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July 2009

# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

# **FULL PUBLIC REPORT**

# 1,3-Cyclohexanedimethanol

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:

Street Address: 334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.

Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.

TEL: + 61 2 8577 8800 FAX + 61 2 8577 8888 Website: www.nicnas.gov.au

Director NICNAS

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# FULL PUBLIC REPORT

# 1,3-Cyclohexanedimethanol

### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Dow Chemical Australia Ltd (ABN 72 000 264 979) 541-583 Kororoit Creek Road ALTONA VIC 3018

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:

Spectral data, methods of detection and determination, impurities, import volume and specified use.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Physical and chemical properties, toxicological, ecotoxicological and environmental fate

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA, Japan and Europe.

# 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Component in UNOXOL Diol (UNOXOL Diol is an approximately 1:1 mixture of the notified chemical and 1,4-Cyclohexanedimethanol)

CAS NUMBER

3971-28-6

CHEMICAL NAME

1,3-Cyclohexanedimethanol

OTHER NAME(S)

1,3-Bis(hydroxymethyl)cyclohexane

[3-(Hydroxymethyl)cyclohexane]methanol

MOLECULAR FORMULA

 $C_8H_{16}O_2$ 

STRUCTURAL FORMULA

MOLECULAR WEIGHT 144.21 Da

ANALYTICAL DATA

Reference <sup>1</sup>H NMR and IR spectra were provided.

# 3. COMPOSITION

DEGREE OF PURITY 99.5% (refers to mixture of 1,3- and 1,4- isomers, both *cis*- and *trans*-)

# 4. PHYSICAL AND CHEMICAL PROPERTIES

Most physicochemical properties relate to UNOXOL Diol, containing approximately 50% of the notified chemical.

APPEARANCE AT 20°C AND 101.3 kPa: UNOXOL Diol is a colourless liquid (MSDS)

Property	Value	Data Source/Justification
Freezing Point	-20°C	MSDS for UNOXOL Diol
Boiling Point	276°C at 101.3 kPa	MSDS for UNOXOL Diol
Density	$1044 \text{ kg/m}^3 \text{ at } 20^{\circ}\text{C}$	MSDS for UNOXOL Diol
Vapour Pressure	< 0.001 kPa at 20°C	MSDS for UNOXOL Diol
Water Solubility	Completely soluble in water at 20°C	MSDS for UNOXOL Diol
Hydrolysis as a Function of pH	Not determined.	Expected to be hydrolytically stable,
Partition Coefficient	$\log P_{\rm ow} = 1.49$	based on the structure. Estimated
(n-octanol/water)	_	
Adsorption/Desorption	$\log K_{oc} = 1$	Estimated
Dissociation Constant	Not determined	The notified chemical does not contain any functional groups that are expected to dissociate in water.
Surface tension	59.8 mN/m at 25°C (1% solution), 47.2 mN/m (10% solution)	Measured. The surface tension of aqueous solutions of the notified chemical is reduced as the concentration increases.
Particle Size	Not determined	Liquid
Flash Point	118°C at (pressure unknown)	MSDS for UNOXOL Diol
Flammability Limits	-	Not determined
Autoignition Temperature	330°C	MSDS for 1,4-Cyclohexanedimethanol
Explosive Properties	Not determined	Based on the chemical structure, the
		result for the explosive properties has
		been predicted to be negative.

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, please refer to Appendix A.

# Reactivity

The chemical is stable under normal conditions.

## 5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be imported by sea as a component (approximately 50%) of UNOXOL Diol in 205 L lined steel drums or isotanks. It will be transported from the dockside to the notifier's warehouse for storage.

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

Year	1	2	3	4	5
Tonnes	10-30	10-30	10-30	30-100	30-100

PORT OF ENTRY

Port Melbourne, Victoria.

**IDENTITY OF RECIPIENTS** 

Dow Chemical Australia Ltd

### TRANSPORTATION AND PACKAGING

UNOXOL Diol containing the notified chemical may be transferred from the isotanks to 205 L drums either at the Dow Chemical site or it may be transported by railcar to a contract terminal site where it will be transferred to 205 L drums prior to distribution by road to resin manufacturers across Australia.

#### USE

Monomer component of polyester and polyol resins, which will be used for industrial coatings.

### OPERATION DESCRIPTION

The notified chemical as component in UNOXOL Diol will not be manufactured in Australia. Local operations will involve repacking, distribution to customers, the manufacture of resins, and formulation and application of industrial coatings.

Repacking into 205 L drums at either the notifier's site or a contract terminal site may be required if UNOXOL Diol is imported in isotanks. The drums would then be transferred to the customer sites for resin manufacture.

The notified chemical will be used in the manufacture of resins at the customer's resin plant. The 205 L drums will be transferred to on-site holding tanks, and automatically dosed into the reaction vessel. All transfer operations will take place in a purpose-built, bunded area which is supplied with local and general ventilation. The polymer will be manufactured in a closed reaction vessel supplied with cooling, paddle mixer and local ventilation/scrubber. The resin solution is then pumped to holding tanks or filled into 205 L drums for subsequent formulation into coating products.

The resin containing < 1% residual notified chemical will be formulated into coating products and used in industrial coating processes.

