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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

SER-AD FX510

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 Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

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FULL PUBLIC REPORT

SER-AD FX510

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
International Sales and Marketing (ABN 36 467 259 314)
262 Highett Rd
HIGHETT VIC 3190

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, CAS No., Molecular and Structural formulae, Molecular weight, Spectral data, Purity, Impurities, Recipients details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

Melting/Freezing Point
Boiling Point
Density
Vapour Pressure
Partition Coefficient
Adsorption/Desorption
Dissociation Constant
Flash Point
Autoignition Temperature
Explosive Properties

Acute toxicity (oral, dermal, inhalation)
Irritation (skin, eye)
Repeat Dose Toxicity
Genotoxicity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
None known.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
SER-AD FX510

SPECTRAL DATA

METHOD	Infrared (IR) spectroscopy
Remarks	A reference spectrum was provided.

METHODS OF DETECTION AND DETERMINATION

METHOD IR spectroscopy.

3. COMPOSITION

DEGREE OF PURITY
> 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

One impurity, though a type I hazard, is present at < 100 ppm.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
Two impurities not likely to be hazardous are present.

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported by sea in 195 L blue steel drums.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	20	20	20	20	20

USE
Component of architectural paints.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne.

TRANSPORTATION AND PACKAGING
The notified chemical is to be imported in 195 L blue steel drums and, following manufacture of paint is packed in 1 – 20 L steel pails.

5.2. Operation description

The drums containing the notified chemical will be transported to a warehousing facility and thence to the customer for formulation into paint. The drums are opened by a mechanical vacuum pump and the contents transferred to a storage tank and then automatically to a mixing vessel at a final concentration of < 10% (w/w). Following mixing and QC testing the batch is automatically filled into the final containers for transport to retail outlets and sale to consumers.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hrs/day)*	*Exposure Frequency (days/year)*
Delivery to wharf	2	2	4
Distribution (transport and storage)	4	4	10
Paint formulation	200	6	240
Point of sale	1000	6	240

Exposure Details

Transport and storage

Worker exposure should only occur in the event of an accident involving rupture of containers.

Paint formulation

Workers involved in paint formulation are potentially exposed to spills during transfer to the mixing vessel and washing of the mixing vessel. Workers are provided with rubber gloves, eye/face protection and coveralls. Following mixing the process is automated and exposure is unlikely.

QC Testing

There is potential for dermal exposure to the notified chemical at a concentration of < 10% during sampling and testing of the paint formulation. Workers are expected to be provided with appropriate personal protective equipment (PPE).

5.4. Release

RELEASE OF CHEMICAL AT SITE

No release during manufacture is expected as the notified chemical will not be manufactured in Australia. The notified chemical will be used in the formulation of architectural paints. During the reformulation process losses of the notified chemical will be due to spills (up to 65 kg per year) and equipment washing (up to 111 kg per year). The site is fully bunded so any loss due to spills will be caught and treated before release to sewer. Equipment washing would result in the notified chemical being released directly to the sewer. Residues (1%) remaining in the import container will ultimately be landfilled together with the container itself.

RELEASE OF CHEMICAL FROM USE

The formulated product will be used by do-it-yourself painters using brushes or rollers. Following use approximately 2.5% of the notified chemical will be left in tins which would dry and be disposed of to landfill with the container. Another 2.5% (up to 500 kg per year) of the notified chemical will be washed down the drain due to cleaning of brushes, rollers and other painting equipment. It is assumed that the remaining notified chemical is applied and encapsulated on the paint surface.

5.5. Disposal

Some waste notified chemical generated during the manufacture of the paint and from the end use will be discharged to sewer and some old paint will be disposed of to landfill.

5.6. Public exposure

The notified chemical is provided to the public as part of a paint formulation at < 10% and will be applied by brush or roller. Consumers will probably be exposed dermally (mainly on the hands) and the paint may remain there for long periods. Once the paint is applied to an architectural surface and dried, exposure is not expected to be significant.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Clear liquid

Melting Point/Freezing Point < - 18°C

METHOD DGF-C-IV-3A

Remarks Test report not provided (from MSDS for the product SER-AD FX 510).

Boiling Point > 255ºC at 101.3 kPa

Remarks Test report not provided (from MSDS for the product SER-AD FX 510).

Density 940 kg/m^3 at 20ºC

METHOD DIN 53217/3
Remarks Test report not provided (from MSDS for the product SER-AD FX 510).

Viscosity < 50 mPas

Remarks Test report not provided (from MSDS for the product SER-AD FX 510).

Vapour Pressure 1.4 x 10^{-5} kPa at 25ºC (estimated)

METHOD MPBWIN (v1.41)
REMARKS The result is based on the program MPBPWIN (v1.41) for the notified chemical using an estimated boiling point and melting point of 293.80 and 55.78ºC, respectively. The calculated vapour pressure was 0.000104 mm Hg based on the Modified Grain Method.

Water Solubility 33 mg/L at 20ºC

METHOD OECD TG 105 'Water Solubility' Flask Test

Remarks Approximately 2.0 g of the test substance was added to 500 mL of deionised water in triplicate and agitated at 30ºC. The solution was allowed to cool at 20ºC until saturation equilibrium was reached. The concentration of the test substance in aqueous phase was then determined by GC-MS. The test solution remained clear and colourless throughout the test. There was no indication of any chemical instability over the 48 h period.

WSKOW v1.41 estimates a water solubility of 77.2 mg/L.

