File No: STD/1115

July 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Component B of HIT-RE 500

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Cytec Australia Holdings Pty. Ltd. (ABN: 45 081 148 629)
21 Solent Circuit
Norwest Business Park
Baulkham Hills NSW, 2153
and
Hilti (Aust) Pty Ltd (ABN: 44 007 602 100)
23 Egerton St
Silverwater NSW 2128

NOTIFICATION CATEGORY
Standard: Polymer with NAMW < 1000 (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical identity
Purity
Identity of impurities/adjuvants
Import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting Point
Boiling Point
Vapour Pressure
Hydrolysis as a function of pH
Adsorption/Desorption
Dissociation Constant
Flammability Limits
Autoignition temperature
Explosive Properties
Acute dermal toxicity
Acute Inhalation toxicity
Skin Irritation
Eye Irritation
Skin Sensitisation
Repeat dose Toxicity
Bioaccumulation
Inhibition of Microbial Activity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
NA/852 (withdrawn)
CEC/512 (January 2000 – January 2001)
CEC/558 (June 2002 – June 2004)

NOTIFICATION IN OTHER COUNTRIES
USA (1999)
Canada (2002)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
BECKOPOX VEH 2626 (contains 82-86% notified polymer*)
Component B of Hilti HIT-RE 500 (contains ~50% notified polymer*)
* These percentages treat the residual monomers as impurities and part of the notified polymer.

3. COMPOSITION

DEGREE OF PURITY
~50% (Based on residual monomer content)

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	1,3-benzenedimethanamine
CAS No.	1477-55-0 *Weight %* > 40%
Hazardous Properties	NOHSC exposure standard 0.1 mg/m^3 (peak limitation) with skin notation (HSIS, 2006).

See section 7 of the full public report for toxicity information.

Other impurities are confidential

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Importation as a component of Hilti HIT-RE 500, in ready-to-use containers.

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

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

USE
Epoxy hardener in adhesive mortar. The product is used as an adhesive to fasten threaded rods and sleeves, or rebar into concrete during construction.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Unknown

TRANSPORTATION AND PACKAGING
Notified polymer is imported as a component of Hilti HIT-RE 500, which is supplied in 330 or 500 mL foil packs or in 1100 mL or 1400 mL cartridges. These foil packs/cartridges contain two parts. Component B which contains the notified polymer is packed in the smaller part. The ratio of component A: component B is 3:1.

5.2. Operation description

The notified polymer is not manufactured in Australia.

The product containing the notified polymer is imported and sold to customers without any repackaging.

End Use

The product packs/cartridges may be dispensed using manual, battery operated, or pneumatic dispensers. During use, the two components of the epoxy resin are mixed in a 1:3 ratio (1 part the product containing the notified polymer) within the application tip, and setting occurs over 72 hours. After a hole has been drilled in concrete or stone, the adhesive mortar is dispensed into the hole, and the metal rod is inserted into the hole. Holes may be horizontal or vertical, and the product is viscous, so that it may be used overhead.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and warehousing	20	8 hours/day	260 days/year
Construction workers	2000	1 hour/day	20 days/year

Exposure Details

Transport and Storage

Transport and warehouse workers will only be exposed to the notified polymer (up to 50%) in the case of a spill or a rupture.

End Use

A large number of construction workers (>1000) may be exposed to the products. The most likely route of exposure for construction workers is via the dermal route to the product containing the notified polymer during application of the adhesive mortar (concentration up to 12%), before the adhesive mortar cures. Dermal exposure may also occur as a result of overspill of the product containing the notified polymer (up to 12%) from holes where rods have been inserted. Workers are expected to have been trained in the proper handling of adhesives

Accidental ocular exposure is possible although minimised by the high viscosity of the two-component end use product which contains up to 12% notified polymer. Inhalation exposure is considered to be low due to the normal high viscosity and low volatility of the final mixed adhesive products.

Personal protective equipment (PPE) such as gloves and safety glasses when using products containing the notified polymer will further minimise exposure.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The polymer is imported into Australia as the finished product. There will be no release of the product from any sites except in the event of a spill resulting from the rupture of the packaging during transportation or storage. As the packaging size is small, spills resulting from damaged packaging are expected to be small.

