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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Silquest WetLink 78 Silane

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
GE Silicones (Australia) Pty Ltd (ABN 47 105 651 63) of 175 Hammond Road DANDENONG VIC 3175.

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 name, CAS number, molecular and structural formula, molecular weight, spectral data and purity.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: manufacturing process, particle size, flammability limits, explosive properties, reactivity, acute inhalation toxicity, induction of germ cell damage, chromosome damage, and bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
CEC516 and CEC594.

NOTIFICATION IN OTHER COUNTRIES
USA, EU and Japan.

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Y-15078
Y-11012

MARKETING NAME(S)
Silquest WetLink 78 Silane

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD: UV/Visible, IR, ^{13}C and ^{1}H NMR and Mass Spectroscopy

3. COMPOSITION

DEGREE OF PURITY
High

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Import.

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

Year	*1*	*2*	*3*	*4*	*5*

Tonnes	3-10	3-10	3-10	3-10	3-10

USE
The notified chemical is used in the manufacture of sealants, adhesives and surface coatings.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
GE Silicones (Australia) Pty Ltd.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported either in 20 L pails, 200 L closed head drums or 1000 L totes.

Formulated products containing the notified chemical will be transported in a number of different types of sealed containers.

5.2. Operation description

Sealants and adhesives

Formulation
The notified chemical is pumped to a mixing vessel from drums via a metering device. However, manual decanting may needed for the small packages. The drum is sealed immediately after decantation and transferred back to the storage area. The transfer container is rinsed with further additions of other ingredients. After formulation, the concentration of the notified chemical in the final sealant or adhesives products will be approximately 0.15%. Tubes of the final product are filled by pumping the product from the drums through a filling machine. This may occur via a temporary filling storage tank such as plastic lined 200 L drums. The product is then distributed to hardware and retail outlets.

Samples of the notified chemical and formulated product are taken for quality control testing.

At the end of a manufacturing run, the mixing vessel and pump lines are rinsed with water. This water is pumped to a holding tank or drums for disposal.

End Use
The sealant or adhesive will be applied by squeezing or gunning the tube directly onto the surface or gap. Sealants are usually smoothed off.

Surface coatings

Formulation
The surface coatings are manufactured via a polymer emulsion intermediate. The notified chemical is poured or pumped via transfer lines into the blending vessel where it is mixed with a polymer emulsion. The concentration of the notified chemical in the polymer emulsion is expected to be <1%. The finished polymer emulsion is pumped into tankers or one tonne tanks using hoses and pipes, and distributed to surface coating manufacturers.

At the surface coating manufacturing site, the polymer emulsion containing the notified chemical is pumped via transfer lines to a mixing vessel. The finished surface coating, containing approximately 0.5% notified chemical, is transferred by hosing until it reaches an automated filling line. The filling packaging processes for the surface coating products is automatic. The final product is then distributed to commercial hardware and similar retail outlets.

Laboratory technicians will take small samples of the surface coating for testing.

Process equipment is rinsed with water. These rinsings are returned to the manufacturing process by reuse of washing water.

End Use
The surface coating is applied using rollers and/or brushes.

5.3. Occupational exposure

Formulation and packaging
At the formulation site, formulation and packaging are automatic processes. However, some manual handling may be required when measuring and/or transferring the notified chemical in small quantities. Skin contact is expected to be the main route of occupational exposure during the formulation processes. Ocular contact may be possible if splashing occurs. Skin contact may also occur during sampling and testing, trouble shooting, maintenance and cleaning of equipment.

For the surface coating manufacture, the duration of exposure for the workers is estimated to be 30 minutes per day and 24 days per year at the polymer emulsion manufacturing site, and 30 minutes per day and 60 days per year at the surface coating formulation site. The laboratory chemists may have exposure to the notified chemical 20 to 30 minutes per day and 47 days per year.

Local exhaust systems are in place to control inhalation exposure. Workers handling the notified chemical wear PVC gloves, safety goggles, overalls, safety boots, face shield, and respirator when necessary.

End use
Both sealant/adhesive and surface coating products containing the notified chemical are applied manually. Skin contact particularly on hand surface is expected. If the surface coating is applied by spray, some inhalation exposure may occur.

After application and once dried, the sealant/adhesive and surface coating product containing the notified chemical is cured into an inert matrix and is hence unavailable to exposure.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Environmental release of the notified chemical is unlikely during importation, storage and transportation, and accidental spills, leaks and catastrophic mechanical failure during a transport accident is the most likely reason for environmental release. Engineering controls (eg. container specifications), personnel training and emergency clean-up procedures (ie. spill response instructions on Safety Data Sheet and label) will limit the impact on the environment of such incidents.

Sealants and adhesives

Minor release of the notified chemical is expected during sealant/adhesive manufacture due to engineering controls, chemical storage bunding, personnel training, spill response procedures and automated work practices. On exposure to air, the sealant/adhesive is expected to dry and remain crosslinked and immobile within the sealant matrix.