Conclusion The notified chemical is moderately soluble in water (Mensink et al 1995).
TEST FACILITY Leeder Consulting Laboratories (2004)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	$t_{½}$
4	50	>1 year
7	50	>1 year
9	50	>1 year

Remarks The tests were performed at pH 4.0, 7.0 and 9.0 for a period of one week at 50°C. Sub samples were collected in duplicate every 24 h and analysed by GC-MS. The level of propylene glycol, ethylene glycol and neodecanoic acid in the aqueous phase was determined over the 7 day period. At pHs of 4.0, 7.0 and 9.0, there was less than <0.05% by weight of the product hydrolysed over the 7 day period indicating that the product is hydrolytically stable.
TEST FACILITY Leeder Consulting Laboratories (2004)

Partition Coefficient (n-octanol/water) log Pow = 3.63

Remarks KOWWIN (v1.67) calculation estimates the log Pow of the notified chemical to be 3.63 using the fragment method.

Adsorption/Desorption log K_{oc} = 1.68

Remarks Based on the PCKOC program (v 1.66), the log Koc of the notified chemical was estimated to be 1.68.

Dissociation Constant Not expected to dissociate.

Remarks Dissociation constants were not able to be determined as there are no dissociable groups from the notified chemical.

Particle Size Not applicable

Flash Point > 200°C

METHOD ASTM D6450
Remarks Test report not provided (from MSDS for the product SER-AD FX 510).

Flammability Limits Not flammable in use.

Autoignition Temperature > 400°C

Explosive Properties Does not present an explosion hazard.

Remarks Test report not provided (from MSDS for the product SER-AD FX 510).

Reactivity Expected to be stable under normal environmental conditions.

7. TOXICOLOGICAL INVESTIGATIONS

Data on acute oral toxicity were not available. However, a study was provided for a close analogue, Analogue A. Data on acute dermal toxicity also were not available but there were data available on analogues B – E from the same class of chemical and some information on the predicted metabolites following skin absorption of the notified chemical.

Data for skin and eye irritation were available for Analogue A.

A mouse Local Lymph Node Assay was conducted on the notified chemical.

Repeat dose toxicity data were unavailable for the notified chemical. Under the conditions of an oral toxicity study, hydrolysis of a chemical linkage is expected either in the gastro-intestinal tract or after absorption from the gut, in the blood, liver and most tissues throughout the body. Therefore, chronic and subchronic toxicity data for the hydrolysis products (Metabolites 1 and 2) are considered to be adequate to predict the toxicity of the notified chemical.

Genotoxicity data were available for a range of analogues as well as for the predicted metabolites.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw (Analogue A)	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw (a range of analogues and the two metabolites)	low toxicity
Rabbit, skin irritation (Analogue A)	slightly irritating
Rabbit, eye irritation (Analogue A)	slightly irritating
Mouse, skin sensitisation – Local Lymph Node Assay.	evidence of sensitisation
Repeat dose chronic oral and inhalation toxicity.	Predicted metabolites were of low toxicity via the oral route and also of low toxicity via the inhalation route for one of the metabolites
Genotoxicity – bacterial reverse mutation	non mutagenic (analogues and metabolites)
Genotoxicity – in vitro chromosomal aberrations	non genotoxic (analogues and metabolites)
Genotoxicity – in vivo micronucleus test	non genotoxic (one of the metabolites)
Pharmacokinetic/Toxicokinetic studies	Hydrolysed to two metabolites on absorption through the skin or gastrointestinal tract which then further metabolised or excreted
Developmental and reproductive effects	No clear teratogenic effects for metabolites or analogues; one of the metabolites exhibited maternal and reproductive effects at high concentration
Carcinogenicity	One of the metabolites did not induce tumours in lifetime feeding studies

7.1. Acute toxicity – oral

TEST SUBSTANCE Analogue A

METHOD
- Species/Strain: Rat/Sprague-Dawley
- Vehicle: None.
- Remarks - Method: No deviations from protocol noted.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	None

LD50 > 2000 mg/kg bw

Signs of Toxicity	Hunched posture, lethargy and ataxia with an isolated incidence of decreased respiratory rate. Animals had returned to normal within one day of dosing.
Effects in Organs	No abnormalities noted at necropsy.
Remarks - Results	None.

CONCLUSION The test substance is of low toxicity via the oral route.

7.2. Acute toxicity – dermal

Patty's Toxicology, 5th Edition, 2001 notes that analogue B has a dermal LD50 of 11 g/kg in the rabbit and Analogue C has a dermal LD50 in the rabbit of 14 g/kg. No effects were noted when Analogues D and E were applied to human skin for 5 min to 5 hours.

It is also noted that practically all the common chemicals of this class are inert. Many of the materials are so inert that any LD50 value is impractical to determine.

The acute dermal toxicity of Metabolite 1 of the notified chemical, is reported to be > 3640 mg/kg bw. Metabolite 2, the other metabolite expected following dermal absorption of the notified chemical is widely used in preparations for topical application with no evidence of systemic injury to humans.

7.3. Acute toxicity – inhalation

No data provided.

7.4. Irritation – skin

TEST SUBSTANCE Analogue A

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (2M, 1F)
Vehicle	None
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No deviations from protocol.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1	1	0.7	1	72 hours	0
Oedema	0.3	1	0	1	72 hours	0

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

Remarks - Results	Desquammation was observed at 2 – 7, 7 and 3 - 7 days, respectively for rabbits 1, 2 and 3 and persisted to the end of the observation period.

