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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in Niax additive RA-1

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)
Momentive Performance Materials Australia Pty Ltd (ABN 47 105 651 063)
Level 2, 600 Victoria Street
Richmond VIC 3121

Isochem Australia Pty Ltd
25 Valley Park Crescent
North Turramurra NSW 2074

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, Other Names, CAS Number, Molecular Formula, Structural Formula, Molecular Weight, Spectral Data, Methods of Detection and Determination, Purity, Hazardous Impurities, Additives/Adjuvants, Import Volume, Use Details, Identity of Manufacturer/Recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Boiling point, Particle size, Flammability, Hydrolysis, Bioaccumulation, Explosive properties, and Oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA, Canada, China

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Niax Additive RA-1 (product containing the notified chemical at <40% concentration)

OTHER NAME(S)
UAX-1231 (notified chemical)

MOLECULAR WEIGHT
<500 Da,

ANALYTICAL DATA
Reference IR spectra was provided.

3. COMPOSITION

DEGREE OF PURITY >85 %

NON HAZARDOUS IMPURITIES (>1% by weight) None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Clear, dark brown liquid, like honey (notified chemical)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	--	No definitive melting point temperature was able to be determined.
Boiling Point	--	Not determined.
Density	1143kg/m^3 at 20°C	Measured.
Vapour Pressure	0.29 kPa at 25°C	The high vapour pressure measured is attributed to impurities contained in the test substance. The notified chemical is not expected to be volatile based on the apparently high molecular weight and hydrophilic structure.
Water Solubility	>500 g/L at 20°C	Measured.
Hydrolysis as a Function of pH	Not tested	The notified chemical, as a salt, will dissociate into its respective ions in water. The notified chemical is not expected to hydrolyse over the environmental pH range (4–9).
Partition Coefficient (n-octanol/water)	log P_{ow} <0.3 at 25°C	Measured.
Adsorption/Desorption	Not tested	The notified chemical contains functional groups that are expected to be cationic in the environmental pH range (4–9), hence the cationic component is likely to adsorb to solid particles and be immobile in soils.
Dissociation Constant	pKa = 4.73	Measured.
Particle Size	--	Not determined.
Flash Point	108°C at 97.7 kPa	Measured.
Flammability	--	Not determined.
Autoignition Temperature	248°C	Measured.
Explosive Properties	--	Not determined.

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

Reactivity
The notified chemical is not unstable and is not considered reactive. The notified chemical is also unlikely to be an oxidant.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table, the notified chemical is not classified according to the Australian Dangerous Goods Code (NTC,2007). However, the data above does not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia and will be imported into Australia as a component of Niax Additive RA-1 product at <40% concentration.

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

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

PORT OF ENTRY
Sydney and Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified chemical will be imported into Australia. Recipients will be polyurethane foam manufacturers and plastic moulders.

TRANSPORTATION AND PACKAGING
The product containing the notified chemical will be imported as 1200 kg (IBC), 25 kg (pails), 250 kg (drums) and also sample packages of 5 kg by sea. At certain occasions, end-use products containing the notified chemical may arrive by air.

USE
The notified chemical will be used as a catalyst in the manufacturing of polyurethane foam.

OPERATION DESCRIPTION
The notified chemical will be imported into Australia in a product (Niax additive RA-1) containing <40% of the notified chemical. The notified chemical will be used at an anticipated concentration of <5.0% to make foam.

At the polyurethane manufacturing sites, it will be pumped directly from the delivery container via a closed system into a mixing system (closed) and then on to mixing head (closed). All other chemicals used in the foam formulation are also dispensed from their storage tanks via a closed system to a mixing system (closed) and to mixing head (closed). This creates a closed loop system which eliminates any waste of individual ingredients and also reduces exposure to foam manufacture workers during foam production. Local exhaust ventilation systems are used to remove fugitive vapours or dust from all possible emission points when handling the ingredients.

As the notified chemical is mixed with the other chemicals in the foam machine mixer, the reacting foam mixture is deposited continuously onto a conveyor in a semi-enclosed system. The chemicals react with each other and expand to create a polyurethane foam. The fresh foam is cut into buns before being cured overnight in a ventilated building. Once cured, the buns are moved to the storage building. The finished foam will be used in building construction/thermal insulation.

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 (days/year)*
Transport & storage	1	Max 10 min/day	10
Process operators	1	1 hour/day	300
Laboratory/QC	1	1 hour/day	300

EXPOSURE DETAILS
Worker exposure to the notified chemical during importation and transportation is not expected, except in the unlikely event of an accident where the packaging may be breached.

