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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

EnviroGem AD 01

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)
IMCD Australia Limited (ABN 44 000 005 578)
Level 1, 372 Wellington Road
Mulgrave VIC 3170

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 and Structural formulae, Molecular weight, Spectral data, Methods of detection and determination, Purity, Impurities, Additives/adjuvants, Use details, Identity of manufacturers, Analogue chemical (identity and other information).

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
United Kingdom (date unknown).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
EnviroGem AD 01

MOLECULAR WEIGHT
<500 Da

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

3. COMPOSITION

DEGREE OF PURITY >95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20ºC AND 101.3 kPa: Colourless to pale yellow, viscous liquid.

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-37ºC	Measured
Boiling Point	278ºC	Measured
Density	900 kg/m^3 at 20.1ºC	Measured
Vapour Pressure	1.94×10^{-5} kPa at 20ºC 2.88×10^{-5} kPa at 25ºC	Measured
Water Solubility	1.57±0.11 g/L at 19.8ºC	Measured
Hydrolysis as a Function of pH	$t_{½}$ >1 year at pH 4,7 and 9	Measured (data for an acceptable analogue chemical)
Partition Coefficient (n-octanol/water)	$logP_{ow}$ = 3.8 (CLOGP) $logP_{ow}$ = 4.32 (KOWWIN)	Estimated
Surface tension	33.4 mN/m at 20ºC	Measured
Adsorption/Desorption	$logK_{oc}$ = 3.88 at 25ºC	Estimated by HPLC simulation
Dissociation Constant	Not determined	Contains no water-dissociable groups
Particle Size	Not determined	Liquid chemical
Flash Point	>110ºC at 101.3 kPa	Measured
Flammability	Not expected to be highly flammable	Estimated based on vapour pressure, autoignition temperature and experience in use
Autoignition Temperature	385±5ºC	Measured
Explosive Properties	Not explosive	Measured

DISCUSSION OF PROPERTIES
The notified chemical is of limited water solubility, estimated to be reasonably lipid soluble, and is surface active in water. It is non-volatile and is not expected to present a physical hazard (based on the available data).

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

Reactivity
The notified chemical is stable under normal conditions of use and does not react with water.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia by sea.

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

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

PORT OF ENTRY
All major sea ports throughout Australia.

IDENTITY OF MANUFACTURER/RECIPIENTS
IMCD Australia Limited

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as a neat liquid in 200 L and 250 L steel drums or 22.7 L steel pails.

USE
The notified chemical will be used as a surfactant in paints, inks, and adhesives for industrial applications (~95%) and in domestic products (~5%, mainly in decorative paints). The primary industrial use is in coatings. Industrial coatings may contain <2% notified chemical, while decorative paints will contain <1% notified chemical.

OPERATION DESCRIPTION

Transport and storage

The notified chemical will be imported as a raw material in liquid form. The notified chemical will be transported from the docks to the notifier's manufacturing facility where it will be stored on site until required. The notified chemical will be usually transferred into 'day' tanks at reformulation sites, from where it will subsequently be delivered into mixing vessels through automated processes.

Formulation of coatings, inks and adhesives

The notified chemical will be pumped into the mixing vessel and mixed with resin, pigments, solvents, fillers and other additives until all components are adequately blended. Small samples of the blended formulation are likely to be taken for quality control purposes and tested by in-house laboratories to ensure that they meet set specifications. The finished coating product (<2% notified chemical) will then be filled into cans, pails, drums or totes via pipes and transfer lines.

In formulations for Do-It-Yourself (DIY) domestic applications, the imported notified chemical will be used by resin manufacturers (i.e., emulsions or binder manufacturers) to formulate a binder (containing 2% maximum of the notified chemical). These binders will be sent to paint manufacturers who will combine it with other ingredients (fillers, extenders, pigments, etc.) to form the final paint formulations (containing 1% maximum of the notified chemical).

Industrial application of coatings, inks and adhesives

Industrial use will vary depending on the formulated coating product. Typically, the notified chemical will be applied to substrates by experienced personnel under controlled conditions. For industrial paint/lacquer coating applications, the coatings will be predominantly applied by spray (~99%), either through the use of robotics or by worker-operated spray guns, within spray booths. The remainder may be applied using a roller or brush. Any overspray will be allowed to dry and collected for disposal.

When used in printing inks, the ink formulation (containing the notified chemical) will be transferred to the printing equipment and stored in an enclosed vessel; transfer of the material will occur via automated lines that are connected to the storage drums.

The application of industrial adhesives is expected to be via brushes or rollers (or equivalent).

DIY application of coatings

A small proportion of the notified chemical (<5% of annual importation volumes) may be available for use by the general public as decorative paints. The DIY public users will manually decant a small amount of the paint into paint trays for roller application, and are expected to only use rollers and/or brushes for paint application. Brushes and rollers may be cleaned with water, with potential residues likely washed into drains.

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)*
Waterside workers	10	4	50
Storage and transport personnel	30	5	150
Coatings formulation personnel			
-Charging of mixing vessel	2	<1	100
-Blending	2	2	100
-Equipment cleaning	2	2	100
-Product packaging	2	2	100
Quality Assurance personnel	5	3	100
Application			
-Transfer to equipment	1	0.5	60
-Application to substrate	1	6	60
-Cleanup of equipment	1	0.5	60

EXPOSURE DETAILS

Transport and storage

Transport workers are not expected to come into contact with the notified chemical, as it will be sealed within import containers. Exposure is only possible in the case of accidental spillage.

Workers involved with transferring the notified chemical to 'day tanks' may experience dermal and ocular exposure to the notified chemical during connection and disconnection of lines.

Formulation of coatings, inks and adhesives

Dermal and ocular exposure to the neat notified chemical is possible during connection and disconnection of lines. Similar exposures to lower concentrations in blended or partially blended products containing the notified chemical (<2%) are possible during connection and disconnection of lines, sampling for quality assurance, cleaning of equipment, or filling of product containers.