CONCLUSION The test substance is slightly irritating to the skin.

7.5. Irritation – eye

TEST SUBSTANCE Analogue A

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White

Number of Animals	3 (2M, 1F)
Observation Period	72 hours
Remarks - Method	No deviations from protocol

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	0.3	0.3	1	24 hours	0
Conjunctiva: chemosis	0	0	0	1	1 hour	0
Conjunctiva: discharge	0	0	0	2	1 hour	0
Corneal opacity	0	0	0	0		0
Iridial inflammation	0	0	0	0		0

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

Remarks - Results	None.

CONCLUSION The test substance is slightly irritating to the eye.

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay.
EC Directive 67/548/EEC B.42 Skin Sensitisation: Local Lymph Node Assay.
EPA, OPPTS 870.2600 Skin Sensitisation.

Species/Strain	Mouse, CBA strain.
Vehicle	Acetone/olive oil (4:1 (v/v))
Remarks - Method	No deviations from protocol.

RESULTS

Group	*Treatment*	*Stimulation Index ± SEM*
1	Acetone/olive oil (4:1 (v/v))	1.0
2	10% test substance	1.0 ± 0.4
3	50% test substance	1.9 ± 0.3
4	100% test substance	5.1 ± 0.3

Remarks - Results	An EC3 value of 67% was calculated. The six month reliability check with hexylcinnamic aldehyde indicated the test system performed appropriately.

CONCLUSION There was evidence of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY Notox (2006).

7.7. Repeat dose toxicity

7.7.1 Metabolite 1

The following studies were reported by individual companies in the IUCLID/HEDSET format.

1. A 30% preparation of Metabolite 1 was fed to albino rats (strain unspecified) in the feed at 500, 1500, 5000 and 15000 ppm for a period of 3 months. The 15000 ppm dose group exhibited decreased body weight and a decrease in haematocrit, haemoglobin and red blood cell counts.

There were morphological changes in the thyroid characterised by hyperplasia of the follicular epithelium, manifested by increased cell height, increased cellularity, vacuolisation of the follicular epithelium and irregularity of the follicular walls. These changes were seen at the high dose and as low as 1500 ppm in male rats. Females showed this effect at 5000 and 15000 ppm.

Hepatotoxic changes were seen in 5000 and 15000 ppm animals and renal changes affecting the tubules were seen at 1500, 5000 and 15000 ppm in males and females.

The No Observed Adverse Effect Level (NOAEL) was 500 ppm (25 mg/kg bw/day) and the Low Observed Adverse Effect Level (LOAEL) was 1500 ppm.

2. Beagle dogs were administered Metabolite 1 via oral capsule at 0, 9.48, 30, 94.8 or 300 mg/kg/day for 13 weeks.

Frequent emesis and/or diarrhoea were seen in the 94.8 and 300 mg/kg/day dose groups coupled with weight suppression and declines in haematocrit, haemoglobin and erythrocyte values. Increased liver/body weight ratio was seen in high dose animals.

The NOAEL was about 30 mg/kg/day.

7.7.2 Metabolite 2

The following summary is from Patty's Toxicology (2001).

In two studies rats were shown not to exhibit systemic toxicity (in one study up to 140 days) when given in drinking water at dosages up to 13.2 g/kg/day. Other studies revealed that rats could tolerate up to 30 mL/kg Metabolite 2 for a 6-month period. For a 24-month period average daily intakes of 0.9 to 1.77 mL/kg Metabolite 2 in the diet did not affect the growth rate. Microscopic examination revealed very slight liver damage but no renal pathology.

Dogs given 5 or 10% Metabolite 2 in the drinking water for 5 to 9 months showed no adverse effects based on liver function, kidney function and histopathological examination of the visceral organs.

Rats of both sexes fed Metabolite 2 in the diet at levels of 6250, 12500 and 50000 ppm for a period of two years exhibited no significant ill effects based on mortality, body weight, food consumption, haematology, urinary cell excretion, urine-concentrating ability of the kidneys, organ weights or histopathology including tumour incidence.

Male and female dogs fed a diet providing Metabolite 2 at 2 g/kg for 2 years were unaffected as judged by mortality, body weight change, diet utilisation and water consumption, histopathology, organ weights of liver, kidney and spleen and measurement of blood, urine and biochemical parameters. At a daily dose of 5 g/kg, the dogs gained more weight than controls due to the higher caloric intake and exhibited an increase in the rate of erythrocyte haemolysis and a slight increase in bilirubin. Haemoglobin, packed cell volume and total erythrocyte count were lowered slightly, whereas the incidence of anisocytes, poikilocytes and reticulocytes increased suggesting that erythrocytes were being destroyed, accompanied by an accelerated replacement from the bone marrow. This effect was not sufficient, even at the 20% dietary level to result in any irreversible changes and there was no evidence of damage to the bone marrow or spleen.

An ATSDR toxicological profile of Metabolite 2 included a number of repeat dose studies as follows:

In rhesus monkeys and rats, continuous exposure to air concentrations of Metabolite 2 up to 112 ppm for 13-18 months caused no adverse effects on body weights or on the spleen or on the gastrointestinal, renal, endocrine or hepatic systems but caused increased hemoglobin counts.