Surface coatings

The notified chemical will be transported from the port by road/rail to a precursor formulation facility where it will be blended with other constituents to a precursor product. This product is then packaged in 1000 kg IBCs and transported to customer formulation facilities where it will be used as a precursor in surface coating finished products. Emptied imported containers, containing residues potentially comprising ≤0.01% of the notified chemical, are allowed to air dry and are sent to landfill for disposal. Aqueous wastes (potentially containing ≤2% of the notified chemical import volume) are generated at the precursor manufacturing facility during container rinsing and equipment cleaning. These are sent to

an on-site wastewater treatment plant (WWTP), with treated effluent discharged to sewer. The notified chemical is hydrolytically very unstable, and is expected to degrade rapidly in wastewater. Batch mixing vessel washwaters are reused in the next batch.

At surface coating manufacturing facilities, engineering controls (eg. bunding) are likely to contain spills and leaks of products containing the notified chemical. Equipment/mixing vessel washwaters are likely to be reused in subsequent batches. Residues or spills, containing an estimated 0.025% (~22.5 kg/annum) of notified chemical, would be sent to licensed landfills. None of the manufacturing facilities is expected to dispose of wastewaters containing the notified chemical to municipal sewer.

Finished products will be transported to retail and trade outlets for sale to professional and general public consumers. Unsold or damaged retail stock is probably returned to the manufacturer for recycling or disposal.

RELEASE OF CHEMICAL FROM USE

Sealants and adhesives

The majority of the sealant/adhesive containing the notified chemical will be used by professionals in the construction and building industry, although products may also be available to the do-it-yourself (D-I-Y) market. Release to the environment is expected to be negligible due to the use pattern in building and construction, and an expected small quantity of wastes generated (eg. residues in emptied container potentially comprising ≤0.2% of the notified chemical) are likely to be disposed of to industrial or solid waste landfill with building/construction wastes.

Surface coatings

Use of surface coatings containing the notified chemical would be widespread and diffuse throughout Australia, with concentrations at urban areas/cities. The products will contain <0.01% of the notified chemical. Most of the coating containing the notified chemical is applied to surfaces where it dries and hardens to a film of low potential for environmental release. However, in the treated surface may be recoated or coated materials may be demolished and sent to landfill for disposal or material recycling facility. Brush/roller cleanup with water will result in copious amounts of wastewater containing low concentrations of the notified chemical (~0.01% based on adhered residue of 2%). The notified chemical is hydrolytically very unstable and contact with water is likely to initiate its degradation. The product the notified chemical may also be sprayed onto surfaces, and overspray may occur onto drop sheets (eg. paper, cloth, plastic) or the immediate ground area. The former will be landfilled while the latter is likely to remain where it deposits. When dried, the notified chemical is expected to be bound within the coating matrix.

5.5. Disposal

Sealants and adhesives

For the commercial/industrial applications of the sealants, container residues are expected to be collected by licensed waste contractors for disposal to landfill or incineration. It is likely that used containers from the D-I-Y market will be disposed of with household garbage to landfill. In both cases the residual sealants in the containers are expected to have cured prior to disposal. The vast majority of the sealants/adhesives containing the notified chemical crosslinked within the sealant matrix will share the fate of the building material to which they have been applied (ie. recycling or landfill). If disposed of to landfill the notified chemical is expected to remain immobile crosslinked within the sealant matrix. Disposal by incineration of the notified chemical would destroy the notified chemical and liberate water and oxides of carbon, nitrogen and silicon. Hence, the potential environmental hazard of the notified chemical incorporated into formulated sealant products is expected to be low.

Surface Coatings

Aqueous wastes from the precursor formulation facility (<2% of notified chemical) are sent to an on-site WWTP for treatment prior to sewerage system treatment and disposal under a trade waste

agreement with the relevant water utility. Wastes generated during industrial application of surface coating products containing the notified chemical should be disposed of through a licensed waste contractor to landfill after curing. An estimated 0.01% if the notified chemical is expected to be sent to landfill for disposal in residues in emptied containers. Wastes generated during domestic use should be disposed of according to the instructions in Section 12. Brush/roller wastewater is typically disposed of to land (soil) and/or sewer; however, wastewaters generated from washing rollers/brushes should ideally not be sent to sewer for disposal, but should be contained, evaporated, with the residual dried waste sent to landfill for disposal. The hydrolytic instability of the notified chemical is expected to result in the rapid degradation of the notified chemical on contact with water.

5.6. Public exposure

There is low potential for public exposure during the transport and formulation processes.

The final sealants, adhesives and surface coating products will be retailed throughout Australia. The public will be exposed to the notified chemical as these products are applied manually. Skin contact will be the main route of exposure. After application and once dried, the sealant/adhesive and surface coating product containing the notified chemical is cured into an inert matrix and is hence unavailable for exposure.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Clear liquid

Melting Point/Freezing Point -20°C

METHOD OECD TG 102 Melting Point/Melting Range.
Remarks GLP & QA

Duplicate tests were performed. The test material became slightly viscous during cooling.
TEST FACILITY SafePharm Laboratories (2003a).