Workers involved in the manufacturing process are expected to wear personal protective equipment (PPE) including long sleeved clothing, eye protection, safety shoes, coveralls and impermeable gloves.

Inhalation exposure to the notified chemical is not expected, due to its low vapour pressure and the high viscosity of the notified chemical and formulated products (mixed in closed vessels). Nonetheless, the notifier reports that mixing processes are expected to be carried out under local exhaust ventilation.

Industrial application of coatings, inks and adhesives

Dermal, ocular and inhalation exposure to the notified chemical (<2%) is possible during application of coatings by brush, roller and spray.

Workers involved with the application of the notified chemical (i.e. mixing and transferring the formulated coating to the application equipment, applying the coating to the substrate, and cleaning the application equipment) are expected to wear PPE including long sleeved clothing, eye protection, impermeable gloves, coveralls and safety shoes.

Spray application is expected to be carried out in a downdraft spray booth (or similar) under most circumstances. Professional spray painters are expected to wear PPE including protective clothing and boots, chemical resistant gloves and goggles. Where engineering controls are not able to be used (e.g. in outdoor or in large applications) or are not effective to remove airborne droplets, suitable respirators (including the use of air-fed hoods) are expected to be utilised. Inhalation exposure is therefore expected to be low during spray application.

Once applied to the substrate, the notified chemical is expected to be trapped within the dried polymeric layer of the coating, and therefore should not be readily available to cause exposure to workers.

Exposure estimation

The primary route of systemic absorption is via dermal exposure. In the absence of better information, 100% dermal and inhalation absorption is assumed. From the proposed operation description, the expected dermal exposures to the notified chemical can be loosely categorised into two groups: (1) Incidental exposures during reformulation and (2) exposures during application and use.

1. Incidental exposures during reformulation:

The highest probable exposure of this kind is during the coupling and uncoupling of transfer lines for the neat liquid notified chemical (>95%, assumed 100% for exposure estimation purposes). For worst-case estimates, this is assumed to occur daily (although in practice it may be less frequent). The dermal exposure during such processes has been described as a probable half-hand exposure (420 cm^2) and an exposure level of 0.1 mg/cm^2/day to an adult male worker (70 kg body weight (bw)) (EC, 2003). The combination of these gives a worst-case dermal exposure of:

$$(0.1\ mg/cm^2/day \times 420\ cm^2 \times 100\%\ absorption)/70\ kg\ bw = \underline{0.6\ mg/kg\ bw/day}$$

The dermal exposures that are expected during sampling or other formulation steps (where the notified chemical is diluted) are likely to be lower than this estimate.

2. Exposures during application and use:

The worst-case exposure to the notified chemical will occur during the spraying of coatings and adhesives (<2% concentration, assumed 2% for exposure estimation purposes). For worst-case estimates, this is assumed to occur daily (although in practice it may be less frequent). Measured data for dermal exposure during the spraying of large amounts of low-volatility paints has been described by the RISKOFDERM project, which has described reasonable worst-case exposure of 12000 mg/scenario, and typical-case exposures of 3400 mg/scenario (Marquart *et al*, 2006). Assuming one scenario/day for an adult male worker (70 kg bw) wearing gloves and protective clothing (90% protection), the combination of these gives an expected dermal

exposure range of:

((3400× 0.02 × 0.1)/70 kg bw) to ((12000× 0.02 × 0.1)/70 kg bw) = 0.10-0.34 mg/kg bw/day

This exposure estimate is expected to be additionally conservative, as it does not account for interactions of the notified chemical within coating products that might limit the extent of its bioavailability. Also, spray application is expected to be carried out in a downdraft spray booth (or similar) under most circumstances, which will lead to lower dermal exposures from paint overspray. Dermal exposures during cleaning of spray guns and equipment cannot be calculated, but are likely to be small due to the use of automated cleaning apparatus and dilution with water/solvent.

6.1.2. Public exposure

Dermal and ocular exposure to the notified chemical (<1%) is possible during DIY application of coatings by brush and roller, and during the cleaning of equipment. Due to the low volatility of the notified chemical, the public are not expected to experience significant inhalation exposure to the notified chemical. Accidental oral exposure is possible, but not expected.

Exposure estimation

Dermal exposure of the public to the notified chemical is expected during the application of coatings products (<1% concentration, assumed 1% for exposure estimation purposes). For worst-case estimates, this is assumed to occur daily (although in practice it will likely be less than a few days per year). Measured data for dermal exposure during the brush and roller application of relatively viscous, low volatility liquid products on surfaces (average durations of use, 59 and 74 minutes) has been described by the RISKOFDERM project, which has described reasonable worst-case exposures of 6500 mg/scenario, and typical-case exposures of 1000 mg/scenario (Marquart *et al*, 2006). Members of the public are not expected to wear PPE during application of decorative paints (apart from perhaps a long-sleeved shirt or similar). The combination of these factors, for adult males and females (65 kg bw (EC, 2003)), gives an expected dermal exposure range of:

((1000× 0.01)/65 kg bw) to ((6500× 0.01)/65 kg bw) = 0.15-1.0 mg/kg bw/day

This exposure estimate is expected to be additionally conservative, as it does not account for interactions of the notified chemical within coating products that might limit the extent of its bioavailability. Once applied to the substrate, the notified chemical is expected to be trapped within the dried polymeric layer of the coating, and therefore should not be readily available to cause exposure.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the table below. In addition, toxicological data for the acceptable analogue are considered for the acute dermal and acute inhalation toxicity end-points and for comparison with that obtained for the notified chemical.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral	Low toxicity, LD_{50} >2,000 mg/kg bw
Rabbit, skin irritation*	Moderately irritating
Rabbit, eye irritation*	Irritating
Mouse, skin sensitisation – LLNA*	No evidence of sensitisation up to 50% (v/v)
Rat, repeat dose oral toxicity - 28 days*	NOAEL 150 mg/kg bw/day
Bacterial reverse mutation (Ames) test	Non-mutagenic
In vitro chromosome aberration assay	Non-clastogenic
Cytotoxicity – *in vitro*	Cytotoxic to cultured cells

* Details of these studies can be found in Appendix B.