After intermediate inhalation exposure to 321 ppm Metabolite 2, female rats had decreased body weight and white blood cell (WBC) counts, while exposure to 707 ppm of Metabolite 2 caused decreased mean corpuscular haemoglobin concentrations and white blood cell counts; no dose-related changes in RBCs were observed in male rats under the same regimen. There were no adverse hepatic effects in rats after intermediate inhalation

exposure to 707 ppm of Metabolite 2. Also there were no adverse renal effects, although kidney weight was reduced at 321 ppm in males and females.

Rats exposed to 55-112 ppm Metabolite 2 vapor continuously for 18 months showed no effect on the spleen. Young, healthy adult Sprague-Dawley rats divided into 4 groups of 19 males and 19 females each. Three groups were exposed for 5 days per week, 6 hours per day for 13 weeks by nose-only inhalation to mean target aerosol concentrations of 51, 321, or 707 ppm Metabolite 2, respectively. The fourth group (control group) was exposed to humidified, filtered room air. There was no effect on spleen weight.

The heart histopathology of rats after a 2-year oral exposure to 2500 mg/kg/day of Metabolite 2 revealed no changes. A similar lack of cardiovascular effects was observed in rats after a 23-month exposure to 49500 mg/kg/day Metabolite 2 in the feed.

The results from animal studies indicate that intermediate and chronic exposure to Metabolite 2 may lead to haemolysis of red blood cells. Increased numbers of Heinz bodies (sign of red blood cell degeneration) were observed in cats exposed orally to 1200, 1600, 2400, and 3600 mg/kg of Metabolite 2 for 2, 5, and 17 weeks, respectively. Other studies indicate increased Heinz body formation and decreased RBC survival in kittens and adult cats ingesting 3000 mg/kg and 1400 mg/kg/day, respectively. These findings are further supported by results obtained in dogs after chronic oral exposure to 5000 mg/kg/day. Red blood cell haemolysis was evidenced by decreased haemoglobin and haematocrit levels, and decreased total red blood cell counts. In rats, however, there were no changes in any of the haematological parameters after 2 years of chronic oral exposure to 2500 mg/kg/day Metabolite 2. These results indicate that there may be species differences with regard to the effect of Metabolite 2 on red blood cells. Fischer 344 rats exhibited lymphocyte depletion after a single oral dose of 23500 mg/kg Metabolite 2. Hypocellularity of the bone marrow was observed in cats after intermediate oral exposure to 8000 mg/kg/day of Metabolite 2.

The results from chronic-duration animal studies show that there are no adverse hepatic effects in rats fed a diet delivering 2500 mg/kg/day of Metabolite 2 for 2 years and chronic exposure of both rats and dogs to 2500 and 5000 mg/kg/day, respectively, for 2 years, had no nephrotoxic effects in either species. No adverse renal effects were observed in cats fed a diet delivering a dose of 1600 mg/kg/day of Metabolite 2 for 5 weeks. In the same study, however, cats exposed to 8000 mg/kg/day of Metabolite 2 for 3 weeks developed polyuria, considered a less serious adverse effect. In another study, an equal number (5-6) of cats of both sexes were fed 1600 mg/kg/day Metabolite 2 for 5 weeks or a high dose diet containing 8000 mg/kg/day for 22 days. Cats fed the low dose had no adverse clinical signs. Cats fed the high dose had moderate polyuria and polydipsia.

Rats given 2942 mg/kg Metabolite 2 by gavage for 10 days exhibited a 41% reduction in body weight, whereas exposure for 20-30 days caused an increase body weight. Dogs exposed to 5000 mg/kg/day oral Metabolite 2 for 2 years showed no adverse effect on body weight.

Cats fed 1.2 mg Metabolite 2 per gram of feed for 14 days showed increased haptoglobin concentration. Dogs fed 5000 mg/kg/day Metabolite 2 for 2 years showed no adverse immunological effects.

7.8. Genotoxicity

A review of the genotoxicity of 32 chemicals of the class of the notified chemical revealed that one of these was not mutagenic in *Salmonella typhimurium* strains TA 92, TA 94, TA 97, TA 98, TA 100, TA 102, TA 1535, TA 1537 or TA 2637 in the presence or absence of metabolic activation. There was no evidence of clastogenicity in Chinese Hamster fibroblast cells at concentrations up to 2 mg/mL. Although there was some evidence of genotoxicity from one report using the *Bacillus subtilis* rec assay, this was not supported by the results of other rec assays using similar bacterial strains.

A similar review of another set of analogues revealed that 4 chemicals similar to the notified chemical were negative in the *S. typhimurium*/ *Escherichia coli* bacterial reverse mutation test and two of these were negative for clastogenicity in Chinese Hamster fibroblasts and isoamyl formate was negative in the *B. subtilis* rec assay.

Assuming hydrolysis of the notified chemical occurs readily following absorption, the genotoxicity of the metabolites Metabolite 1 and Metabolite 2 should be considered.

Metabolite 2 was negative in the mouse dominant lethal assay when injected intrapertoneally at 10 mg/kg. It was also inactive as a mutagen in *S. typhimurium*. It was reported as negative for mutagenicity in *S. typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100 at concentrations of 0.02 – 5 mg/plate with or without metabolic activation and negative in two parallel cytogenetic studies in human lymphocytes with or without metabolic activation from 476 – 3810 μg/mL. A number of in vivo studies were also reported. Metabolite 2 administered orally at 30 – 5000 mg/kg (5 acute and subacute exposures) to rats was negative in a cytogenetic assay and a dominant lethal assay. Micronuclei were not induced in mice by i.p. injections of 0 – 15000 mg/kg and a host-mediated assay in mice administered 30 – 5000 mg/kg (acute and subacute (5 exposures)) was negative for *Salmonella* strains in vivo and in vitro and positive for recombination in *Saccharomyces* in vivo and in vitro.

