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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Laromer® LR 8981

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

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

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

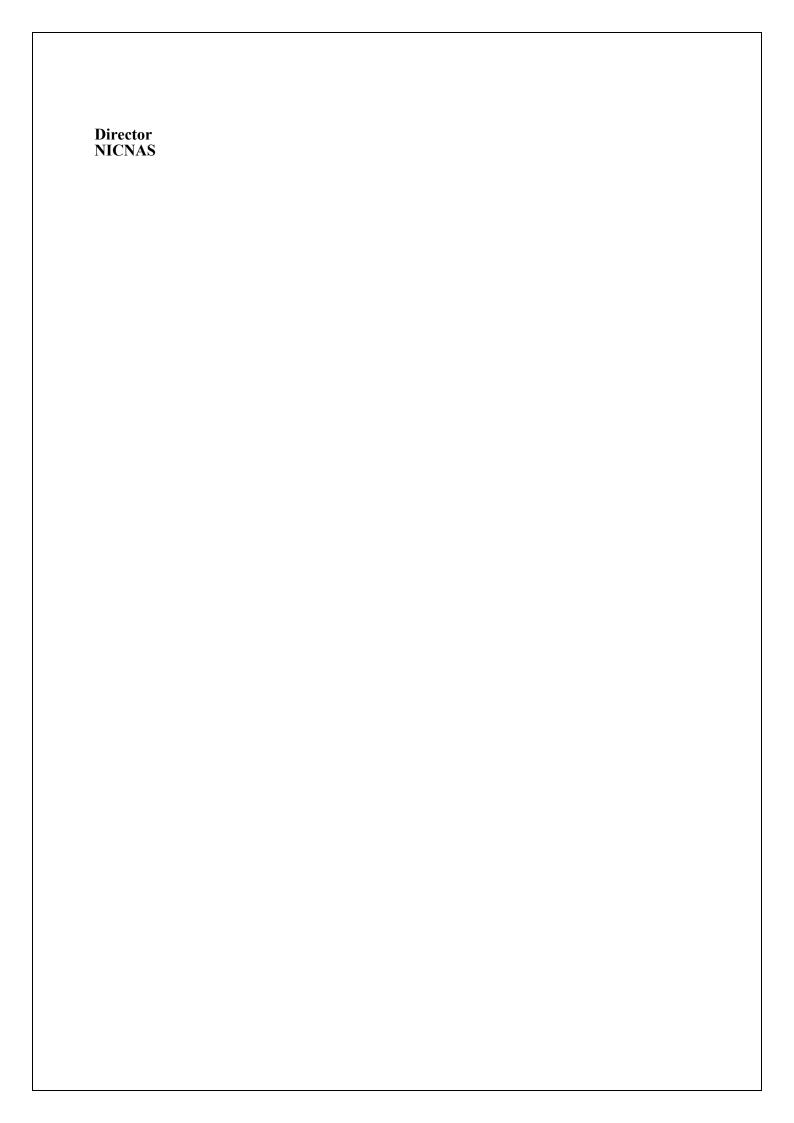


TABLE OF CONTENTS

ULL PUBLIC REPORT	
1. APPLICANT AND NOTIFICATION DETAILS	
2. IDENTITY OF CHEMICAL	5
3. COMPOSITION	
4. INTRODUCTION AND USE INFORMATION	5
5. PROCESS AND RELEASE INFORMATION	
5.1. Distribution, transport and storage	5
5.2. Operation description	6
5.3. Occupational exposure	
5.4. Release	6
5.5. Disposal	7
5.6. Public exposure	7
6. PHYSICAL AND CHEMICAL PROPERTIES	
7. TOXICOLOGICAL INVESTIGATIONS	. 10
7.1. Acute toxicity – oral	. 10
7.2. Irritation – skin	. 10
7.3. Irritation – eye	
8. ENVIRONMENT	. 12
8.1. Environmental fate	. 12
8.2. Ecotoxicological investigations	. 12
9. RISK ASSESSMENT	. 12
9.1. Environment	
9.1.1. Environment – exposure assessment	. 12
9.1.2. Environment – effects assessment	
9.1.3. Environment – risk characterisation	. 12
9.2. Human health	
9.2.1. Occupational health and safety – exposure assessment	
9.2.2. Public health – exposure assessment	
9.2.3. Human health – effects assessment	. 13
9.2.4. Occupational health and safety – risk characterisation	. 13
9.2.5. Public health – risk characterisation	. 13
10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT A	
HUMANS	
10.1. Hazard classification	
10.2. Environmental risk assessment	
10.3. Human health risk assessment	
10.3.1. Occupational health and safety	
10.3.2. Public health	
11. MATERIAL SAFETY DATA SHEET	
11.1. Material Safety Data Sheet	
11.2. Label	
12. RECOMMENDATIONS	
12.1. Secondary notification	. 15
13. BIBLIOGRAPHY	.15