Toxicokinetics

Limited data is available to describe the likely toxicokinetic properties of the notified chemical. Some absorption from the gastrointestinal tract is implicit from the effects observed in the repeat dose oral toxicity study (see below, and Appendix B). Given its $logP_{ow}$ of ~4, its reasonable water solubility and its molecular weight of <500 Da, absorption might be expected following ingestion or inhalation exposure (EC, 2003). Moderate dermal absorption might be expected, and this is likely to be enhanced by its irritant nature and surface-active properties.

Following absorption, no data is available to describe the metabolism, distribution and elimination of the notified chemical. Given the effects observed in the repeat dose toxicity study, and its known physicochemical properties, the notified chemical can be expected to distribute widely.

Acute toxicity
In an acute oral toxicity study in rats, the notified chemical was found to have an LD_{50} of >2000 mg/kg bw (MB Research, 2001a). The method used was an acute toxic class determination, equivalent to OECD TG 423, but based on that published by Schelde and co-authors (Schelde *et al*, 1995). No mortality occurred, and only incidental systemic signs of toxicity were observed.

The acceptable analogue has been reported to be of low toxicity by the oral route (LD_{50} >500 mg/kg bw), the dermal route (>2000 mg/kg) and by inhalation (LC_{50} >20 mg/L) (US EPA, 2002). Given the acceptability of the analogue chemical, and the agreement between the acute oral toxicity information for each, the notified chemical is expected to display low acute dermal and acute inhalation toxicity.

Irritation
The notified chemical is expected to display some degree of irritancy on the basis of its low molecular weight and surfactant properties (Hulzebos *et al*, 2005).

In a primary dermal irritation study in rabbits, the notified chemical was found to be moderately irritating (see Appendix B for details). However, based on the current data, these effects were of insufficient severity for classification as a skin irritant (NOHSC, 2004).

In a rabbit acute eye irritation study, the notified chemical was found to be irritating to eyes (see Appendix B for details). On the basis of the severity of the conjunctival oedema (chemosis) observed, the notified chemical meets the Approved Criteria for classification as an eye irritant (NOHSC, 2004). All effects were reversible after 7 days.

A melted form of the analogue chemical (~55-60ºC) was a severe skin irritant, but only slightly irritating to skin when made into a paste with water (US EPA, 2002). In addition, the analogue is a severe eye irritant. These findings are reasonably consistent with the findings observed for the notified chemical.

Sensitisation
The notified chemical does not contain any structural alerts for skin sensitisation (Barratt *et al*, 1994). Supporting this prediction, it was not found to be sensitising in a mouse local lymph node assay (LLNA). In the test, a clear dose response was observed, and an SI of 2.51 was observed at the maximal dose of 50% (v/v). It is not clear why the neat liquid was not selected as the maximal concentration, given the lack of irritancy observed with the 50% (v/v) solution. It is unknown if the neat liquid notified chemical might have produced an SI >3, had it been tested. See Appendix B for further details.

Repeated Dose Toxicity
In a 28-day oral gavage repeat dose toxicity study in rats, the notified chemical was found to have an NOAEL of 150 mg/kg bw/day, on the basis of thyroid, liver and kidney effects (see Appendix B for details and discussion of the observed effects).

In a 130-day oral study in beagle dogs, the acceptable analogue chemical had a LOAEL of 200 mg/kg bw/day, on the basis of liver effects (US EPA, 2002). In a 28-day feeding study in rats, a NOAEL of 5000 ppm has also been reported (US EPA, 2002). This dose level converts to an estimated NOAEL of 462.6 mg/kg bw/day, using the default parameters for experimental rats and the allometric equations of the US EPA for food consumption (EC, 2003). The magnitudes of these values are comparable to those of the notified chemical, given the duration of the studies and their different species.

Genotoxicity
The notified chemical was negative in a bacterial reverse mutation assay (Ames test), conducted both with and without metabolic activation according to OECD TG 471 (Covance, 2003b). Evidence of cytotoxicity was observed at ≥800 µg/plate both in the absence and presence of metabolic activation, but this did not affect the integrity of the test.

The notified chemical was also found to be non-clastogenic in a chromosome aberration study in cultured Chinese hamster ovary (CHO) cells, conducted according to OECD TG 473 (Covance, 2003c). This study investigated 3-hour exposures in the absence and presence of S9, and 20-hour exposures in the absence of S9. Cytotoxicities of ~50-60% occurred at the highest test concentrations used (~330 µg/mL for 3-hour exposures, and ~200 µg/mL for 20-hour exposures). Slight increases in chromosomal aberration frequency were observed in two single cultures after 3 hours of exposure and in one culture after 20 hours of exposure. These increases were only slightly above the historical negative control range, were not reproducible, and did not occur in a dose-dependent fashion; thus, they were not considered to be of biological relevance.

The cytotoxicity of the notified chemical to cultured cells was also demonstrated in a separate *in vitro* elution study, in which it was found to be cytotoxic with a titre of 1/8, equivalent to agents that are known to be cytotoxic to cultured cells (Huntingdon, 2005).

Similarly, the acceptable analogue chemical was non-mutagenic in two Ames tests, and non-clastogenic in an *in vitro* chromosome aberration study (CHO cells) (US EPA, 2002).

In conclusion, there is no evidence to suggest that the notified chemical has mutagenic or genotoxic properties when tested to the limits of its cytotoxicity.

