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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Hardener LO

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Vantico Pty Ltd
235 Settlement Road
ThomastownVictoria 3074

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
A variation to the schedule of the following data requirements is claimed:
Toxicological studies:
Acute toxicity (except skin sensitisation)
Genetic toxicity (Induction of point mutations and Induction of germ cell damage)
Fish, acute toxicity
Alga, Growth inhibition test
Biodegradation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Commercial Evaluation Permit: CEC 479 (Permit No 437, July 2000)

NOTIFICATION IN OTHER COUNTRIES

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Hardener LO

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Infrared (IR) spectroscopy
Remarks	A reference spectrum was supplied by the notifier

3. COMPOSITION

DEGREE OF PURITY
≥97 %

HAZARDOUS IMPURITIES
None

NON HAZARDOUS IMPURITIES (>1% by weight)
Three major impurities are typically less than 0.4% each (impurities of Hardener LO):
2-thioethylethanol
2-chloroethoxyethanol
cyclic analogue of notified chemical

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported in a ready-to-use form for the retail market and industry. If these products are successful, the notifier may import the notified chemical to locally manufacture the Adduct JW2184 (which contains 12% notified chemical).

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

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

USE
The notified chemical will be used as a component in a mix of hardeners, which will be used in various adhesive systems. The contents of a tube of resin and a tube of hardener are squeezed out and mixed manually using an implement such as an ice cream stick. When the hardener is mixed 1:1 with the resin, the level of the notified chemical is 5-6%. The residual Hardener LO will react with the epoxy resin upon mixing, hence will become chemically bound into the cured polymer matrix.

The adhesives may be applied either by manual mixing and spreading or by the use of automatic mixing/metering equipment.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not provided

IDENTITY OF MANUFACTURER/RECIPIENTS
Vantico Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be imported initially in finished products, in 'toothpaste tube" packs consisting of a resin and a tube of hardener. The products will be imported by ship, and transported by road to the notifier's distribution warehouse. From there it will be sent to retail distribution warehouses and retail stores by road transport.

The Hardener products will be supplied in 4 cm^3 aluminium tubes, 50 cm^3 syringe packs and 200 cm^3 cartridges. The adhesives may also be packaged in large pack sizes ie, 1 kg/5kg/20 kg packs.

5.2. Operation Description

Manufacturing
The notifier does not propose manufacture of the notified chemical in Australia. The chemical will be imported in ready-to-use hardeners containing up to 12% notified chemical for the retail market and possibly industrial customers. If these products are successful, the notified chemical may be imported for manufacture of hardeners in Australia. If such a process were to be used the following information would apply:

The notified chemical would be reacted with other monomers to produce the adduct, Adduct JW 2184, which would subsequently be blended with other ingredients including extenders, fillers, pigments and coupling agents to formulate hardeners. The notified polymer (adduct) containing Hardener LO would be transferred from the import drum to the mixing vessel by a metered pump. A typical batch of Hardener would be 500-1000 kg containing 12% un-reacted notified chemical. The formulated hardeners will be automatically dispensed into 200 L drums for industrial customers or smaller amounts for the retail market.

End Use
The hardeners containing the notified chemical will be used in adhesives systems designed for use on wood, ceramic and glass surfaces. The two components of the adhesive system, the hardener and the epoxy resin, would be mixed 50:50, manually in the case of the Do-It Yourself (DIY) user or perhaps mechanically in the case of the industrial user. Once mixed, the adhesives have short pot-lives of 5-10 minutes as the two components react very quickly. They will be applied manually to the surface to be adhered using a brush, roller or notched spreader. After two to three hours the adhesive film will have dried. Complete curing may take up to 24 hours. Application to marine structures such as boats will be done in dry dock rather than on submerged surfaces.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Dockside and transportation	5-10	1-10 hours/day	20 days/year
Warehousing	15-30	2 hours/day	75 days/year
Manufacturing operators	6-10	8 hours/day	8-16 days/year
Packaging operators	2-4		
Warehouse staff	6-8	2 hours/day	75 days/year
Transportation	5	1-10 hours/day	20 days/year
End users	Large number	6-8 hours/day	300 days/year

Exposure Details
During formulation operations, skin contamination may occur while mixing/blending the ingredients in the mixing vessel, decanting into containers and cleaning up spills and equipment. However, the formulation plant uses a closed process system, where the mixing vessels are closed and fitted with local exhaust ventilation. In addition, the decanting, transfer and cleaning operations are to be carried out in well-ventilated areas. Workers will wear personal protective equipment during decanting, transfer and cleaning operations (chemical goggles/face shields, impermeable gloves and protective overalls). Organic vapour respirators will also be worn if the ventilation is not adequate.

