File No: STD/1130

20 October 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

MR-8A

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

This Full Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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

Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

MR-8A

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Carl Zeiss Vision Australia Holdings Ltd (ABN 47 007 719 708)
Sherriffs Road Lonsdale, South Australia 5162

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
Introduction Volume
Identity of Sites

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
ELINCS listing

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
MR-8A

METHODS OF DETECTION AND DETERMINATION

METHOD	Gas chromatography/mass spectrometry (GC/MS)
Remarks	Reference spectra were provided
TEST FACILITY	Battelle-Europe, Frankfurt, Germany

3. COMPOSITION

DEGREE OF PURITY
>99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

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
Imported neat in 200 L steel drums.

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

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

USE
A component of a thermoset resin system.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne or Adelaide

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 200 L drums, and transported by road or rail from the dock to a single plant in South Australia.

5.2. Operation description

Formulation

The notified chemical will be transferred, in a bunded area, from 200 L drums to a 150 L semi-automated stainless steel blending vessel. The drums of notified chemical have two separate caps. One cap is opened quickly and a dry nitrogen gas line attached to the drum. The other cap is then opened and the automated metering system attached. The flow of nitrogen is then turned on. As the liquid notified chemical is pumped out of the drum, the empty volume inside the drum is replaced with nitrogen gas.

In the blending vessel the notified chemical will be mixed with other liquid resins and additives at room temperature. The blending vessel discharges to a closed filling machine.

Mould Assembly

Formulated liquid resin is filled automatically into reusable glass moulds at room temperature. Waste liquid resin is produced at this stage.

The moulds are transferred via a conveyor system onto a tray. The tray of mould assemblies is manually loaded into an oven. Once the oven is full, it is closed and heated to 80ºC for approximately 21 hours. During this step the notified chemical is incorporated into a polymer.

The cured assemblies are allowed to cool, then removed from the oven. The moulds are cleaned with water, detergent and finally acetone. The moulds are then manually disassembled to remove the finished article.

Cleaning

Equipment dedicated to these processes is cleaned daily. Any unused monomer, including residues in solvent rinsate, may be reused.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hours)*	*Exposure Frequency (days/year)*
Supply Personnel	2	0.5-1	4
Process Workers	20-30	2.5-5	241
Maintenance/Engineering	10-14	1-8	241
Quality Assurance	1-2	0.5-1	104
Emergency Personnel	10-15	0.5-1	1

Exposure Details

Supply Personnel

Workers will transfer sealed 200 L import drums into storage, and from storage to the production area. There is a risk of dermal exposure to the notified chemical from accidental splashes if a drum leaks or if an accident occurs involving breach of the import drum. Workers handling the notified chemical will wear latex gloves, disposable sleeves, protective clothing, disposable aprons and safety glasses.

Process Workers

Workers will open 200 L import drums and connect pumping equipment to the blending vessel. Formulation and filling are then largely automated, and conducted under local exhaust ventilation (LEV). These workers will wear a chemically resistant one-piece suit, respirator with appropriate filtering cartridge, impervious gloves and safety goggles.

Workers will manually load trays of moulds filled with liquid formulated resin into an oven. The curing oven is under LEV.

When curing is completed, workers will manually remove the cooled trays, clean the moulds with water, detergent and acetone, and open the moulds to remove the finished article. There is a risk of dermal, ocular and inhalation exposure to residual notified chemical monomer vapours. The mould cleaning process is conducted within a closed room supplied with LEV. Workers will wear a chemically resistant one-piece suit, positive pressure supplied air respirator, impervious gloves and safety goggles.

Process workers will control any small spill in the production area. If there is a large spill, trained emergency response personnel will control the situation, in accordance with the MSDS.

Workers for whom exposure to the notified chemical is possible will be given a pre-commencement medical examination including blood testing for sensitisation to this chemical class. This will be followed by six monthly lung function testing.

Maintenance & Engineering Workers

Workers will repair existing equipment and commission any new equipment that is to be introduced into the production area. There is a risk of dermal exposure to formulated resin via drips, spills, accidental splashes, and contact with contaminated equipment.

Quality Assurance

QA staff will be involved in sampling and testing the notified chemical upon arrival at the production site. There is a risk of dermal exposure to the notified chemical via drips, spills and accidental splashes during sampling and testing.

Emergency Personnel

Workers will be involved in clean up operations in the event of an accidental spill. There is a risk of dermal exposure to the notified chemical and the formulated resin via accidental splashes during clean up.

5.4. Release

RELEASE OF CHEMICAL AT SITE

During the initial evaluation acetone will be used to clean glass mixing vessels and equipment. Acetone will be collected and incinerated. It is estimated that waste acetone generated from this process will amount to no more than 3 litres per day. Traces of polymer will be removed from glass equipment using 25% potassium hydroxide solution at 75°C. Potassium hydroxide solution will pass through a sedimentation tank and be neutralised before discharge to sewer. The pH of the effluent will be maintained between 5.5 and 10.5 by automatic equipment. Solids from the sedimentation tank are collected and sent to a secure landfill site for disposal. Waste from this process is anticipated to be no more than 50 g per day or about 20 kg/annum.

Specialised mixing and filling equipment will produce waste resin at up to 20 kg per year. Waste resin will be collected, allowed to polymerise and incinerated. Daily cleaning of filling lines containing the formulated resin will be carried out. It is anticipated that waste from this route will not exceed 3 litres per day. The disposal of waste generated from this route will be in accordance with Environment Protection laws.

During the cleaning stage of the process there is no release to the cleaning water as the chemical is in a cured polymeric form.

Spills of the notified chemical and liquid resin will be contained to prevent it from entering drains and absorbed using suitable absorbent material. The absorbent material will be transferred into plastic bags, sealed inside a drum and incinerated. Floors will be washed using a solution containing 5% ammonia and detergent. The disposal of waste generated from this route will be in accordance with Environment Protection laws.