Metabolite 1 has been reported as negative for mutagenicity in *S. typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100 with or without metabolic activation up to 1.5 mg/plate and negative in a cytogenetic assay in cultured human lymphocytes up to 800 μg/mL with or without metabolic activation.

7.9. Reproductive/Developmental Toxicity

Rats fed up to 30% Metabolite 2 in the diet through 6 generations exhibited no effects on reproductive capacity at levels less than 7.5%. At higher levels rats consumed less food, grew slower, had young at an older age, produced smaller litters on average and weaned fewer young than control animals. At the 30% level females did not breed normally and when they had young did not feed them properly. They failed to wean third generation young. When mice were fed 0.1 mL of a 50% water solution Metabolite 2 for several days before mating, mating was reduced to as little as 30% of normal and litters to 15%. The mice swelled visibly with intestinal gases and then recovered.

Metabolite 2 (0.05 mL) was not teratogenic when injected into the yolk sac of chick embryos. However, chicks fed high levels of Metabolite 2 in their diets developed a high incidence of toe deformities, 57/168 chicks as opposed to 9/168 chicks for the control group.

Several studies have been conducted on a class of analogues similar to the notified chemical. One of these was administered to 48 adult white rats by gavage (2 mg in 0.1 mL of "oil") on alternate days for 8 months. The animals were given total doses of 24, 84 or 208 mg prior to the first, second and third generations, respectively. The first offspring also received 15 mg before mating. No significant changes were observed in the number of pregnant females, the number of born offspring, the birth weight of the offspring, or the weight of the offspring after 7 and 21 days.

A second analogue was administered to groups of rats (20/sex) in the diet for 10 weeks prior to mating at an equivalent dosage level of 3125 mg/kg/day. A group of 12 rats/sex was fed a control diet. No adverse effects on fertility, litter size or survival of offspring were observed but there was significantly reduced growth during preweaning and postweaning periods. No gross pathological changes were observed when 24 male or female weanlings were fed the diet for 12 days and killed after 21 days.

In a teratogenicity study a third analogue was administered to groups of pregnant Sprague-Dawley rats on gestation days 6 – 15 at dosage levels of 0, 100, 500 or 1000 mg/kg bw/day. Statistically significant reductions in body weight gain and food consumption were observed in dams in the mid- and high-dose groups. No statistically significant effects on embryo-foetal lethality or foetal growth were observed for any treatment group. In the high dose group only, the incidence of litters with at least one malformed foetus and the mean percentage of the litter malformed was significantly elevated. These effects occurred only at a dose level that was maternally toxic and it was concluded octyl acetate was not developmentally toxic.

In a modified 3 generation feeding study, Metabolite 1 was administered to albino rats in the diet for 9 weeks at dosages of 0, 100, 500 or 1500 ppm. There was no evidence at any test level of adverse effects on the survival, appearance, behaviour, body weight gain or food consumption on the parental generation; on the reproductive performance of the parents or on the growth appearance or behaviour of the offspring. Gross and microscopic pathological findings revealed no evidence of a treatment-related effect.

An ATSDR toxicological profile of Metabolite 2 included a number of reproductive toxicity studies as follows:

Pregnant female Swiss mice were given 10000 mg/kg/day by mouth on Gd 8-12. There was no effect of treatment on their ability to produce live pups, or on the survival of those pups. The effects of Metabolite 2 on reproduction of Swiss (CD-l) mice were tested in a protocol which permitted continuous breeding during a specified interval. Metabolite 2 in drinking water at doses of 0, 1.0, 2.5, and 5.0% yielded mean exposures of 0, 1819, 4796, and 10118 mg/kg/day, based on water consumption. Animals were treated during a l-week pre-cohabitation period and a 14-week monogamous cohabitation period. Any offspring produced during the cohabitation period were examined, sexed, weighed, and killed to allow continuous mating of the parental generation. At the end of the cohabitation period, males and females were separated, and the females were allowed to deliver and raise the last litter to weaning. Metabolite 2 had no adverse effects on any measure of reproduction, including number of litters, litter size, pup weight, or sex ratio. There was no effect on the reproductive capacity of offspring from the high dose group.

7.10. Carcinogenicity

Metabolite 2 induced no tumours in three lifetime feeding studies and did not induce tumours when applied to the skin of rats three times a week for 14 months or to the skin of mice for their lifetimes either undiluted or as a 50% or 10% solution in acetone.

7.18. Pharmacokinetic/toxicokinetic

Chemicals of the class of the notified chemical are hydrolysed rapidly to their components in the intestinal tract, blood and liver and most tissues throughout the body. Hydrolysis is catalysed by 2 classes of enzyme. The rate of hydrolysis of straight chains is approximately 100 times faster than the rate of hydrolysis of branched chains such as the notified chemical.

The further metabolism of Metabolite 1 is expected to be by ω-oxidation as β-oxidation is prohibited. The polar metabolites produced by ω-oxidation are excreted primarily in the urine. Saturation of this pathway may lead to the formation of a product that may be excreted as the glucuronic acid conjugate.

Hydrolysis of the notified chemical will lead to the formation of Metabolite 2. It is oxidised in the body to two components which are then used by the body as sources of energy. From 25% to 50% of an oral dose given to rats, dogs or human beings appears unchanged in the urine within 24 hours. About one third is excreted via the kidneys as a conjugate with glucuronic acid.