Worker exposure during transport and storage will be limited to accidental spillage

During end-use, the adhesive product is expected to be frequently used (industrial users). Workers may mix and apply the adhesive by hand or, in the case of large operations, by use of automatic mixers and metering equipment. Workers will wear chemical goggles/faceshield, impermeable gloves and protective overalls.

Home handy persons may also use the product containing notified chemical. Exposure is

expected to be similar, but on a smaller scale, to that expected in industrial situations and the level of protection worn is likely to be less stringent.

Domestic and building site waste is commonly collected. Dermal exposure to the notified chemical may occur, but at this point, the adhesive mix should be cured and hence exposure to the notified chemical is not bio-available.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Assuming the hardeners are formulated in Australia, the following information is provided:

- Release of the notified chemical during manufacture of the hardeners through accidental spills/leaks, cleaning of plant equipment and as residue on empty import drums is likely to be small. The manufacturing/formulation site is fully bounded and spillages would be collected in the holding pit under the factory. The notifier estimates that 0.1% of each batch of hardener may be spilt resulting in the release of 10 kg of the notified chemical per annum. This estimate is conservative and may be as high as 1%. Spilt material will be contained and collected using an inert material such as sand or vermiculite.

- The plant equipment will be cleaned out using a solvent, Eposolve 70. The notifier estimates that 0.5% hardener per batch will be generated as waste in this way. This equates to a release of 50 kg of notified chemical per annum. The solvent waste will be collected and sent for off-site for recycling.

- The notifier estimates that up to 0.5% residual chemical will remain in the empty import drums. This equates to 50 kg per annum. Empty drums will be collected by a licensed waste contractor and sent off-site for disposal.

RELEASE OF CHEMICAL FROM USE

There are two potential release points for the chemical during use of the adhesive systems. First, residual adhesive mix containing about 6% hardener (50:50 mix) could result in the release of up to 250 kg of notified chemical per annum. The adhesive mix will be allowed to cure and solidify before disposal. Second, 3-10 kg of notified chemical per annum may remain in the hardener residue in empty containers. Further release may result from the disposal of old unmixed partially used containers. Most of this waste would end up in landfill.

5.5. Disposal

Empty containers of hardeners and unused adhesive mix will be disposed to landfill.

If the hardeners are to be manufactured in Australia the following would apply:

- The empty import drums will be collected by a licensed waste contractor and disposed of according to local, state and federal regulations.

- Cleaning solvent waste containing the chemical will be collected in 200 L drums and taken by a licensed solvent recycling contractor for distillation. The notifier indicates that residual sludge is incinerated to a granular material that is disposed of by landfill.

- Waste hardener will either be disposed of by incineration or by reaction in the correct stoichiometric ratio with epoxy resin to form a cured inert polymer that can be disposed of by landfill.

5.6. Public exposure

The public may be exposed to the notified chemical in the unlikely event of an accidental spill during transport, but the packaging in small quantities should prevent widespread exposure.

The public will be exposed to the notified chemical in DIY hardener products containing up to approximately 12% free Hardener LO, when mixing the hardener and resin. The labelling information indicates that suitable gloves and eye/face protection should be worn when using the hardener. Provided the public follows the recommended directions for use of the hardeners, exposure to the notified chemical will be low. Once mixed with the epoxy resin, the residual hardener LO will very quickly react with the resin (5-10 min) and then chemically bind into the cured polymer matrix. Hence, the potential for public exposure thereafter is negligible.

The public is unlikely to contact the notified chemical as an environmental contaminant since residual hardener in the import containers (tubes, syringes, cartridges) will be disposed of to landfill. It is expected that the majority of the notified chemical in the adhesive mix will be allowed to cure and solidify and then be disposed of to landfill. No Hardener LO or formulated hardener containing it will be released to sewer or aquatic environments.

6. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa Slightly yellow, viscous liquid

BOILING POINT 225°C
Remarks No test reports were supplied by the notifier.

DENSITY 1140 kg/mL at 25°C
Remarks Data sourced from the Material Safety Data Sheet (MSDS). No test reports were supplied by the notifier.