Empty chemical drums will be sent to a contractor licensed by the EPA to carry out such work. The drums are decontaminated with an alkaline organic solvent mixture, which is then incinerated. The drums are then washed with water, and the waste from this process is neutralised prior to discharge to the sewer. The drums are crushed and sent to a secure landfill site. The disposal of waste generated from this route will be in accordance with Environment Protection laws.

The notified chemical will be stored in an area where accidental leaks will not be able to enter the sewer. The notified chemical is stable at room temperature, therefore no temperature control of the storage area will be required outside the range of a typical air conditioned room environment. Due to the odour of the notified chemical the area will need to be well ventilated. The notified chemical is incompatible with oxidising agents.

RELEASE OF CHEMICAL FROM USE

There is no risk of release to the environment from the final products made from notified chemical, as the manufacturing process is designed to produce fully cured polymer. The finished articles will contain no residue of liquid resin used in the manufacturing process.

5.5. Disposal

Only a small amount of waste notified chemical is generated and although care is exercised to prevent release to watercourses a small amount may be disposed of to the sewer. However, the main methods of disposal are landfill or incineration. Empty drums will be sent to a contractor, where they will be decontaminated with alkaline organic solvent (which will be incinerated) then washed with water, and the waste from this process is neutralised prior to discharge to the sewer. The drums are crushed and sent to a secure landfill site.

5.6. Public exposure

The notified chemical will not be available to the public. Contamination from the production site is not expected, due to the low vapour pressure and minimal release of the notified chemical.

The public will be exposed to finished articles made from the notified chemical. Finished articles will not contain residual liquid resin, as the manufacturing process is designed to produce fully cured polymer.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Colourless liquid

Freezing Point <-70ºC

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Solidification point measured.
TEST FACILITY Battelle Europe (1993b)

Boiling Point >220ºC at 101.3 kPa

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks The notified chemical decomposed before boiling at 208-220ºC.
TEST FACILITY Battelle Europe (1992a)

Density 1135 kg/m^3 at 20ºC

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Measured with an oscillating density meter.
TEST FACILITY Battelle Europe (1992b)

Vapour Pressure 3.718 x 10^{-5} kPa at 25ºC

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Gas saturation method.

This result is a combined value based on vapour pressure for each of the 3 major isomers of the notified chemical.

Combined vapour pressure at 10, 15 and 20ºC was 0.608, 1.136 and 2.076 x 10^{-5} kPa, respectively.
TEST FACILITY Huntingdon Life Sciences (1999)

Water Solubility Not determined.

Remarks The notified chemical reacts with water (see discussion of hydrolysis below). The notified chemical appears to be relatively insoluble from the ecotoxicity testing where droplets of the test substance were observed floating on the surface when 100 mg was added to 1 L of water.

Hydrolysis as a Function of pH Totally hydrolysed within 24 h.

METHOD Not specified
Remarks As part of the bioaccumulation study, around 100 mg of the test material was added to an unspecified volume of water of unknown pH and stirred for 24 h. Solutions were then analysed using gas chromatography to determine the concentration of the test material. After 24 h no test material was detected in the samples.

During the fish ecotoxicity testing it was noted that when 100 mg of the test substance was added to 1 L of water, test substance remained as droplets on the surface of reconstituted water for 16 h and a white precipitate formed in the solution. This is consistent with hydrolysis of the notified chemical to a relatively soluble species, which reacts to form a polyurea of low solubility. Repeating the test with the pH of the water adjusted to 2 resulted in a more rapid disappearance of the test material and formation of the white precipitate, indicating that the hydrolysis occurs more rapidly at lower pH, as expected.
TEST FACILITY Mitsubishi-Kasei (1992d)

Partition Coefficient (n-octanol/water) Not determined

Remarks The notified chemical reacts with water (see discussion of hydrolysis above). The Log Pow has been calculated using ACD software for both the notified chemical and the hydrolysis product. The values were estimated to be 3.31 and 0.32, respectively.

Fat (or n-octanol) Solubility Miscible

METHOD EC Directive 84/449/EEC A.7 Fat Solubility.
Remarks Two preliminary tests were conducted at 37ºC. First a fixed amount (0.5 g) of test substance was added to various amounts of standard fat (0.5-4.0 g). The second test reversed the process and added a fixed amount of standard fat (0.25 g) to various quantities of test material (0.25-6.0 g). Solubility was assessed visually, with homogeneous solutions observed in all test vessels.
TEST FACILITY Battelle Europe (1992e).

Adsorption/Desorption Not determined

Remarks The notified chemical reacts with water (see discussion of hydrolysis above). Based on the apparent low water solubility and estimated partition coefficient of the notified chemical it would be expected to associate with soil and sediment. The diamine hydrolysis product is expected to have a low affinity for the organic matter in soils and sediments and be potentially relatively mobile in the environment. Given the expected low solubility of the polyurea it would also be expected to associate with soils and sediments.

Dissociation Constant Not determined

Remarks The notified chemical reacts with water (see discussion of hydrolysis above). However, there are no ionisable groups.

Particle Size Not applicable to a liquid.

Flash Point 179ºC at 101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks Pensky-Martens method.
TEST FACILITY Battelle Europe (1993c)

Flammability Limits Not flammable

METHOD EC Directive 92/69/EEC A.13 Flammability
Remarks No flammability was observed for 5 minutes with the notified chemical in contact with air.
TEST FACILITY Battelle Europe (1993c)

Autoignition Temperature 440ºC at atmospheric pressure

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks None.
TEST FACILITY Battelle Europe (1992d)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks None.
TEST FACILITY Battelle Europe (1993d)

Reactivity

Remarks	The notified chemical reacts with water producing carbon dioxide. The notified chemical is incompatible with acids, alcohols, acids, bases and oxidants.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	harmful LD50 1201 and 1842 mg/kg bw for females and males, respectively
Rat, acute inhalation toxicity	very toxic LD50 0.054 mg/L/4 hours
Rabbit, skin irritation	corrosive
Rabbit, eye irritation	severely irritating
Guinea pig, skin sensitisation – adjuvant test	evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOEL 10 mg/kg bw/day
Rat, repeat dose inhalation toxicity – 90 days.	NOEL 0.12 µg/L
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical.