### 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 & warehousing	10	1-2 hours	12 days/year
Resin manufacture process operators	10/site	8 hours/day	200 days/year
Cleaning equipment	2/site	15-30 minutes/day	200 days/year
QA staff	1/site	1 hour/day	200 days/year
End use of resin	1000	8 hours/day	200 days/year

# EXPOSURE DETAILS

Transport and storage

Transport and warehousing workers may come into dermal and ocular contact with UNOXOL diol containing the notified chemical through accidental leaks and spillages. Transport and warehouse workers will wear work clothing or overalls and safety boots. In addition warehouse workers may wear hardhats and safety glasses. If repacking is required, engineering controls and PPE similar to those used in resin manufacture are expected to be in place.

# Resin manufacture

Workers involved in transfer of the UNOXOL diol to onsite tanks and then to the reaction vessel for resin manufacture may have dermal, ocular or inhalation exposure to approximately 50% notified chemical. The notified chemical does not have a high vapour pressure, therefore significant inhalation exposure would not occur unless it was heated and aerosols were formed. Transfer is carried out mechanically and the reaction vessel is a closed system with local ventilation, reducing the risk of exposure. Workers will wear overalls, PVC apron, safety boots, gloves, hardhat and safety glasses.

QA staff will take a small sample via a sample port into a sample jar, seal it and take it to the laboratory for testing within a fume hood. QA personnel will wear laboratory coat, gloves, safety boots, and safety glasses.

Equipment is cleaned by flushing the lines with a suitable solvent which is drummed and is disposed of by a licensed water contractor. Exposure may occur by the dermal, ocular or inhalation routes. Workers are expected to wear overalls, PVC apron, safety boots, gloves, hardhat and safety glasses.

### Coating formulation and end use

Once the polymerisation reaction has been completed the notified chemical is chemically bound within the resin structure and is no longer available for exposure, except for a low level (< 1%) of unreacted residual monomer. Dermal/ocular exposure to this low concentration may occur during formulation and application of coatings. In addition, inhalation exposure may occur during spray application of coatings, and during drying/curing of coatings. While the scenarios of end-use are expected to be varied, in general dermal/ocular exposure is expected to be limited by the use of PPE. Inhalation exposure to the notified chemical in spray painting is considered to be low if application occurs in spray booths and may also be controlled by appropriate PPE such as a respirator. Significant inhalation exposure during drying/curing would not be expected unless ventilation is inadequate.

After the coating has been dried/cured, it is expected that the residual monomer would have been lost to the atmosphere. Therefore exposure to the notified chemical from cured coatings is not expected.

Overall, the exposure of workers to the notified chemical is expected to be low considering described controls in place.

# 6.1.2. Public exposure

The notified chemical, the resin or coatings containing the residual notified chemical will not be sold to the public. The public may be exposed to coated articles. After the coating containing a low level of residual notified chemical is dried and cured, it is expected that the residual monomer would be lost to the atmosphere. Therefore, exposure of the public to the notified chemical is considered low.

# 6.2. Human health effects assessment

The results from toxicological investigations conducted on UNOXOL Diol (an approximately 1:1 mixture of the notified chemical and the related chemical 1,4-Cyclohexanedimethanol) 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
Rat, acute inhalation toxicity	LC50 > 13.1  ppb 4 hour
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	severely irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOEL = 100  mg/kg bw/day
	NOAEL = 1000  mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration	non genotoxic

### Toxicokinetic and metabolism

No toxicokinetic studies on the notified chemical were available. Given the low molecular weight of the notified chemical and its log  $P_{ow}$  of 1.49, it is likely to be significantly absorbed following oral, dermal or inhalation exposure. The notified chemical is stated to have a vapour pressure of < 0.001 kPa and thus not highly volatile.

Information on the related chemical 1,4-cyclohexanedimethanol through its SIDS Initial Assessment Profile (OECD, 2008) is expected to be also relevant to the notified chemical. 1,4-Cyclohexanedimethanol (cis and trans isomers) was converted to the corresponding mono- and di-carboxylic acids after oral administration. It was rapidly absorbed and 95% was excreted in urine. No change in the ratio of isomers was seen after metabolism. The elimination half life in plasma was approximately 3 minutes.

### Acute toxicity

Based on the characteristics of UNOXOL diol, the notified chemical is considered to be of low acute toxicity *via* the oral and dermal routes, and was not toxic by inhalation up to 13.1 ppb, which is calculated to be the saturated vapour concentration at room temperature.

### Irritation

Based on the studies provided on UNOXOL diol, the notified chemical is considered to be slightly irritating to skin. It was severely irritating to eyes, causing conjunctival, iridial and corneal effects that were not reversible after 21 days.

### Sensitisation

There was no evidence of a lymphocyte proliferative response indicative of skin sensitisation to UNOXOL diol in a mouse LLNA.

# Repeated Dose Toxicity

The No Observed Effect Level (NOEL) was established as 100 mg/kg bw/day in a 28-day feeding study in rats of UNOXOL diol, based on lower urine pH values seen in males and females given 500 or 1000 mg/kg/day. The change may be related to formation of acid metabolites.

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study because lower urine pH values seen in males and females given 500 or 1000 mg/kg/day was considered not to be an adverse effect in the absence of related effects in organs or histopathological changes.