At foam manufacturing sites, there is a potential for dermal, ocular and inhalation exposure to the notified chemical (at <40%) as it is pumped directly from the delivery container into a mixing system. A small amount of notified chemical may drip or splash out of the hose after each unloading, resulting in skin and ocular exposure to the liquid and inhalation of vapours. However, exposure will be low as workers will wear protective clothing (overalls), safety boots, rubber gloves and safety goggles during this procedure. Furthermore, exposure by inhalation would be minimal as the unloading area will have local exhaust ventilation.
After initial transfer of the notified chemical to a mixing system, exposure is expected to be low during further transfer to a mixing head as this is done in a closed system. Exposure is also expected to be low when the reacting foam mixture is deposited continuously onto a conveyor to create a polyurethane foam, due to the low concentration of the notified chemical in the mixture and the use of semi-enclosed system, personal protective

equipment and local exhaust ventilation. Furthermore, by this time, the notified chemical will be consumed during the polymerisation process to form part of the polyurethane foam matrix and will not be bioavailable. Therefore, dermal and inhalation exposure to workers involved in handling the foam buns during storage or cutting is also expected to be low.

The quality control and R&D staff will be involved in taking samples from the mixing tanks to perform laboratory tests prior to production and during product development. This procedure may result in exposure to liquid and vapours from drips, splashes and spills to skin (hands), eyes and inhalation. However, exposure is expected to be low as small samples will be handled and protective clothing (laboratory coat), safety glasses and rubber gloves will also be worn during sampling and testing to reduce exposure to the notified chemical.

Workers may be exposed to the notified chemical during cleaning of filters and maintaining pumps. However, exposure is expected to be low as workers involved in maintenance will wear protective clothing (overalls), safety glasses, safety boots and rubber gloves.

6.1.2. Public exposure

The notified chemical is intended for industrial use only and therefore, general public will not be exposed to the notified chemical as such. Exposure is expected to be limited during end-use applications in buildings construction/thermal insulation, as the foam material containing the notified chemical will be hidden away from the general public. Furthermore, the notified chemical is unlikely to be bioavailable as it will be physically bound within the final foam. Therefore, exposure to the general public from the use of polyurethane foam is expected to be low.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical (at <40%) 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	LD50 >2000 mg/kg bw low toxicity
Rat, acute dermal toxicity	LD50 >2000 mg/kg bw low toxicity
Rat, acute inhalation toxicity	LC50 >4.75 mg/L/4 hour low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test.	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOEL=1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	weakly mutagenic
Genotoxicity – in vivo mouse micronucleus test	non genotoxic

Toxicokinetics, metabolism and distribution

No data were available to assess toxicokinetics, metabolism and distribution of the notified chemical. Based on the log Pow and molecular weight <500 Da, dermal absorption may occur. However, no systemic effects were observed in a 28-day repeat dose oral study at the maximum tested dose of 1000 mg/kg bw/day. It is not clear whether this was due to lack of absorption through the gastrointestinal tract or due to lack of toxicity effects as such.

Acute toxicity

The notified chemical is of low acute oral, dermal and inhalation toxicity, with oral and dermal LD50 of being >2000 mg/kg bw and inhalation LC50 of >4.75 mg/L/4 hour.

Irritation and Sensitisation

The notified chemical was slightly irritating to the skin and eyes of rabbit. It was not a skin sensitiser in guinea pigs.

Repeated Dose Toxicity (sub acute, sub chronic, chronic)

In an oral toxicity study in rats, the notified chemical was administered orally by gavage once daily (7 days/week) for 28 days at 0, 50, 250 or 1000 mg/kg bw/day. Recovery groups of the control group and of the

high dose group were also observed for 14 days after the termination of the main study.

No treatment related effect was noted on clinical symptoms, behaviour and reaction of animals to different type of stimuli, food consumption, body weight gain, and haematological or clinical chemistry parameters. There were no pathological findings related to the treatment either at gross necropsy, organ weight or at histopathological examinations. The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day in this study, based on effects not seen at this highest dose tested.

Mutagenicity
The notified chemical showed positive results in a bacterial reverse mutation test (in the initial or main assay) performed using plate incorporation method of exposure. However, it is noted that increase in the frequency of revertants was not consistent with respect to the dose and strain of the bacteria used, with and without metabolic activation. In the confirmatory assay performed using the pre-incubation method of exposure, no statistically significant increases in the frequency of revertants in any of the strains exposed to the same concentrations of the test substance, with and without metabolic activation, was observed. The genotoxic potential of the notified chemical was further investigated in mouse micronucleus assay in vivo. The notified chemical showed no evidence of clastogenicity or genotoxicity in this assay.