FULL PUBLIC REPORT

Laromer® LR 8981

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ABN 62 008 437 867)
500 Princes Hwy
NOBLE PARK VIC 3174

NOTIFICATION CATEGORY

Limited-small volume: Polymer with NAMW < 1000 (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT) No details are claimed exempt from publication.

Data items and details claimed exempt from publication:

Chemical name

Other name

CAS No.

Molecular/Structural formulae

Molecular weight

Spectral data

Composition

Polymer constituents

Degradation products

Import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

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

Melting point

Density

Vapour pressure

Water solubility

Hydrolysis

Partition coefficient (n-octanol/water)

Dissociation constant

Particle size

Flammability limits

Autoignition temperature

Explosive properties

Reactivity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None.

NOTIFICATION IN OTHER COUNTRIES US (TSCA, 1996)

China (2003)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S) Laromer® LR 8981

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn) < 1000 Weight Average Molecular Weight (Mw) > 1000

SPECTRAL DATA

METHOD Infrared, ultraviolet/visible and ¹H nuclear magnetic resonance spectroscopy.

Remarks Reference spectra were provided.

METHODS OF DETECTION AND DETERMINATION

METHOD Infrared, ultraviolet/visible and ¹H nuclear magnetic resonance spectroscopy and gel

permeation chromatography.

3. COMPOSITION

DEGREE OF PURITY

High.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

A number of impurties were identified but all at levels below concentration cut-offs for hazardous properties.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

None.

ADDITIVES/ADJUVANTS

None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS The notified chemical (Laromer® LR 8981) is imported neat in 220 kg steel drums.

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

Year	1	2	3	4	5
Tonnes	< 1	< 1	< 1	< 1	< 1

Use

UV radiation curing additive in a prefinished timber flooring formulation.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS

One formulator in Victoria.

TRANSPORTATION AND PACKAGING

The notified polymer with be transported in 220 kg steel drums. The final formulation containing the notified chemical at 10% will be contained in 20 kg metal pails. The imported product will be transported by road and the final formulation will be transported to a single customer in Tasmania by road and sea.

5.2. Operation description

The 220 kg drums of the notified polymer will be decanted with a manually operated drum hoist into a 1000 L open headed floor pot. Approximately 100 kg of the notified polymer will be used per batch and added together with other components over a 2 hour period. Once the components have been added, the floor pot is moved to a large spindle (mixing blade) fitted with a safety lid to prevent access to the mixture. After blending, photoinitiators are added and blending is conducted for a further 2 hours. A 0.2 L sample is taken for QC testing and the mixture is drummed off to 20 L pails. QC testing involves application of the product to raw timber with a doctor blade followed by UV curing. The research and development team may make up and send out samples ranging from 0.2 - 20 L three times per month.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	Number	Exposure Duration	Exposure Frequency
Transport	1-3	1 hour 15 minutes	4 times/year
Import storage worker	1 - 3	25 minutes	4 times/year
Raw material storage worker	2	5 minutes	12 times per year
(formulation plant)			
Plant operators	8	5 hours	12 times per year
QC technicians	3	10 minutes	12 times per year
R & D technicians	5	3 hours	36 times per year
Customer operators	4	8 hours/day	48 weeks/year

Exposure Details

Transport and storage workers have the potential to be exposed if there is accidental container breach but not otherwise.

Formulation workers have the potential to be dermally exposed to drips and spills during transfer operations. The mixing vessel is enclosed and precautions are taken to prevent exposure to contents. In addition to engineering controls, personal protective equipment (PPE) includes industrial clothing and footwear, safety goggles, nitrile gloves, face shields and vinyl aprons. Inhalation exposure is controlled by the use of local exhaust ventilation where natural ventilation of the workplace is considered inadequate.

Laboratory staff are provided with laboratory coats, latex gloves, safety glasses with side shields and extraction fume cupboards in which laboratory work is conducted.