### Genotoxicity

UNOXOL diol was not mutagenic in a bacterial reverse mutation study and not genotoxic in an *in vitro* mammalian chromosome aberration study. An in vivo study was not performed, however the related chemical 1,4-cyclodimethanol was negative in an *in vivo* mammalian bone marrow chromosome test to OECD guidelines (OECD, 2008),

## Toxicity for reproduction

The reproductive toxicity of the related chemical, 1,4-cyclohexanedimethanol has been investigated in a reproductive and developmental toxicity screening test in rats [OECD TG421] and is considered not to be a reproductive/developmental toxicant (OECD 2008).

### Health hazard classification

Based on the eye irritation study on UNOXOL diol the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Xi: Irritant

R41: Risk of serious damage to eyes

### 6.3. Human health risk characterisation

### 6.3.1. Occupational health and safety

Based on available studies on a mixture of the notified chemical and a related chemical, it is expected to cause severe eye irritation and slight skin irritation.

Workers who may be exposed to the highest concentrations of the notified chemical (50%) include transport and storage workers, repackers, resin plant operators and QC staff. Significant engineering controls are in place during resin manufacture, and the risk of eye damage would be further reduced by use of PPE and the provision of emergency eye wash facilities at all sites where exposure may occur.

Once the chemical is incorporated into the resin, only exposure to the residual monomer (<1%) can occur. Potential exposure to this low concentration of the chemical may occur during coating formulation and application, and while it volatilises during the drying/curing process of the coatings. While effects on the eye are expected to lessen as concentration is reduced, the risk of eye irritation/damage from contact with vapours or aerosols cannot be ruled out. This would be minimised by adequate ventilation.

Once the coating is dried/cured, no exposure of workers to the notified chemical is expected.

As no adverse effects were seen in the 28 day study, the risk of systemic effects to workers is not considered to be of concern.

Under the scenarios described the exposure and risk to the workers from the notified chemical is expected to be low.

### 6.3.2. Public health

Once the coating containing the notified chemical is applied to articles, any residual notified chemical is expected to evaporate from the paint film as it cures/dries. Therefore the risk to the public from the notified chemical is expected to be low.

### 7. ENVIRONMENTAL IMPLICATIONS

### 7.1. Environmental Exposure & Fate Assessment

### 7.1.1 Environmental Exposure

### RELEASE OF CHEMICAL AT SITE

Release at the notifier's warehouse may result only from accidental spills. It is estimated that a maximum of 50 kg per year (< 0.1 % of import volume) 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.

### RELEASE OF CHEMICAL FROM USE

Release at the resin manufacturing site may result from accidental spills, cleaning of equipment and residues in containers. It is estimated that a maximum of 300 kg per year < 0.5 % of import volume) 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.

Residues in import containers are expected to be an additional 600 kg/year (< 1% of import volume). These will be disposed of to landfill with the 205 L drums. The transfer line, holding tanks, and reaction vessel will be rinsed with an appropriate solvent. The rinsate will be collected in 205 L drums and sent off site for disposal via a licensed waste contractor. Cleaning of equipment is expected to account for a further 300 kg per year (< 0.5 % of import volume)

### RELEASE OF CHEMICAL FROM DISPOSAL

Disposal of the notified chemical will be to landfill.

### 7.1.2 Environmental fate

Most of the notified chemical will be incorporated into resins, with minimal potential for environmental release, but a minor proportion (< 1%) will remain unreacted and is expected to slowly volatilise to the atmosphere as the coating is dried and cured. Volatilisation is to be expected, as the Henry's law constant for the 1,4 isomer suggests moderate volatilisation from water at 25°C, as reported by the OECD (2008) in its SIDS Initial Assessment Profile (SIAP). Atmospheric persistence is expected to be limited by analogy with the susceptibility of the 1,4 isomer to photo-oxidation (half-life 0.5 days) as reported in the SIAP. Atmospheric residues will also be washed out by rain as the notified chemical is water soluble.

Minor wastes will be disposed of to landfill. The high level of water solubility indicates that the notified chemical will have low adsorption to organic matter and may be mobile in the environment with a tendency to partition to water. However, mobility will be limited as the notified chemical is readily biodegradable. The notified chemical has a low potential for bioaccumulation in fish because of its high water solubility.

## 7.1.3 Predicted Environmental Concentration (PEC)

The PEC can be determined as tabulated below based on the hypothetical worst case assumption that all wastes from resin manufacture (up to 2% of the import volume) are discharged to sewer once per month without treatment, and subsequently to receiving waters. Note that this scenario is not expected to arise when the notified chemical is used and handled as proposed, and is used as a conservative basis for risk assessment rather than a reliable predictor of exposure. The PEC is based on the assumption that the upper limit of 100 tonnes for the import volume is evenly distributed to 10 resin manufacturers in city and country locations, with discharge occurring on a monthly basis to large or small sewage treatment plants (respective daily flows of 100 and 4 ML). The table below considers only the country scenario, with discharge to inland waters.

Predicted Environmental Concentration (PEC) for the Aquatic	Compartment	
Total Annual Import/Manufactured Volume	100 000	kg/year
Annual use at a single site	10000	kg/year
Monthly use at a single site	833	kg/month
Proportion expected to be released to sewer	2%	
Monthly quantity of chemical released to sewer	16.7	kg/month
Removal within STP	0%	
Daily sewage flow:	4	ML
Dilution Factor - River	1.0	
PEC - River:	4175	μg/L

### 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 hours)	EC50 > 1038  mg/L	Not harmful
Daphnia Toxicity (48 hours)	EC50 = 1015  mg/L	Not harmful
Algal Toxicity (96 hours)	$E_r C50 > 1035 \text{ mg/L}$	Not harmful

The tests were conducted with UNOXOL Diol, as the notified chemical is never isolated from this mixture. Results indicate that the notified chemical is not harmful to aquatic life, similar to its 1,4 isomer for which comparable endpoints in the SIAP exceed 100 mg/L.