Based on the weight of evidence, the possibility of mutagenicity is not expected. Therefore, the notified chemical is not considered mutagenic.

Carcinogenicity:
No data were available to assess the potential for carcinogenicity.

Toxicity for reproduction:
No data were available to assess the potential for reproductive toxicity.

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

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The primary risk to workers from exposure to the notified chemical is slight skin and eye irritation. There is a potential for dermal and ocular exposure during various processes involving the notified chemical such as foam manufacturing, quality control, R&D, cleaning, and maintenance. Inhalation exposure could occur during the polyurethane formation when heat is generated. However, considering the use of PPE and engineering controls, the level of risks to workers presented by the use of notified chemical is expected to be low.

Furthermore, during foam manufacturing process, the notified chemical will be consumed during the polymerisation process to form part of the polyurethane foam matrix and will not be bioavailable. Therefore, risks to workers involved in handling the foam buns during storage or cutting is also expected to be low.

6.3.2. Public health
The primary risk of exposure to general public will result during end-use applications of foam material in buildings construction/thermal insulation. However, the foam material containing the notified chemical will be hidden away from the general public and the notified chemical will be physically bound within the final foam material and is unlikely to be bioavailable. Therefore, the risk to general public from the use of polyurethane foam is low.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported into Australia as a ready-to-use formulation. Accidental spills and leaks during transport are expected to be physically contained and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
During the manufacture of polyurethane foam, the notified chemical (in formulated product) will be transferred from the storage container to the mixing vessel by closed system or under exhaust ventilation. Accidental spills and leaks during manufacture are expected to be physically contained and disposed of to landfill. Empty import containers with residual amounts of the formulated product (<1%) are cleaned with water, which is sent to a wastewater treatment plant before release to sewer.

The notified chemical, in the final polyurethane product, will be physically bound within the foam matrix.

RELEASE OF CHEMICAL FROM DISPOSAL
The notified chemical in polyurethane/polyisocyanurate foam core panels will be used in building construction and thermal insulation. It is expected that the articles containing the notified chemical will be disposed of to landfill at the end of their useful life, where they will slowly degrade to form water and oxides of carbon and nitrogen.

7.1.2 Environmental fate

Accidental spills and leaks are expected to be physically contained and disposed to landfill. In landfill, the notified chemical is expected to adsorb to solid particles and not leach through soil, given its adsorption properties.

Waste water from cleaning residue from import containers will be treated on-site, whereby it is likely that the notified chemical will partition to sludge which will be disposed to landfill. Any notified chemical remaining in the water phase will be released to the sewer. The notified chemical is readily biodegradable, based on studies conducted on the ready-to-use formulated product, and is not expected to bioaccumulate due to its high water solubility and low partition coefficient.

The majority of the notified chemical, physically bound within the polyurethane foam, will share the fate of the foam articles and are expected to be disposed of to landfill at the end of their useful life. In landfill, the notified chemical will undergo biotic and abiotic degradation to form water and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

The PEC was not calculated as very limited aquatic exposure is expected based on the reported use pattern.

7.2. Environmental effects assessment

The results from the ecotoxicological investigations were conducted on a formulated product (<40% notified chemical) and the endpoints, corrected to reflect the concentration of the notified chemical in the product, are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) >10 mg/L	Not toxic to fish
Daphnia Toxicity	EC50 (48 h) <56 mg/L	Harmful to aquatic invertebrates
Algal Toxicity	E_bC50 (72 h) 1–10 mg/L	Toxic to algae
Inhibition of Bacterial Respiration	IC50 (3 h) >100 mg/L	Not harmful to microbial respiration

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009), the notified chemical is not toxic to fish and is not expected to be harmful to microbe respiration, based on studies conducted using the formulated end-use product (<40% notified chemical). The notified chemical is not classified as a long term hazard based on the ready biodegradability of the formulated end-use product. The notified chemical was found to be harmful to aquatic invertebrates and toxic to algae, however, the proposed use pattern indicates that there will be very little release to the aquatic environment. Details of these studies can be found in Appendix C.

7.2.1 Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) was not calculated as low potential for aquatic exposure is expected based on the reported use pattern.

