 10 where severe erythema and slight eschar formation was observed. All animals were free of oedema by the Day 14 observation point. Other significant dermal observations include atonia (lack of skin resilience), obvious skin exfoliation, deep cracks (fissures) and the appearance of leathery skin in 100% of animals tested. Around 40% of the animals showed skin cracking, scab formations (eschar) and noticeable shedding of small flakes of skin (desquamation). Two rats showed skin blanching, and one female rat showed skin necrosis.
Signs of Toxicity - Systemic	There were no signs of systemic toxicity.
Effects in Organs	There were no gross macroscopic changes observed at necropsy.

Remarks - Results	Several animals recorded weight loss and sores on the mouth and neck during the study, but these were attributed to stress and physical irritation caused by the Elizabeth collars used to prevent ingestion of the test substance. Although there were localised skin effects due to exposure, no deaths occurred during the study period.
CONCLUSION	The notified chemical of low toxicity via the dermal route.
TEST FACILITY	Exxon Biomedical Sciences Inc (1995b)

B.3. 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	6 Males
Vehicle	Test substance administered as supplied
Observation Period	14 days.
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	1.94	3	> 14 days	1
Oedema	1.44	3	< 10 days	0

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

Remarks - Results	The test substance elicited erythema in all six animals after exposure. Signs of well-defined erythema were observed in most animals at the 24 and 48-hour observation period, which progressed to moderate/severe erythema in 50% of animals tested at 72 hours after exposure. Very slight erythema was observed in four animals on Day 7, two animals on Day 10 and one animal on Day 14. All six animals displayed very slight oedema at the 48-hour observation. Three animals showed slight oedema and the remaining three had moderate oedema at 72 hours after exposure. Slight oedema was observed in two animals on Day 7. All animals were free of oedema at the Day 10 and 14 observations. Desquamation and leathery skin were also observed in animals during the study.
CONCLUSION	The notified chemical is moderately irritating to the skin.
TEST FACILITY	Exxon Biomedical Sciences Inc (1995c)

B.4. 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	6
Observation Period	10 days
Remarks - Method	The investigators have noted that the pH of the test substance was

inadvertently not measured prior to dose initiation.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	2.67	3	<10 days	0
Conjunctiva: chemosis	2.94	4	< 7 days	0
Conjunctiva: discharge	2.00	3	<10 days	0
Corneal opacity	0.78	2	<72 hrs	0
Iridial inflammation	0.67	1	<72 hrs	0

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

Remarks - Results

All six animals showed diffuse, beefy red-coloured conjunctiva at the 24 and 48-hour observations. Severe conjunctival swelling and discharge around the eyes were observed in all animals up to 48 hours after exposure to the test substance.
Other observations include necrosis and ulceration of the conjunctiva in up to five animals and retention of fluorescein dye in the conjunctival membranes.
The investigators note that the pH of the test substance was measured upon termination of the study and was determined to be 2.

CONCLUSION

The notified chemical is irritating to the eye.

TEST FACILITY

Exxon Biomedical Sciences Inc (1995d)

B.5. Skin sensitisation

TEST SUBSTANCE

Notified chemical

METHOD

EC Directive 96/54/EC B.6 Skin Sensitisation - Guinea Pig Maximization Test.

Species/Strain

Guinea pig/Hartley Albino

PRELIMINARY STUDY

Maximum Non-irritating Concentration:
intradermal: 1.0% in peanut oil
topical: 0.1% in peanut oil (irritation was observed, but resolved by 48 hours).
Concentration causing mild-moderate irritation: topical 5.0%.