RELEASE OF CHEMICAL FROM USE

The chemical is the active ingredient of the hardener (commonly referred to as part B) for a two part epoxy resin, used in the construction industry. The product is designed as an adhesive mortar for rebar and anchor fastenings in solid concrete. The product is injected into holes formed in the concrete, where it will react with “part A” of the epoxy resin and upon setting will not be available for release to the environment.

During use it is expected that waste will be generated. A portion of the epoxy resin should be expelled from the dispenser prior to use. It is expected that 25 mL of the adhesive will be expelled from the “jumbo” cartridge containing 1100 mL prior to use. The rate of wastage is 2.3% of the total. Although no precise amount is given for the smaller packages other than 3 trigger pulls, it is expected that the rate of wastage would be similar. Both component A and B are expelled together onto waste packaging or other suitable material such as waste paper and will react. It is therefore expected that although up to 230 kg per annum of the notified polymer will be released in this manner, the polymer will form part of a cured epoxy resin and will not be available for release to the environment.

It is expected that approximately 11% of the original contents will remain un-reacted in the 330 and 500 mL foil packages and 5% in the 1100 mL cartridges and presumably similar amounts for the 1400

mL. The notifier indicates that approximately 91.5% will be imported in the 330 and 500 mL foil packages with the remaining 8.5% of the polymer being imported in the 1100 and 1400 mL cartridges. The weighted average waste is 10.5%. This results in up to 1050 kg per annum of the notified polymer remaining in the packaging. Small amounts of the polymer are also expected to remain in the packaging due to it not being consumed before its use by date. The notified polymer is expected to remain in its original packaging where it will be collected for disposal.

5.5. Disposal

The unused portion of the notified polymer is expected to remain in its original packaging and will be collected for separate disposal. The notifier indicates that incineration is suitable; however landfill is the more likely disposal route in Australia.

5.6. Public exposure

It is expected that during transport, storage, and industrial use, exposure of the general public to the notified Polymer in Component B of HIT-RE 500 will be minimal. The product containing the notified polymer is designed and marketed for industrial use only and consequently no public exposure is anticipated except in the case of an accidental spill during transport.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa	Beckopox VEH 2626 is a dark red liquid. The notified polymer manufactured without the excess of residual monomer 1 is red solid crystals
Melting Point/Freezing Point	Not determined.
Boiling Point	Not determined.
Remarks	The notified polymer undergoes decomposition at high temperatures. The product Beckopox VEH 2626 is reported to boil in the range 100 – 200 ºC.
Density	1100 kg/m^3 at 20ºC (Beckopox VEH 2626)
METHOD	ISO 2811-2:1997 Paints and varnishes -- Determination of density -- Part 2: Immersed body (plummet) method.
Remarks	Test report not supplied.
Vapour Pressure	< 0.01 kPa at 25 ºC (Component B)
Remarks	No test report provided, however due to the molecular weight of the telomer and the low vapour pressure of the residual monomers (< 0.4 kPa), the vapour pressure of the notified polymer is expected to be low.
Water Solubility	pH 1: 0.0491 ± 0.0036 g/L at 20ºC pH 10: 0.0068 ± 0.0008 g/L at 20ºC
METHOD	EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	The notified polymer was subjected to two preliminary tests at pH 1 and 10. The approximate solubility was 13 mg/L and 2 mg/L respectively. The Flask Method was then used to determine the water solubility at pH 1 and 10. pH 1: Duplicate analyses were performed by adding 50 mL of water to approximately 70 mg of test substance. The test substance was protected from light and no further deviations from the protocol were recorded. A blank determination was also performed. pH 10: Duplicate analyses were performed by adding 400 mL of water to between 150 – 200 mg/L. The test substance was protected from light. Equilibrium had not been established by 73 hours and solutions were allowed to equilibrate until 211

hours. A blank determination was also performed.
Detection was by UV Spectrophotometry.

TEST FACILITY Clariant (1999a)

Hydrolysis as a Function of pH Not determined.

Remarks The notified polymer does not contain any functional groups which are likely to undergo hydrolysis.

Partition Coefficient (n-octanol/water) log Pow = 1.8 ± 0.2 at 20ºC

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Flask Method. A stock solution containing 136.6 mg/L of the test substance was prepared. Analyses were performed in duplicate on the following solutions and the pH was also measured.