METHOD Japanese Guidelines for Toxicity Study of Drugs (1989)
Species/Strain Rat/Sprague-Dawley (SPF)
Vehicle Olive oil
Remarks - Method None.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	700	0/10
2	5/sex	1000	0/10
3	5/sex	1400	3/5 females 1/5 males
4	5/sex	2000	4/5 females 3/5 males

LD50 1201 and 1842 mg/kg bw for females and males, respectively
Signs of Toxicity Soiled hair around the anus, soft faeces, diarrhoea, reduced spontaneous movement, crouching and irregular respiration. Male rats also showed cyanosis, tiptoe gait and lying. The symptoms in surviving rats disappeared on the 3rd day after administration. Surviving rats of both sexes had normal weight gains.
Effects in Organs Dead rats had greyish white gastric wall, retention of yellow contents in the small intestine, dark red patch on the thymus and discolouration of the spleen. Autopsy at the end of the observation period revealed thickening of the internal wall of the stomach, atrophy of the testes and retention of white contents in the testes. Autopsy at the end of the observation period revealed thickening of the internal wall of the stomach, atrophy of the testes and retention of white contents of the testes.
Remarks - Results None.

CONCLUSION The notified chemical is harmful via the oral route.

TEST FACILITY Mitsubishi-Kasei (1991c)

7.2. Acute toxicity – inhalation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 403 Acute Inhalation Toxicity.
Species/Strain	Rat/Fischer 344
Vehicle	Air
Method of Exposure	Oro-nasal exposure.
Exposure Period	4 hours
Physical Form	Liquid aerosol
Particle Size	2.09-2.57 μm
Remarks - Method	None

RESULTS

Group	*Number and Sex of Animals*	*Concentration mg/L*		*Mortality*
		Nominal	*Actual*	
1	5/sex	0.015	0.016	0
2	5/sex	0.05	0.053	1/5 females 2/5 males
3	5/sex	0.1	0.12	All animals
4	5/sex	0.25	0.24	All animals
5	5/sex	0.5	0.65	All animals
6	5/sex	5	4.65	All animals

LC50	0.054 mg/L/4 hours
Signs of Toxicity	Thin appearance, rough coat, laboured respiration, rales and red nasal discharge in all but the 0.015 mg/L dose group. Animals at the highest dose were lethargic and had tremors on day 1 and were dead on day 2. Animals in the 0.05 mg/L dose group surviving until necropsy appeared to have recovered slightly, with animals exhibiting only rough coat and thin appearance on day 15.
Effects in Organs	All animals in the 0.5 mg/L and the 0.25 mg/L dose groups had a pale or red discolouration of the lungs. A single animal in the 0.1 mg/L dose group had multiple diffuse white nodules in the left lung but all other animals in the group had no abnormal findings.
Remarks - Results	None
CONCLUSION	The notified chemical is very toxic via inhalation.
TEST FACILITY	Battelle Europe (1992f)

7.3. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	6 male
Vehicle	None
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	Skin reactions were graded according to the Draize scale at 0.5 h, 1 h, 6 h, 24 h, 48 h, 72 h and 4, 7, 10 and 14 days after patch removal.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	3	4	14 days	4
Oedema	1.3	4	14 days	2

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

Remarks - Results: Severe erythema was noted, starting half an hour after patch removal, and persisting to the end of the 14-day observation area. At necroscopy the treated skin of 6/6 animals was red, and was scabby in 5/6 animals. In 2/6 animals at necroscopy petechiae were seen in the subcutaneous connective tissue underneath the treated area, indicating severe damage to the skin.
The Primary Irritation Index was calculated to be 4.92.

CONCLUSION: The notified chemical is corrosive to the skin.

TEST FACILITY: Battelle Europe (1992g)

7.4. Irritation – eye

TEST SUBSTANCE: Notified chemical

METHOD: US EPA Pesticide Assessment Guidelines, Subdivision F, Part 81-4.
Species/Strain: Rabbit/New Zealand White
Number of Animals: 6
Observation Period: 21 days
Remarks - Method: None

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	2.8	3	21 days	1
Conjunctiva: chemosis	3.9	4	21 days	1
Conjunctiva: discharge	1.4	3	21 days	1
Corneal opacity	0.7	1	21 days	1
Iridial inflammation	0.2	1	72 hours	0

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

Remarks - Results: None

CONCLUSION: The notified chemical is severely irritating to the eye.

TEST FACILITY: Battelle Europe (1992h)

7.5. Skin sensitisation

TEST SUBSTANCE: Notified chemical

METHOD: US EPA Pesticide Assessment Guidelines, Subdivision F, Part 81-6.
Species/Strain: Guinea pig/Dunkin Hartley.
PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: Primary irritation observed from 0.2% to 10% (w/w)
topical: 0.01% (w/w)
MAIN STUDY
Number of Animals: Test Group: 22 Control Group: 22

INDUCTION PHASE	Induction Concentration: intradermal: 0.2% (w/w) topical: 1% (w/w)
Signs of Irritation	Moderate irritation at induction sites
CHALLENGE PHASE	
1st challenge	topical: 0.01% (w/w)
Remarks - Method	None

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	0.01%	7/21	16/21
Control Group	0.01%	0/22	1/22

Remarks - Results	One animal died during the observation period for reasons unrelated to treatment with the test substance.
CONCLUSION	There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Battelle Europe (1993e)

7.6. Repeat dose toxicity

7.6.1. 28-day oral toxicity

TEST SUBSTANCE	Notified chemical
METHOD	Japanese Guidelines for Screening Toxicity Testings of Chemicals (1986)
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Olive oil
Remarks - Method	None

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	6/sex	0	0/12
II (low dose)	6/sex	15	0/12
III (mid dose)	6/sex	100	0/12
IV (high dose)	6/sex	500	0/12
V (control recovery)	6/sex	0	0/12
VI (high dose recovery)	6/sex	500	0/12

Clinical Observations

Most rats of the high dose group showed salivation for the first 5 days of treatment. Some high dose males had soft faeces on day 6, reduced spontaneous movement at days 7 and 8 and rales at day 10.