7.3. Environmental risk assessment

The Risk Quotient, Q (= PEC/PNEC), has not been calculated since a PEC is not available. Based on the reported use pattern the notified chemical is not expected to pose a risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data, the notified chemical is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

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***
Aquatic toxicity	Acute category 2	Toxic to aquatic life

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 reported use pattern, the notified chemical is not expected to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in the product Niax Additive RA-1:
  - Avoid contact with the skin and eyes

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to notified chemical as introduced in the product Niax Additive RA-1:
  - Gloves, protective clothing, safety goggles

  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 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 manufacturing of polyurethane foam, or is likely to change significantly;
- importing at a concentration >40% (test data was submitted only for <40%)
- the amount of chemical being introduced has increased from 30 tonnes, 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 notified chemical and product containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Physico-chemical properties were conducted on a preparation containing >85% of notified chemical.

Melting Point/Freezing Point No definitive melting point temperature was able to be determined.

Method	In-house method
Remarks	The notified chemical remained clear on freezing at -27°C with no signs of crystallization. Upon thawing, at no point did the temperature stabilise, nor there were any signs of solid/liquid phase equilibrium. The material slowly became less vicous, and eventually returned to its original state. It was determined that because of the unique physcio-chemical properties of the notified chemical, a melting point would not be able to determined using standard ASTM guidelines, or by any alternative method of analysis.
Test Facility	Momentive Performance Materials (2009)

Density 1143±2.7 kg/m^3 at 20ºC

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Determined using a MINIDENS Density Meter.
Test Facility	LAB International Research Centre Hungary Ltd (2006a)

Vapour Pressure 0.29 kPa at 25ºC (or 0.20 kPa at 20ºC)

Method	EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Determined in 20-100ºC range using a vacuum-sealed measuring chamber of an overall volume of 5 mL. A regression line was fitted on the measured data and the vapour pressure was extrapolated for 20ºC and 25ºC.
Test Facility	LAB International Research Centre Hungary Ltd (2006b)

Water Solubility >500 g/L at 20ºC

Method	SOP of LAB International Research Centre Hungary Ltd. (Based on OECD TG 105 Water Solubility; EC Directive 92/69/EEC A.6 Water Solubility.)
Remarks	Flask Method. Five mixtures of the notified chemical/pure water were prepared in approximately 1:1 ratio, and were thoroughly homogenized and equilibrated for 24 h at 20 ± 1ºC. A single homogenous phase was obtained in each vessel. After centrifugation, replicate samples were taken from lower, middle and upper parts of each vessel. The concentrations of the samples were determined by HPLC, and the mean value was determined to be 506 ± 6.7 g/L. As only one concentration was examined (albeit in replicate), the water solubility of the notified chemical may be greater than determined, and is thus quoted as >500 g/L.
Test Facility	LAB International Research Centre Hungary Ltd (2007)

Partition Coefficient (n-octanol/water) log P_{OW} < 0.3

Method	OECD TG 117 Partition Coefficient (n-octanol/water). EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks	HPLC Method. The partition coefficient was determined by comparing the retention time of the notified chemical to those of known standards. The dead time was determined to be 2.80 min (thiourea). The notified chemical eluted at 2.97 min, before the first calibration standard (3.88 min for 2-butanone, log P_{OW} = 0.3). Thus, the log P_{OW} for the notified chemical is therefore determined to be < 0.3.
Test Facility	LAB International Research Centre Hungary Ltd (2006c)

Dissociation Constant pKa = 4.73

Method	Not stated
Remarks	Determined by titration. Test report not provided.

Flash Point 108ºC at 97.7 kPa

Method	EC Directive 92/69/EEC A.9 Flash Point.
Remarks	Determined with the help of MINIFLASH automatic flash point tester with the continuously closed cup-electric arc method.
Test Facility	LAB International Research Centre Hungary Ltd (2006d)

Autoignition Temperature 248ºC

Method	EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Test Facility	LAB International Research Centre Hungary Ltd (2006e)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical (at <40%)
METHOD	OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure.
Species/Strain	Rat/Outbred Albino, female
Vehicle	Test substance administered as supplied.
Remarks - Method	No significant protocol deviations. A total of five females were tested.