Boiling Point 265°C at 102.05 kPa

METHOD OECD TG 103 Boiling Point: : Differential Scanning Calorimetry
Remarks GLP & QA
TEST FACILITY SafePharm Laboratories (2003a).

Density 981 kg/m^3 at 20°C

METHOD OECD TG 109 Density of Liquids and Solids: Pycnometer.
Remarks GLP & QA
TEST FACILITY SafePharm Laboratories (2003a).

Vapour Pressure 4.2×10^{-4} kPa at 25°C

METHOD OECD TG 104 Vapour Pressure: Vapour Pressure Balance method. A sequence of runs was performed between 15°C and 28°C with test material under a vacuum.
Remarks Moderately volatile according to Mensink et al. (1995).
TEST FACILITY SafePharm Laboratories (2003b).

Water Solubility 17.0 g/L at 20°C and pH 7

METHOD OECD TG 105 Water Solubility: shake flask method
Remarks GLP & QA
Due to hydrolytic instability (half life = 5.06 hours), the flasks were shaken for 1 hour only.
Analytical method: Gas Chromatography.

TEST FACILITY SafePharm Laboratories (2003a).

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ (hours)*
1.2	25	Spontaneous hydrolysis
4	25	Spontaneous hydrolysis
7	25	5.06
9	25	0.986

Remarks The test was performed with buffer solutions held at 25°C for 4 h and the decline of the notified chemical was monitored by GC analysis. The notified chemical is hydrolytically unstable and spontaneously hydrolytic under acidic conditions.
TEST FACILITY Safepharm Laboratories (2003d)

Partition Coefficient (n-octanol/water) log Pow = 1.32 at 25ºC (estimated)

METHOD OECD TG 107 or 117 was unable to be used because of notified chemical's instability in aqueous solution. The fragment method of KOWWIN software (version 1.66) was used (Safepharm Laboratories, 2003d).

Adsorption/Desorption log K_{oc} = 1.71 (estimated)

METHOD OECD TG 112 was unable to be used because of the instability of the notified chemical in aqueous solution. A QSAR for the chemical class of non-hydrophobic was used where Log Koc = (0.52 x Log Kow) + 1.02 (SafePharm Laboratories, 2003a)

Dissociation Constant Not determined

Remarks The chemical structure would indicate that the notified chemical has no mode of dissociation.
TEST FACILITY SafePharm Laboratories (2003a).

Particle Size Not determined

Remarks Not applicable for a liquid.

Flash Point 107±2ºC

METHOD EC Directive 92/69/EEC A.9 Flash Point: Closed cup equilibrium method.
Remarks GLP & QA
TEST FACILITY SafePharm Laboratories (2003b).

Flammability Limits Not determined

Remarks The notified chemical is non-combustible based on experience in use.

Autoignition Temperature 210±5ºC

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks GLP & QA
TEST FACILITY SafePharm Laboratories (2003b).

Explosive Properties Not predicted to be explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks GLP & QA

There are no chemical groups that would imply explosive properties, therefore the result has been predicted to be negative.

TEST FACILITY SafePharm Laboratories (2003b).

Reactivity Expected to be stable under normal conditions

Remarks The notified chemical does not have oxidising properties. It is considered to be stable. Hence, there are no known hazardous decomposition products. However, the chemical is combustible and will burn if involved in a fire, evolving noxious fumes, such as carbon oxides.

Fat (or n-octanol) Solubility Totally miscible with standard fat in all proportions at 37±0.5°C.

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.

Remarks Mixtures of test material and standard fat were added to 3 replicate flasks and shaken (37°C for 3 h). Samples were visually examined for phase separation. The flasks contained a uniform single phase solution with no excess undissolved test material remaining.

TEST FACILITY SafePharm Laboratories (2003a)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	LD50>2000 mg/kg bw, low toxicity
Rat, acute dermal	LD50>2000 mg/kg bw, low toxicity
Rabbit, skin irritation	Slightly irritating
Rabbit, eye irritation	Slightly irritating
Guinea pig, skin sensitisation –non-adjuvant test	Evidence of sensitisation
Mouse, skin sensitisation – LLNA	Evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days	NOAEL=1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	Mutagenic
Genotoxicity – in vivo micronuclei test	Non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Y-11012 (the notified chemical)

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).

Species/Strain Rat/Sprague-Dawley

Vehicle None.

Remarks - Method GLP & QA.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0

LD50 >2000 mg/kg bw

Signs of Toxicity One male had dried yellow material around the mouth, and one female had impaired muscle coordination at one-hour post-doing.

Effects in Organs None.

Remarks - Results None.

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

TEST FACILITY	WIL Research Laboratories (2000a).