High dose males exhibited reduced bodyweight gain through treatment and recovery. This was statistically significant from day 7 to the end of the recovery period. High dose females showed statistically significantly lower body weight at week 1 of recovery.

Food consumption decreased significantly in high dose animals at week 1 of treatment, and at week 1 of recovery.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

High dose animals showed increased alanine aminotransferase and males show elevated aspartate transaminase. Females showed decreased glucose and increases A/G ratio. Mid dose males had decreased urea nitrogen. High dose males had decreased aspartate transaminase and total protein at the end of the recovery period.

Low and high dose females showed decreased haematocrit and high dose females showed lower haemoglobin that resolved during recovery. Low and high dose males showed increased mean corpuscular volume. High dose females showed lower APTT at the end of the recovery period.

Urinalysis showed statistically significantly lower levels of occult blood in high dose males compared to controls, and significantly less protein in high dose females.

Effects in Organs

Statistically significant findings for organ weights were as follows: High dose females showed increased absolute and relative liver weights and decreased absolute and relative ovary weights. High dose males showed decreased liver weights. Low high dose females showed decreased absolute adrenal weights and the relative brain and testis weights of high dose males and the relative adrenal weights of low and mid dose females decreased. At the end of the recovery period absolute brain and kidney weights decreased in high dose males.

There were no adverse macroscopic findings.

The lesion considered to be treatment related was glycogen deposition in the livers observed in all high dose females.

Remarks – Results

Haematology revealed anaemia in high dose females. Effects on the liver were noted at the high dose. Because some effects occurred at low and high doses, no NO(A)EL or NOEL was determined.

All changes described above returned to normal during recovery, except for reduced haemoglobin in female rats.

CONCLUSION

It was not possible to establish a No Observed (Adverse) Effect Level (NO(A)EL) was established, based on decreased haematocrit and adrenal weights in high and low dose females, and a further study was undertaken (see 7.6.2, below).

TEST FACILITY Mitsubishi-Kasei Institute (1992b)

7.6. Repeat dose toxicity

7.6.2. Additional 28-day oral toxicity

TEST SUBSTANCE	Notified chemical
METHOD	Japanese Guidelines for Screening Toxicity Testings of Chemicals (1986)
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: None
Vehicle	Olive oil
Remarks - Method	This study included only a limited range of observations, because it was an extension of the previous study described above (7.6.1).

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	6 females	0	0/6
II (low dose)	6 females	2	0/6
III (high dose)	6 females	10	0/6

Clinical Observations
One rat in the low dose group had rales temporarily on the 5th day of treatment.

No changes were observed in bodyweight or food consumption.

Laboratory Findings –Haematology
No significant changes were observed in haematological parameters.

Effects in Organs
No changes were observed in adrenal weights.

No macroscopic or microscopic abnormalities were observed.

Remarks – Results
The previous study demonstrated adverse effects at 15 mg/kg bw/day, which provides the upper limit of the NOEL established in this study.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 10 mg/kg bw/day in this study, based on the absence of treatment-related changes in either of the treatment groups.

TEST FACILITY Mitsubishi-Kasei Institute (1992c)

7.6. Repeat dose toxicity

7.6.3. 90 day inhalation toxicity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 413 Subchronic Inhalation Toxicity: 90-day Study.
US EPA Guideline 799.9346

Species/Strain	Rat/Sprague-Dawley
Route of Administration	Inhalation – whole body
Exposure Information	Total exposure days: 65 days Dose regimen: 5 days per week Post-exposure observation period: None
Vehicle	Air
Physical Form	Liquid aerosol
Remarks - Method	None

RESULTS

Group	*Number and Sex of Animals*	*Dose µg/L (Actual)*	*Mortality*
I (control)	10/sex	0	0/10
II (low dose)	10/sex	0.12	0/10
III (mid dose)	10/sex	0.55	0/10
IV (high dose)	10/sex	2.03	0/10

Clinical Observations
High dose animals showed lower response to external stimuli compared to controls, and signs of exposure to an irritant atmosphere.

There were no treatment-related effects on bodyweight gain or food and water consumption.

Laboratory Findings – Clinical Chemistry, Haematology, Ophthalmic examination
No adverse effects were observed in any treatment group.

Effects in Organs
No adverse effects were observed on organ weights or after macroscopic examination.

Erosion/hyperplasia with or without rhinitis were detected in the transitional epithelium of high dose animals and low incidence in mid dose animals. Hyperplasia was seen in the respiratory epithelium of high dose animals and mid dose males.

Remarks – Results
None

CONCLUSION
The No Observed Effect Level (NOEL) was 0.12 µg/L/day based on erosion/hyperplasia of the transitional epithelium and hyperplasia of the respiratory epithelium in the 0.55 µg/L group.

TEST FACILITY Huntingdon Life Sciences (2000)

7.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD EA/MHW/MITI (1986)
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2 uvrA
Metabolic Activation System	Phenobarbital/5,6-benzoflavone-induced rat liver S9 fraction
Concentration Range in Main Test	a) With metabolic activation: 39 - 2500 µg/plate b) Without metabolic activation: 20 - 1250 µg/plate
Vehicle	DMSO
Remarks - Method	None

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	Not reported	313	None observed	None observed
Test 2		313	None observed	None observed
Present				
Test 1	Not reported	1250	2500	None observed
Test 2		1250	2500	None observed

Remarks - Results Positive controls induced significant increases in number of revertant colonies and negative controls were within historical limits.