RESULTS

LD50	>2000 mg/kg bw
Signs of Toxicity	There were no signs of systemic toxicity and there were no deaths.
Effects in Organs	There were no remarkable necropsy findings.
Remarks - Results	None

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Toxikon Corporation (2005a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical (at <40%)
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rat/CRL:(WI) BR Wistar
Vehicle	Test substance administered as supplied.
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 males	2000	0
2	5 females	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	None
Signs of Toxicity - Systemic	There were no treatment related clinical signs observed.
Effects in Organs	There were no treatment related effects observed in organs.
Remarks - Results	
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	LAB International Research Centre Hungary Ltd (2006f)

B.3. Acute toxicity – inhalation

TEST SUBSTANCE	Notified chemical (at <40%)
METHOD	OECD TG 403 Acute Inhalation Toxicity. EC Directive 92/69/EEC, 93/21/EEC B.2 Acute Toxicity (Inhalation).
Species/Strain	Wistar Crl:(WI) BR strain rats
Vehicle	The test substance was used as such.
Method of Exposure	Nose only exposure
Exposure Period	Four hours followed by a fourteen-day observation period.
Physical Form	liquid aerosol

Particle Size	< 4μm (74%)
Remarks - Method	The notified chemical was aerosolidised using a stainless steel concentric jet nebuliser. The Mean Mass Median Aerodynamic Diameter (MMAD) was 2.30 μm.

RESULTS

Group	*Number and Sex of Animals*	*Concentration (mg/mL)*		*Mortality*
		Nominal	*Actual*	
1	5 (M), 5 (F)	67.0	4.75	0

LC50	>4.75 mg/L/4 hours
Signs of Toxicity	Significant clinical signs noted during the exposure period were limited to mild to moderate laboured respiration or increased respiration rate. In male animals, on removal from restraint, these clinical signs persisted and/or increased in severity and one animal presented a hunched posture. One hour post exposure, no marked improvement was observed in the condition of male animals. In female animals, the clinic signs persisted and/or decreased in severity on removal from restraint and one animal presented a hunched posture. One hour post exposure, only one female still presented significant clinical signs (moderate laboured respiration and hunched posture). No significant clinical signs were observed in any animals from the first day of observation onward.
Effects in Organs	No treatment related macroscopic abnormalities were detected at necropsy.

CONCLUSION The notified chemical is of low toxicity via inhalation.

TEST FACILITY LAB Research Ltd. (2008)

B.4. Irritation – skin

TEST SUBSTANCE Notified chemical (at <40%)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Test substance administered as supplied.
Observation Period	14 days
Type of Dressing	Occlusive
Remarks - Method	No significant protocol deviations. 0.5 mL of the test material was applied to the test site for 4 hours. The untreated skin of each animal served as a control.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.66	0	0.66	1	48 hr	0
Oedema	0	0	0	0	0	0

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

Remarks - Results	General state and the behaviour of the animals were normal throughout the study period. There were no notable body weight changes during the contact and observation period.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY LAB International Research Centre Hungary Ltd (2006g)

B.5. Irritation – eye

TEST SUBSTANCE Notified chemical (at <40%)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 21 days
Remarks - Method No significant protocol deviations. 0.1 mL of the test substance was used in a single dose and instilled into the conjunctival sac of the left eye.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.33	0.66	0.66	1	48 hr	0
Conjunctiva: chemosis	0.66	0	0	1	48 hr	0
Conjunctiva: discharge	0.33	0	0	1	24 hr	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results General state and the behaviour of the animals were normal throughout the study period. There were no notable body weight changes during the contact and observation period.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY LAB International Research Centre Hungary Ltd (2006h)

B.6. Skin sensitisation

TEST SUBSTANCE Notified chemical (at <40%)

METHOD OECD TG 406 Skin Sensitisation - adjuvant test.
EC Directive 96/54/EC B.6 Skin Sensitisation - adjuvant test.
Species/Strain Guinea pig/Dunkin Hartley
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 1% (local irritation consisting of very slight to well defined erythema was observed at 5%)
topical: 100%
MAIN STUDY
Number of Animals Test Group: 20 (female) Control Group: 10 (female)
INDUCTION PHASE Induction Concentration:
intradermal: 5%
topical: 100%
Signs of Irritation
CHALLENGE PHASE
1st challenge intradermal: 100%
topical: 100%
2nd challenge topical: 100%
Remarks - Method Before the dermal exposure, the test area was painted with 0.5 mL of 10% sodium dodecyl sulphate in Vaseline 24 hrs prior to topical induction application, in order to create local irritation. Control animals were treated similarly except that during the induction phase, the test item was omitted.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100%	0/20	0/20	Not performed	Not performed
Control Group	100%	0/10	0/10	Not performed	Not performed

Remarks - Results

No overt clinical adverse signs were noted during the conduct of the study. There were no moribund or dead animals during the study.