7.2. Acute toxicity - dermal

TEST SUBSTANCE	Y-11012 (the notified chemical)
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Sprague-Dawley
Vehicle	None.
Type of dressing	Semi-occlusive.
Remarks - Method	GLP & QA

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Very slight erythema was observed in four animals and desquamation was noted in six animals. One animal had focal eschar on day 11.
Signs of Toxicity - Systemic	None treatment-related effects were observed, except discolouration due to discharges/excretions.
Effects in Organs	No treatment-related effects.
Remarks - Results	None.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	WIL Research Laboratories (2000b).

7.3. Acute toxicity - inhalation

No study report provided.

7.4. Irritation – skin

TEST SUBSTANCE	Y-11012 (the 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	3
Vehicle	None.
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	GLP & QA

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.3	0	0.3	2	24 hours	0
Oedema	0	0	0	-	-	0

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

Remarks - Results	Primary irritation index (PII) is calculated as 0.6.
CONCLUSION	The notified chemical is slightly irritating to skin.
TEST FACILITY	WIL Research Laboratories (2000c).

7.5. Irritation - eye

TEST SUBSTANCE	Y-11012 (the notified chemical)
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	GLP & QA

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	0.3	0	0.3	1	24 hours	0
Conjunctiva: chemosis *Conjunctiva: discharge* *Corneal opacity* *Iridial inflammation*	The Draize scores were zero for all these observations.					

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

Remarks - Results	None.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	WIL Research Laboratories (2000d).

7.6. Skin sensitisation - Buhler Test

TEST SUBSTANCE	Y-11012 (the notified chemical)
METHOD	OECD TG 406 Skin Sensitisation – Buhler Test
Species/Strain	Guinea pig/Himalayan spotted
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 10%
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
INDUCTION PHASE	Induction Concentration: topical: 100%
Signs of Irritation	After the 1st, 2nd and 3rd induction, discrete/patchy erythema was observed in 75%, 100% and 100% animals, respectively.
CHALLENGE PHASE	
1st challenge	topical: 10% in ethanol
Remarks - Method	GLP & QA

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*	
		24 h	*48 h*

Test Group	10%	17/20	12/20
Control Group	10%	0/10	0/10

Remarks - Results: Historic positive control data were provided by the test lab.

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

TEST FACILITY: RCC (2003).

7.7. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE: Wetlink 78 (the notified chemical)

METHOD: OECD TG 429 Skin Sensitisation: Local Lymph Node Assay.
Species/Strain: Mouse/CBA/Ca
Vehicle: Acetone/olive oil (4:1)
Remarks - Method: GLP & QA.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	1053.1	-
25	975.3	0.9
50	3795.9	3.6
100	4886.0	4.6
Positive Control		
5	Not provided	2.8
10	Not provided	2.3
25	Not provided	5.5

Positive control: α-hexylcinnamaldehyde

Remarks - Results: The stimulation index (SI) for the two higher concentration groups was greater than 3.

CONCLUSION: There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY: SafePharm Laboratories (2004a).

7.8. Repeat dose oral toxicity

TEST SUBSTANCE: Wetlink 78 (the notified chemical)

METHOD: OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain: Rat/Sprague-Dawley
Route of Administration: Oral – gavage
Exposure Information: Total exposure days: 28 days;
Dose regimen: 7 days per week;
Vehicle: Arachis oil BP
Remarks - Method: GLP & QA

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	15	0
III (mid dose)	5/sex	150	0
IV (high dose)	5/sex	1000	0

Mortality and Time to Death
There were no death during the study.

Clinical Observations
No treatment-related effects were observed except salivation in the high-dose group.

In the behavioural assessment and functional performance test, no treatment-related effects were observed except one high-dose female animal had hunched posture and the high-dose males had higher forelimb grip strength.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No treatment-related effects were observed.

Pathology – organ weight, macroscopic findings, histopathology
No treatment-related effects were observed.

Remarks – Results
The clinical observations are not considered to be treatment-related.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study (the highest dose tested).

TEST FACILITY SafePharm Laboratories (2004b).

7.9. Genotoxicity – bacteria

TEST SUBSTANCE Y-11012 (the notified chemical)

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
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	S9-mix
Concentration Range in Main Test	a) With metabolic activation: 0-5000 µg/plate. b) Without metabolic activation: 0-5000 µg/plate.
Vehicle	DMSO
Remarks - Method	GLP & QA.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	>5000		>5000	
Test 1		≥3333	>5000	positive
Test 2		≥3333	>5000	positive
Present	>5000		>5000	

Test 1	>5000	>5000	positive
Test 2	≥3333	>5000	positive

Remarks - Results: The test material caused positive responses in TA100, TA1535 and WP2uvrA in the presence and absence of rat liver S9-mix.

CONCLUSION: The notified chemical was mutagenic to bacteria under the conditions of the test.

TEST FACILITY: BioReliance (2000).