MAIN STUDY

Number of Animals

Test Group: 20

Control Group: 20 (10 used for challenge, 10 for rechallange)

INDUCTION PHASE

Induction Concentration:
intradermal: 1.0% in peanut oil
topical: 5.0% in peanut oil

Signs of Irritation

100% of animals in the intradermal test group showed slight to moderate redness, with one animal displaying extreme redness in one of the injection sites. Several animals in the control group administered with the vehicle (peanut oil) showed very slight erythema.
Topical application produced well-defined to moderate/severe erythema in all animals, and very slight to slight oedema in 17 animals at the 1-hour evaluation. At the 24-hour observation, all animals showed very slight to well-defined erythema, and only very slight oedema was noted in ten animals. Peanut oil produced well-defined erythema in all control group animals and very slight oedema in 14 animals at the 1-hour evaluation. At the 24-hour observation slight to well-defined erythema were observed in nine of the control group animals.

CHALLENGE PHASE

1st challenge

topical: 0.1% in peanut oil

2nd challenge	topical: 0.1% in peanut oil
Remarks - Method	No significant protocol deviations.

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	0.1%	19/20	13/20	20/20	20/20
Control Group	0.1%	9/10	5/10	6/10	0/10

Remarks - Results

1st challenge – At 24 hours post challenge the observations seen in the test group animals included: very slight erythema in 5 animals, well-defined erythema in 13 animals and moderate/severe erythema in 1 animal; very slight edema in 4 animals and slight edema in 1 animal. These were more severe than the responses seen in the control group animals (very slight erythema in 6 animals, well defined erythema in 3 animals, no edema).
At 48 hours post challenge the responses seen in the test group animals (very slight erythema in 9 animals, well-defined erythema in 4 animals, very slight edema in 3 animals). Was again greater in severity than the responses seen in the control group animals (very slight erythema in 4 animals, well defined erythema in 1 animal, no edema).
2nd challenge – At 24 hours post challenge the responses seen in the test group animals (very slight erythema in 1 animal, well defined erythema in 10 animals, moderate erythema in 2 animals and severe erythema in 7 animals, 4 animals with very slight edema, 9 animals with slight edema) were of much greater severity than the responses seen in the control animals (very slight erythema in 6 animals).
At 48 hours post challenge no responses were seen in the control animals, while the test group animals responses included 8 animals with very slight erythema, 4 animals well-defined erythema, 1 animal with moderate erythema and 7 animals with severe erythema, 4 animals with very slight edema and 7 animals with slight edema.

The test response indicates that the test substance should be considered to be a strong sensitiser.

CONCLUSION

There was evidence of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY

Exxon Biomedical Sciences Inc (1995e)

B.6. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE

Notified chemical

METHOD

Species/Strain	Mouse/CBA/Ca/Ola/Hsd
Vehicle	Acetone in olive oil (4:1)
Remarks - Method	Male mice used in the study; body weights not recorded. In a preliminary irritation study using a 5% solution of the test substance no irritation was observed, 5% was selected as the high dose level. The lymph nodes from each group were pooled. The EC3 was determined using the quadratic regression method.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*

Test Substance		
0 (vehicle control)	317	1
0.05	206	0.65
0.1	259	0.82
0.5	401	1.26
1.0	561	1.77
5.0	4055	12.79
Positive Control		
0	123	1
1	251	2.04
3	689	5.60
10	1201	9.76

Remarks - Results: The EC3 value was calculated to be 1.70%.
The positive control confirmed the validity of the test system.

CONCLUSION: There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY: Central Toxicology Laboratory (2001)

B.7. Repeat dose toxicity

TEST SUBSTANCE: Notified chemical

METHOD: EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain: Rat/Crl:CD BR
Route of Administration: Oral – gavage
Exposure Information: Total exposure days: 28 days
Dose regimen: 7 days per week
Post-exposure observation period: none
Vehicle: Test substance administered as a solution in corn oil
Remarks - Method: No significant protocol deviations. No recovery period, however there were no toxic effects observed. GLP compliant.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5 per sex	0	0
low dose	5 per sex	100	0
mid dose	5 per sex	500	0
high dose	5 per sex	1000	0

Mortality and Time to Death
No test item related mortality occurred during the study.