### 7.2.1 Predicted No-Effect Concentration

The PNEC can be calculated as tabulated below by application of a hundred-fold assessment factor to the most sensitive aquatic endpoint.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment				
Daphnid EC50	1015	mg/L		
Assessment Factor	100			
PNEC:	10150	μg/L		

# 7.3. Environmental risk assessment

The Risk Quotient (Q = PEC/PNEC) is tabulated below.

Risk Assessment	PEC μg/L	PNEC μg/L	Q
Q – River	4175	10150	0.41

The notified chemical is not considered to pose a risk to the environment as the risk quotient is less than one, even when based on an unrealistic and highly conservative exposure scenario.

### 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: Irritant

R41: Risk of serious damage to eyes

S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S39: Wear eye/face protection

and

As a comparison only, the classification of 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
Serious eye damage/eye irritation	1	Cause serious eye damage

# 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 chemical is not considered to pose a risk to the environment.

### Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Safe Work Australia should consider the following health hazard classification for the notified chemical:
  - Xi: Irritant
  - R41: Risk of serious damage to eyes
- The following safety phases for the notified chemical are recommended:
  - S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
  - S39: Wear eye/face protection
- Use the following risk phrases for products/mixtures containing the notified chemical:
  - $\ge 10\%$ : R41
  - 5% ≤ concentration ≤ 10%: R36

### CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in UNOXOL Diol, in the resin product and in the formulated paint products:
  - Spray application should be carried out in an enclosed automated spray booth
  - Adequate ventilation in situations where aerosols are formed or there is potential for formation of vapours during drying/curing of coatings
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in UNOXOL Diol (during repacking and resin manufacturing) and in the resin product:
  - Avoid contact with skin and eyes
  - Avoid splashes and spills
  - Wash eye promptly if exposed
  - Do not breathe spray
  - Provision of emergency eye wash facilities
  - Avoid generation of aerosols during paint formulation and preparation
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in UNOXOL Diol and in the resin product:
  - Suitable protective clothing
  - Eye/face protection
  - Suitable gloves
  - Suitable respirators where inhalation exposure is possible

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

- Employers should implement the following measures to minimise occupational exposure to the notified chemical in the resin product and in coatings:
  - Minimise the concentration of residual notified chemical in the resin
- 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 *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 to landfill.

# Emergency procedures

• Spills or accidental release of the notified chemical should be handled by 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(2) of the Act; if
  - the function or use of the chemical has changed from monomer component of polyester and polyol resins, which will be used for industrial coatings, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 100 tonne per year, or is likely to increase, significantly;
  - 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.

### Material Safety Data Sheet

The MSDS of the product 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**

Test substance in this section is UNOXOL Diol (UNOXOL Diol is an approximately 1:1 mixture of the notified chemical and 1,4-Cyclohexanedimethanol).

## Water Solubility

Completely soluble in water at 20°C

Method No formal testing was conducted.

Remarks UNOXOL Diol is completely soluble in water at 20°C (MSDS).

Water solubility estimate from log Kow (WSKOW v1.41): water solubility at 25°C:

4312 mg/L (log Kow used: 1.49 (estimated); no melting point equation was used)

Water solubility estimate from Fragments:

water solubility (v1.01 est) =  $1.4331 \times 10^5$  mg/L

# Hydrolysis as a Function of pH

Method No testing was conducted.

Remarks The notified chemical is expected to be stable to hydrolysis, based on its structure and the

hydrolytic stability of its 1,4 isomer as documented in the SIAP. This expectation is supported by the stability of UNOXOL Diol in the abiotic control that was used in the

ready biodegradability test, and in the aquatic toxicity test media.

# Partition Coefficient (n-

 $\log P_{\rm ow} = 1.49$ 

octanol/water)

Method No testing was conducted.

Remarks The notified chemical is expected to have a low partition coefficient based on its high

water solubility and the calculated value above, determined by EPIWIN modelling.

### Adsorption/Desorption

 $\log K_{oc} = 1$ 

- screening test

Method No testing was conducted.

Remarks The notified chemical is expected to be mobile in soils with a low soil organic carbon

partion coefficient, based on its high water solubility and the calculated value above,

determined by EPIWIN modelling.

### **Surface Tension**

59.8 mN/m at 25°C (1% aqueous solution)

Method Surface tensions were measured using a Krüss Processor Tensionmeter K12

Remarks UNOXOL Diol reduces aqueous surface tension, to 55.9 mN/m (2% solution),

50.7 mN/m (5% solution), 47.2 mN/m (10% solution).

Test Facility The Dow Chemical Company (2006a)

# **Flash Point**

118°C at (pressure unknown)

Remarks Closed cup

# **APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**

Test substance in this section is UNOXOL Diol (UNOXOL Diol is an approximately 1:1 mixture of the notified chemical and 1,4-Cyclohexanedimethanol).

### **B.1.** Acute toxicity – oral

TEST SUBSTANCE UNOXOL Diol

METHOD OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure.

Species/Strain Rat/Fischer 344; Charles River

Vehicle None

Remarks - Method No deviation from the protocol.