8. ENVIRONMENT

8.1. Environmental fate

No data were provided for the notified chemical. However, the notifier has provided the biodegradability data derived from the IUCLID database on the proposed analogue, Analogue F, which are presented below.

8.1.1a. Ready biodegradability

TEST SUBSTANCE	Analogue F
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Domestic activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Remarks - Method	Activated sludge and test substance were combined prior to the test. Test medium consisted of glass distilled water and mineral salts. Test vessels were 1 L glass flasks placed in water bath and electronically monitored for oxygen consumption. Test substance was tested in triplicate, and controls and blanks were tested in duplicate. The test substance concentration was between 31-50 mg/L. Sodium benzoate (positive control) concentration was approximately 44 mg/L. Biodegradation was based on oxygen consumption and the theoretical oxygen demand of the test material as calculated using results of an elemental analysis of the test material.

RESULTS

Test substance		*<Reference Substance>*	
Day	*Mean % degradation*	*Day*	*Mean % degradation*
28	11.6	28	97.2

Remarks - Results	11.6% degradation of the test substance was observed by day 28. Degradation in the positive control reached >60% by day 14 which appears to meet the guideline requirement.
CONCLUSION	The analogue of the notified chemical is considered not readily biodegradable.
TEST FACILITY	Exxon Biomedical Sciences Inc. (1996)

8.1.1b. Ready biodegradability

TEST SUBSTANCE	Analogue F
METHOD	OECD TG 301 F Ready Biodegradability: Closed Bottle Test.
Inoculum	Non-adapted domestic activated sludge
Concentration	20 mg/L
Exposure Period	28 days
Remarks - Method	No details of the test method were provided
Remarks - Results	The results indicate that 7-8% of the test substance was degraded after 28 days.
CONCLUSION	The analogue of the notified chemical is considered not readily biodegradable.
TEST FACILITY	Stone and Watkinson (1982)

8.1.2. Bioaccumulation

Based on the estimated calculated BCF value of 125.5 using BCF Program (v2.15) and the estimated log Kow of 3.63, the notified chemical is considered to be potentially bioaccumulative.

8.1.3. Inherent biodegradability

TEST SUBSTANCE	Analogue F
METHOD	OECD TG 302 A Inherent Biodegradability: Modified SCAS Test
Inoculum	Domestic activated sludge
Exposure Period	14 days
Concentration	20 mg/L
Remarks - Results	No details of the test report were provided. The test substance underwent 68% degradation by day 14.
CONCLUSION	The analogue of the notified chemical is considered to be inherently biodegradable.
TEST FACILITY	Turner and Battersby (1989)

8.1.4. Inherent biodegradability

TEST SUBSTANCE	Analogue F
METHOD	OECD TG 302 A Inherent Biodegradability: Modified SCAS Test
Inoculum	Domestic activated sludge
Exposure Period	36 days
Concentration	20 mg/L
Remarks - Results	Brief details of the test report are available. Removal was based on DOC reduction in replicate SCAS systems. The mean effluent DOC concentration in the test substance SCAS systems on day 22 was 7.22 ± 0.63 ppm. The control systems DOC concentration was 2.88 ± 0.29 ppm. The influent DOC value, 13.68 ppm used to calculate test substance removal was based on the theoretical % carbon content of the test substance. The % DOC removal between days 22 and 36 was 68 ± 5%. The test substance underwent 68% degradation by day 36.
CONCLUSION	The analogue of the notified chemical is considered to be inherently biodegradable.
TEST FACILITY	Battersby and Turner (1989)

CONCLUSION

The results indicate that the analogue of the notified chemical is not readily biodegradable but is inherently biodegradable based on the 68% degradation of the analogue between days 22 and 36.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test –static test.
Species	Juvenile rainbow fish (*Melanotaenia fluviatilis*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not stated
Remarks – Method	Six concentrations of the notified chemical (0.9, 1.8, 3.75, 7.5, 15 and 30 mg/L) were prepared with diluent water (treated Sydney tap water). A diluent water control was also prepared. Four replicates for each

concentration and control were prepared with five fish per concentration. The fish were incubated for 96 h and were not fed over the test period. Temperature (21.3 – 24.5ºC) pH (7.34 - 8.02), conductivity (281 – 280 µS/cm and dissolved oxygen (>60% saturation) of the test solutions were within acceptable limits during the test. The cumulative number of imbalanced fish was recorded at 48 and 96 h.

RESULTS

Nominal concentration mg/L	*Number of Fish*	*Imbalance (%)*		
		0 h	*48 h*	*96 h*
0	5	0	0	0
0.9	5	0	0	0
1.8	5	0	0	0
3.75	5	0	0	0
7.5	5	0	0	0
15	5	0	100	100
30	5	0	100	100

NOEC 7.5 mg/L at 96 hours.

Remarks – Results In the diluent control no fish were imbalanced, indicating test acceptability. At concentrations of the test solution up to 7.5 mg/L there were no imbalances. However, at 15 and 30 mg/L there were 100% imbalances. As there were no partial values for imbalances at the concentration tested, an EC50 could not be determined. At 48 h the mean concentration of 15 mg/L was measured at 57% but at 96 h, it was measured at 91.5%. The reason for this variation is not known.

CONCLUSION The notified chemical exhibited acute sub-lethal toxicity to juvenile rainbow fish at <15 mg/L.