Reproductive and developmental toxicity
No test data describing the notified chemical's potential to cause toxicity for reproduction were available. However, the acceptable analogue chemical has been found to have a NOAEL of 500 mg/kg bw/day in a rat reproductive and developmental toxicity study (US EPA, 2002). No effects on fertility, viability of offspring or gestation indices were observed. In the reproduction phase, toxic effects on the F0 generation were observed at ≥1000 mg/kg bw/day, including decreased body weight and feed consumption. Liver effects were observed in the F1 generation at ≥1000 mg/kg bw/day.

Health hazard classification
Based on its potential to cause eye irritation, the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Xi; R36 Irritating to eyes.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The primary risk presented by the notified chemical is that of its irritancy. Eye and skin irritation is a potential risk to reformulation and/or transportation workers, because of their handling of the neat liquid notified chemical (>95% concentration) as introduced. The risk of skin sensitisation that might result from repeated exposure to the neat notified chemical is unknown, but possible, given the available data. Appropriate handling techniques and the use of PPE (goggles/face-shield, gloves, protective clothing) should be in place to minimise any of these risks to workers during its handling.

Irritation from the notified chemical is not expected when it is formulated into coatings and adhesive products (<2% concentration), because of its low concentration and likely retention with the hydrophobic components of coatings products should dermal or ocular exposures occur.

In addition, there may be some risk of systemic effects upon repeated exposure, given that dermal absorption is probable. A combination of the exposure estimates above with the NOAEL of the notified chemical (150 mg/kg bw/day) gives the following Margin of Exposure (MoE) values:

MoE (exposures during reformulation)	=	(150 mg/kg bw/day)/(0.6 mg/kg bw/day)
	=	250
MoE (exposures during application)	=	(150 mg/kg bw/day)/(0.10-0.34 mg/kg bw/day)
	=	441-1500

These MoE values, based on conservative exposure estimates, show a sufficient safety margin to conclude that the notified chemical is unlikely to pose an unacceptable risk of systemic effects in workers upon repeated exposure (an MoE <100 indicates possible risk).

6.3.2. Public health
The risk of skin and/or eye irritation to members of the public during DIY use of coatings products containing the notified chemical (<1%) is not considered to be unacceptable because of its low concentration, and its likely retention with the hydrophobic components of coatings products should dermal or ocular exposures occur.

A worst-case risk estimate of systemic effects upon repeated dermal exposure may be calculated, using the conservative assumptions already described. A combination of the exposure estimates above with the NOAEL of the notified chemical (150 mg/kg bw/day) gives the following MoE values:

MoE (public use) = (150 mg/kg bw/day)/(0.15-1.0 mg/kg bw/day) = 150-1000

These MoE values show a sufficient safety margin to conclude that the notified chemical is unlikely to pose an unacceptable risk of systemic effects in members of the public, should repeated exposures occur during DIY use (an MoE <100 indicates possible risk). The worst-case MoE of 150 is not considered to represent a risk, given the conservative worst-case assumptions used.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Release of the notified chemical during blending is possible; an estimated 1% of the annual import quantity may be lost from accidental spills or leaks. In the unlikely event that a major spill occurs, the notified chemical will be contained by existing plant bunding and appropriately collected for disposal to landfill or for incineration.

Residues of the notified chemical that remain in the empty storage containers are estimated to account for less than 1% of the annual import volume. Residues in packaging will be disposed of by incineration.

Small amounts of the notified chemical (estimated at 1% of annual import volume) may be lost in washings from cleaning of the manufacturing equipment. These small quantities are likely to be recycled internally or incinerated.

A maximum of 2% of the total release of the notified chemical at site may be assumed lost to sewers; it is expected that the notified chemical will be adequately removed at sewage treatment works and ultimately be disposed of by incineration or landfill.

RELEASE OF CHEMICAL FROM USE

During industrial spray application of formulated coatings, the losses from overspray are predicted to be approximately 10-20% of the applied product. Spray application using robotics is expected to result in less overspray. This will be captured on kraft paper or newspaper in spray booths for disposal to landfill or incineration.

About 1% per annum of the imported notified chemical may be lost in washings from cleaning of industrial application equipment. These releases are likely to be recycled internally or be incinerated. Manufacturing sites are likely to have primary treatment processes that will handle any waste before wastewater is discharged into the municipal system. If residues from spilling or washings unintentionally enter waste water treatment systems, the notified chemical is expected to be treated and removed at sewage treatment works and ultimately be disposed of by incineration or landfill.

Approximately 5% of the annual importation volume will be available for public use, and some release of the notified chemical to waterways may occur as a result of DIY applications. These releases would result from cleaning the application equipment (i.e. brush or roller) with the residues likely to be washed down the drain. Up to 5% of the volume available to the public is predicted to be released to sewers in a disperse manner across Australia. Any residues present in the end-use cans will be disposed of in household garbage or will be disposed at dedicated waste deposits.

RELEASE OF CHEMICAL FROM DISPOSAL

The predominant method of disposal for the neat notified chemical will be incineration; however, low volumes may be sent to landfill. Disposal of the formulated preparations is likely to be via landfill or by incineration. Disposal of painted substrate material would predominantly be to landfill.

As a result of DIY use and industrial spills, some release of the notified chemical to drains and, hence, sewage treatment works may occur. The notified chemical is expected to be treated and removed at sewage treatment works and be disposed of to landfill or by incineration.

7.1.2 Environmental fate

The majority of the notified chemical will share the fate of the substrates to which the notified chemical will be applied and these will most likely be disposed of to landfill.

Product containers used by the public may be disposed to landfill or recycled. Notified chemical disposed of to landfill (as associated with substrates, as residues in paint containers or as overspray) is not expected to be mobile, as it will be bound within the inert paint matrix. Although the notified chemical is not expected to be readily biodegradable (based on analogue data), it is inherently biodegradable and it is anticipated that it will degrade slowly through a combination of biotic and abiotic pathways, to form simple organic compounds.

Any incineration of the paints containing the notified chemical, or the notified chemical itself, will result in its decomposition to form water and oxides of carbon.