The sensitivity and reliability of the experimental procedure is assessed twice a year by use of substances which are known to have moderate skin sensitisation properties such as 2-Mercaptobenzothiazole. On the basis of the last reliability study, the reference item (2-Mercaptobenzothiazole) evoked positive response in 60% of the test animals.

CONCLUSION

There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY

LAB International Research Centre Hungary Ltd (2007a)

B.7. Repeat dose toxicity

TEST SUBSTANCE

Notified chemical (at <40%)

METHOD

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

Species/Strain: Crl:(WI) BR rats

Route of Administration: Oral – gavage

Exposure Information: Total exposure days: 28 days
Dose regimen: 7 days per week
Post-exposure observation period: 14 days

Vehicle: Distilled water

Physical Form: Liquid

Remarks - Method: No significant protocol deviations.
General clinical observations were made daily and detailed clinical observations were performed weekly. A functional observation battery was conducted on day 27. Body weight and food consumption were measured weekly. Clinical pathology and necropsy were conducted one day after the last treatment. Selected organs were weighed. A full histological examination was performed on the preserved organs and tissues of the animals of the Control and High dose groups. The livers and kidneys were evaluated histologically in Groups 2 and 3. Animals of recovery groups were processed in the same manner at termination.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5 (M), 5 (F)	0	0
low dose	5 (M), 5 (F)	50	0
mid dose	5 (M), 5 (F)	250	0
high dose	5 (M), 5 (F)	1000	0
control recovery	5 (M), 5 (F)	0	0
high dose recovery	5 (M), 5 (F)	1000	0

Mortality and Time to Death

There were no mortalities.

Clinical Observations

No test substance related clinical symptoms were noted. There were no differences between control and test substance treated groups in the behaviour and reaction of animals to different type of stimuli. There were no test substance related differences in the mean food consumption at any dose levels and there was also no effect on the body weight gain of treatment with the test substance.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No haematological or clinical chemistry alternations related to test substance were found.

Effects in Organs

There were no pathological findings related to the test substance either at gross necropsy, organ weight or at histopathological examinations.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day in this study, based on no effects seen at this highest dose tested.

TEST FACILITY LAB International Research Centre Hungary Ltd (2007b)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical (at <40%)

METHOD

	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure/Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2 (pKM101)
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254.
Concentration Range in Main Test	a) With metabolic activation: 0.0001, 0.001, 0.01, 0.1, 1, 5 µL/plate b) Without metabolic activation: 0.0001, 0.001, 0.01, 0.1, 1, 5 µL/plate
Vehicle	Acetone
Remarks - Method	No significant protocol deviations. A range finding assay was performed without metabolic activation with TA100 strain and dosing concentrations of 5, 1, 0.1, 0.01, 0.001 and 0.0001 µL/plate. Since no toxicity was observed at any of the tested dose, using both the plate incorporation method and the pre-incubation method of exposure, the same six concentrations of the test substance were used in the main experiments, with and without metabolic activation. The initial or main assay (Test 1, with & without metabolic activation) was performed using plate incorporation method of exposure while the confirmatory assay (Test 2, with & without metabolic activation) was performed using pre-incubation method of exposure. In the pre-incubation method, the bacteria were exposed to the test substance solution in top agar for 30 minutes at 37±1°C and then placed on minimal medium.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1 (initial assay)	>5	>5	>5	Positive*
Test 2 (confirmatory assay)	Not performed	>5	>5	Negative
Present				
Test 1 (initial assay)	Not performed	>5	>5	Positive**
Test 2 (confirmatory assay)	Not performed	>5	>5	Negative

*At 1 and 5 µL/plate in TA 98, at 1 µL/plate in the TA 100 and at 5 µL/plate concentrations in the WP2 strain.

**At 1 μL/plate in TA 98 and at 5 μL/plate concentrations in the WP2 strain.

Remarks - Results	In the initial or main assay performed using plate incorporation method of exposure, a statistically significant increase in the frequency of revertants was observed in both tests, with and without metabolic activation. However, it is noted that increase in the frequency of revertants was not consistent with respect to the dose and strain of the bacteria, with and without metabolic activation. The confirmatory assay performed using the pre-incubation method of exposure revealed no statistically significant increases in any of the strains exposed to the same concentrations of the test substance, with and without metabolic activation. All positive controls showed a statistically significant increase in the number of mutants as compared to the corresponding negative control.
CONCLUSION	The notified chemical was weakly mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Toxikon Corporation (2005b)