7.10. Genotoxicity – in vivo

TEST SUBSTANCE: Y-11012 (the notified chemical)

METHOD: OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
- Species/Strain: Mouse/ICR
- Route of Administration: Oral – gavage
- Vehicle: Corn oil
- Remarks - Method: GLP & QA

Group	*Number and sex of animals*	*Dose (mg/kg bw)*	*Sacrifice Time (hours)*
Vehicle control	10/sex	0 (corn oil)	24 (5/sex) 48 (5/sex)
Low-dose group	5/sex	500	24 (5/sex)
Mid-dose group	5/sex	1000	24 (5/sex)
High-dose group	10/sex	2000	24 (5/sex) 48 (5/sex)
Positive control	5/sex	5 (CP)	24 (5/sex)

CP=cyclophosphamide.

RESULTS
- Doses Producing Toxicity: Not observed.
- Genotoxic Effects: Slight reduction (1-2%) in the ratio of polychromatic erythrocytes to total erythrocytes was observed in some of the test groups when comparing to the vehicle controls. These reductions suggested that the test material did not inhibit erythropoiesis.
- Remarks - Results: The number of micronucleated polychromatic erythrocytes per 2000 polychromatic erythrocytes in the test groups was not statistically increased in either male or female animals, regardless of dose level or bone marrow collection time.

CONCLUSION: The notified chemical was not clastogenic in this in vivo micronucleus test under the conditions of the test.

TEST FACILITY: BioReliance (2001).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test (Modified Sturm test).
Inoculum	Mixed population of activated sludge micro-organisms from a plant that predominantly treats domestic sewage.
Exposure Period	28 d
Auxiliary Solvent	None
Analytical Monitoring	DOC was measured on day 0 (prior to addition of test material) and day 28. pH was measured on day 28. CO_2 was collected from CO_2 absorbers and measured throughout the test.
Remarks - Method	The test material (56.4 mg) was dissolved directly in culture medium (~200 mL) prior to dispersal in inoculated culture medium. The volume was adjusted to 3 L to give a final test material concentration of 18.8 mg/L (10 mg C/L). Each test vessel had an inoculum concentration of 30 mg suspended solids/L and the temperature was maintained at 21°C. For the 24 hours prior to the commencement of the test, the test vessels containing the inoculum were aerated. On day 0 the test and standard material were added and the vessels sealed. CO_2 free air at 40 mL/min was bubbled through the solutions, which were continuously stirred via a magnetic stirrer. Through out the study, the CO_2 was collected in two 500 mL Dreschel bottles containing 350 mL of 0.05 M NaOH. Reference material – sodium benzoate. Toxicity control was conducted with the test material (18.8 mg/L) and sodium benzoate (17.1 mg/L), equivalent to a total of 20 mg C/L.

RESULTS

Test substance		Sodium Benzoate		Test Material and Sodium Benzoate	
Day	*% degradation*	*Day*	*% degradation*	*Day*	*% degradation*
1	3	1	29	1	13
3	15	3	64	3	38
7	20	7	62	7	46
11	31	11	64	11	52
15	27	15	77	15	54
23	31	23	75	23	55
28	28	28	78	28	55

Remarks - Results	The test material achieved 28% degradation by day 28. The sodium benzoate reached 78% degradation in 28 days (satisfactory). The toxicity control reached 55% degradation by day 28 indicating that the material was not toxic to sewage micro-organisms.
CONCLUSION	Since it did not meet the 10-day 60% degradation criterion, the notified chemical cannot be classified as readily biodegradable.
TEST FACILITY	SafePharm Laboratories (2003c)

8.1.2. Bioaccumulation

No bioaccumulation data were submitted. The estimated octanol:water partition co-efficient of 1.32 indicates that the notified chemical is unlikely to have a high affinity to lipids or bioaccumulate. It is also hydrolytically unstable in water.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – static.

Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	100 mg/L (as $CaCO_3$)
Analytical Monitoring	Gas chromatography
Remarks – Method	Preliminary and range-finding tests were performed. A stock solution (1 g/L) was prepared by dissolving test material (2 g) in a final volume of 2 L of dechlorinated tap water with the aid of ultrasonication. Aliquots of stock solution (360 and 640 mL) were each separately dispersed in a final volume of 20 L of dechlorinated tap water to give the 18 and 32 mg/L test solution concentrations. To prepare the remaining test solution concentrations, test material (1120, 2000, 3600 mg) were each separately dissolved in a final volume of 2 L of dechlorinated tap water prior to dispersion in 20 L to give the 56, 100 and 180 mg/L test solution concentrations. Temperature, pH and dissolved oxygen were measured daily. Temperature was maintained at 14°C, pH ranged from 7.5-8.2 and dissolved oxygen ranged from 81-97% ASV. All solutions were clear and colourless at the beginning of the study but were cloudy after 72 and 96 h with increasing turbidity as the concentration increased.