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

7.1.3 Predicted Environmental Concentration (PEC)

Up to 2.25% of the notified substance may be released to the sewage system as a result of cleaning of manufacturing and application equipment. As a worst case the predicted environmental concentration (PEC) has been determined assuming that none of the notified substance will be removed as a result of sewage treatment.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total annual import/manufactured volume	10,000	kg/year
Proportion expected to be released to sewer	2.25%	
Annual quantity of chemical released to sewer	225	kg/year
Days per year where release occurs	365	days/year
Daily chemical release	0.616	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River	0.15	µg/L
PEC - Ocean	0.01	µg/L

7.2. Environmental effects assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	31.9 < LC50 < 88.6 mg/L	Harmful to rainbow trout
Daphnia Toxicity	E_iC50 = 127 mg/L (48 hr)	Not harmful to *Daphnia magna*
Algal Toxicity	E_rC50 = 127 mg/L	Not harmful to green algae
Inhibition of Bacterial Respiration	E_iC50 >500 mg/L	Not inhibitory to microbial respiration

7.2.1 Predicted No-Effect Concentration

Based on the most sensitive endpoint (fish) the PNEC has been calculated as follows:

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (fish)	>31.9	mg/L
Assessment Factor	100	
PNEC	>319	µg/L

7.3. Environmental risk assessment

Risk Assessment	*PEC (µg/L)*	*PNEC (µg/L)*	*PEC/PNEC*
River	0.15	>319	<0.01
Ocean	0.01	>319	<0.01

The PEC/PNEC ratios presented above are nearly zero. Therefore, the notified chemical is not considered to pose an unacceptable risk to the aquatic environment under the proposed use pattern and volume.

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; R36 Irritating to eyes

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***
Human Health	Category 2B	Warning: Causes eye irritation
Environment	Acute Category 3 Chronic Category 3	Harmful to aquatic life (with long lasting effects)

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 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 classification for the notified chemical:
  - Xi; R36 Irritating to eyes

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥20%: Xi; R36

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical during spray application of formulated products:
  - *Spray applications should, wherever practicable, be carried out in a well-maintained downdraft (or equivalent) spray booth.*

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical and products containing the notified chemical:
  - *Spray painting should be carried out according to the NOHSC* National Guidance Material For Spray Painting *(NOHSC, 1999).*
  - *Measures should be taken to minimise the likelihood of skin and eye exposure during the handling of the neat notified chemical.*
  - *Eye wash stations should be maintained wherever the notified chemical is handled.*

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and in formulated products:
  - *Gloves and coveralls*
  - *Goggles or face-shield*
  - *Appropriate respirator (where required during spray application)*

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

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *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.

Environment
Disposal

- The notified chemical should be disposed of by incineration 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(2) of the Act; if
  - the function or use of the chemical has changed from a surfactant in paints, inks, and adhesives, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 10 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.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of 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

Melting Point/Freezing Point -37ºC

Method OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Determined by differential scanning calorimetry (DSC). The observed change may be a glass transition.
Test Facility Covance (2003a)

Boiling Point 278ºC

Method OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Determined by DSC. Atmospheric pressure not specified.
Test Facility Covance (2003a)

Density 900 kg/m^3 at 20.1ºC

Method OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Determined using a gas comparison pycnometer.
Test Facility Covance (2003a)

Vapour Pressure 1.94×10^{-5} kPa at 20ºC
2.88×10^{-5} kPa at 25ºC

Method OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks The vapour pressure was determined using the effusion method between 10ºC and 30ºC. The values at 20ºC and 25ºC were determined using regression from the Clausius-Clapeyron relationship.
Test Facility Covance (2003a)

Water Solubility 1.57 ± 0.11 g/L at 19.8ºC

Method OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask Method. Analytical Method: Gas chromatography – Flame ionisation detection.
The notified chemical solution had a nominal pH of 6.2.
Test Facility Covance (2003a)

Hydrolysis as a Function of pH $t_{1/2}$ >1 year at pH 4, 7 and 9 at 25°C (acceptable analogue)

Method OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	*t½*
4	50	>1 year
7	50	>1 year
9	50	>1 year

Remarks A test was not conducted for the notified chemical. Test data of an acceptable analogue substance was provided (without test report), showing hydrolytic stability. The notified chemical is considered to be even more stable based on its molecular structure. Therefore, the notified chemical would also be hydrolytically stable ($t_{½}$ >1 year) under equivalent conditions to those of this test.

Quantum-mechanical calculations for the analogue and notified chemicals were conducted and charge distributions of the carbon atoms were calculated. The results indicate that there would be no hydrolysis reaction in either the analogue or the notified

chemical.
Test Facility US EPA (2002)

Partition Coefficient (n-octanol/water) $logP_{ow}$ = 3.8 (CLOGP)
$logP_{ow}$ = 4.32 (KOWWIN)

Method Test not conducted. Values were estimated using EPI Suite v3.20 and OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks The notified chemical is not expected to adsorb strongly to soils due to its low water solubility. Based on the surface-active nature of the notified chemical, modelling of the partition coefficient was conducted with EPI Suite v3.20, giving an estimated $logP_{ow}$ of 4.32. Using OECD TG 117 by calculation, $logP_{ow}$ was estimated to be 3.8.
Test Facility US EPA (2007)

Surface Tension 33.4 mN/m at 20ºC

Method OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks The surface tension was determined using the ring method.
Concentration: 90% saturated solution.
The notified chemical is considered to be surface active.
Test Facility Covance (2003a)

Adsorption/Desorption log K_{oc} = 3.88 at 25ºC (estimated)

Method OECD 121 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC)
EC Directive 2001/59/EC C.19 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using HPLC
Remarks Due to the surface-active nature of the notified chemical, the absorption to soil was calculated using EPIWIN 3.04. The calculated value was 1.328.
Test Facility Covance (2003a)

Flash Point >110ºC at 101.3 kPa

Method EC Directive 92/69/EEC A.9 Flash Point.
Remarks Closed cup equilibrium method. The notified chemical did not flash at any temperatures up to 110ºC.
Test Facility Covance (2003a)

Autoignition Temperature 385±5ºC

Method EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Test Facility Covance (2003a)

Explosive Properties Not explosive

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Determined by structural analysis, determination of the oxygen balance, and through measurement of the exothermic decomposition energy by DSC.
Test Facility Covance (2003a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – skin

TEST SUBSTANCE: Notified chemical

METHOD
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 1 male and 2 females
- Vehicle: None (used undiluted)
- Observation Period: 14 days
- Type of Dressing: Semi-occlusive
- Remarks - Method: The test was performed with dermal exposures of 3 min, 1 hour and 4 hours.