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

TEST FACILITY Mitsubishi-Kasei Institute (1991a)

7.8. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD EA/MHW/MITI (1986)
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line	Chinese hamster lung cells
Metabolic Activation System	Phenobarbital/5,6-benzoflavone-induced rat liver S9 fraction
Vehicle	DMSO
Remarks - Method	None

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	20, 40, 80	24	24
	17.5, 35, 70	48	48
Test 2	15, 30, 60	6	24
Present			
Test 1			
Test 2	15, 30, 60	6	24

All cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	25	25	125	None observed
Test 2	25	25	125	None observed
Present				
Test 1	25			
Test 2	25	25	125	None observed

Remarks - Results The number of cells showing chromosomal gaps was significantly higher compared to controls for cells treated with 80 μg/mL for 24 hours in the absence of metabolic activation, and also for cells treated with 30 μg/mL in the presence of metabolic activation. However, in the absence of any other observed increase in aberrations, this is not in itself considered strong evidence of a clastogenic effect.

Positive controls showed significant increases in the number of cells with chromosomal aberrations. Negative controls showed numbers of cells with aberrations that were within historical control ranges.

CONCLUSION The notified chemical was not clastogenic to Chinese hamster lung cells treated in vitro under the conditions of the test.

TEST FACILITY Mitsubishi-Kasei Institute (1991b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

No data on the biodegradability of the notified chemical have been provided. For the purposes of the assessment it will be assumed that the notified chemical is not readily biodegradable.

8.1.2. Bioaccumulation

TEST SUBSTANCE		Notified chemical
METHOD		OECD TG 305C Bioconcentration: Flow-through Fish Test. MITI Chemical Substances Control Law.
Species		*Cyprinus carpio*
Exposure Period		Exposure: 8 weeks
Auxiliary Solvent		Acetone, HCO-30 and PVA-500.
Concentration Range	Nominal	1 and 27.5 mg/L, based on a 48 h acute pre-test with orange killifish which showed 10% mortality at 100 mg/L
	Actual	11.6 and 126 µg/L (based on the measured soluble radioactivity)
Analytical Monitoring		Liquid scintillation counting of radiolabelled test substance.
Remarks - Method		The measured concentration of the test substance was based simply on the level of radioactivity in the test water no attempt was made to identify the radioactive species. The levels of the test substance in the fish were determined for the whole fish
RESULTS		
Concentration Range in Fish		High Exposure – 1673 – 3814 ng/g Low exposure – 153 – 369 ng/g
Bioconcentration Factor		13 ~ 32.
CT50		
Remarks - Results		No fish mortalities were observed. The test substance hydrolyses in water. Hence, the results reflect the bioconcentration of the hydrolysis products rather than the notified chemical. Steady state concentrations were achieved within the first two weeks of the study.
CONCLUSION		The notified chemical is not bioconcentrating.
TEST FACILITY		Mitsubishi-Kasei (1992d)

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	"Richtlinie 79/831/EWG Anhang V Teil C.1 “Akute Toxizität für Fische, aktualisierte Fassung Februar 1990” (Guideline 79/831/EWG appendix V part of C.1 of "acute toxicity for fish, updated version February 1990).
Species	*Oncorynchus mykiss*
Exposure Period	96 hours
Auxiliary Solvent	Acetone.
Water Hardness	249.9 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	The test substance hydrolyses in water to form a sequence of oligomers. The report notes that there are indications that traces of the notified chemical may cause highly toxic effects to fish prior to complete hydrolysis. This was concluded from a water solubility trial in which 100

mg of the test substance was added to 1 L of water and stirred for 24 h, during the first 16 h droplets of test substance were observed on the surface. At the end of 24 h small white particles remained in the solution. Two fish were added to this solution and both were dead within 1 h of exposure. However, if the test was conducted at pH 2, then adjusted to pH 7.5 after 24 h (prior to the addition of the fish) no mortalities were observed. Stock solutions for the definitive study were therefore prepared by stirring the test substance in the media at pH 2 for 24 h prior to adjusting the pH to 7.8 to ensure complete hydrolysis of the test material.

The measured results are expressed in terms of the concentrations of the hydrolysis product. The test solutions were renewed after 48 h. Water quality parameters of pH (7.8), water temperature (14-15ºC) and dissolved O_2 content (97-101%) were within normal limits throughout study.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal [Notified Chem.]	*Actual [hydrolysis product]*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	-	10	0	0	0	0	0
6.25	5.59	10	0	0	0	0	0
12.5	-	10	0	0	0	0	0
25.0	19.5	10	0	0	0	0	0
50.0	-	10	0	0	0	0	0
100.0	81.1	10	0	0	0	0	0

LC50	> 100 mg/L at 96 hours (nominal).
NOEC (or LOEC)	≥ 100 mg/L at 96 hours.
Remarks – Results	Due to the preparation of the test solutions, the above results indicate toxicity of the hydrolysis products only.

CONCLUSION The hydrolysis product of the notified chemical is practically non- toxic to *Oncorynchus mykiss.*

TEST FACILITY Battelle Europe (1992i)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD "Richtlinie 79/831/EWG Anhang V Teil C.2 “Akute Toxizität für Daphnien, aktualisierte Fassung Februar 1990” (Guideline 79/831/EWG appendix V part of C.2 of "acute toxicity for Daphnia, updated version February 1990).

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Acetone.
Water Hardness	Not Stated
Analytical Monitoring	HPLC
Remarks - Method	The test substance hydrolyses in water to form a sequence of oligomers.

The report notes that there are indications that the traces of the notified chemical may cause toxic effects to Daphnia prior to complete hydrolysis. This was concluded from a trial in which a stock solution of 10 mg/L of the test substance was used to prepare concentrations down to 0.001 mg/L. Ten daphnids were exposed to the freshly prepared test

concentrations. After 48 h all daphnids exposed to the 10 mg/L were immobilised and a single daphnid at a concentration of 0.01 mg/L. The latter immobilisation was not believed to be treatment related.