TEST FACILITY University of Technology Sydney (2004)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD ESA SOP 101, based on USEPA (1993)

Species *Ceriodaphnia dubia*

Exposure Period 48 hours

Auxiliary Solvent None

Water Hardness Not stated

Remarks - Method Limited details of the test report were provided. Four replicates of 5 daphnids per concentration were exposed to the test item for a period of 48 h. The % of survival was recorded at 24 and 48 h during the test. Survival of control and reference toxicant concentration met the test criteria. Temperature (25-25.5ºC), pH (7.8 – 8.1) conductivity (171.6 – 172.3 µS/cm) and dissolved oxygen (97.6 – 99 %) were within acceptable limits.

RESULTS

Nominal Concentration mg/L	*Number of D. magna*	*% Survival*	
		24 h	*48 h*
0	20	100	100
0.9	20	100	100
1.8	20	100	100
3.8	20	100	100
7.5	20	100	100

15	20	90	30
30	20	15	0

LC50	13.1 mg/L at 48 hours (CI = 11.3 – 15.1 mg/L)
NOEC	7.5 mg/L at 48 hours
CONCLUSION	The notified chemical is considered to be moderately toxic to *Ceriodaphnia dubia*
TEST FACILITY	Ecotox Services Australasia (2004)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test and USEPA protocol.
Species	*Scenedesmus capricornutum*
Exposure Period	72 hours
Concentration Range	
Nominal	0.04, 0.12, 0.37, 1.1, 3.3, 10 and 30 mg/L
Auxiliary Solvent	None
Water Hardness	Not stated
Remarks - Method	Limited details of the test report were provided. The concentration of 30 mg/L was prepared by weighing 15 mg of the notified chemical into 500 mL of USEPA media (with EDTA). The solution was stirred for an hour to completely dissolve the chemical. Nominal test concentrations of 0.04, 0.12, 0.37, 1.1, 3.3, 10 and 30 mg/L were used in the definitive test which measures the decrease (inhibition) in algal growth rate of the test species after exposure to the sample for 72 h (initial cell density 1.4 X 10^4 cells/mL). The 72 h IC50, LOEC and NOEC values were calculated using ToxCalc Version 5.0.23.

RESULTS

Growth	
IC50	*NOEC*
mg/L at 72 h	*mg/L*
>30	3.3

Remarks - Results	The test substance was of low toxicity to the algae with a 72 h IC50 of >30 mg/L and a NOEC of 3.3 mg/L. It is noted that the % inhibition compared with control at 10 and 30 mg/L were 71 and 54, respectively, significantly less than QA controls.
CONCLUSION	The test substance is at worst harmful to algae.
TEST FACILITY	CSIRO Centre for Advanced Analytical Chemistry (2004)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is considered to be moderately water soluble and volatile. Therefore, its loss to the atmosphere is likely to be significant. The notified chemical is expected to be inherently biodegradable and is unlikely to bioaccumulate in aquatic organisms despite its relatively high log Kow of 3.63. Based on the data provided, the majority of the notified chemical is likely to partition to sludge, where biological and physical processes can mediate its degradation, which is expected to occur at a slow rate.

It is expected that the exposure of the notified chemical to the environment is likely to be low. It is assumed that a maximum of 500 kg of the notified chemical will be released to sewer per annum from washwater discharge and not removed during sewage treatment processes. Assuming a national population of 20 million and that each person contributes an average 200 L/day to overall sewage flows, the predicted concentration in sewage effluent on a nationwide basis is estimated as 0.34 µg/L.

Amount entering sewer annually	500 kg
Population of Australia	20 million
Amount of water used per person per day	200 L
Number of days in a year	365
Estimated PEC	0.34 µg/L

Based on the respective dilution factors of 1 and 10 for inland and ocean discharges of effluents, the PECs of the notified chemical in freshwater and marine water may approximate 0.34 or 0.034 µg/L, respectively.

At the formulation site, it is assumed that 111 kg of the notified chemical will be discharged to the sewage in Melbourne. Assuming a population of 3.5 million, and that each person contributes an average 200 L/day to overall sewage flows, the predicted concentration in sewage effluent is estimated as 0.5 µg/L. This is higher than the PEC on a nationwide basis. Therefore, a PEC of 0.5 µg/L will be used as the worst case scenario in the risk assessment.

9.1.2. Environment – effects assessment

In summary, the aquatic toxicity data for the notified chemical indicate:

Algae: 72 h IC50 >30 mg/L, NOEC = 3.3 mg/L
Daphnia magna: 48 h LC50 = 13.1 mg/L
Rainbow fish: 96 h NOEC = 7.5 mg/L

The Predicted No Effect Concentration (PNEC) is 131 µg/L, using a safety factor of 100 since toxicity data are available for three trophic levels, and the lowest acute 48 h LC50 for *Daphnia magna* of 13.1 mg/L.

9.1.3. Environment – risk characterisation

The worst case PEC/PNEC ratio for the aquatic environment assuming a single site discharge is (0.5/131) 0.004 and (0.05/131) 0.0004 for fresh water and marine water, respectively. These values are significantly less than 1, further indicating no immediate concern to the aquatic compartment. On the basis of its relatively low discharge to sewer and the nationwide diffuse use of the notified chemical, it is not considered to pose an unacceptable risk to the aquatic life.