RESULTS

Concentration mg/L (parent material))			*Number of Fish*	*Cumulative Mortality*				
Nominal	*Actual*	*0 h and 96 h*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	-		10	0	0	0	0	0
18	12.6	0.762	10	0	0	0	0	0
32	21.9	1.43	10	0	0	0	0	0
56	41.3	2.69	10	0	0	0	0	0
100	133	2.57	10	0	0	0	0	0
180	261	4.39	10	0	0	3	4	5

LC50 (notified chemical and hydrolysis products)	180 mg/L at 96 hours (based on initial nominal concentration).
NOEC (sublethal effects)	56 mg/L at 96 hours (based on initial nominal concentration)
Remarks – Results	Caution is advised when interpreting the test results as the notified chemical is hydrolytically unstable (half-life ~5 h at pH 7). Therefore, the test solutions probably contained a mixture of the parent compound and hydrolysed products. At time 0 hour the measured concentration of parent material in the vessels ranged from 68-145% of nominal but by 96 h it ranged from 2-5% of nominal. The toxicity could not be attributed to the notified chemical solely or any of the hydrolysis products but rather to the whole mixture. Sub-lethal effects were observed at ≥100 mg/L; however, their severity declined over time. After 24 hours the test solutions were cloudy, and this increased with time and concentration.
CONCLUSION	The mixture of the notified chemical and hydrolysis products is only very slightly toxic to fish (LC50 >100 mg/L, Mensink *et al*., 1995).
TEST FACILITY	Safepharm Laboratories (2004c)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test - static
Species	*Daphnia magna* (<24 h old, 1st instar)
Exposure Period	48 h
Auxiliary Solvent	None
Water Hardness	Approx. 250 mg/L (as $CaCO_3$).

Analytical Monitoring	Spectrometric analysis was by GC/MS.
Remarks - Method	Range-finding and definitive tests were performed. An amount of test material (200 mg) was dissolved in reconstituted water and the volume adjusted to 2 L to give the 100 mg/L test concentration. Aliquots of this test concentration were each separately dispersed to give the other test concentrations. Test temp: 21°C. pH range: 8.0-8.1. DO: 8.1-8.7 mg/L.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
	0 h and 48 h			
0	-	20 (2 reps of 10)	0	0
1.0	<LOQ*	20 (2 reps of 10)	0	0
1.8	0.02 <LOQ	20 (2 reps of 10)	0	0
3.2	0.027 <LOQ	20 (2 reps of 10)	0	2
5.6	0.106 0.009	20 (2 reps of 10)	0	5
10	0.25 0.05	20 (2 reps of 10)	0	8
18	0.59 0.07	20 (2 reps of 10)	0	9
32	0.88 0.19	20 (2 reps of 10)	0	12
56	1.82 0.39	20 (2 reps of 10)	0	15
100	3.09 0.89	20 (2 reps of 10)	0	17

*LOQ limit of quantitation = 0.0038 mg/L.

EC50 (notified chemical and hydrolysis products)	20 mg/L at 48 hours (based on initial nominal concentration).
NOEC	1.8 mg/L at 96 hours (based on initial nominal concentration)
Remarks - Results	Caution is advised when interpreting the test results as the notified chemical is hydrolytically unstable (half-life ~5 h at pH 7). Therefore, the test solutions probably contained a mixture of the parent compound and hydrolysed products. At time 0 hour the measured concentration of parent material in the vessels ranged from <LOQ-97% of nominal but by 96 h test substance concentration ranged from <LOQ-6% of nominal. The toxicity could not be attributed to the notified chemical solely or any of the hydrolysis products but rather to the whole mixture. All of the test solutions remained clear and colourless throughout the test duration.
CONCLUSION	The mixture of the notified chemical and hydrolysis products is harmful to aquatic organisms (L(E)C50 of 10-100 mg/L, United Nations, 2003).
TEST FACILITY	Safepharm Laboratories (2004d)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test - static
Species	Green algae *Scenedesmus subspicatus*
Exposure Period	72 h
Concentration Range	
Nominal	<LOQ, 0.32, 1.0, 3.2, 10, 32, 100 and 320 mg/L (0 h)
Actual	<LOQ, 2.46, ND, ND, 9.55, ND, ND, 278 mg/L (0 h) <LOQ, <2%, ND, ND, <1%, ND, ND, <1% (% of nominal at 72 h) *LOQ limit of quantitation = 0.0025 mg/L.
Auxiliary Solvent	None
Water Hardness	Not stated
Analytical Monitoring	Test solutions were sampled at 0 and 72 hours with analysis by GC.
Remarks - Method	Range-finding and definitive tests were performed. Test material was dissolved directly in culture medium. Amounts of test material (640 and 200 mg) were each separately dissolved in culture medium and volumes adjusted to 2 L to give 320 and 100 mg/L stock solutions, respectively. Aliquots were subsequently diluted to prepare additional stock solutions (32, 10, 3.2, 1.0 and 0.32 mg/L). Aliquots (1 L) of each stock solution were separately inoculated

with algal suspension (5.0 mL) to give the required test solution concentrations and an initial cell density of ~10^4 cells/mL. Temperature: 21±1°C. pH was monitored at 0 and 72 h (pH 7.3-8.1) (acceptable). The test solutions were exposed to continuous illumination (7000 lux) and aerated during the test. The test material was hydrolytically unstable.