### RESULTS

Group	Number and Sex	Dose	Mortality
	of Animals	mg/kg bw	•
1	1 F	2000	0
2	4 F	2000	0

LD50 > 2000 mg/kg bw

Signs of Toxicity There were no signs of gross toxicity, and adverse clinical signs, or

abnormal behaviour.

Effects in Organs No gross abnormalities were noted for any of the animals when

necropsied at the conclusion of the 14-day observation period.

Remarks - Results All animals survived, gained body weight, and appeared active and health

during the study.

CONCLUSION The test substance is of low toxicity via the oral route.

TEST FACILITY eurofins Product Safety Laboratories (2006a)

# **B.2.** Acute toxicity – dermal

TEST SUBSTANCE UNOXOL Diol

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.

Species/Strain Rat/Fischer 344; Charles River

Vehicle None
Type of dressing Occlusive

intestinal tract of 2 of 5 males and 2 of 5 females, and in the stomach of 2/5 males) appeared to be inconsistent with the lack of findings noted during the in-life observations. Therefore, the study was repeated to

confirm the necropsy findings and the results are reported below.

### RESULTS

Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
1	5 per sex	2000	0
LD50	> 2000 mg/kg bw		
Signs of Toxicity	There were no sign signs, or abnormal b		al irritation, adverse clinical
Effects in Organs		ulities were noted for a nelusion of the 14-day obs	any of the animals when servation period.
Remarks - Results			d appeared active and health

CONCLUSION The test substance is of low toxicity via the dermal route.

TEST FACILITY eurofins Product Safety Laboratories (2007a)

### **B.3.** Acute toxicity – inhalation

TEST SUBSTANCE UNOXOL Diol

METHOD OECD TG 403 Acute Inhalation Toxicity.

Species/Strain Rats/F344/Ducrl

Vehicle None

Method of Exposure Nose-only exposure

Exposure Period 4 hours Physical Form Vapour

Remarks - Method The difference between the analytical and nominal concentrations is due

to the dilution of the test stream into the exposure chamber and the loss of the test substance due to adherence to the glass generation system. Necropsy included examination of eyes. No histopathological

examination was carried out.

### **RESULTS**

Number and Sex of Animals	Concentration		Mortality
·	Nominal	Actual	
5 per sex	332 ppm	13.1 ppb	0

LC50 > 13.1 ppb

Signs of Toxicity All animals survived the four-hour exposure to the test substance as well

as the two-week post-exposure period. Clinical effects noted during the four-hour exposure period were limited to soiling of the haircoat in two male and three female rats. In-life observations noted post-exposure were limited to perineal, abdominal or extensive body soiling. All rats appeared normal by test day 2. Mean body weight losses of 2 and 0.9% were noted for male and female rats, respectively, on test day 2. Pre-

exposure mean body weight values were exceeded on test day 4.

Effects in Organs There were no visible treatment-related lesions noted in any of the rats at

the test day 15-scheduled necropsy.

CONCLUSION LC50 > 13.1 ppb 4 hours

TEST FACILITY The Dow Chemical Company (2007a)

# B.4. Irritation – skin

TEST SUBSTANCE UNOXOL Diol

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain Rabbit/New Zealand albino

Number of Animals 2 M, 1 F Vehicle None Observation Period 7 days

Type of Dressing Semi-occlusive

Remarks - Method No deviation from the protocol.

### **RESULTS**

Lesion	Me	Mean Score*		Maximum	Maximum Duration	Maximum Value at End
	Ai	Animal No.		Value	of Any Effect	of Observation Period
	1	2	3			
Erythema/Eschar	1	1	0	1	< 7 days	0
Oedema	0	0	0	0	=	0

<sup>\*</sup>Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results

Apart from the skin irritation noted, there were no other signs of gross toxicity, adverse clinical signs, or abnormal behaviour.

There was no oedema observed at any treated site during this study. Within one hour of patch removal, all three treated sites exhibited very slight erythema. The overall incidence and severity of irritation decreased with time. All animals were free of dermal irritation by Day 7 (study termination).

CONCLUSION

The test substance is slightly irritating to the skin.

TEST FACILITY

eurofins Product Safety Laboratories (2006b)

# **B.5.** Irritation – eye

TEST SUBSTANCE

**UNOXOL Diol** 

**METHOD** 

OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain

Rabbit/New Zealand albino

Number of Animals Observation Period 3 F 21 days

Remarks - Method

Fluorescein was used to aid the eye examination per-test and at the 24 h,

and 10, 11, 14, 17 and 21 day observations.

Prior to instillation, two drops of ocular anaesthetic (Tetracaine Hydrochloride Ophthalmic Solution, 0.5%) were placed into both the

treated and control eye of each animal.

### RESULTS

Lesion	Mean Score*		Maximum	Maximum Duration	Maximum Value at End	
	Animal No.		Value	of Any Effect	of Observation Period	
	1	2	3			_
Conjunctiva: redness	2	2	2	2	< 21 d	1
Conjunctiva: chemosis	1.3	1.7	1	2	< 10 d	0
Conjunctiva: discharge	1.7	2	1.3	2	< 21 d	1
Corneal opacity	1	1	1	1	< 21 d	1
Iridial inflammation	1	1	1	1	< 21 d	1

<sup>\*</sup>Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results

Apart from the eye irritation noted, there were no other signs of gross toxicity, adverse clinical signs, or abnormal behaviour.