Stock solutions for the definitive study were thus prepared by stirring the test substance in the test media at pH 2 for 24 h prior to adjusting the pH to 8.2 to ensure complete hydrolysis of the test material.

The measured results are expressed in terms of the concentrations of the hydrolysis product. Water quality parameters of pH (7.8), water temperature (18-22ºC), dissolved O_2 (94%) content were within normal limits throughout study.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal [Notified Chem.]	*Actual [hydrolysis product]*		*24 h*	*48 h*
0		20	0	0
12.5	9.44, 12.7	20	0	0
25.0		20	0	3
50.0		20	0	5
100.0	74.6, 83.5	20	2	13
200.0		20	3	20
400.0	295, 281	20	6	20

EC50	77.5 mg/L at 48 hours (nominal)
NOEC	12.5 mg/L at 48 hours
Remarks – Results	Due to the preparation of the test solutions, the above results indicate toxicity of the hydrolysis products only.

CONCLUSION The hydrolysis products of the notified chemical are slightly toxic to *Daphnia magna*.

TEST FACILITY Battelle Europe (1992j)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

It is expected that very little exposure to the environment is likely to occur during the use of the imported notified chemical. The majority of wastes containing the notified chemical generated during formulation and moulding are expected to be disposed of to landfill or incinerated. Up to 50 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 polymeric resin in which the chemical will be incorporated into the inert matrix of the resin and be unavailable to the environment. If the containers are destroyed in landfill the notified chemical is unlikely to leach into the water compartment due to its low water solubility. A small amount may be disposed of to sewers as a result of the reconditioning of drums. However, this is likely to be very small and the calculation of the Predicted Environmental Concentration (PEC) could not be done.

Any incineration of the notified chemical or polymer containing it will result in the destruction of the chemical and the formation of water and oxides of carbon and nitrogen.

At the end of their useful lives articles made from the resin containing the notified chemical would be disposed of to landfill.

9.1.2. Environment – effects assessment

The ecotoxicological data provided by the notifier indicate that the chemical may be highly toxic to fish and aquatic invertebrates. However, the chemical hydrolyses into species that are practically non toxic to fish and slightly toxic to daphnia. The most sensitive species to the hydrolysis products was *Daphnia magna* with a reported EC50 of 77.5 mg/L (nominal concentration based on added notified chemical) at 48 hours. Hence, a predicted no effect concentration (PNEC - aquatic ecosystems) of 0.0775 mg/L has been derived by dividing the end point of 77.5 mg/L by a worst-case scenario uncertainty (safety) factor of 1000 (as toxicity data are only available for two trophic levels).

9.1.3. Environment – risk characterisation

The notified chemical does not pose a significant risk to the environment based on its reported use pattern because there will be very low environmental exposure. The majority of the chemical will form a cured polymeric matrix. The majority of the notified chemical will eventually be disposed of to landfill including the final products at the end of their useful lives.

Despite the low PNEC, it is not anticipated that there will be any release of the chemical into the aquatic environment under the proposed use patterns and levels are expected to be well below the safety margin.

Tests show that the notified chemical has a low potential to bioaccumulate. Abiotic or slow biotic processes are expected to be largely responsible for the eventual degradation of the notified chemical as it is not expected to be readily biodegradable.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport & Supply

Exposure during transport will only occur in the event of an accident involving breach of the import drums. This is expected to be infrequent and acute, and will be limited by the use of personal protective equipment (PPE) and clean up operations as specified in the MSDS.

There is potential for dermal exposure to the notified chemical during transfer of sealed import drums into storage, and from storage to the production area. Exposure will be limited by the use of extensive PPE including gloves, disposable sleeves, protecting clothing, aprons and safety glasses.

Formulation
There is potential for dermal exposure during opening of the import drums and connection of pumping equipment between import drum and blending vessel. Exposure will be limited by local exhaust ventilation (LEV) and extensive PPE including chemically resistant clothing, impervious gloves, safety goggles and respirator with chemically appropriate filtering cartridge.

Exposure during blending and mould filling is expected to be low, as these steps are largely automated and conducted under LEV.

Mould Assembly
There is potential for dermal exposure when workers manually load trays of moulds filled with liquid formulated resin into the oven. There is further potential for dermal, ocular and inhalation exposure to residual vapours of notified chemical when workers manually remove cooled trays from the oven after curing, and during mould cleaning and disassembly. Exposure will be limited by LEV and extensive PPE including chemically resistant clothing, impervious gloves, safety goggles and positive pressure supplied air respirator. Mould cleaning will be conducted in a closed room supplied with LEV.

Quality Assurance; Maintenance
There is potential for dermal exposure to the notified chemical during QA sampling and testing, and during equipment maintenance, as a result of accidental spills. Exposure will be limited by PPE as described above.

Monitoring
Exposure will be monitored in all process workers, including testing for sensitisation to this class of chemical and periodic lung function tests.

9.2.2. Public health – exposure assessment

Public exposure during transport of imported drums of notified chemical is only likely in the event of a major accident or industrial spill.

The public will be exposed to finished, cured articles containing the notified chemical; however the notified chemical will not be biologically accessible.

Overall, public exposure is expected to be low.

9.2.3. Human health – effects assessment

In acute studies in rats, the notified chemical is harmful when administered orally and very toxic when administered by inhalation. Acute dermal toxicity data were not provided.

The notified chemical is severely irritating to rabbit eyes and corrosive to rabbit skin, with effects persisting to the end of the observation periods. In the skin irritation test, subcutaneous bleeding at the test site in the form of petechiae was observed in 2/6 animals at necropsy..

There was evidence of sensitisation in a Guinea pig adjuvant test.

The notified chemical is not mutagenic and is not clastogenic to Chinese hamster lung cells in vitro.