RESULTS

Biomass	*Growth*	*NOEC*
E_bC50 mg/L at 72 h	*E_rC50 mg/L at 72 h*	*mg/L at 72 h*
32	280	1.0

Remarks - Results

Caution is advised when interpreting the test results as the notified chemical is hydrolytically unstable (half-life ~5 h at pH 7). Therefore, the test solutions probably contained a mixture of the parent compound and hydrolysed products. At time 0 hour the measured concentration of parent material in the vessels ranged from <LOQ-97% of nominal but by 96 h test substance concentration ranged from <LOQ-6% of nominal. The toxicity could not be attributed to the notified chemical solely or any of the hydrolysis products but rather to the whole mixture. All of the test solutions remained clear and colourless throughout the test duration.

CONCLUSION

The mixture of the notified chemical and hydrolysis products is harmful to algae (L(E)C50 of 10-100 mg/L, United Nations, 2003).

TEST FACILITY

Safepharm Laboratories (2004e)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical, though estimated to be relatively soluble in water, is not itself likely to be persistent in solution in the environment as it is hydrolytically unstable (half-life 3-5 hours at neutral pH). Based on its low Log Kow, the notified chemical is unlikely to bioaccumulate. Its moderately volatility suggests a proportion may volatilise to the atmosphere.

After application and once dried, the sealant/adhesive and surface coating products containing the notified chemical are cured into an inert matrix and hence unavailable to exposure. Once landfilled, the notified chemical is unlikely to be mobile and is expected to degrade over time. If incinerated, the notified chemical will degrade to liberate water and oxides of carbon, nitrogen and silicon.

Sources of the notified chemical to the sewerage system may potentially arise from the surface coating manufacturing industry (estimated at ≤2% of the annual import volume of the notified chemical, <250 kg/y), which is discharged to a specific system after treatment. Application of surface coatings may also result in the discharge of wastewaters containing the notified chemical to the sewerage system Australia-wide (<50 kg/y), based on the expected widespread and diffuse use pattern. In the sewerage system, the notified chemical will undergo rapid hydrolysis to simpler compounds, and other attenuation processes are also expected (eg. dilution, partial biodegradation and volatilisation).

9.1.2. Environment – effects assessment

Aquatic toxicity data were available for 4 taxa: fish, invertebrates, algae and micro-organisms (Safepharm Laboratories, 2003c, 2004c-e). A mixture containing the notified chemical and hydrolysis products is considered harmful to some freshwater species if exposed. The results of the aquatic toxicity tests available indicate that the lowest available EC50 is for daphnids; 20 mg/L. In each of the three tests available, the test material was hydrolytically unstable and consequently toxicity data refer to a mixture of the parent compound and hydrolysis products. A

predicted no effect concentration for aquatic organisms ($PNEC_{aquatic}$) of 0.2 mg/L has been derived by dividing the lowest acute EC50 value by a safety factor of 100, used to account for interspecies sensitivity, acute to chronic effects ratio and other adverse factors that may potentially arise in the environment if organisms are exposed to the notified substance. No toxicity data were available for marine species, or sediment- or soil-dwelling organisms.

9.1.3. Environment – risk characterisation

A risk quotient (RQ) approach is adopted for assessment of environmental risks, where RQ = PEC/PNEC. A discharge of ≤2% of the notified chemical and hydrolysis products (≤200 kg/y) to a specific sewerage system that treats 500 ML/d would result in negligible risk to the aquatic environment (RQ ~0.14; where PEC = 500 x 10^6 mg/y ÷ 365 d/y ÷ 500 x 10^6 L/d and PNEC = 0.02). Wastewaters generated from cleaning brushes/rollers used to apply the surface cotings may potentially contribute up to <50 kg/y of the notified chemical to sewer. The national wastewater system treats ~4020 ML/day, this may result in an average wastewater concentration of the notified chemical and hydrolysis products of up to 0.00003 mg/L (50 x10^6 mg per annum ÷ 365 days/ year ÷ 4020 x 10^6 L/day). This assumes the Australian population of 20.1 million people discharges 200 L of wastewater per person per day into the sewerage system. A negligible risk to the aquatic environment is expected (RQ ~0.0017).

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Formulation

During formulation of sealant/adhesive, or the polymer emulsion, workers involved in operating the blending vessels have the potential of dermal or eye exposure to the notified chemical in its neat form. Formulation is carried out in closed vessels with local ventilation. Workers involved in other processes, such as surface coating formulation, quality control testing and equipment maintenance, may also experience dermal and eye exposure to the notified chemical at lower concentrations. After formulation, the chemical is present at lower concentrations (<0.5%). All workers involved in formulation activities, including quality control and equipment maintenance will wear gloves and safety glasses and overalls.