Within 24 hours after test substance instillation, all three treated eyes exhibited corneal opacity, iritis and conjunctivitis. Pannus were noted in 2 animals at the 10, 11, 14, 17 and 21 day observations and in 1 animal at the 17 and 21 day observations. Although the overall severity of irritation decreased gradually with time, effects persisted in all animals to day 21 (study termination).

CONCLUSION The test substance is severely irritating to the eye.

TEST FACILITY eurofins Product Safety Laboratories (2006c)

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

TEST SUBSTANCE UNOXOL Diol

METHOD OECD TG 429 Skin sensitisation: mouse local lymph node assay.

Species/Strain Female Mice/CBA/J

Vehicle AOO (4:1 acetone : olive oil)

Remarks - Method Screening study: three daily topic application of 1%, 5%, 10%, 20%,

40%, or 80% UNOXOL Diol were given to one animals at each dose level. Erythema was absent in the mice dosed with 1%, 5%, 10%, and 20% UNOXOL Diol, while the mice treated with 40% and 80% demonstrated slight erythema on day 3 which resolved by day 6. Body weights were unaffected in all dose groups. Results from this study were used to determine the dosing concentrations for UNOXOL Diol in the

LLNA.

### **RESULTS**

Proliferative response	Stimulation Index	
(DPM/lymph node)	(Test/Control Ratio)	
$626 \pm 218$		
$515 \pm 141$	0.8	
$576 \pm 305$	0.9	
$604 \pm 327$	1.0	
$5354 \pm 1799$	8.6	
	$(DPM/lymph\ node)$ $626 \pm 218$ $515 \pm 141$ $576 \pm 305$ $604 \pm 327$	

groups.

CONCLUSION There was no evidence of induction of a lymphocyte proliferative

response indicative of skin sensitisation to the test substance.

TEST FACILITY The Dow Chemical Company (2006b)

### **B.7.** Repeat dose toxicity

TEST SUBSTANCE UNOXOL Diol

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

Species/Strain Rats/F344/Ducrl; Charles River

Route of Administration Oral –diet

Exposure Information Total exposure days: 28 days
Dose regimen: 7 days per week

Post-exposure observation period: none

Vehicle LabDiet Certified Rodent Diet #5002 (PMI Nutrition International, St.

Louis, Missouri)

Remarks - Method No significant deviation from the protocol.

### RESULTS

Number and Sex of Animals	Concentration <mg bw="" kg=""></mg>		Mortality
oj minuis	Nominal	Actual	
10 per sex	0	0	0
10 M	10	11	0
10 F	10	10	0
10 M	100	108	0
10 F	100	103	0
10 M	500	538	0
10 F	500	509	0
10 M	1000	1097	0
10 F	1000	1010	0

Mortality and Time to Death

All rodents survived the 28-day test period.

### Clinical Observations

### Detailed clinical and case-side observations

Cloudy eyes, enlarged/protruding eyes, perineal soiling (urine), and inability to evaluate pupil size were occasionally noted. These observations were incidental and had no relationship to treatment as some effects existed pre-exposure in several animals. There were no treatment-related detailed clinical or cage-side observations at any dose level.

### **Ophthalmology**

Pre-exposure examination indicated a few animals with incomplete pupillary dilation and cloudy corneas; however, all rats were suitable to be placed on study.

### *Functional observation battery(FOB)*

There were no observation in the FOB that were identified as statistically significant when compared to control.

# Body weights/body weight gain

There were no statistically identified differences in the body weight of male or female rats at any dose levels when compared to their respective controls.

## Feed consumption

There were no statistically identified differences in feed consumption of male or female rats at any dose level when compared to their respective controls and no differences related to treatment.

### Test substance intake

The data indicate that the rats in the different treatment groups received the targeted concentrations of the test substance.

### Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis Haematology

Platelet counts for males and females given 100 or 1000 mg/kg/day were statistically lower than controls. These differences were within the historical control range, lacked a dose response and were considered not to be treatment related. Percent neutrophil counts of males given 500 or 1000 mg/kg/day were 10% or 16% lower compared to controls respectively. These values in this study were within or close to the historical control range, demonstrating normal biological variability in this parameter. Also, the bone marrow evaluations of the high-dose males and total white blood cell counts were within normal range. This apparent difference was not considered to be treatment related.

Reticulocyte counts were statistically lower than controls in males and females given 10 or 1000 mg/kg/day, while the red blood cell counts, haemoglobin, and hematocrits were within normal limits. This apparent difference was considered to reflect normal variation, and lacked a dose response; therefore, was not considered to be treatment related.

### Prothrombin time

There were no treatment-related alterations in the prothrombin times of males or females.

### Clinical chemistry

The albumin level for males given 500 mg/kg/day was statistically lower than controls and was not considered to be treatment related due to lack of a dose response and the value was within historical range. Males at all treated dose levels had lower triglycerides relative to the control and were statistically identified for males given  $\geq 100$  mg/kg/day. These values were outside of the historical control range; however the differences were not proportional to the dose and were not clearly treatment related.

Females given  $\geq 100$  mg/kg/day also had lower triglyceride levels than controls and were statistically identified. These differences were within the historical control data, lacked a dose response and were also not considered to be toxicologically significant.