RESULTS

3-minute exposure:

No erythema, oedema or eschar formation was observed.

1-hour exposure:

The mean score after 24, 48 and 72 hours was <1.33 for erythema (the maximum mean score in a single animal).

4-hour exposure:

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1.0	1.33	2.0	2	<7 days	0
Oedema	0.33	0.67	1.0	1	<7 days	0

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

Remarks - Results: Skin flaking was observed in one animal at the 7-day observation. No abnormal physical signs were observed during the observation period.

CONCLUSION: The notified chemical is moderately irritating to the skin.

TEST FACILITY: MB Research (2001b)

B.2. Irritation – eye

TEST SUBSTANCE: Notified chemical

METHOD
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3 males
- Observation Period: 14 days
- Remarks - Method: No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2.0	2.0	1.7	2	<14 days	0
Conjunctiva: chemosis	2.0	2.7	1.7	3	<14 days	0
Conjunctiva: discharge	1.3	2.0	1.7	2	<14 days	0
Corneal opacity	0	1.3	0	2	<7 days	0
Iridial inflammation	0.3	1.0	0.3	1	<7 days	0

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

Remarks - Results: Lack of normal corneal lustre was observed in all animals between 1 and 72 hours after treatment.

CONCLUSION The notified chemical is irritating to the eye.

TEST FACILITY MB Research (2001c)

B.3. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain Mouse/CBA/CaOlaHsd
Vehicle Acetone/olive oil (4:1)
Remarks - Method No significant protocol deviations.

RESULTS

Test Substance Concentration (% v/v)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
0 (vehicle control)	1580	-
10	1878	1.19
25	3414	2.16
50	3972	2.51

Remarks - Results Most recent positive control data were presented (~2 months prior to study date) using α-hexylcinnamaldehyde in the same vehicle, showing an SI of 6.8 with 25% concentration.

A clear dose response was observed, but an SI of 3 was not exceeded at the maximal dose. It is unclear why the neat liquid was not selected as the maximal dose, given the lack of irritancy observed with the 50% (v/v) solution. Given this, the study stands only up to the concentration tested.

CONCLUSION There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical at concentrations up to 50% (v/v).

TEST FACILITY SafePharm (2003)

B.4. Repeat dose toxicity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain Rat/HsdBrlHan:WIST
Route of Administration Oral – gavage
Exposure Information Total exposure days: 28
Dose regimen: 7 days per week
Post-exposure observation period: None
Vehicle Corn oil
Remarks - Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw/day)*	*Mortality*
Control	5M, 5F	0	0
Low dose	5M, 5F	15	0
Intermediate dose	5M, 5F	150	0
High dose	5M, 5F	1000	0

Clinical Observations
No clinical signs were observed that were related to treatment.

A significant 15% increase in body weight was observed amongst males treated with 1000 mg/kg bw/day, but the increases in body weight amongst females at the same dose occurred earlier and final body weight was not significantly different compared with control animals. A statistically significant increase in food consumption appeared to correlate with these increases.

Laboratory Findings – Haematology, Clinical Chemistry
Group mean platelet count increased in a dose-dependent manner in males, and males treated with 1000 mg/kg bw/day showed an increased platelet crit compared to control. Prothrombin time was decreased in both males and females treated with 150 and 1000 mg/kg bw/day.

Treatment-related increases in total plasma cholesterol were seen in both males and females. Increases of 71% and 29% were observed in males treated with 1000 and 15 mg/kg bw/day, and increases of 63% and 25% were seen in females treated with 1000 and 15 mg/kg bw/day (respectively).

Treatment-related increases in plasma globulin were seen in males treated with 150 and 1000 mg/kg bw/day and for the group mean of treated females.

Effects in Organs
Group mean body weight-relative liver weights were significantly higher than control in animals treated with 150 mg/kg bw/day (males: 18%; females: 10%) and 1000 mg/kg bw/day (males: 72%; females: 70%). No increases were observed at 15 mg/kg bw/day. Upon necropsy, the liver appeared to be large and/or mottled in some treated animals. Microscopically, centrilobular hypertrophy, characterised by large pale hepatocytes, was observed in animals treated with 150 mg/kg bw/day and 1000 mg/kg bw/day.

Group mean absolute kidney weights were significantly higher than control in animals treated with 1000 mg/kg bw/day (males: 18%; females: 5%). Upon necropsy, the kidneys appeared to be pale and/or mottled in some treated animals. Male animals, microscopically, were found to have an increased incidence and severity of hyaline droplets (150 and 1000 mg/kg bw/day) that were characterised by eosinophilic inclusions in the cytoplasm of proximal tubular cells. Focal nephropathy in male animals at 1000 mg/kg bw/day was characterised by groups of basophilic tubules in the renal cortex with occasional degenerating tubules, casts and cellular debris.

Thyroid follicular cell hypertrophy was observed in animals treated with 1000 mg/kg bw/day (5M, 2F). Thyroid effects were characterised by larger, cuboidal to columnar, lightly basophilic follicular cells, and by reduced colloid in the follicles.

Minor squamous cell hyperplasia of the forestomach epithelium was observed in some animals treated with 1000 mg/kg bw/day (4M, 1F).