Stock mL	*Water mL*	*n-octanol mL*	*Mean pH*	*Mean Pow*
5.0	30.0	10.0	8.8	119.2
10.0	20.0	10.0	9.0	65.5
20.0	15.0	10.0	9.2	43.4

The variation in pH is likely to be due the basicity of the notified polymer, which also explains the variation in Pow. The mean Pow is 76.05 ± 35.15.

TEST FACILITY Clariant (1999b)

Adsorption/Desorption
Preliminary Test Not determined.

Remarks At pH 8.8 to 9.2, the polymer is more soluble in n-octanol than water. The polymer is unlikely to be mobile in the soil compartment, due to its predicted tendency to assimilate with the organic component of the soil compartment. In addition, in the environmental pH range of 4 to 9, the functional groups in the polymer will bear positive charges which are likely to weakly associate with the surface of negatively charged clay minerals and the carboxylate groups of humic material in soil, thereby reducing mobility.

TEST FACILITY

Dissociation Constant Not determined.
Remarks The notified polymer contains functional groups which should display typical basicity and are potentially cationic.

Particle Size Not applicable.
Remarks Notified polymer at the purity introduced is a liquid.

Flash Point >100ºC (Component B)

METHOD ISO 2719:2002 Determination of flash point - Pensky-Martens closed cup method.
Remarks Test report not supplied.

Flammability Limits Not determined.
Remarks Based on the flash point of the component B the notified polymer is not expected to be flammable.

Autoignition Temperature Not determined.
Remarks Not expected to auto-ignite.

Explosive Properties Not determined.
Remarks Not expected to be explosive. The notified polymer does not contain functional groups that infer explosive properties.

Reactivity

Remarks	The notified polymer will polymerise further when reacted with Component A of the product.

7. TOXICOLOGICAL INVESTIGATIONS

Limited toxicological data have been provided for the notified polymer with low levels of residual polymer constituents. The notified polymer as introduced contains >40% of one of the polymer constituents, 1,3-benzenedimethanamine (mXDA) as a residual monomer impurity. The toxicology profile of the notified polymer (as introduced) is predicted to be dictated by the residual polymer constituents present. Available toxicology information for the notified polymer with low levels of residual monomer and a summary of the toxicological profile of mXDA (present at >40%) is provided below. Another monomer is present in the polymer at up to 5%, this monomer has a toxicity profile similar to mXDA (IUCLID 2000).

7.1. Toxicological Investigations for the notified polymer

Endpoint	*Test Substance*	*Result and Assessment Conclusion*
Rat, acute oral	Notified polymer	LD50 > 2000 mg/kg bw, low toxicity
Genotoxicity – bacterial reverse mutation	Notified polymer	non mutagenic
Genotoxicity – in vivo <mouse micronucleus assay>	Notified polymer	non genotoxic

7.1.1 Acute toxicity – oral

TEST SUBSTANCE	Notified polymer (with low levels [not specified] of residual monomers)
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/Sprague-Dawley
Vehicle	Sesame oil
Remarks - Method	No significant protocol deviations. Statement of GLP.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity	There were no deaths or remarkable body weight changes during the study period.
Effects in Organs	No macroscopic findings were recorded at necropsy.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	LPT (1999)

7.1.2. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer (with low levels [not specified] of residual monomers).
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA98, TA100, TA102, TA97a
Metabolic Activation System	S9 mix

Concentration Range in Main Test	a) With metabolic activation: 0.4-270 µg/plate b) Without metabolic activation: 0.4-270 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	No significant protocol deviations. Statement of GLP.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 67 µg/plate	90 µg/plate	None	None
Test 2		90 µg/plate	None	None
Present				
Test 1	≥ 200 µg/plate	270 µg/plate	None	None
Test 2		270 µg/plate	None	None

Remarks - Results	Positive control substances increased the mutation frequency above the threshold values.

CONCLUSION The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY ARC (1999)

7.1.3 Genotoxicity – in vivo

TEST SUBSTANCE Notified polymer (with low levels [not specified] of residual monomers).

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.