At the customer facility where coating is done, the formulated product is applied by vacuum coater in an enclosed chamber which applies the product to timber. The chamber is cleaned periodically with solvent and up to 1 L of coating is collected by a licensed contractor.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The release of the notified polymer during manufacture and dilution to the end use product is expected to be minimal as the process is automated. Any spills during manufacture and storage will be contained by plant bunding and collected by adsorbing onto an inert material. This material will then be sent to landfill by a licensed waste contractor. These losses are expected to be less than 0.5% (5 kg) of the manufactured polymer.

It is estimated that <1% of the import volume, up to 10 kg/annum, will remain as residue in the containers to be disposed to landfill with the drums.

At the completion of each production cycle, the uncleaned floor pot is moved to the cleaning area, where it is washed with recycled solvent. The washings are drained from the pot and sent to a solvent recovery facility where the solvent is recovered and the residue containing the notified polymer will be sealed in 200 L closed head drums and sent off site for incineration. Equipment washings is expected to account for <1%, up to 10 kg/annum of the import volume.

RELEASE OF CHEMICAL FROM USE

The application of the coating to timber will occur in sealed chamber using a vacuum coater. Waste generated during this process is expected to be minimal. If cleaning is required, for example if there is a product changeover, the small amount of waste generated (<1 kg) will be sent to a licensed waste contractor as solvent washings. The frequency of equipment cleaning cannot be estimated.

5.5. Disposal

The majority of the notified polymer will be disposed of to landfill at the end of its useful life either as sanding dust from timber floors or adhering to the boards themselves. A small amount (<21 kg) may be incinerated as drum residues or residues from cleaning of reformulation or application equipment.

5.6. Public exposure

The notified polymer will only be used in industrial processes and will not be available to the public except in the form of a timber coating in which the notified polymer will be fixed and not biologically available. Some potential exposure may occur in the event of a transport accident.

6. PHYSICAL AND CHEMICAL PROPERTIES

Test reports for physico-chemical properties are for the notified polymer, except for the water solubility and partition coefficient which were provided for a closely related analogue.

Appearance at 20°C and 101.3 kPa Slightly yellow liquid.

Melting Point/Freezing Point -13°C

Remarks No test report provided.

Boiling Point Not determined.

Density 1150 kg/m³ at 23°C; 1100 kg/m³ at 75°C

Remarks No test report provided.

Vapour Pressure 0.0074 kPa @ 100°C

Remarks No test report provided.

Water Solubility 99 g/L at pH 1 20°C

60 g/L at pH 7 20°C 61 g/L at pH 10 20°C

METHOD OECD TG 105 Water Solubility.

EC Directive 92/69/EEC A.6 Water Solubility.

Remarks Flask Method.

The test data was provided for a closely related analogue of the notified polymer. However, the analogue polymer has a significantly lower number average molecular weight than the notified polymer.

Pre-tests were conducted at three pH values (1, 7 and 10), ~30 mg of the test material was added to 100 mL of solutions. Undissolved material was observed in all tests vessel after two hours stirring at 23°C, suggesting a water solubility <0.3 g/L at all three pH values. Definitive tests were conducted at two loading levels, 211-260 mg and 15 g, in 75 and 10 mL of the solutions, respectively, at the three pH values and stirred for up to 72 h at 23°C before conditioning at 20°C for 24 h. Samples were filtered and extracted with dichloromethane prior to analysis. Results for the lower loading rates for the pH values of 1, 7 and 9 were 1.1, 1.2 and 0.4 g/L, respectively. The higher loading rates are presented above because the saturation limit had not been reached in the lower loadings.

GPC analysis of the water soluble fractions indicated that they consisted of the lower molecular weight fraction of the polymer. Less than 10% of the notified polymer is in the weight range that was found to be soluble for the analogue polymer. Hence the solubility of the notified polymer is expected to be significantly lower than the analogue.

The structure of the notified polymer would suggest a low water solubility.

TEST FACILITY BASF (2002)

Hydrolysis as a Function of pH Not determined

Remarks The notified polymer contains functional groups which are capable of undergoing

hydrolysis. However, this is not likely to occur under the environmental pH range

(4-9) due to the expected low water solubility.

Partition Coefficient (n-octanol/water) log Pow < 0.3-5.6.at 23°C

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).

EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks HPLC Method/Flask Method

The test data was provided for a closely related analogue of the notified polymer. However, the analogue polymer has a significantly lower number average molecular weight than the notified polymer.

The test was conducted twice with two lots of standards covering two different ranges of log Kow. The peaks of the test substance show a wide distribution in the chromatograms. Therefore a range of partition coefficients has been determined for the test substance. Similarly the notified polymer would be expected to display

a range of partition coefficients, but more the higher end.

TEST FACILITY BASF (2002)

Adsorption/Desorption

Not determined

Remarks From its structure the majority of the notified polymer is expected to bind to soils

and sediments. However, the water solubility and lower partition coefficients of some of the lower molecular weight fractions of the polymer may potentially be

less tightly bound.

Dissociation Constant

Not determined.

Remarks The notified polymer potentially cationic and would be expected to become

protonated at the lower end of the environmental pH range (4-9). This is reflected

by the increase in water solubility under low pH conditions.

Particle Size

Not determined.

Remarks Not relevant for a liquid.

Flash Point 133°C

METHOD DIN EN 22719

Remarks None.

TEST FACILITY BASF (2002)

Flammability Limits Not determined.

Autoignition Temperature

~ 400 °C

Remarks No test report provided.

Explosive Properties

Not determined.

Reactivity

Can polymerise if the shelf life or storage temperature are greatly exceeded. Reacts with peroxides and other radical components. The imported product contains stabilisers

against spontaneous polymerisation.

7. TOXICOLOGICAL INVESTIGATIONS

An acute oral toxicity study with a close analogue was submitted together with eye and skin irritation studies for the notified polymer.

Endpoint and Result	Assessment Conclusion
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating

7.1. Acute toxicity - oral

TEST SUBSTANCE Analogue.

METHOD OECD TG 423 Acute Oral Toxicity - Acute Toxic Class Method.

EC Directive 96/54/EC B.1tris Acute Oral Toxicity - Acute Toxic Class

Method.

US EPA Health Effects Test Guidelines OPPTS 870.1100 Acute Oral

and diarrhea from hour 4 up to and including hour 5 after administration.

Toxicity. August 1998.

Species/Strain Rat/Wistar Vehicle Olive oil.

Remarks - Method No protocol deviations.

RESULTS

Group	Number and Sex	Dose	Mortality
	of Animals	mg/kg bw	
1	3 females	2000	0
2	3 females	2000	0
LD50	> 2000 mg/kg bw		
Signs of Toxicity	None for group 1.	Group 2 exhibited impair	red general state, dyspno

Effects in Organs Remarks - Results

CONCLUSION

The notified chemical is of low toxicity via the oral route.

Experimental Toxicology and Ecology (2003). **TEST FACILITY**

None.

Irritation - skin

TEST SUBSTANCE Notified chemical.

Метнор OECD TG 404 Acute Dermal Irritation/Corrosion.

EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

US EPA Health Effects Test Guidelines OPPTS 870.2500 Acute Dermal

Irritation, August 1998.

No protocol deviations.

Species/Strain Rabbit/New Zealand White

Number of Animals Vehicle None. Observation Period 72 hours. Type of Dressing Semi-occlusive. Remarks - Method

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	0.33	0.67	0.33	1	48 hrs	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 None.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY Experimental Toxicology and Ecology (2001a).

7.3. Irritation – eye

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

US EPA Health Effects Test Guidelines OPPTS 870.2400 Acute Eye

Irritation, August 1998.

Species/Strain Rabbit/New Zealand White

Number of Animals 3 Observation Period 7 days.

Remarks - Method No protocol deviations.

RESULTS

Lesion	Mean Score*		Maximum	Maximum	Maximum Value at End	
	Ai	nimal N	Vo.	Value	Duration of Any	of Observation Period
					Effect	
	1	2	3			
Conjunctiva: redness	1	1.33	1.67	2	72 hours	0
Conjunctiva: chemosis	1.33	0.33	0.33	3	48 hours	0
Conjunctiva: discharge	1	0	0.33	3	48 hours	0
Corneal opacity	0	0	0	0		
Iridial inflammation	0	0	0	0		

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

Remarks - Results None.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Experimental Toxicology and Ecology (2001b).

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Waste from product formulation (<15 kg per annum) will end up being disposed of to landfill as an inert solid by a licensed waste contractor. In landfill the polymer will be bound within a polymer matrix and is expected to remain immobile.