Clinical Observations
All animals showed increases in their body weight over the study period. The mean body weight of male animals in the high dose group was significantly less than the control group at the Day 27 interval. Adverse clinical signs were limited to infrequent incidences from animals in the high dose group. These clinical signs included nasal discharge, rales, oral discharge, soft stools, low food consumption and anogenital/abdominal staining.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
There was an increase in the mean white blood cell counts for male (39%) and female (47%) animals in the high dose group, which was statistically significant for the female animals only. Statistically significant increases in the neutrophils (67%), prothrombin time (28%) and thromboplastin time (37%) were also seen in male animals in the high dose group. Mid dose male animals also showed statistically significant increases in thromboplastin time (37%). There was a statistically significant increase in the mean eosinophil in the low

dose female animals, however, in the absence of a clear dose response this was considered to be a spurious response.
There were statistically significant increases in mean alanine aminotransferase of high dose males (133%) and females (81%) and mid dose males (40%). There were statistically significant decreases in the mean triglycerides of high (44%) and mid dose (49%) males and increases in the urea nitrogen of high dose (27%) males.

Effects in Organs
There were statistically significant increases in the mean absolute liver weight of the high dose females (24%) and mean relative liver weight of the high dose males (26%) and females (23%). There was also a statistically significant increase in the mean relative testes weight of the high dose males (18%). Nine of the ten high dose animals and one mid dose female had a roughened/thickened and/or whitened non-glandular portion of the stomach. All male rats and female rats in the high and mid dose groups had hyperplasia and hyperkeratosis of the forestomach mucosa with associated oedema/inflammation of the submucosa. Focal necrosis of the forestomach mucosa occasionally extending into the submucosa was seen in a few rats in the mid and high dose groups.

Remarks – Results
The effects seen in the forestomach of the treated animals were attributed to the irritant nature of the test substance, which had a low pH of 2.0. The clinical signs, food consumption and body weight decreases, and the white blood cell effects were likely to be a consequence of this gastric irritation. Although changes in the clinical chemistry and the liver weight were suggestive of liver effects, this was not supported as no histopathological changes were observed in the liver.

CONCLUSION
Since the gastric irritation effects were observed at all dose levels in the treated males a NOAEL for males cannot be determined. The LOAEL for males is 100 mg/kg bw/day. The NOAEL for females was established as 100 mg/kg bw/day based on the absence of gastric irritation in the low dose females.

TEST FACILITY Exxon Biomedical Sciences Inc (1995f)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD EC Directive 2000/32/EC B.14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100
Metabolic Activation System	S9 fraction derived from Aroclor 1254 induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 125, 250, 500, 750 and 1000 µg/plate b) Without metabolic activation: 125, 250, 500, 750 and 1000 µg/plate
Vehicle	Tetrahydrofuran
Remarks - Method	No significant protocol deviations. GLP compliant.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	1000	500	> 5000	Negative
Test 2		500		Negative
Present				
Test 1	500	500	> 5000	Negative
Test 2		1000		Negative

Remarks - Results No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, either with or without metabolic

activation.
Although no precipitation was mentioned in the test report, a test substance related haze was observed on plated treated at or above 250 µg/plate.
The positive, vehicle and non-treated controls gave satisfactory responses, confirming the validity of the test system.

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

TEST FACILITY Exxon Biomedical Sciences Inc (1995g)

B.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.
EC Directive 2000/32/EC B.17 Mutagenicity - In vitro Mammalian Cell Gene Mutation Test.

Cell Type/Cell Line	Mouse lymphoma L5178Y
Metabolic Activation System	S9 fraction derived from Aroclor 1254 induced rat liver
Vehicle	Acetone
Remarks - Method	No significant protocol deviations. GLP compliant.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	0, 10, 20, 30, 40, 50	4 hours	72 hours	10-11 days
Test 2	0, 10, 15, 20, 30, 40	4 hours	72 hours	10-11 days
Present				
Test 1	0, 20, 40, 60, 80, 100	4 hours	72 hours	10-11 days
Test 2	0, 10, 20, 40, 50, 60	4 hours	72 hours	10-11 days
Additional test	0, 20, 40, 60, 70, 80	4 hours	72 hours	10-11 days

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	31.25	30	1000	Negative
Test 2		30	1000	Negative
Present				
Test 1	62.5	40	1000	Negative
Test 2		40	1000	Negative
Additional test		40	1000	Negative

Remarks - Results The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.