VAPOUR PRESSURE 6.4×10^{-5} kPa at 20°C
Remarks Data sourced from MSDS. The notified chemical would be classified as non-volatile (Mensink et al. 1995).

WATER SOLUBILITY 15-20 g/L at 20°C
Remarks Data sourced from MSDS

HYDROLYSIS AS A FUNCTION OF PH
Remarks Not determined. The notified chemical does not contain any functional groups that are likely to participate in hydrolysis reactions.

PARTITION COEFFICIENT (n-octanol/water) $\log P_{OW} = 1.31 \pm 0.41$
Remarks This was estimated using ACD software. Given its high water solubility the notified chemical would be expected to partition into the water compartment.

ADSORPTION/DESORPTION $\log K_{oc}$ of 2.09
Remarks A Koc of 124, was calculated using ACD software. Given the calculated adsorption coefficient and the high water solubility, the notified chemical is not expected to adsorb strongly to organic matter and is likely to be highly mobile in soils and sediments (McCall et al., 1980).

DISSOCIATION CONSTANT
Remarks Not determined. The notified chemical is not likely to dissociate under environmental conditions, pH 4-9, as the pKa for this class of chemicals is in the range 9-11.

PARTICLE SIZE
Remarks Not applicable as the notified chemical is a liquid

FLASH POINT >129°C (closed cup)
Remarks Data sourced from MSDS. No test reports were supplied by the notifier.

FLAMMABILITY LIMITS Not determined

Remarks The notified chemical is not flammable. However, it is combustible.

AUTOIGNITION TEMPERATURE
Remarks Not provided

EXPLOSIVE PROPERTIES
Remarks Not expected to be explosive, based on structure. However, the notified chemical will support combustion and produce carbon monoxide, aldehydes, nitrogen oxides and compounds

REACTIVITY
Remarks Stable under normal environmental conditions. Upon heat, liberates toxic and flammable decomposition products

7. TOXICOLOGICAL INVESTIGATIONS

The notifier did not submit toxicology studies on the acute systemic toxicity and skin and eye irritation potential of Hardener LO. Data on analogous mono- and dithio compounds were provided from published literature.

The notifier submitted a repeat dose toxicity study on 1,8-octanedithiol, which has a similar structure to the notified chemical and has a molecular weight of 98.2.

7.1. Acute toxicity – oral, dermal and inhalation

The LD_{50} for analogous mono- and dithio compounds were provided from published literature as follows:

Chemical	Acute oral LD_{50}	Acute dermal LD_{50}	Acute inhalation LC_{50}	Reference
n-Hexyl mercaptan	Rat: 1254 mg/kg	Rat: >2000mg/kg	Rat 4-hr: 1080 ppm Mouse 4-hr: 528 ppm	Shertzer 2001
n-Octyl mercaptan	Rat: 2000 mg/kg	Rat and rabbit: >2000 mg/kg	Rat 4-hr: >508 ppm	Shertzer 2001
n-Decyl mercaptan	Rat: 2300 mg/kg	Rat and rabbit: >2000 mg/kg	No data	Shertzer 2001
1-Dodecyl mercaptan	Rat: >5000 mg/kg Mouse: 4225 mg/kg	Rat LD_{50} >2000 mg/kg	No data	Shertzer 2001
1,8-octanedithiol	Mouse: 988 mg/kg Mouse: 882-1262 mg/kg	No data	No data	Schafer and Bowles 1985 Moran and Easterday, 1980

A preliminary study was conducted on female mice in order to find the maximum tolerated dose to use in the micronucles test (refer to Section 7.6). The study demonstrated that at 600 mg/kg bw/day (maximum dose tested) all mice exhibited subdued behaviour, partial eye closure and tremors.

The MSDS for Hardener LO stated that the oral LD_{50} in rats is 835 mg/kg and the inhalation (aerosol) LC_{50} in rats is 1.34 mg/L (179 ppm)/4 hr (source of this information was not provided).

Based on the above, the notified chemical is expected to have an acute oral LD_{50} of >600 mg/kg and is probably similar to that of 1,8-octanedithiol. The acute dermal LD_{50} is expected to be >2000 mg/kg/day. The inhalation LC_{50} in rats is 1.34 mg/L/4hr (aerosols).

In conclusion the notified chemical is expected to be harmful via the oral route and by inhalation, and is of low toxicity via the dermal route.