In 28-day repeat dose oral toxicity studies in rats, the NOEL was determined to be 10 mg/kg bw/day, based on reduced adrenal weights and relative brain and testis weights, reduced haematocrit, and increased mean corpuscular volume in animals treated with the next highest dose of 15 mg/kg bw/day.

In a 90-day repeat dose inhalation toxicity study in rats, the NOEL was determined to be 0.12 µg/mL/day, based on erosion and hyperplasia of the transitional epithelium and hyperplasia of the respiratory epithelium in animals treated with the next highest dose of 0.55 µg/mL/day.

Based on the available data, the notified chemical is classified as a hazardous substance in

accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004) and assigned the following risk phrases:

R26 Very toxic by inhalation
R22 Harmful if swallowed
R34 Causes burns
R42/43 May cause sensitisation by inhalation and skin contact

9.2.4. Occupational health and safety – risk characterisation

The notified chemical presents a risk of adverse health effects via dermal, ocular, inhalation or oral exposure. Predicted adverse effects include systemic toxicity via ingestion or inhalation, severe dermal and/or ocular irritation, and dermal and/or respiratory sensitisation.

Given the sensitising properties of the notified chemical, precautions to prevent exposure must be taken for all personnel, but especially those who either have had prior contact with this chemical class or suffer from any form of compromised respiratory function (NOHSC, 1990).

The most likely routes of exposure are dermal and possible ocular contact during formulation, mould assembly and QA sampling and testing; and inhalation of residual vapours when removing mould trays from the oven. Dermal and ocular exposure will be limited by the use of extensive PPE. Inhalation exposure will be limited by LEV and, provided the mould trays are sufficiently cooled before being removed from the oven, the low vapour pressure of the notified chemical.

There is a lower likelihood of exposure during transport, supply and maintenance work. Exposure during these stages will be limited by extensive PPE.

Overall, the control measures in place and the use of PPE are expected to ensure sufficient protection against exposure to the notified chemical. Therefore the risk to occupational health & safety is expected to be low.

9.2.5. Public health – risk characterisation

Although the notified chemical is classified for a number of health hazards, public exposure is expected to be negligible. Therefore, the overall risk to public health is expected to be low.

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

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R26 Very toxic by inhalation
R22 Harmful if swallowed
R34 Causes burns
R42/43 May cause sensitisation by inhalation and skin contact

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Acute toxicity	1	Fatal if inhaled
	4	Harmful if swallowed

Skin corrosion/irritation	1	Causes severe skin burns and eye damage
	1	Causes serious eye damage
Respiratory sensitiser	1	May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.
Skin sensitiser	1	May cause allergic skin reaction

The notified chemical could not be classified for environmental hazard due to its tendency to hydrolyse. However, it appears to exhibit some toxicity.

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 to produce cured, finished articles for sale to the public.

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

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations should consider the following health hazard classification for the notified chemical:
  - T^+: R26 Very toxic by inhalation
  - X_n: R22 Harmful if swallowed
  - C: R34 Causes burns
  - R42/43 May cause sensitisation by inhalation and skin contact

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 25%:
    - R26 Very toxic by inhalation
    - R22 Harmful if swallowed
    - R34 Causes burns
    - R42/43 May cause sensitisation by inhalation and skin contact
  - 25%> conc ≥10%
    - R26 Very toxic by inhalation
    - R34 Causes burns
    - R42/43 May cause sensitisation by inhalation and skin contact

- 10%> conc ≥7%:
  - R26 Very toxic by inhalation
  - R36/38 Irritating to eyes and skin
  - R42/43 May cause sensitisation by inhalation and skin contact
- 7%> conc ≥5%
  - R23 Toxic by inhalation
  - R36/38 Irritating to eyes and skin
  - R42/43 May cause sensitisation by inhalation and skin contact
- 5%> conc ≥1%
  - R23 Toxic by inhalation
  - R42/43 May cause sensitisation by inhalation and skin contact
- 1%> conc ≥0.1%
  - R20 Harmful by inhalation

Health Surveillance

- As the notified chemical is a health hazard, and belongs to a chemical class that is a Schedule 3 sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of inhalation or dermal exposure, in accordance with the relevant NOHSC guidelines (NOHSC, 1990).

CONTROL MEASURES

Exposure to the notified chemical should be controlled in all cases in accordance with the NOHSC guidelines for this chemical class (NOHSC, 1990).

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Automated pumping of notified chemical from import containers to mixing vessel
  - Automated dispensation of liquid resin to fill moulds
  - Local exhaust ventilation during formulation, mould assembly, QA sampling and maintenance work

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced, and after curing during mould cleaning and assembly:
  - Avoid spills and splashing
  - Ensure oven is cooled before opening to remove mould trays
  - Only carry out mould assembly in a well ventilated room

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced, and after curing during mould cleaning and assembly:
  - Chemically impervious gloves
  - Clothing that protects the body, arms and legs
  - Goggles or face shield
  - Respirator with appropriate filtering cartridge during transfer of notified chemical from import containers to mixing vessel
  - Positive pressure supplied air respirator during manual mould cleaning and mould assembly

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

- Atmospheric monitoring should be conducted during manufacture of cured articles from the notified chemical, to ensure that workplace concentrations of notified

chemical do not exceed the exposure standards for this chemical class (NOHSC, 1990; NOHSC, 1995).

- 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 chemical should be disposed of by incineration or secure landfill.

Storage

- The following precautions should be taken regarding storage of the notified chemical:
  - Store in a fully bunded, well ventilated area

Emergency procedures

- Spills of the notified chemical and liquid resin should be contained with suitable adsorbent material and care should be exercised not to allow material to enter drains and watercourses. The adsorbent material should be transferred to plastic bags sealed inside a drum and incinerated.

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 use pattern changes in such a way as to increase the exposure to the aquatic compartment. At this time a full set of test aquatic toxicity testing should be supplied for the notified chemical.

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.