B.9. Genotoxicity – in vivo

TEST SUBSTANCE	Notified chemical (at <40%)
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Swiss albino mice
Route of Administration	Oral – gavage
Vehicle	NaCl
Remarks - Method	No significant protocol deviations. An initial range finding study was conducted to determine doses for the main study. There were no signs of toxicity at the highest dose of 2000 mg/kg bw and therefore, the highest dose of 2000 mg/kg bw was tested in the main study.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	3M , 3F	0	24, 48
II (Test group)	5M , 5F	2000	24, 48
III (positive control, mitomycin C)	3M , 3F	0	24

RESULTS

Doses Producing Toxicity	There were no signs of toxicity at the highest tested dose of 2000 mg/kg bw.
Genotoxic Effects	The test substance did not induce a statistically significant increase in the frequency of micronucleated PCE over the levels observed in the vehicle control group.
Remarks - Results	There was no statistically significant increase in the number of micronucleated cells in the test substance group at all time points, as compared to the concurrent vehicle control groups. There was a statistically significant increase in the number of micronucleated cells in the positive control group, as compared to the vehicle control group, thus validating the conduct ed assay.
CONCLUSION	The test substance was not clastogenic under the conditions of this in vivo mouse micronucleus assay.
TEST FACILITY	Toxikon Corporation (2005c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical (at <40%)
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sludge
Exposure Period	29 days
Auxiliary Solvent	None
Analytical Monitoring	Evolved carbon dioxide was quantified by titrating unreacted $Ba(OH)_2$ in the CO_2 adsorption solution. Carbon concentrations of the test and reference stock solutions were determined by elemental analysis.
Remarks - Method	The test was conducted on a formulated product containing the notified chemical (<40%), and non hazardous organic fluid (≤60%) in aqueous solution. After acidification (to release remaining CO_2 in the test bottles) on day 29, the mean degradation extent of the test substance was 82.2%. As biodegradation was >60%, complete mineralisation was demonstrated, and therefore the notified chemical is inferred to be readily biodegradable. The test and reference substances degraded by more than 60% each in the ten day window, thus validating the test. The test substance was found not to be toxic to the inoculum, as biodegradation reached 54.3% on day 14 in the toxicity control.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	6.60	2	18.6
14	64.2	14	79.5
19	72.1	19	83.6
29	82.2	29	93.6

Remarks - Results	The test was conducted on a formulated product containing the notified chemical (<40%), and non hazardous organic fluid (≤60%) in aqueous solution. After acidification (to release remaining CO_2 in the test bottles) on day 29, the mean degradation extent of the test substance was 82.2%. As biodegradation was >60%, complete mineralisation was demonstrated, and therefore the notified chemical is inferred to be readily biodegradable. The test and reference substances degraded by more than 60% each in the ten day window, thus validating the test. The test substance was found not to be toxic to the inoculum, as biodegradation reached 54.3% on day 14 in the toxicity control.
CONCLUSION	The notified chemical is readily biodegradable.
TEST FACILITY	Toxikon Corporation (2004)

C.1.2. Bioaccumulation

METHOD	Test not conducted
Remarks - Results	The high water solubility, ready biodegradability and the low partition coefficient of the notified chemical indicate that it is not likely to partition into membranes, thus, the notified chemical is not expected to bioaccumulate.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical (at <40%)
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Juvenile Fathead Minnow 96 h static
Species	Juvenile fathead Minnow (*Pimephales promelas*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	62 mg $CaCO_3$/L
Analytical Monitoring	The test substance concentrations were determined by HPLC
Remarks – Method	After a range-finding test was performed, a limit test was conducted at a nominal concentration of 100 mg test substance/L. The test concentration and control were prepared in triplicate, and each had seven fish added. The test chambers were maintained at 23 ± 1°C under static conditions for 4 days. The fish were observed for mortality and sub-lethal effects.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
100	90.6	21	0	0	0	0	0

LC50	>10 mg/L at 96 hours.
NOEC	~40 mg/L at 96 hours.
Remarks – Results	There was no observed mortality of fathead minnow exposed for 96 h to the test substance at a concentration of 100 mg/L. The test was conducted on a formulated product containing the notified chemical (<40%), and non hazardous organic fluid (≤60%) in aqueous solution. Therefore, the results have been corrected to reflect the endpoint of the notified chemical. There was 5% mortality (1 fish) in the control, thus validating the test.
CONCLUSION	The notified chemical is not toxic to fish.
TEST FACILITY	Toxikon Corporation (2005d)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical (at <40%)
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test and Reproduction Test – 48 h static EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – 48 h static
Species	*Daphnia magna*
Exposure Period	48 h hours
Auxiliary Solvent	None
Water Hardness	62 mg $CaCO_3$/L
Analytical Monitoring	The test substance concentrations were determined by HPLC
Remarks - Method	Five nominal concentrations (63, 130, 250, 500 and 1000 mg/L) of the test substance were prepared. Four replicates for each test concentration and the control were prepared, and each had 5 daphnia added. The daphnia were observed for immobilisation over two days (test conditions: artificial light dark cycle of 16 to 8 h, 20.6 ± 0.3°C, pH 7.1–7.7). Daphnia unable to swim within 15 seconds of gentle agitation were considered to be immobile. The end-points were calculated by computational analysis (ToxCalc v5.0).