Species/Strain	NMRI BR Mice
Route of Administration	Intraperitoneal injection
Vehicle	Corn oil
Remarks - Method	No significant protocol deviations. Animals were treated with the test substance once. Statement of GLP.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5/sex	0	24
II (low dose)	5/sex	190	24
III (mid dose)	5/sex	375	24
IV (high dose)	5/sex	750	24
V (high dose)	5/sex	750	48
VI (positive control, CP)	5/sex	50	48

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity	Rough coat and hunched posture were observed in all treated groups, although the incidence and duration of effect varied between groups. Lethargy and closed eyes was also noted in animals treated with 750 mg/kg bw. A statistically significant decrease in ratio of polychromatic (PCE)/normochromatic erythrocytes (NCE) was observed in animals treated with 190 and 750 mg/kg bw demonstrating toxic effects on erythropoiesis. However, no similar effetct was noted in group III animals.

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. Positive controls confirmed the sensitivity of the test system.
Remarks - Results	
CONCLUSION	The notified chemical was not clastogenic under the conditions of this in vivo erythrocyte micronucleus test.
TEST FACILITY	Notox (2006)

7.2. Toxicological summary for mXDA

The following toxicological summary was taken from SIDS Initial Assessment report for mXDA (OECD (2001)). A detailed review of the source data for this summary has not been conducted.

Endpoint	*Test Substance*	*Result and Assessment Conclusion*
Rat, acute oral	mXDA	LD50 1090 mg/kg bw for males, LD50 980 mg/kg bw for females, harmful toxicity
Rat, acute dermal	mXDA	LD 50 approximately 2000 mg/kg bw
Rat, acute inhalation	mXDA	LC50: 0.8 mg/L/4 hour for females LC50: > 1.42 mg/L/4 hour for males
Rabbit, skin irritation	mXDA	corrosive
Rabbit, eye irritation	mXDA	corrosive
Guinea pig, skin sensitisation – adjuvant test	mXDA	sensitiser
Rat, repeat dose oral toxicity – 28 days	mXDA	50 mg/kg bw/day
Developmental and reproductive effects	mXDA	NOAEL 450 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	mXDA	non mutagenic
Genotoxicity in vivo – <mouse micronucleus assay>	mXDA	non mutagenic

Acute Toxicity
Oral LD50 of rats was 1090 mg/kg for males and 980 mg/kg for females [OECD TG 401]. The oral LD 50 of mice was 1180 mg/kg [OECD TG 401]. The inhalation LC 50 (4h) of rats was 0.8 mg/L for females, while an LC50 value could not be derived in males or in both sexes combined (i.e. LC50 > 1.42 mg/L/4hr). No clear dose-response relationship was seen in females for mortality, while the only death in males was seen in the mid dose group. No significant difference was seen between the mid and high dose groups in the time of death of females. Apart from lethargy (on Days 10-21 in one to two rats) and variable food consumption was seen in high dose females but not males, together with congestion of the lungs in one surviving high dose female at schedule necropsy, overall, the effects seen in both sexes were similar and suggestive of a corrosive/irritant effect. The toxicity via oral administration and inhalation was tissue damage in the digestive and respiratory organs, respectively, which are the first contact sites.

Irritation and sensitisation
The chemical is corrosive to rat and mouse skin and a sensitiser in the guinea pig maximisation test.

Repeat Dose Toxicity
In the 28-day repeated dose toxicity study [OECD TG 407], the chemical was given to rats by gavage at doses of 0, 10, 40, 150 and 600 mg/kg bw/day. One male and four females died, and salivation, low locomotor activity and piloerection were noted in the 600 mg/kg group. Furthermore, ulceration, acanthosis with hyperkeratosis and
submucosal inflammation were observed in the forestomach. No adverse effects were observed in the 150 mg/kg
and the lower dose groups.

A reproductive /developmental toxicity screening test [OECD TG 421] of rats by gavage at 50, 150 and 450 mg/kg bw/day for at least 41 days resulted in death in one male in the 150 mg/kg group, and three males and one female in the 450 mg/kg group. In almost all 450 mg/kg animals, the same histopathological changes as the above 28-day study were observed in the forestomach. No adverse effects were found at 50 mg/kg bw/day. Based on this information, the NOAEL for repeated dose toxicity is considered to be 50 mg/kg bw/day. In the above reproductive/developmental toxicity screening test [OECD TG 421] the substance was administered from 14 days before mating to 20 days after mating in males and to day 3 of lactation in females. No adverse effects were observed in terms of copulation, fertility, delivery and nursing of parents, and the viability, body weight and morphology of offsprings. The NOAEL for reproductive/developmental toxicity (F1 offspring) was 450 mg/kg bw/day.