7.2. Irritation – eye and skin

The following published results were provided on similar chemicals to the notified chemical:

Chemical	Skin irritation	Eye Irritation	Reference
n-Hexyl mercaptan	Moderate erythema which resolved at 24 hours	Eye irritation seen at the high dose levels	Shertzer 2001
n-Octyl mercaptan	Rabbit: slight irritant	Rabbit: moderate to slight irritant	Shertzer 2001
n-Decyl mercaptan	Not irritating	Corrosive: caused conjungtival corneal, irideal damage that did not reverse after 7-days	Shertzer 2001
1-Dodecyl mercaptan	Not irritating	Severe irritant	Shertzer 2001
1,8-octanedithiol	Mouse: 988 mg/kg	No data	Schafer and Bowles 1985

From the results above, it can be deduced that the notified chemical is expected to be a mild skin irritant. The potential for eye irritation appears to be highly variable. The high molecular weight compounds, such as the C10 and C12 mono-thio compounds, cause severe irritation/corrosion, whereas, the C8 compound is a slight to moderate eye irritant. The notified chemical being more closely related to the C8 compound, is expected to be a moderate eye irritant.

In conclusion, the notified chemical is expected to be slightly irritating to skin, and irritating to the eye.

7.3. Skin sensitisation – Maximisation test

TEST SUBSTANCE Hardener LO

METHOD

Study Design OECD 406 Skin Sensitisation – Magnusson and Kligman Maximisation Study:
Induction test
Day 1: intradermal injection of Freud's complete adjuvant mixed with the test substance or the vehicle.

Day 8: topical induction: same site received a cutaneous application of the test substance (treated group) or the vehicle (control group) and covered by an occlusive dressing for 48 hours.

Challenge test
Day 22: all animals of treated and control groups were challenged by a cutaneous application and covered by an occlusive dressing for 24 hours.

Study Group 30 guinea pigs:

Control group (five males and five females)
Treated group (ten males and ten females)

Vehicle Paraffin oil

Induction Procedure	Day 1: Intradermal injections: 1-FCA[1] diluted at 50% with 0.9% NaCl (treated and control group) 2-Notified chemical at 5% in paraffin oil (treated group) Vehicle (control group) 3-Notified chemical at 5% in a mixture FCA/0.9% NaCl 50/50 (treated group) Vehicle at 50% in a mixture FCA/0.9% NaCl 50/50 (control group) Day 8: Cutaneous route: Occlusive dressing applied for 48 hours- Control received vehicle Treated group received undiluted notified chemical
Rest Period	12 days
Challenge Procedure	Topical application: Both groups received notified chemical at 10% in paraffin oil to the right flank and vehicle was applied to the left flank. Occlusive dressing was applied for 24 hours.
Remarks - Method	Scoring was performed 24 and 48 hours after removal of the dressing of the challenge application Positive sensitisers: *Induction period* DNCB at 0.1% (day 1) and 1% (day 8) Mercaptobenzothiazole at 1% (day 1) and 20% (day 8) *Challenge period* DNCB at 1% Mercaptobenzothiazole at 20%

RESULTS

Remarks - Results	No clinical signs and no deaths were noted in any of the groups. On day 10 after the cutaneous application of the induction period, signs of irritation were observed in the control group only and signs of necrosis were observed in the treated group. Scores of skin reactions after challenge application of 10% notified chemical were reported to be zero. Therefore, no cutaneous reactions were observed after the challenge application DNCB at 1% and Mercaptobenzothiazole at 20% (positive sensitisers) induced positive skin sensitisation reaction in 90% and 30% of the tested animals, respectively.
CONCLUSION	The notified chemical was not a skin sensitiser under the conditions of the test.
TEST FACILITY	Centre International de Toxicologie, 1998

7.4. Repeat dose toxicity - 90-day feeding study in rats

TEST SUBSTANCE	Analogue chemical/1,8-octanedithiol
METHOD	The study, performed in 1974, predates development of guidelines for studies for regulatory purposes. The study design was similar to OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.