13. BIBLIOGRAPHY

Battelle Europe (1992a) Determination of the Boiling Point of [Notified Chemical] in Accordance with EEC-Guideline A.2. (84/449/EEC). Study No. BE-P-32-92-A02-04. Battelle Europe, Frankfurt, Germany. (unpublished report submitted by the notifier)

Battelle Europe (1992b) Determination of the Relative Density of [Notified Chemical] in Accordance with EEC-Guideline A.3. Study No. BE-P-32-92-A03-02-BG. Battelle Europe, Frankfurt, Germany. (unpublished report submitted by the notifier)

Battelle Europe (1992c) Determination of the Flash Point of [Notified Chemical] in Accordance with EEC-Guideline A.9. Study No. BE-P-32-92-A09-02-BG. Battelle Europe, Frankfurt, Germany. (unpublished report submitted by the notifier)

Battelle Europe (1992d) Determination of the Auto-Flammability of [Notified Chemical] in Accordance with EEC-Guideline A.15 (84/449/EEC). Study No. BE-P-32-92-A15-04. Battelle Europe, Frankfurt, Germany. (unpublished report submitted by the notifier)

Battelle Europe (1992e) Determination of the Fat Solubility of [Notified Chemical] in Accordance with EEC-Guideline A.7. Study No. BE-P-32-92-A07-04. Battelle Europe, Frankfurt, Germany. (unpublished report submitted by the notifier)

Battelle (1992f) Inhalation Toxicity Study of Liquid Aerosol in Rats: Limit Test/LC-50. Study No. SC920038. Battelle, OH, USA. (unpublished report submitted by the notifier)

Battelle Europe (1992g) Acute Dermal Irritation/Corrosion Study of [Notified Chemical] in Rabbits. Study No. BE-MT-32-92-01-DIK-02. Battelle Europe, Frankfurt, Germany. (unpublished report submitted by the notifier)

Battelle Europe (1992h) Acute Eye Irritation/Corrosion Study of [Notified Chemical] in Rabbits. Study No. BE-MT-32-92-02-EIK-02. Battelle Europe, Frankfurt, Germany. (unpublished report submitted by the notifier)

Battelle Europe (1992i) Study on the Freshwater Fish (Rainbow Trout) Acute Toxicity of [Notified Chemical]. Study No. BE-EA-32-92-03-F1A-02. Battelle Europe, Frankfurt, Germany. (unpublished report submitted by the notifier)

Battelle Europe (1992j) Study on the Daphnia Acute Toxicity of [Notified Chemical]. Study No. BE-EA-32-92-03-DAK-02. Battelle Europe, Frankfurt, Germany. (unpublished report submitted by the notifier)

Battelle Europe (1993a) Determination of the Purity of [Notified Chemical] by Gas Chromatography. Study No. BE-P-32-92-GC-04. Battelle Europe, Frankfurt, Germany. (unpublished report submitted by the notifier)

Battelle Europe (1993b) Determination of the Solidification Point of [Notified Chemical] in Accordance with EEC-Guideline A.1. (84/449/EEC). Study No. BE-P-32-92-A01-04. Battelle Europe, Frankfurt, Germany. (unpublished report submitted by the notifier)

Battelle Europe (1993c) Determination of the Flammability of [Notified Chemical] in Accordance with EEC-Guideline A.13. (84/449/EEC). Study No. BE-P-32-92-A13-04. Battelle Europe, Frankfurt, Germany. (unpublished report submitted by the notifier)

Battelle Europe (1993d) Determination of the Explosive Properties of [Notified Chemical] in Accordance with EEC-Guideline A.14. (84/449/EEC). Study No. BE-P-32-92-A14-04. Battelle Europe, Frankfurt, Germany. (unpublished report submitted by the notifier)

Battelle Europe (1993e) Acute Dermal Sensitisation Study of [Notified Chemical] in Guinea Pigs. Study No. BE-MT-32-92-03-SIG-02. Battelle Europe, Frankfurt, Germany. (unpublished report submitted by the notifier)

Huntingdon Life Sciences (1999) [Notified Chemical] Vapour Pressure Determination. Study No. MTO101/972373. Huntingdon Life Sciences Ltd, Suffolk, U.K. (unpublished report submitted by the notifier)

Huntingdon Life Sciences (2000) [Notified Chemical] 90 Day Repeat Dose Inhalation Toxicity Study in Rats. Study No. MTU 043/994932. Huntingdon Life Sciences, Cambridgeshire, U.K. (unpublished report submitted by the notifier)

Mitsubishi-Kasei Institute (1991a) Bacterial Reverse Mutation Test of [Notified Chemical]. Study No. 0L281. Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Ibaraki, Japan. (unpublished report submitted by the notifier)

Mitsubishi-Kasei Institute (1991b) Chromosomal Aberration Test of [Notified Chemical] in Cultured Mammalian Cells. Study No. 0L282. Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Ibaraki, Japan. (unpublished report submitted by the notifier)

Mitsubishi-Kasei Institute (1991c) Acute Oral Toxicity Study of [Notified Chemical] in Rats. Study No. OL279. Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Ibaraki, Japan. (unpublished report submitted by the notifier)

Mitsubishi-Kasei Institute (1992b) Toxicity Study of [Notified Chemical] Oral Administration to Rats for 28 Days. Study No. OL280. Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Ibaraki, Japan. (unpublished report submitted by the notifier)

Mitsubishi-Kasei Institute (1992c) Additional Study for Determination of the Toxicity of [Notified Chemical] by Repeated Oral Administration to Rats for 28 Days. Study No. OL465. Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Ibaraki, Japan. (unpublished report submitted by the notifier)

Mitsubishi-Kasei Institute (1992d) Bioaccumulation Study of [Notified Chemical] with Carp. Study No. 0B320G. Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Japan. (unpublished report submitted by the notifier)

NOHSC (1990) Worksafe Australia Guide-[Chemical Class]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1995) Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment [NOHSC:1003(1995)]

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.