Mutagenicity
The chemical was not mutagenic in bacteria [OECD TG 471 & 472]. It induced neither chromosomal aberrations in mammalian cells *in vitro* [OECD TG 473] nor micronuclei in mouse bone marrow *in vivo* [OECD TG 474].

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer (with low levels [not specified] of residual monomers).
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test. Modified Sturm Test
Inoculum	Activated sludge from Hildesheim sewage plant treating predominantly municipal sewage.
Exposure Period	96 hours
Auxiliary Solvent	NIL
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks - Method	Duplicate analyses were performed on 15 mg/L of the test substance. 35 mg/L of sodium acetate was inoculated as a standard, as well as a toxicity control containing 35 mg/L of sodium acetate and 15 mg/L of the test substance. A blank was also run, although no details are provided to the results. The CO_2 evolved was compared with the theoretical amount of CO_2.

RESULTS

Test Substance		Control		Control + Test Substance	
Day	% Degradation	Day	% Degradation	Day	% Degradation
6	8	6	81	6	22
14	8	14	100	14	24
21	7	21	100	21	25
28	3	28	100	28	27

Remarks - Results	The test substance inhibits biodegradation of the control.
CONCLUSION	Less than 10% of the test substance was biodegraded, therefore the substance is considered to be not readily biodegradable.
TEST FACILITY	Dr U Noack- Laboratorium (1999a)

8.1.2. Bioaccumulation

Not determined.

METHOD The notified polymer contains many oligomers which indicate a potential to bioaccumulate, however the notified polymer is unlikely to bioaccumulate due to its low Pow value.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer (with low levels [not specified] of residual monomers).
METHOD	US EPA Subd E, §72 1/EPA OPPTS draft 850 1075 Static test
Species	*Oncorhynchus mykiss* (Rainbow trout)
Exposure Period	96 hours
Auxiliary Solvent	NIL

Water Hardness	40 - 180 mg $CaCO_3$/L
Analytical Monitoring	Nominal Concentrations Only
Remarks – Method	A range finding test was conducted using 7 fish per test concentration of nominal values of 10, 100 and 1000 mg/L.

Nominal Conc.	*Cumulative Mortality %*			
mg/L	24 h	48 h	72 h	96 h
1000	100	100	100	100
100	0	86	100	100
10	0	0	0	0
Control	0	0	0	0

Main Test:
Duplicate analyses of 7 fish were subjected to nominal concentrations of 6.25, 12.5, 25, 50, and 100 mg/L of the test substance and observed at 6, 24, 48, 72 and 96 hours. The temperature was 12 ± 2°C, with the light intensity at 1 - 10 µmol photons/m^2/s. A daily 12 hour photoperiod with 30 min transition occurred during the test. The pH was adjusted to 7.
All solutions were dispersed using a laboratory blender.

RESULTS

The fish were not fed throughout the test period. No further control test was conducted.

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
6.25		14	0	0	0	0	0
12.5		14	0	0	0	0	0
25		14	0	0	0	0	0
50		14	0	0	0	4	8
100		14	0	0	7	14	14

LC50	49.5 mg/L at 96 hours.
NOEC	12.5 mg/L at 96 hours.
Remarks – Results	In all concentrations of test substance, concentration related turbidity and sedimentation was observed. Fish in concentrations above 12.5 mg/L showed abnormal behaviour. The LC50 was calculated using probit analysis

CONCLUSION

The notified polymer is harmful to fish.

TEST FACILITY

Dr U Noack- Laboratorium (1999b)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE

Notified polymer (with low levels [not specified] of residual monomers).

METHOD

US EPA Subdivision E § 72 2, EPA OPPTS Draft Guideline No. 850 1010 and 40 CFR 797 1300 Static Test

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Nil
Water Hardness	159 mg $CaCO_3$/L

Analytical Monitoring: Nominal Concentrations Only

Remarks - Method: A range finding test was conducted using 20 daphnids divided into 4 groups of 5 per test concentration of nominal values of 1, 10, 100 and 1000 mg/L.