[1] FCA Freud's complete adjuvant

Species/Strain	Rat/Wistar (30 male and 30 female rats)
Route of Administration	Oral –diet
Exposure Information	Total exposure days: 90 days; Dose regimen: 7 days per week; daily intake of 0.752 mg/kg bw Post-exposure observation period: None
Vehicle	Mixed in diet, with test material prepared as a solution in acetone
Remarks - Method	The study predates GLP guidelines. In each group, 16 animals (8 males and 8 females) were sacrificed during the 6th and 12th weeks of the study; haematology, blood chemistry, and urine analysis were performed. The remaining 7 animals were sacrificed on day 91 and were examined for histopathological changes. Reason for using such a low dose of 1,8-octanedithiol is because it was tested for its use as a flavouring in food.

RESULTS

Group	*Number and Sex of Animals*	*Dietary level mg/kg/day*	*Mortality*
Control	15 male	0	0/15
Treated	15 male	0.752	0/15
Control	15 female	0	0/15
Treated	15 female	0.752	0/15

Clinical Observations

The level of the test substance fed had no significant effect on body weight and food consumption.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

The haematological, biochemical and urinary findings were not significantly different from controls.

Effects in Organs

The gross and microscopic findings in the treated group were variable and were seen in the control animals. Vacuolation of liver cells was not regarded to have any pathologic significance. The cause of death of one test animal was not determined.

Remarks – Results

The study did not show treatment-related effects at a dosage feeding level of approximately 0.705 mg/kg bw/day.

CONCLUSION

The No Observed Effect Level (NOEL) was established at 0.7 mg/kg bw/day in this study, based on lack of treatment related effects at this level.

TEST FACILITY Food and Drug Research Laboratories, Inc (1974)

7.5. Genotoxicity – in vitro

There are no data on the notified chemical. N-Butyl mercaptan, tert-butyl mercaptan and 1-dodecylmercaptan have been tested in the Salmonella typhimurium reverse mutation assay and were found to be devoid of gene mutation potential (Shertzer, 2001). N-Butylmercaptan and tert-butyl mercapatan were mutagenic in the mouse lymphoma forward mutation assay, while 1-dodecyl mercaptan was not mutagenic in this assay (Shertzer, 2001).

7.6. Genotoxicity – in vivo

TEST SUBSTANCE Notified chemical

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Two experiments were conducted as the first one did no show clinical signs of toxicity.

Species/Strain Specific pathogen free female mice

Route of Administration Oral – gavage

Vehicle Water

Remarks – Method Water was used as negative vehicle control
9,10-Dimethyl benz[a]anthracene (DMBA) was used as the positive control (sacrificed at 48 hours) in Expt 1.

For Expt 2, a preliminary study was performed in 3 groups of 2 mice at doses of 600, 400 and 300 mg notified chemical/kg. The dose of 400 mg/kg bw was selected for the test as animals exhibited signs of toxicity (hyperactive behaviour and partial eye closure).

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time Hours**	*PCE/NCE ratio %*	
				24 hrs	*48 hrs*
Expt 1					
Control	10	0	24, 48	55.5	53.3
Low dose	10	10	24, 48	59.4	56.4
Medium dose	10	40	24, 48	57.4	50.7
High dose	10	80	24, 48	53.2	53.8
Expt 2					
Control	10	0	24, 48	55.7	58.0
Dose	10	400	24, 48	51.5	48.7

* groups of 5 mice were sacrificed at each time point

RESULTS

Doses Producing Toxicity Expt 1: no statistically significant depression of polychromatic erythrocytes (PCE) and normochromatic erythrocytes (NCE) ratio was seen in test-sample-treated groups Low dose.

Expt 2: index of toxicity was seen at 400 mg/kg bw. There was a significant depression of PCE/NCE ratio in the treated group.

Genotoxic Effects No significant increases in the frequency of micronucleated polychromatic erythrocytes (MPCE) in the any of treated groups (Expt 1 and 2).

Remarks - Results Expt 1: No significant weight loss was observed in all test-sample-treated groups during the 24 to 48 hour observation period. No clinical abnormalities was observed throughout the observation period.

Mice treated with DMBA (positive control) produced a statistically significant weight loss, depression of the PCE/NCE ratio at 48 hours and a statistically significant increase in the frequency of MPCE.

Expt 2: Treated mice showed a statistically significant weight loss after 24 and 48 hours. Some treated animals showed clinical signs of abnormality (one treated mouse was dead after 48 hrs).

CONCLUSION The test substance was not clastogenic in this in vivo cytogenicity assay under the conditions of the test.