The residues left in tins after use would be dry and be disposed of to landfill with the container. Leaching in landfill is unlikely to occur as it is expected that the notified polymer will form complexes with other soil matrix components with further possibility of abiotic or slow biotic processes largely responsible for the degradation of the notified chemical. As the majority of the notified chemical will be incorporated into the paint surface, it is likely to be bound within a cured film, from which it is unlikely to be bioavailable. Treated articles as such when landfilled or incinerated are unlikely to pose an environmental risk.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be transported to a single paint manufacturing facility as a neat raw material and formulated into architectural paint products which will be applied by brush or roller by consumers. The final concentration of notified chemical in the paint product is low (< 10%).

Typical exposure scenarios for paint formulation involve transfer of the raw material to a storage tank, thence to a mixing vessel and finally the product is automatically packed off into consumer sized containers. Other operations involve sampling and testing paint and cleaning and maintenance of equipment and vessels.

Dermal exposure to the notified chemical can be estimated using the EASE model using reasonable worst case defaults for a particular activity (European Commission, 2003) as follows:

Activity	*Estimated exposure for activity <mg/day>*	*Estimated exposure for notified chemical <mg/kg bw/day>**
Manual addition of liquids	420	6
Coupling and decoupling of transfer line	42	0.6
Quality control sampling	21	0.3

* for a 70 kg worker and a 100% dermal absorption factor

Transport and storage workers should be exposed only in the event of an accident involving rupture of the import containers.

9.2.2. Public health – exposure assessment

The dermal exposure from brushing and rolling of liquids is estimated by the EASE model (European Commission, 2003) as 1700 mg for typical exposure and 10000 mg as a worst case. As the notified chemical is present at < 10% typical exposure should be 170 mg/day and worst case 1000 mg/day.

9.2.3. Human health – effects assessment

The notified chemical expected to be readily metabolised to two components in the gastrointestinal tract, blood, liver and body tissues. These components are further metabolised or excreted.

Based on toxicological studies of analogues or metabolites, the notified chemical is predicted to exhibit low acute oral toxicity, low acute dermal toxicity, to be a slight skin and eye irritant and is likely to be a skin sensitiser. It is unlikely to be genotoxic or to exhibit reproductive or developmental toxicity and is not expected to be carcinogenic. It is not predicted to exhibit severe effects on repeated or prolonged exposure. The NOAEL can be estimated from studies of one of the metabolites to be approximately 50 mg/kg bw/day.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) and assigned the risk phrase R43: May cause sensitisation by skin contact.

9.2.4. Occupational health and safety – risk characterisation

Based on a NOAEL of 25 mg/kg bw/day for Metabolite 1 (or approximately 50 mg/kg bw/day for the notified chemical) derived from a 28-day rat oral repeat dose study the margins of exposure (MOE) for various activities are as follows:

Activity	*Estimated exposure for notified chemical <mg/kg bw/day>*	*Margin of Exposure*
Manual addition of liquid form	6	8.5

Coupling and decoupling of transfer line	0.6	85
Quality control sampling	0.3	170

MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data may not be acceptable for workers involved in addition of the notified chemical to mixing vessels if any manual addition occurs. The notifier has stated that the drums containing the notified chemical are unloaded via a vacuum pump. Therefore, maximum exposure should be about 0.6 mg/kg bw/day with an acceptable MOE provided PPE is employed.

The likelihood of irritant effects and genotoxic effects are unlikely based on the tests for these endpoints.

However, there is a risk of skin sensitisation to workers based on the fact that the notified chemical is positive in a mouse LLNA test and that dermal exposure can occur. Thus, there is a need for workers to wear adequate personal protective equipment (PPE) to manage this risk. The PPE required would be expected to mitigate any risk of systemic effects.

9.2.5. Public health – risk characterisation

Given the likely public exposure during brushing or rolling of paint products, the dosage would be between 2.4 and 14.3 mg/kg bw/day based on a body weight of 70 kg and the MOE between 3.8 and 21. Therefore gloves should be used when applying paint containing the notified chemical. Also, given that the notified chemical is a skin sensitiser and is contained in the paint at up to 10% there is a risk of skin sensitisation to the public and gloves would be required when applying paint products.

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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

R43: May cause sensitisation by skin contact

or

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 Skin sensitiser, category 1 with a hazard statement: “May cause allergic skin reaction”. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

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 Moderate Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

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

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the *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 *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 (DEWR), should consider the following health hazard classification for the notified chemical:
  - R43: May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 1%: R43

- The National Drugs and Poisons Standing Committee (NDPSC) should consider the notified chemical for listing on the SUSDP.

- Products available to the public must carry the following safety directions on the label:
  - S2 Keep out of the reach of children
  - S13 Keep away from food, drink and animal feeding stuffs
  - S24 Avoid contact with skin
  - S25 Avoid contact with eyes
  - S37 Wear suitable gloves

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Transfer of the imported raw material should employ a chemical pump and dry break couplings where feasible.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Chemical safety goggles, impervious gloves, coveralls.

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

- Employers should ensure that any worker who exhibits an allergic response should cease handling the notified chemical or products containing it.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to

health in accordance with the *Approved Criteria for Classifying Hazardous Substances* NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public Health

- The following measures should be taken by the public to minimise exposure to the notified chemical:
  - When mixing and applying paint containing the notified chemical and during clean up avoid skin contact by the use of impervious gloves and protective clothing and footwear.

Environment

Disposal

- The notified chemical should not be disposed together with household garbage. Wastes generated should ultimately be disposed of by landfill or incineration.

Emergency procedures

- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to Local, State and Federal Government waste regulations.

12.1. Secondary notification

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

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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