Nominal Conc. mg/L	*Immobilisation % 24 hours*	*48 hours*
Control	0	0
1	0	50
10	5	50
100	10	50
1000	95	100

Main Test:
20 daphnids divided into 4 groups of 5 per test concentration of nominal values of 0.01, 0.1, 1, 10, 100 and 1000 mg/L. Stock solutions of 1000 and 10 mg/L were homogenised at the beginning of the test. A control was conducted using 20 daphnids divided into 2 groups of 10. The temperature was 20 ± 2°C, with the light intensity at 1.5 - 5 µmol photons/m^2/s. A daily 16/8 hour light/dark cycle with 30 min transition occurred during the test. The pH was adjusted to 7 ± 0.1.
Five tests of concentrations between 0.58 and 5.8 mg/L of a reference item were conducted. The EC50 was 2.3 mg/L, which was within the prescribed concentration range. No further control test was conducted.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0.01		20	0	0
0.1		20	1	3
1		20	0	14
10		20	1	13
100		20	0	17
1000		20	15	20

LC50: 702 mg/L at 24 hours
2.4 mg/L at 48 hours

LOEC: 0.22 mg/L at 48 hours

Remarks - Results: For concentrations above 1 mg/L a pink sediment was observed and the toxicity shown is possibly a physical effect. The LC50 was calculated using probit analysis

CONCLUSION: The notified polymer is toxic to daphnia.

TEST FACILITY: Dr U Noack- Laboratorium (1999c)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE: Notified polymer (with low levels [not specified] of residual monomers).

METHOD: US EPA Guideline § 123-2/ EPA OPPTS draft No 850 5400, Static Test
Species: *Pseudokirchneriella subcapitata*
Exposure Period: 96 hours
Concentration Range: Nominal: 1.56 - 100 mg/L
Actual: Not determined.

Auxiliary Solvent	Nil
Water Hardness	Not Specified
Analytical Monitoring	Nominal Concentrations Only
Remarks - Method	A range finding test was conducted using duplicate algae samples subjected to concentrations of nominal values of 0.01, 0.1, 1, 10, 100 and 1000 mg/L.

Nominal Conc. mg/L	Cell Density cells/mL 0 hours	96 hours
Control	15211/ 15595	1067803/ 1031803
0.01	15691/ 16411	1046203/ 945403
0.1	14683/ 15931	979003/ 1022203
1	16075/ 16507	1034203/ 1017403
10	16027/ 18427	743803/ 741403
100	19675/ 19291	104539/ 50347
1000	24472/ 24235	62155/ 72811

Main Test:
3 replicates containing approximately 1 x 10^4 cells/mL were subjected to concentrations of nominal values of 1.56, 3.13, 6.25, 12.5, 25, 50 and 100 mg/L. Observations were made at 24, 48, 72 and 96 hours. 6 replicates were conducted as a control. The temperature was 24 ± 2°C, with the light intensity at 66.5 ± 10 µE/m^2/s for 24 hours per day. The pH was adjusted to 7.0 ± 0.1. Chlorophyll- fluorescence was determined during the test.

RESULTS

Biomass		*Growth*	
EbC50	*NOEC*	*ErC50*	*NOEC*
mg/L at 96 h	*mg/L*	*mg/L at 96 h*	*mg/L*
20.1	6.25	44.3	12.5
mg/L at 72 h		mg/L at 72 h	
14.1	6.25	31.8	6.25
mg/L at 48 h		mg/L at 48 h	
8.2	6.25	24.3	6.25
mg/L at 24 h		mg/L at 24 h	
16.9	6.25	22.6	6.25

Remarks - Results	No self fluorescence was found up to 100 mg/L
CONCLUSION	The test substance is toxic to algae.
TEST FACILITY	Dr U Noack- Laboratorium (1999d)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Not determined.
	The biodegradation test showed toxicity to sewage sludge organisms at 15 mg/L.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The polymer is used as a hardener (commonly called part B) for a two part epoxy resin package, for use in the construction industry. In use the polymer is reacted to form an epoxy mortar and is not available for environmental release. Unused amounts of the notified polymer are expected to remain in their original packaging. The notifier indicates that incineration is a suitable method of disposal; however landfill is more likely in Australia. If incinerated the polymer will be completely combusted, whilst in landfill it is likely to be immobile until eventually degrading by biotic and abiotic processes to form landfill gases; oxides of nitrogen and water vapour.