TEST FACILITY ICP Firefly Pty Ltd, 2001

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were provided. The data provided was for a compound that is not structurally similar enough to indicate particular relevance for the environmental fate of the notified chemical. The MSDS refers to a test carried out according to OECD TG 301A but the notifier was unable to obtain the full test report so the validity of the test cannot be confirmed.

8.1.1. Ready biodegradability

TEST SUBSTANCE Hardener LO

METHOD OECD TG 301 A Ready Biodegradability: DOC Die-Away Test.

RESULTS

Test substance	
Day	*% degradation*
28	< 10%

Remarks – Results

CONCLUSION The notified chemical would be classified as not readily biodegradable.

TEST FACILITY Sourced from the MSDS.

8.1.2. Bioaccumulation

No bioaccumulation data were provided for the notified chemical. The notifier has provided information on the bioaccumulation of a similar compound, however, it is not structurally similar enough to the notified chemical to be relevant. The low molecular weight indicates that the notified chemical has the potential to bioaccumulate. However, bioaccumulation is not expected to occur due to the moderate water solubility and low aqueous exposure of the notified chemical (Connell, 1990).

8.2. Environmental Effects

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Hardener LO
METHOD	Similar to OECD TG 203 Fish, Acute Toxicity Test – static, pH 6.9-7.4
Species	*Gambusia holbrooki*, mosquito fish
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not determined
Analytical Monitoring	None
Remarks – Method	The fish were only acclimated for a period of 48 hours rather than the 12 days recommended in OECD TG 203. Fish imbalance was examined as the end point rather than mortality. There is no indication of mortality in either the test solutions or solutions containing the reference toxicant, phenol. It is noted that glass tanks were used in the test and it is possible that the chemical adhered to the surface of the tanks, though this should be minimal given the high solubility.
RESULTS	
Remarks – Results	The results of the fish toxicity test are not included in this report because provided data were hard to verify without reference to the raw data. For example, 13% imbalance was detected in the control solutions indicating that 2 fish showed some effect (faecal matter was observed in the beakers so ammonia was suspected). Since it was not defined, it is not clear from the report how imbalance was scored to achieve this figure. No effect was observed over the concentration range of the chemical used in the test (0.5-20 mg/L) except for imbalance observed in 1 fish at 0.5 and 1.5 mg/L. Imbalance was seen in the positive control using phenol and the estimated EC50 of 33 mg/L is said to be within the range (25-56 mg/L) seen in the testing laboratory for the more usual test species, the eastern rainbowfish *Melanotaenia duboulayi*. According to OECD TG 203 a >10% response in the controls invalidates the test and therefore the conclusion of an EC50 of >20 mg/L should be treated with considerable caution. The notified chemical in the test solutions was not measured analytically therefore it is not possible to conclude with certainty that the chemical is not toxic to fish.
TEST FACILITY	Ecotoxicology Unit, Department of Environmental Sciences, University of Technology (2001)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Hardener LO
METHOD	EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – static, pH 7.9-8.2
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Analytical Monitoring	Yes
Remarks - Method	
RESULTS	The actual concentrations of the notified chemical in the test solutions used showed less than 20% variation from the nominal concentrations.

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h [acute]*	*48 h [acute]*
0	0	20	0	0
0.1		20	0	0
0.2		20	1	2
0.4		20	2	13
0.8		20	3	17
1.6		20	6	15
3.1		20	1	13
6.25		20	3	11
12.5	9.9	20	7	18
25	17.4	20	7	19
50	43.7	20	14	20
100	87.2	20	17	20

LC50 25 mg/L at 24 hours (CI 2.3-60 mg/L)
1.7 mg/L at 48 hours (CI 0.15-2.8 mg/L)

Remarks - Results Calculation of the 24 and 48 hour EC50 was performed using Probit analysis. Nominal concentrations were used in the calculation of these values. No effect was observed at a concentration of 0.1 mg/L. There was no immobilisation in the control group during the period of the test. The reference substance, potassium dichromate, gave an EC50 at 48 hours of 0.85 mg/L.

CONCLUSION The notified chemical would be classified as moderately toxic to daphnids (Mensink et al. 1995).

TEST FACILITY Elf Atochem S.A. (1997)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Hardener LO

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species *Pseudokirchineriella subcapitata*
Exposure Period 72 hours
Concentration Range Nominal 0-20 mg/L
Concentration Range Actual Not determined.
Auxiliary Solvent None
Analytical Monitoring
Remarks – Method

RESULTS

Biomass	
EC50	*No-observed-effect-concentration*
mg/L at72 h	*mg/L*
0.7	0.5

Remarks – Results The biomass of the algae was affected by the presence of the test substance over the exposure period. Nominal concentrations of the notified chemical in test solutions were used in the calculation of EC50 values.