Remarks – Results
Liver centrilobular hypertrophic changes are often considered to be a sign of enzyme induction as a result of xenobiotic treatment. However, given the extent of the liver weight gain (~70%) and severity of microscopic changes observed at 1000 mg/kg bw/day, only the changes at 150 mg/kg bw/day are considered to be adaptive effects of treatment with the notified chemical.

The thyroid follicular cell hypertrophy observed at 150 and 1000 mg/kg bw/day is considered to be a secondary, adaptive change to increased thyroid hormone metabolism in the liver. The increased sensitivity of the rodent thyroid gland to perturbations by drugs and chemicals is related to the shorter plasma half-life of thyroxine (T4) in rodents (12-24 hrs) when compared to humans (5-9 days), due to the considerable differences in the transport proteins for thyroid hormones between species (Capen, 1997). In humans, serum T4 is bound primarily to thyroxine-binding globulin, a protein that is not present in rodents. Therefore, the observed follicular hypertrophic effects are not considered relevant to human hazard evaluation. However, the

reduction in follicular colloid observed at 150 mg/kg bw/day, although possibly related to follicular cell hypertrophy, is not a known consequence of liver enzyme induction.

The hyaline droplet deposition observed in proximal kidney tubules of male rats are considered to be signs of a typical hydrocarbon nephropathy that occurs only in male rats, and is thus not relevant to human hazard evaluation. However, the focal nephropathy observed in cortical tubules (which also occurred in one female) is considered to be a relevant effect of treatment at 1000 mg/kg bw/day.

Changes in liver function may be a causative factor in the increases in plasma cholesterol, globulin and total protein, and in the decreases in prothrombin time. However, these effects are considered to be of unknown toxicological significance.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 150 mg/kg bw/day in this study, based on the effects on thyroid, liver and kidney.

TEST FACILITY Covance (2004a)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Acceptable analogue of the notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test (Modified Sturm Test).
Inoculum	Activated sludge (domestic)
Exposure Period	Not reported.
Auxiliary Solvent	None reported.
Analytical Monitoring	Not reported.
Remarks - Method	The test substance was tested at 18.15 mL/L, corresponding to 12 mg TOC/L.
RESULTS	5% degradation after 28 days.
Remarks - Results	The relative degradation values calculated from the measurements performed during the test period revealed no significant degradation of the test substance. In the toxicity control, the test substance was found not to be inhibitory. The theoretical CO_2 production ($ThCO_2$) of the test substance was calculated to be 2.72 mg CO_2/mg, corresponding to 2.42 mg CO_2/mL.
CONCLUSION	The test substance cannot be classed as ready biodegradable. Based on the chemical similarities between the analogue substance and the notified chemical, the notified chemical cannot be classed as ready biodegradable.
TEST FACILITY	IUCLID (2002)

C.1.2. Inherent biodegradability

TEST SUBSTANCE	Acceptable analogue of the notified chemical
METHOD	OECD 302A Inherent Biodegradability: Modified SCAS Test
Inoculum	Activated sludge (domestic).
Exposure Period	57 days
Auxiliary Solvent	None reported.
Analytical Monitoring	Not reported.
Remarks – Method	The test was run at 20-25 °C under low light conditions. The test volume was 1500 mL total. The renewal volume was 1000 mL daily. The test substance was tested at a daily dosage level starting at approximately 8-10 ppm as TOC, but later continued at an average dosage level of 15 ppm.
RESULTS	Degradation was 25.4% (daily in the last 16 days of the study) and 15.7% (57 day daily average).
Remarks – Results	Less than 5% physical removal (abiotic absorption) was detected in an intra-test sludge treatment trial. In the toxicity control, the test substance was found not to be inhibitory. Aniline (positive control) degraded on average >95%, thus validating the test system. When examining the test data, it was concluded that the daily degradation rates in the last 2 weeks were statistically above the 20% pass level. A result of >20% loss in this SCAS test corresponds to an inherently biodegradable substance. Thus, under the conditions of this test, the test

substance is considered inherently biodegradable.

CONCLUSION The test substance can be considered inherently biodegradable.

Based on the chemical similarities between the analogue chemical and the notified chemical, the notified chemical can also be considered as inherently biodegradable.

TEST FACILITY SGS U.S. Testing Company Inc., as cited in US EPA (2002) and IUCLID (2002)

C.1.3. Bioaccumulation

CONCLUSION The notified chemical is not considered to be readily biodegradable according to the available test result for an acceptable analogue chemical. It may have some potential for bioaccumulation in organisms, based on its water solubility and logP_{ow} of 4.32. However, due to the low release to the aquatic environment predicted from the reported use pattern, any bioaccumulation potential will be restricted and is not considered to be significant.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified chemical

METHOD OECD TG 203 Fish, Acute Toxicity Test – (static).
Species Juvenile rainbow trout (*Oncorhynchus mykiss*).
Exposure Period 96 hours
Auxiliary Solvent DMF
Water Hardness 82 mg $CaCO_3$/L
Analytical Monitoring Gas chromatography with flame ionisation detection.
Remarks – Method At test initiation, no undissolved test substance was observed in any of the test chambers for treatments 1-4. In both replicates of treatment 5 an oily haze was observed at the surface of the water. The test substance was no longer observed in treatment 5 replicates, or any other treatments, from Day 1.

Some protocol deviations occurred in the test, however, they are not considered to have effects on the results of the test.

RESULTS

Concentration (mg/L)		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Water Control	<2.52	20	-	0	0	0	0
Solvent control	<2.52	20	-	0	0	0	0
6.25	5.21	20	-	0	0	0	0
12.5	6.87	20	-	0	0	0	0
25	16.2	20	-	0	0	0	0
50	31.9	20	-	0	0	0	0
100	88.6	20	-	20	20	20	20

LC50 31.9 < LC50 < 88.6 mg/L at 96 hours.
NOEC 31.9 mg/L at 96 hours.
Remarks – Results Slight decreases in concentrations of the notified chemical were observed in all test treatments, except the treatment with nominal concentration of 100 mg/L and 100% mortality at the first day of test. This may indicate the bioaccumulation potential of the notified chemical.