### Urinalysis

Males and females given 500 or 1000 mg/kg/day had lower pH values which were considered to be treatment related, but not as adverse effects. This conclusion is based on the lack of organ weight or histological effects in the urinary system and the strong likelihood that the acidic urine was the result of oxidation of the dialcohol to a dialdehyde by alcohol dehydrogenase and further oxidation to an acid.

Females given  $\geq$  500 mg/kg/day had slight increases in urinary protein than controls. The urine protein alterations in females were considered not to be treatment related because of the lack of effects on kidney, liver or bladder histological effects.

Triple phosphate crystals were not observed in the urine of females given  $\geq 100$  mg/kg/day although were observed in the urine of the control and low-dose groups. This difference in females given 500 or 1000 mg/kg/day may reflect an equivocal treatment-related effect as lower urine pH levels decrease the probability that these crystals would form in the urine; however, females given 100 mg/kg/day also had no urine triple phosphate crystals and the urine pH was comparable to the controls. All of these differences in triple phosphate crystals were within the historical control range suggesting that they were not toxicologically significant.

### Effects in Organs

# Final body weights and organ weights

The relative kidney weights of males and females given 500 or 1000 mg/kg/day were higher than controls. However, the final body weights and kidneys of male and female rats were not statistically different from control and were within historical control ranges, indicating a lack of biological relevance associated with the relative kidney weights. Also, the values for the relative kidney weights of control males and females were lower than the historical control range. The absence of histopathologic alterations in the kidney for both sexes also supports the conclusion of normal biological variation in the kidney weights. When the kidney weights were calculated relative to brain weight, there were no statistical differences, further supporting normal biological variation. There were no other statistically identified organ weights for male and female rats in the remaining dose levels.

### Gross pathology and histopathology

There were no treatment-related gross pathological and histopathologic observations. All observations were considered to be spontaneous alterations, unassociated with exposure.

### Remarks - Results

There were no treatment-related effects in clinical signs, body weights, feed consumption, cage-side observations, detailed clinical observations, functional observation battery, motor activity, hematogology, prothrombin time, clinical chemistry, organ weights, gross pathology, or histopathologic observations.

The incidence of cloudy eye was higher before testing than after, and was not dosed related. Therefore it was not considered to be treatment related.

Lower urine pH values were seen in males and females given 500 or 1000 mg/kg/day. This urine alteration was considered not to be an adverse effect due to the lack of histological changes in the kidney, liver, or bladder, and likely resulted from the presence of acidic metabolic products of test substance in the urine.

### **CONCLUSION**

The No Observed Effect Level (NOEL) was established as 100 mg/kg bw/day in this study based on lower urine pH values seen in males and females given 500 or 1000 mg/kg/day.

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study because, in the absence of related effects, lower urine pH values seen in males and females given 500 or 1000 mg/kg/day was considered not to be an adverse effect.

TEST FACILITY The Dow Chemical Company (2007b)

# **B.8.** Genotoxicity – bacteria

TEST SUBSTANCE UNOXOL Diol

METHOD OECD TG 471 Bacterial Reverse Mutation Test.

Pre incubation procedure

Species/Strain S. typhimurium: TA1535, TA1537, TA98, TA100

E. coli: WP2uvrA

Metabolic Activation System

Concentration Range in

Main Test

Microsomal enzymes prepared from Aroclor-induced rat liver (S9).

a) With metabolic activation: 0, 33.3, 100, 333, 1000, 330 and 5000

 $\mu g/plate$ 

b) Without metabolic activation: 0, 33.3, 100, 333, 1000, 330 and 5000

μg/plate

Vehicle Deionised water

Remarks - Method The initial mutagenicity study for all strains except for TA1537 was

repeated due to contamination.

RESULTS

increases in the mean number of revertants per plate were observed with

any of the test strains in either the presence or absence of S9 mix.

In the confirmatory mutagenicity assay, all data were acceptable and no positive increases in the mean number of revertants per plate were observed with any of the test strains in either the presence or absence of

S9 mix.

All of the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the

activity of the S9-mix and the sensitivity of the bacteria strains.

CONCLUSION The test substance was not mutagenic to bacteria under the conditions of

the test.

TEST FACILITY Covance Laboratories Inc. (2007)

**B.9.** Genotoxicity – in vitro

TEST SUBSTANCE UNOXOL Diol

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Species/Strain Male rats/Sprague-Dawley derived CD ISG (outbred Crl:CD(SD))

Cell Type Rat lymphocyte cultures

Metabolic Activation System Microsomal enzymes prepared from Aroclor-induced rat liver (S9).

Vehicle Deionised water

Remarks - Method No preliminary test was carried out. A second assay with treatment of

cultures in the presence of S9 was not considered necessary since the results of the initial tests were clearly negative. The highest concentration

was based on the limit dose of 10 mM in this assay system.

Metabolic	Test Substance Concentration (µg/mL)	Exposure	Harvest
Activation		Period	Time
Absent			
Test 1	0*, 22.5, 45.1, 90.1, 180.25, 360.5*, 721*, 1442*	4 hours	24 hours
Test 2	0*, 11.3, 22.5, 45.1, 90.1, 180.25, 360.5*, 721*, 1442*	24 hours	24 hours
Present			
Test 1	0*, 22.5, 45.1, 90.1, 180.25, 360.5*, 721*, 1442*	4 hours	24 hours

<sup>\*</sup>Cultures selected for metaphase analysis.