ONCLUSION	The notified chemical would be classified as highly toxic to algae (Mensink et al. 1995).
TEST FACILITY	CSIRO Centre for Advanced Analytical Chemistry (2001)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

It is expected that minimal exposure to the environment is likely to occur during the use of imported ready-to-use hardeners containing the notified chemical. Up to 300 kg per annum of the notified chemical could be disposed of to landfill, including as residues in empty containers of hardener. Most of this waste would be cured adhesive in which case the chemical will be incorporated into the inert matrix of the epoxy resin and unavailable to the environment. If the containers are destroyed in landfill the notified chemical could leach into the water compartment dues to its high solubility.

At the end of their useful lives articles adhered with the adhesive (and cured through the agency of the hardeners containing the notified chemical) would be disposed of to landfill.

If the notifier chooses to use the chemical to manufacture the hardeners in Australia, rather than import them in a ready-to-use form, there is potential for increased environmental exposure. In this case an additional release of up to 200 kg per annum may occur. A proportion of this waste would be incinerated, destroying the chemical and generating water and oxides of sulfur and carbon. The remainder would be disposed to landfill where it may persist until it is slowly degraded through abiotic and biotic processes. In landfill the chemical could leach into the water compartment due to its moderate water solubility and predicted low Koc.

9.1.2. Environment – effects assessment

The ecotoxicological data provided by the notifier indicate that the chemical ranges from at worst slightly toxic to highly toxic to aquatic organisms. The most sensitive species were algae with a reported EC50 of 0.7 mg/L at 72 hours.

The validity of the fish test cannot be confirmed because the actual concentrations of the test substance in the solutions used was not measured and the control showed a more than 10 % response. Given that the chemical is moderately toxic to daphnia and highly toxic to algae, it seems unlikely that it would not be toxic to fish. While it is appreciated that there is unlikely to be any release of the chemical into the aquatic environment under the proposed use patterns, a reliable test result for toxicity to fish is a schedule requirement for a standard notification. This will be relevant if the notifier intends to use the chemical to manufacture the hardeners rather than import them in a ready-to-use form only.

9.1.3. Environment – risk characterisation

The notified chemical does not pose a significant hazard to the environment based on its reported use pattern because there will be very low environmental exposure. The majority of the chemical will be chemically bound into the cured polymeric matrix of the adhesives in which it is used once the hardeners and resins have been mixed and applied.

Chemical that may be released if the notifier finds that sales of the adhesive system justifies local manufacture of the hardeners should not be to the aquatic environment. A proportion of this waste may be disposed by landfill where the chemical may leach into the water compartment but not in quantities that pose a threat to aquatic organisms. The chemical should not bioaccumulate given its moderate water solubility and predicted low log Pow (Connell, 1990).

9.2. Human Health

9.2.1. Human health - effects assessment

SUMMARY OF TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Acute oral LD_{50}>600 mg/kg (835 mg/kg in rats)	Harmful *test not conducted*
Acute dermal LD_{50}>2000 mg/kg	Low toxicity *test not conducted*
Acute inhalation LC_{50} 1.34mg/L/4 hr (aerosols) in rats	Harmful *reported in the MSDS*
Skin irritation	Slightly irritating *test not conducted*
Eye irritation	Irritating to the eye *test not conducted*
Guinea pig, skin sensitisation	no evidence of skin sensitisation.
Genotoxicity – Mouse *in vivo* Micronucleus Assay	Non genotoxic

DISCUSSION

No results for the acute toxicity of the notified chemical were provided by the notifier. However, based on the acute toxicity of analogue chemicals, it can be concluded that the notified chemical is harmful by the oral route and inhalation, slightly irritating to skin, and irritating to the eye. Acute dermal toxicity is expected to be low.

The skin sensitisation test conducted using Hardener LO showed that it is not a skin sensitiser. However, the applicant indicated that prolonged exposure to imported products containing Hardener LO can cause allergic reactions and sensitisation.