CONCLUSION The notified chemical was not mutagenic to mouse lymphoma L5178Ycells treated in vitro under the conditions of the test.

TEST FACILITY Huntingdon Life Sciences (1996)

B.10. 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.

Cell Type/Cell Line: Chinese Hamster Ovary (CHO) Cells
Metabolic Activation System: S9 fraction derived from Aroclor induced rat liver
Vehicle: Tetrahydrofuran and dimethylsulfoxide
Remarks - Method: A non-treated group was used in the initial study, this group was not evaluated for chromosome aberrations. T75 flasks were utilized instead of T25 flasks, the volume of the medium and the dose volumes were adjusted to accommodate these changes. The observations performed for culture medium solubility at the 30 minute interval were performed approximately 10 minutes beyond the acceptable time limit.
GLP compliant.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	5*, 10*, 15*, 20, 25, 30	20 hours	20 hours
Test 2a	0.2, 0.5*, 1, 2, 5*, 10*	20 hours	20 hours
Test 2b	0.2*, 0.5, 1, 2*, 5*, 10	20 hours	44 hours
Present			
Test 1	5, 10, 15, 20*, 30*, 40*	3 hours	20 hours
Test 2a	0.5, 1, 2, 5, 40*, 50*, 60*	3 hours	20 hours
Test 2b	0.5, 1, 2*, 5*, 40, 50*, 60	3 hours	44 hours

*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	20	20	78	Negative
Test 2		20		Negative
Present				
Test 1	100	100	10	Negative
Test 2a		100		Negative
Test 2b		100		Negative

Remarks - Results: The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.

CONCLUSION: The notified chemical was not clastogenic to Chinese Hamster Ovary (CHO) Cells treated in vitro under the conditions of the test.

TEST FACILITY: Exxon Biomedical Sciences Inc (1995h)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE: Notified substance

METHOD
- Inoculum: Activated sewage sludge from a domestic STP.
- Exposure Period: 29 d
- Auxiliary Solvent: Nil
- Analytical Monitoring: TOC
- Remarks - Method: Significant protocol deviations were not reported.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
1	1.38	1	8.44
3	3.36	3	47.93
8	6.10	8	80.27
15	17.69	15	90.58
22	24.47	22	92.92
29	28.36	29	94.04

Remarks - Results: The positive control material degraded to 94.0% within twenty-nine days and therefore this test may be considered valid.

CONCLUSION: The notified substance cannot be classified as being readily biodegradable.

TEST FACILITY: Exxon Biomedical Sciences, Inc (1995i)

C.1.2. Bioaccumulation

Remarks - Results: Using an alternative method, the solubility of the notified substance was measured in *n*-octanol (observation of single phase in *n*-octanol) with a solubility of > 1.5g/L. The calculated log K_{OW} of > 6.5 suggests that bioconcentration in aquatic organisms may occur. Using the Gobas BCF_BAF Model with the input value of log K_{OW} of 6.5, the resulting log BCF is 4.41 and log BAF is 6.21. Some components of the notified substance may therefore be expected to be bioaccumulative.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified Substance

METHOD
- Species: *Oncorhynchus mykiss* (Rainbow Trout)
- Exposure Period: 96 h
- Auxiliary Solvent: Nil
- Water Hardness: 194-202 mg $CaCO_3$/L
- Analytical Monitoring: TOC
- Remarks – Method: Individual treatment solutions were prepared daily by adding the appropriate amount of the test substance to Laboratory dilution water in glass carboys. The solutions were mixed for approximately 24 hours on

magnetic stirplates with Teflon® coated stirbars. After mixing, the solutions were allowed to settle for approximately one hour before the WAF was removed by glass tube siphons from the bottom of the vessels.