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual (± SD)*		*24 h*	*48 h*
63	64.2 (12.1)	20	0	0
130	132 (24.2)	20	0	11
250	273 (60.1)	20	7	16
500	469 (17.0)	20	14	20
1000	909 (171)	20	19	19

EC50	<140 mg/L at 24 hours <56 mg/L at 48 hours
NOEC	~25 mg/L at 48 hours
Remarks - Results	The test was conducted on a formulated product containing the notified chemical (<40%), and non hazardous organic fluid (≤60%) in aqueous solution. Therefore, the results have been corrected to reflect the endpoint of the notified chemical. There were no immobilised daphnids in the control group, and the dissolved oxygen in the control group and test vessels were ≥3 mg/L, thus validating the test. The measured concentrations deviated from the nominal by <20%, thus, the statistical calculations were conducted using the nominal concentrations.

CONCLUSION	The notified chemical is harmful to aquatic invertebrates.
TEST FACILITY	Toxikon Corporation (2005e)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical (at <40%)
METHOD	OECD TG 201 Alga, Growth Inhibition Test – static
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range	Nominal: 4.4–100 mg/L Actual: <LOQ–66.1 mg/L
Auxiliary Solvent	None
Water Hardness	0 mg $CaCO_3$/L (deionised water)
Analytical Monitoring	The test substance concentrations were determined by HPLC
Remarks - Method	Static test. The test substance was added to mineral salt solution inoculated with a 4-day old pre-culture of the algae (3.7–8.9 × 10^3 cells/mL). The test solutions (in triplicate) and control solutions (six replicates) were irradiated 24 h/day at pH 6.8–7.6 and a temperature range of 21.2–21.5°C for a period of 72 h. Algal growth was measured daily and end-points were calculated by computational analysis (US EPA Probit Analysis, v1.5).

RESULTS

Biomass		*Growth*	
E_bC_{50}	*NOEC*	*E_rC_{50}*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
1–10	~3.8	Not reported	Not reported

Remarks - Results	The test was conducted on a formulated product containing the notified chemical (<40%), and non hazardous organic fluid (≤60%) in aqueous solution. Therefore, the results have been corrected to reflect the endpoint of the notified chemical.

	The rate end-points (E_rC_{50} and NOEC) could not be calculated due to a reported interrupted dose-response. The biomass in the control cultures increased by a factor >16, thus validating the test.
CONCLUSION	The notified chemical is toxic to algae.
TEST FACILITY	Toxikon Corporation (2005f)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical (at <40%)
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Activated synthetic sewage sludge
Exposure Period	3 hours
Concentration Range	Nominal: 10–1000 mg/L
Remarks – Method	Tests were conducted by exposing activated sewage sludge to synthetic sewage and 10, 31, 98, 313 and 1000 mg/L concentrations of the test substance for a period of 3 h at 20 ±2°C. Reference material (3,5–dichlorophenol), at concentrations of 5, 16 and 32 mg/L, was prepared in order to confirm the suitability of the inoculum. The total hardness of the test water was not reported.
RESULTS	
IC50	>100 mg/L
NOEC	>400 mg/L
Remarks – Results	The test was conducted on a formulated product containing the notified chemical (<40%), and non hazardous organic fluid (≤60%) in aqueous solution. Therefore, the results have been corrected to reflect the endpoint of the notified chemical. Slight inhibition (1.9%) of microbial activity was observed at the highest test concentration. Variation in respiration rates of the two controls after 3 h contact time was <15%, and the IC_{50} (3-hour contact time) for reference substance 3,5-dichlorophenol was 8.87 mg/L (95% CI: 7.04–11.18), thus validating the test.
CONCLUSION	The notified chemical is not harmful to microbial respiration.
TEST FACILITY	LAB International Research Centre Hungary Ltd. (2006i)

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