Washings from the cleaning of application equipment (up to <10 kg per annum) is expected to be incinerated.

The majority of the notified polymer will end up being applied to timber flooring as a coating. The polymer coating will react under UV radiation to form an inert cross-linked coating on the surface of the timber. It will remain on the timber until it is gradually worn down by human traffic, being slowly dispersed on shoes etc. At the end of its useful life it will either be removed by sanding (and presumably replaced by another coat of a similar product) or disposed of to landfill bound to the timber to which it has been applied. If removed by sanding, the coating containing the notified polymer will be broken up into solid particulate matter and most likely disposed to landfill or simply fall to the ground.

9.1.2. Environment – effects assessment

The notified polymer has a number average molecular weight below 1000 and therefore has the potential to cross biological membranes. The polymer is also potentially polycationic. Low molecular weight polycationic polymers have been shown to be very highly toxic to aquatic organisms (Boethling and Nabholz 1997).

9.1.3. Environment – risk characterisation

Waste polymer from formulation into coatings or residues in containers (either polymer transport drums or paint tins) will be disposed of to landfill as an inert solid where it is expected to be immobile or incinerated.

The majority of waste polymer generated during application (through spills and washing) will either be disposed of in landfill or incinerated. Incineration of the polymer would destroy the material with the production of water vapour, and oxides of carbon and nitrogen.

Although the notified polymer is potentially very highly toxic to aquatic organisms, the lack of exposure of the polymer to the aquatic compartment indicate that use of the polymer as proposed is unlikely to have an adverse effect on aquatic organisms.

The majority of the notified polymer will be applied to timber flooring and either share the fate of the timber at the end of its useful life (most likely to landfill) or be removed by sanding. If removed by sanding the coating containing the notified polymer will be broken up into solid particulate matter and most likely disposed to landfill where it will be immobile.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

During formulation and drum filling of the coating to be applied and cured on to timber, containment is used during transfer and mixing stages so that the mainly dermal exposure is mitigated. Any residual likelihood of exposure is further reduced by the use of adequate PPE.

The 20 kg pails resulting from reformulation are transported to a single customer and applied to timber in a contained vacuum coater. Again the residual low exposure from use of this equipment is controlled by PPE and the reduced concentration of the notified polymer (10%) in the coating. Once irradiated the notified polymer on the coated wood product is no longer bioavailable.

9.2.2. Public health – exposure assessment

Exposure of the public may be possible in the event of a transport accident. Other than this the public will only be exposed to the notified polymer as part of a cured coating on timber.

9.2.3. Human health – effects assessment

An analogue of the notified polymer was of low acute oral toxicity in rats. The notified polymer was a slight skin and eye irritant in rabbits.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

9.2.4. Occupational health and safety – risk characterisation

Given the low vapour pressure of the notified polymer, inhalation exposure is unlikely during formulation of the timber coating containing the notified polymer. In addition, local exhaust ventilation is used in cases where general ventilation is inadequate. Some limited dermal and possibly ocular exposure may be possible during transfer of the notified chemical to the mixing vessel and during cleaning and maintenance of equipment. During application of the coating, the system is enclosed. Minor dermal exposure to the notified polymer may occur during transfer operations and this is controlled by the use of PPE. Limited toxicological data suggest the notified polymer is not acutely toxic and is at most a mild skin or eye irritant. The molecular weight the notified chemical should limit absorption and there are no residual monomers in sufficient concentration to render the notified chemical a hazardous substance according to the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC, 2002). Therefore, the risk of adverse health effects during transport, storage, use or disposal of the notified polymer is considered to be low.

9.2.5. Public health – risk characterisation

The public is unlikely to come into contact with the notified polymer in an uncured state except in the event of a transport accident and the risk to public health is therefore negligible

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC, 2002).

and

As a comparison only, the notified polymer also is not classified 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.

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. 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:
 - Avoid contact with eyes and skin
- 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 the timber coating formulated from the notified chemical:
 - Impervious gloves and safety glasses
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified chemical:
 - Do not allow material or contaminated packaging to enter drains, sewers or water courses.

Disposal

 Wastes generated during industrial application should be disposed of through a licensed waste contractor.

Emergency procedures

• Spills/release of the notified chemical should be handled by absorbing onto an inert material, scooping up and placing in marked containers for disposal.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

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