Two replicate chambers were prepared per treatment by filling the test chambers with the WAF and maintaining only a minimal headspace. All of the test substance remained adhered to the capliner in the 1mg/L treatment with some of it observed suspended throughout the water column in the other treatments. Daily renewals were performed by removing approximately 80% of the WAF from each test chamber using a glass tube siphon and refilling with fresh WAF. Daily renewals were performed to minimize loss of volatile material.

No significant protocol deviations were reported.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
0		10	0	0	0	0
1		10	0	0	0	0
10		10	0	0	0	0
70		10	1	1	1	1
300		10	0	0	0	0
1000		10	0	0	0	1

LC50	>1000 mg/L at 96 hours (WAF)
NOEC	1000 mg/L at 96 hours (WAF)
Remarks – Results	Sub-lethal effects observed include dark pigmentation and lethargy. These sub-lethal effects were observed at 24 hours in the 300 and 1000 mg/L nominal concentration treatments.

CONCLUSION The notified substance is not harmful to fish up to the limit of its solubility in water.

TEST FACILITY Exxon Biomedical Sciences, Inc (1995j)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified substance

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Nil
Water Hardness	200 – 202 mg $CaCO_3$/L
Analytical Monitoring	TOC
Remarks - Method	Individual treatment solutions were prepared daily by adding the appropriate amount of the test substance to Laboratory dilution water in glass aspirator bottles. The solutions were mixed for approximately 24 hours on magnetic stirplates with Teflon® coated stirbars. All or most of the test substance remained adhered to the capliners in all of the treatments with some of it observed suspended throughout the water column in the 120 mg/L and 300 mg/L treatment levels. After mixing, the solutions were allowed to settle for approximately one hour before the WAF was removed through the outlet at the bottom of the vessels.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual: New – Old*		*24 h*	*48 h*
0	1.7 +/- 1.2 – 3.7 +/- 0.7	20	0	2
7.7	1.6 +/- 0.3 – 2.8 +/- 0.6	20	0	3
19.2	3.6 +/- 2.6 – 4.1 +/- 1.6	20	0	2
48	3.6 +/- 1.2 – 7.4 +/- 3.8	20	1	11
120	4.6 +/- 0.8 – 5.5 +/- 0.6	20	10	15
300	6.2 +/- 0.8 – 7.4 +/- 1.5	20	10	16

LC50 56.7 mg/L at 48 hours (95% CI: 35.8 – 92.3) WAF

Remarks - Results There were no treatment levels which displayed either no immobilization or complete immobilization.

CONCLUSION The notified substance was found to be harmful to Daphnids at the limit of its solubility in water.

TEST FACILITY Exxon Biomedical Sciences, Inc (1995k)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified substance.

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species *Selenastrum capricornutum*

Exposure Period 96 hours

Concentration Range Nominal: 0, 5.12, 12.8, 32, 80 and 200 mg/L
Actual (Day 4): 4.8, 3.4, 5.2, 4.1, 4.9, 8.8 mg/L (DOC)

Auxiliary Solvent Nil

Analytical Monitoring DOC

Remarks - Method Individual treatment solutions were prepared by adding the appropriate amount of the test substance to Laboratory dilution water in glass aspirator bottles. The solutions were mixed for approximately 24 hours. All or most of the test substance remained adhered to the capliners in all of the treatments with some of it observed suspended throughout the water column in the 120 mg/L and 300 mg/L treatment levels. After mixing, the solutions were allowed to settle for approximately one hour before the WAF was removed through the outlet at the bottom of the vessels.

No significant protocol deviations were reported.

RESULTS

Growth	
E_rC50 *mg/L at 72 h*	*LOE_rC* *mg/L*
21.6	5.12

Remarks - Results An acceptable NOEC value could not be calculated. The test validation criteria were satisfied and the test was considered valid.

CONCLUSION The notified substance was found to be harmful to algae at the limit of its solubility in water.

TEST FACILITY Exxon Biomedical Sciences, Inc (1995l)

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