9.1.2. Environment – effects assessment

The toxicity for Beckopox VEH 2626 polymer is listed below.

	Duration hours	*End Point*	*Toxic Dose mg/L*
Rainbow Trout	96	LC50	49.5
Daphnia	48	LC50	2.4
Algae Biomass	48	EbC50	8.2
Algae Growth	24	ErC50	22.6

The notified polymer is expected to be persistent if released to the environment but is unlikely to bioaccumulate due to its low Pow value. A PNEC of 24 µg/L may be calculated using 100 as the safety factor (as three test results have been provided) and the lowest endpoint, even though the effects may be physical for this result.

9.1.3. Environment – risk characterisation

No release of the notified polymer to the environment is expected to occur except from accidental spills. Although a PEC cannot be calculated it is expected to be very low. Consequently the risk quotient is expected to be very low. The notified polymer will therefore not pose an unacceptable risk to the environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified polymer is imported as a component of a product at a concentration of up to 50%. Exposure during transport and storage would only occur through accidental breaching of the transport containers containing products in which the notified polymer is a component.

A large number of construction workers (>1000) may be exposed to the products during use as an adhesive. The most likely route of exposure for construction workers is via the dermal route to the product containing the notified polymer during application of the adhesive mortar (concentration up to 12%), before the adhesive mortar cures. Exposure would be limited by the use of the dispensers but would be dependent on the size of the application area and the accuracy of, and care taken by, the worker. Workers are expected to have been trained in the proper handling of adhesives

Accidental ocular exposure is possible, although minimised by the high viscosity of the two-component end use product which contains up to 12% notified polymer. Inhalation exposure is considered to be low due to the normal high viscosity and low volatility of the final mixed adhesive products.

Use of ersonal protective equipment such as gloves and safety glasses when using products

containing the notified polymer will further minimise exposure.

9.2.2. Public health – exposure assessment

The notified polymer is marketed for industrial use only. Public exposure is only anticipated in the event of a spill during transport and storage through accidental breaching of the transport containers containing the notified polymer. Public exposure during normal use patterns will be negligible.

9.2.3. Human health – effects assessment

Limited toxicological data on the notified polymer were available. The notified polymer at the purity introduced contains > 40% of one polymer constituent, mXDA. The toxicology profile of the notified polymer (as introduced) is predicted to be dictated by the presence of this residual polymer constituent.

Acute toxicity
The notified polymer with low levels of residual monomers is of low acute oral toxicity, however, due to the level of impurities (primarily the residual monomer) the notified polymer would be harmful if swallowed and harmful by inhalation.

Irritation and sensitisation
The notified polymer contains high-concern reactive functional groups. Data exists on molecules with carbon chain lengths comparable to the notified polymer containing this functional group. These molecules are generally irritating or corrosive to skin, irritating to eyes, and may cause sensitisation (Visek, 1995) The irritation and sensitisation potential of the polymer itself has not been established, however, due to the level of impurities (residual monomer) the notified polymer at the purity introduced is considered to be corrosive to skin and eyes and a skin sensitiser.

Repeat Dose toxicity
Based on two repeat dose studies with the residual monomer mXDA, a NOAEL was established as 50 mg/kg bw/day based on adverse effects observed in the stomach. Similar effects may be expected for the notified polymer based on the high levels of impurities present.

Mutagenicity
The notified polymer with low levels of residual monomers was not mutagenic in bacteria and was negative in a *in vivo* mouse micronucleus test. The main impurity (residual monomer) was also non mutagenic in vitro and in vivo.

Hazard classification
Based on the limited toxicological data provided for the notified polymer, the notified polymer cannot classified as hazardous in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances. (NOHSC 2004), however, the notified polymer may have corrosive or irritating effects and sensitising properties that have not been investigated.