A close analogue of the notified chemical was tested in a repeat dose feeding study in rats at a very low dose. No significant indications of toxicity were found. The NOEL was established at 0.7 mg/kg bw/day (dose used in the diet). An *in vivo* genotoxicity study (mouse micronucleus test) showed no indications of genotoxic effects of the notified chemical. Toxicity information on analogue chemicals reported that N-Butyl mercaptan, tert-butyl mercaptan and 1-dodecylmercaptan were negative in the Ames test. N-Butyl mercaptan and tert-butyl mercaptan were not mutagenic in the mouse lymphoma forward mutation assay, while 1-dodecyl mercaptan was not mutagenic in this assay.

HEALTH HAZARD CLASSIFICATION

Based on the available data the notified chemical is classified as hazardous under the National Occupational Health and Safety Commission's (NOHSC) *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). The classification and labelling details are:

R20/R22: Harmful by inhalation and if swallowed
R36/38: Irritating to eyes and skin

9.2.2. Human health – risk characterisation

OCCUPATIONAL HEALTH AND SAFETY

Dermal and ocular exposure can occur during certain formulation processes. However, given that exposure to significant amounts is limited because of the engineering controls and personal protective equipment worn by workers, the risk of adverse effects is low.

During end-use, hand/ocular contamination with the adhesive may occur (up to 12% notified chemical), particularly, when the adhesive product is mixed and applied by hand. Therefore, there is some risk of eye irritation, and perhaps slight skin irritation arising from contact with the notified chemical during this process. Inhalation exposure to the notified chemical is not expected as it is not volatile. In order to minimise the risk of adverse health effects, workers using the hardener products containing the notified chemical should wear personal protective equipment including overalls, gloves and face shield/goggles. Organic vapour respirators should be worn if the area is poorly ventilated.

After application and once dried, the adhesive containing the notified chemical is cured into an inert matrix of the epoxy resin and is hence unavailable to exposure. Therefore, the risk of adverse health effects to cured material is minimal.

During transport and storage, the health risk to workers is not considered significant given the physical form of the product and the packaging.

PUBLIC HEALTH

Indirect exposure of the public to the notified chemical during transport or through environmental release is assessed as low. There is potential for public exposure to the notified chemical in DIY hardener products since the hardeners containing the notified chemical will be used in adhesives systems designed for use on wood, ceramic and glass surfaces. The public will only come into contact with the hardeners containing up to approximately 12% free hardener LO. Since the working concentration is low, the public exposure to the notified chemical by inhalation is minimal. The notified chemical has low dermal toxicity. Therefore, provided the public follows the recommended directions for use of the hardeners, the risk to public health will not be significant. As the residual hardener LO very quickly reacts with the epoxy resin (5-10 min) when mixed with the resin and then chemically binds into the cured polymer matrix, the potential for public exposure thereafter is negligible. On this basis, it is expected that the risk of the notified chemical to public health will be low.

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

10.1 Environment

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

10.2 Human health – Occupational health and safety

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

10.3 Human health – public

There is Negligible Concern to public health when used according to the set conditions.

11. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical, Hardener LO, the Adduct JW 2184, and Hardeners HW 2934 and XD 4414 containing the notified chemical were provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a).

These MSDS were provided by the applicant as part of the notification statement. They are reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

12. LABEL

The label for the notified chemical, Hardener LO, the Adduct JW 2184, and Hardeners HW 2934 and XD 4414 containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

13. RECOMMENDATIONS

REGULATORY CONTROLS

- Use the following risk and safety phrases for the notified chemical:
  - R20/R22: Harmful by inhalation and if swallowed
  - R36/38: Irritating to eyes and skin
  - S36 Wear suitable protective clothing
  - S37 wear suitable gloves
  - S39 wear eye/face protection
  - S24 Avoid contact with skin
  - S25 Avoid contact with eyes

The risk phrases R20/22 and R36/38 should be used for products/mixtures containing ≥25 and ≥20%, respectively.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical during manufacture of the Adduct JW2184 and formulation of the hardener products:
  - Exhaust ventilation during formulation operations.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical and hardeners:
  - Prevent splashes and spills
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Chemical resistant gloves, protective overalls, and goggles/faceshield. Organic vapour respirator if ventilation is not adequate.

  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 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

Disposal

- The notified chemical should be disposed of by landfill or incinerated according to local regulations.

Emergency procedures

- Spills/release of the notified chemical should be handled by absorbing with inert material and collection into a sealed container for disposal.

Secondary notification

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

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.

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