Based on the results presented, the calculation of a precise LC50 value using probit analysis was not possible due to the lack of partial responses.

The NOEC was determined based on a lack of mortality and sublethal effects.

CONCLUSION The notified chemical is considered harmful to rainbow trout.

TEST FACILITY Toxikon (2000b)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – (static).

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	76 mg $CaCO_3$/L
Analytical Monitoring	Gas chromatography with flame ionisation detection.
Remarks - Method	No significant protocol deviations.

RESULTS

Concentration (mg/L)		*Number of* D. magna	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	<2.62	20	0	0
31.3	28.5	20	0	0
62.5	56.7	20	0	3
125	114	20	1	4
250	232	20	20	20
500	471	20	20	20

E_iC50	157 mg/L (95% CI 147 – 168 mg/L) at 24 hours 127 mg/L (95% CI 108 – 151 mg/L) at 48 hours
LOEC	<28.5 mg/L at 48 hours
Remarks - Results	Some daphnids were observed to be lethargic in testing concentrations 28.5, 56.7 and 114 mg/L on Day 2 of the study, which was considered to be a sublethal effect. No decrease in concentration was observed through out the test course.

CONCLUSION The notified chemical is considered not harmful to *Daphnia magna.*

TEST FACILITY Toxikon (2000c)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test (static).

Species	Green algae (*Selenastrum capricornutum*)
Exposure Period	72 hours
Concentration Range	Nominal: 6.25, 12.5, 25, 50 and 100 mg/L Actual: 6.18-109 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported.
Analytical Monitoring	Gas chromatography with flame ionisation detection.
Remarks - Method	No significant protocol deviations.

All test solutions were prepared by mixing the appropriate amount of notified chemical stock with algal medium. Approximately 0.0685 g of the notified chemical was sonicated with 600 mL of algal medium to prepare the stock and highest test concentration (100 mg/L).

EC50 values and 95% confidence limits were estimated using a US EPA program (US EPA, 1994).

RESULTS

Biomass		*Growth*	
E_bC50 (mg/L at 72 h)	*NOEC (mg/L)*	*E_rC50 (mg/L at 72 h)*	*NOEC (mg/L)*
10.2	6.25	127	-

Remarks - Results

Mean measured concentrations of the notified chemical for the duration of the test ranged from 107-110 % of nominal concentrations. As measured concentrations were only taken in the low, middle and high testing concentrations, the mean measured concentrations were not used to run the statistical analyses and the nominal concentrations were used instead.

No undissolved test substance was observed in the test chambers during the duration of the study. The initial pH of the test and control solutions ranged from 6.5-6.9 and ranged from 7.4-7.5 after 72 hours.

The E_rC50 (24-72 hours) was estimated to be 127 mg/L by probit analysis.

CONCLUSION

The notified chemical is considered not harmful to green algae based on the E_rC50.

TEST FACILITY

Toxikon (2000d)

C.2.4a. Inhibition of microbial activity

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 87/302/EEC C. Biodegradation: Activated Sludge Respiration Inhibition Test.

Inoculum: Activated sludge from local sewage treatment works.
Exposure Period: 3 hours
Concentration Range: Nominal: 125-2000 mg/L
Remarks – Method: No significant protocol deviations. The required test concentrations were achieved by direct addition of the notified chemical followed by 20 minutes of dispersing in an ultrasonic bath.

RESULTS

IC50: >500 mg/L
NOEC: 125 mg/L
Remarks – Results

Evidence of inhibition observed in a preliminary range-finding test was subsequently confirmed by a definitive experiment. The notified chemical caused significant inhibition of the respiration of activated sludge at a concentration of 2000 mg/L. However, based on the data from the definitive experiment, the effective concentration of test substance that caused a 50% reduction in respiration rate, relative to untreated controls (EC50), could not be evaluated. The data did not produce a linear regression, and were not considered to reflect true dosage-related inhibition. However, less than 50% inhibition was seen in all tested concentrations up to 500 mg/L. The EC50 value therefore is considered to be in excess of 500 mg/L.

No significant inhibition percentage (3.7%-6.7%) was tested at the lowest

	test concentration 125 mg/L, which is considered to be the NOEC.
CONCLUSION	The notified chemical is not considered inhibitory to microbial respiration under the conditions of this test.
TEST FACILITY	Covance (2003d)

C.2.4b. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 87/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.
Inoculum	Activated sludge from local sewage treatment works.
Exposure Period	3 hours
Nominal Concentration Range	90, 217, 521, 1250, and 3000 mg/L
Remarks – Method	No significant protocol deviations. The required test concentrations were achieved by direct addition of the notified chemical followed by 20 minutes of dispersing in an ultrasonic bath.
RESULTS	
EC50	>1000 mg/L
LOEC	217 mg/L
Remarks – Results	In an initial range-finder test, samples of activated sludge were exposed, in duplicate, to the notified chemical with a 3 hour contact time at nominal concentrations of 1, 10, 100 and 1000 mg/L. The results of this test were variable with poor consistency between replicate vessels. At the highest concentration (1000 mg/L) the results of the two replicates were 51% inhibition and 20% inhibition; therefore, although the results were variable, they indicated the need for a definitive assessment. A definitive test was then performed in duplicate. The results of this test were inconclusive; there was no clear concentration-related effect and the variability in respiration rates was high between replicates. Additionally, the test substance appeared to adhere to the surface of the dissolved oxygen probe that was used to make the respiration rate measurement. On the basis of the continued poor reproducibility, it was thought that the notified chemical was affecting the probe, and that its physical presence was influencing the measurement rather than having an effect upon the respiration of the microbes within the activated sludge.
CONCLUSION	The notified chemical is not considered inhibitory to microbial respiration under the conditions of this test.
TEST FACILITY	Covance (2004b)

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