# RESULTS

aberration in either the presence or absence of S9 activation.

Cultures treated with the positive control chemicals had significantly

higher incidence of abnormal cells in the assay.

CONCLUSION The test substance was not genotoxic to rat lymphocyte cultures treated in

vitro under the conditions of the test.

TEST FACILITY The Dow Chemical Company (2007c)

# APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

### **C.1.** Environmental Fate

Test substance in this section is UNOXOL Diol (UNOXOL Diol is an approximately 1:1 mixture of the notified chemical and 1,4-Cyclohexanedimethanol).

# C.1.1. Ready biodegradability

TEST SUBSTANCE UNOXOL Diol

METHOD OECD TG 301 F Ready Biodegradability: Manometric Respirometry

Test.

Inoculum Activated sludge

Exposure Period 28 days Auxiliary Solvent Water

Analytical Monitoring Gas phase measurements of O<sub>2</sub> and CO<sub>2</sub> were performed using the

Columbus Micro-Oxymax respirometry system. DOC concentrations in the reaction mixtures were determined using a Shimadzu model TOC-V analyser equipped with an ASI-V autosampler. The concentrations of nitrite and nitrate were determined by ion chromatography, using a

standardised procedure.

Remarks - Method Aniline was used as reference substance.

### RESULTS

Test	substance	1	Aniline
Day	% Degradation	Day	% Degradation
6.3	10	2.5	10
10.6	60	5.8	60
16.3	81.8 <u>+</u> 11.1	12.5	91.7
28	92.2 + 11.1	28	101.2

consumption or carbon dioxide evolution in the abiotic control. The test substance had no apparent toxic or inhibitory effect on the inoculum,

based on the results from the toxicity control.

CONCLUSION The test substance, and by inference the notified chemical, are readily

biodegradable.

TEST FACILITY The Dow Chemical Company (2007d)

### C.1.2. Bioaccumulation

No testing was conducted. The notified chemical is not expected to bioaccumulate in fish because it is water soluble and readily biodegradable. A low bioconcentration factor of 2.8 (estimated value)

has been determined by EPIWIN modelling.

# C.2. Ecotoxicological Investigations

# C.2.1. Acute toxicity to fish

TEST SUBSTANCE UNOXOL Diol

METHOD OECD TG 203 Fish, Acute Toxicity Test - static.

Species Oncorhynchus mykiss (rainbow trout).

Exposure Period 96 hours.
Auxiliary Solvent None

Water Hardness 68 mg CaCO<sub>3</sub>/L.

mass spectrometric detection in the negative chemical ionisation mode

(GC/MSnci).

Remarks - Method

### **RESULTS**

Concer	Concentration mg/L			Mortality		
Nominal	Actual		24 h	48 h	72 h	96 h
0 (Control)	< limit of quantitation	10	0	0	0	0
129	128	10	0	0	0	0
242	225	10	0	0	0	0
375	374	10	0	0	0	0
627	652	10	0	0	0	1
1038	1066	10	0	0	0	2

LC50 > 1038 mg/L at 96 hours NOEC 375 mg/L at 96 hours

Sublethal effects (lethargy, loss of equilibrium, ascities and swimming at surface) were seen towards the end of the exposure period at the two

highest test concentrations.

CONCLUSION The test substance, and by inference the notified chemical, are not

harmful to fish.

TEST FACILITY The Dow Chemical Company (2007e)

# C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE UNOXOL Diol

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

Test - static.

Species Daphnia magna

Exposure Period 48 hours Auxiliary Solvent None

Water Hardness 170 mg CaCO<sub>3</sub>/L Analytical Monitoring GC/MSnci

Remarks - Method

### RESULTS

Conce	entration mg/L	Number of D. magna	Number In	ımobilised
Nominal	Actual		24 h	48
0 (control)	< limit of quantitation	20	0	0
62.5	55.1	20	0	0
125	114	20	0	0
250	347	20	0	0
500	478	20	0	0
1000	921	20	0	8
2000	1969	20	0	20

EC50 >1969 mg/L at 24 hours 1015 mg/L at 48 hours NOEC 114 mg/L at 48 hours

Remarks - Results Daphnids were seen floating at the solution surface at test termination at

concentrations above the NOEC, consistent with the reduced surface tension. The test substance was stable based on the analytical

measurements.

CONCLUSION The test substance, and by inference the notified chemical, are not

harmful to daphnids.

TEST FACILITY The Dow Chemical Company (2007f)

# C.2.3. Algal growth inhibition test

TEST SUBSTANCE

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species Pseudokirchneriella subcapitata

Exposure Period 96 hours

Concentration Range Nominal: 0, 31.3, 62.5, 125, 250, 500, 1000 mg/L

Actual: 0, 32.0, 61.1, 130, 257, 529, 1035 mg/L

Auxiliary Solvent None

Water Hardness US EPA algal assay medium

Analytical Monitoring GC/MSnci

Remarks - Method All validity criteria were met.

### RESULTS

Biomass	5	Growth		
$E_bC50$	NOEC	ErC50	NOEC	
mg/L at 96 h	mg/L	mg/L at 96 h	mg/L	
447	32	> 1035	32	
Remarks - Results	-	evaluation of the algal cell any test level. The test substar surements.		
CONCLUSION	The test subs harmful to gree	tance, and by inference the a	notified chemical, are not	
TEST FACILITY	The Dow Cher	mical Company (2007g)		

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