Based on the presence of residual polymer constituents and the cut-off concentrations for classification (NOHSC 2004), the classification and labelling details for the notified polymer at the level of purity introduced are:

R20 Harmful by inhalation
R22 Harmful if swallowed
R34 Causes burns
R43 May cause sensitisation by skin contact

Although a LC50 value of 0.8 mg/L/4hr was determined in females in this study a clear dose-response relationship was not observed for mortality, while the male LC50 value was > 1.42 mg/L/4hr. Although the significance of this observed difference in mortality between the sexes is unknown, no such difference in sensitivity was observed in an acute oral and repeat oral study. Consequently, considering the above findings and that the female LC50 value is close to the cut-off value for aerosols for harmful ($1<LC50\leq5$ mg/L/4h) it is considered that classification with

R20 is more appropriate.

9.2.4. Occupational health and safety – risk characterisation

The notified polymer itselfmay have corrosive or irritating effects and sensitising properties. Due the presence of residual polymer constituents, the notified polymer at the purity introduced is considered to be acutely toxic by inhalation and ingestion, corrosive to skin and eyes and a potential skin sensitiser. Although dermal and ocular exposure to the notified polymer during application is expected to be limited by the method of application and the highly viscous nature of the adhesive mortar, dermal and ocular protection would be required to minimise the risk of corrosive/sensitisation effects. Although inhalation exposure is expected to be low due to the method of application and low vapour pressure of the notified polymer, application should be carried out in well ventilated areas in order to minimise the risk, due to the possible adverse effects following exposure by inhalation.

9.2.5. Public health – risk characterisation

Although the notified polymer is hazardous, public exposure to products containing the notified polymer will be low. The risk to the public from importation of the notified polymer for use and disposal in the manner described is considered to be negligible.

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

10.1. Hazard classification

Based on the limited toxicological data provided for the notified polymer, the notified polymer is not classified as hazardous in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances. (NOHSC 2004), however, the notified polymer may have corrosive or irritating effects and sensitising properties that have not been investigated.

Based on the presence of residual polymer constituents and the cut-off concentrations for classification (NOHSC 2004), the classification and labelling details for the notified polymer at the level of purity introduced are:

R20 Harmful by inhalation
R22 Harmful if swallowed
R34 Causes burns
R43 May cause sensitisation by skin contact

and

Based on the limited toxicological data provided for the notified polymer, the notified polymer is not classifiable as hazardous for health effects using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003). The classification of notified polymer for environmental effects 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*
Chronic hazards to the aquatic environment	2	Toxic to aquatic life with long lasting effects

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

The polymer 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 moderate concern to occupational health and safety under the conditions of the occupational settings described due to the potential corrosive and sensitising effects of the polymer. The possibility of adverse effects concern would be minimised by the use of PPE.

10.3.2. Public health

There is Negligible Concern to public health when used as a component in industrial adhesives.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing 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 of the product containing 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

REGULATORY CONTROLS
Hazard Classification and Labelling

- The notifier should give the following health, hazard classification for the notified polymer (at the purity introduced):
  - R20 Harmful by inhalation
  - R22 Harmful if swallowed
  - R34 Causes burns
  - R43 May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified polymer (at the purity introduced):
  - Conc > 25%: R20, R22, R34, R43
  - 10% ≤ Conc <25%: R34, R43
  - 5% ≤ Conc <10%: R36/37/38, R43
  - 1% ≤ Conc <5%: R43

- The following safety phrases should appear on the MSDS and label for the notified polymer as introduced:
  - S24: Avoid contact with skin
  - S25: Avoid contact with eyes
  - S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advise
  - S36/37/39 Wear suitable protective clothing/gloves and eye/face protection.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure to the notified polymer as introduced:

- Apply in well ventilated areas
- Clean up spills and excess adhesive promptly
- Avoid skin contact with soiled clothing or

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer in the product Component B of HIT-RE 500:
  - Gloves
  - Safety glasses
  - Coveralls
  - Respiratory protection were ventilation is insufficient

  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.

Disposal

- The notified polymer should be disposed of by authorised landfill or incineration.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by physical containment followed by collection with inert absorbent such as sand, vermiculite etc. with subsequent disposal. Prevent entry into waterways or soil.

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(1) of the Act; if
  - the notified polymer is introduced with a lower concentration of the residual monomer mXDA.

or

(2) 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.

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