End use

End use of the sealant/adhesive or surface coating product in commercial situations may potentially result in frequent exposure. Overalls typically are worn by the end uses, however it is unlikely that gloves or goggles would routinely be used. The occupational exposure to the notified chemical is low given that is present below 0.5%.

Occupational exposure during formulation and end use is also estimated by the EASE (Estimation and Assessment of Substance Exposure) program developed by the Health and Safety Executive, UK (1997). In the estimation of occupational exposure, the surface area of occupational exposure is 1000 cm^2 (NICNAS, 1996), and the concentration of the notified chemical in product is selected to be 0.5%.

Results of the EASE estimation from the table below indicate that occupational exposure is very low during formulation processes. For end use, dermal exposure is proportional to the frequency of use, ranging from 0.5 to 75 mg/day.

Exposure predicted using EASE		
Physical state	Liquid	
Temperature	25°C	
Dermal exposure	*Formulation*	*End Use*
Use pattern	Closed system No-dispersive	Wide dispersive
Contact pattern	No direct handling	Direct handling

	(worst-case incidental exposure) Breached for sampling/ maintenance	Incidental (1 event/day)	Intermittent (1-10 event/day)	Extensive (>10 event/day)
Predicted dermal exposure	< 0.1 mg/cm^2/day	0.1-1 mg/cm^2/day or 0.1-1 g/day	1-5 g/cm^2/day or 1-5 g/day	5-15 mg/cm^2/day or 5-15 g/day
Predicted dermal exposure (expressed as wt notified chemical*)	< 0.1 g/day (neat) < 0.5 mg/day (in formulated product)	0.5-5 mg/day	5-25 mg/day	25-75 mg/day

* Assuming 0.5% notified chemical in formulated product

9.2.2. Public health – exposure assessment

The public is unlikely to use the sealant/adhesive and surface coating products frequently. The low level of notified chemical in the finished products, <0.5%, means that skin and eye exposure will be low even in the event of these products remaining on the skin for extended periods of time (up to several hours). Protective clothing may be worn by the D-I-Y users, however it is unlikely that gloves or goggles would be used.

From the above EASE calculation, the predicted dermal exposure to the notified chemical in the public can be estimated in the range of 0.5-25 mg/day, assuming a contact pattern between incidental and intermittent.

9.2.3. Human health - effects assessment

The notified chemical is of low acute oral and dermal toxicity in rats. It is a slight skin and eye irritant in rabbits. Both a Buhler test and a local lymph node assay indicated that the notified chemical is a skin sensitiser. The NOAEL from a 28-day oral repeat-dose study was 1000 mg/kg/day, the highest dose used in the study.

Although the Ames test indicated that the notified chemical is mutagenic in bacteria, the in vivo micronucleus test confirmed that the notified chemical is not a mutagen. No other genotoxicity studies were submitted.

The notified chemical should be classified as Xn (sensitisation by skin contact).

9.2.4. Occupational health and safety – risk characterisation

The main health concern for the notified chemical is skin sensitisation so there is some risk of sensitisation wherever the notified chemical may be handled. Workers who handle the notified chemical in its most concentrated form, for example, during formulation, are at greatest risk. Any products containing ≥1% notified chemical are classified as hazardous substances on the basis of this adverse effect. Workers who become sensitised with the notified chemical should be advised to stop handling the notified chemical.

For repeated exposure, no significant adverse effects were identified in toxicological studies, with the NOAEL in a 28-day oral rat study being 1000 mg/kg/day, the highest dose. Using the exposure estimates predicted by EASE, the following margins of exposure (MOEs) are calculated for the various scenarios (MOE = NOAEL/internal dose). The dermal absorption rate is assumed to be 10% and a bodyweight of 70 kg is used in the calculation.

Workers involved in formulation will handle the notified chemical in its neat form as well as the products containing <1% notified chemical. At the formulation sites, closed systems will be used for formulation, and local exhaust ventilation will minimise any fumes or aerosols. In addition, workers typically wear protective clothing, goggles and gloves. Therefore, exposure to the notified chemical will be further reduced. Exposure will be to drips and spills during transfer and clean up, should be mainly dermal and intermittent and will be controlled by the use of engineering controls and personal protective equipment. Thus, the risk of adverse health effects at formulation sites is expected to be low.

The concentrations of notified chemical in sealants/adhesives, polymeric emulsion and surface coating products are low, less than 1%. End use may lead to some dermal exposure, however, the health risk is considered to be low.

No health risk is expected after the sealant/adhesive and surface coating products containing the notified chemical dried up since the notified chemical will not be bioavailable.

MOE estimates				
	Formulation	*End Use*		
		Incidental (1 event/day)	Intermittent (1-10 event/day)	Extensive (>10 event/day)
Predicted dermal exposure	< 0.1 g/day (neat)			
	< 0.5 mg/day (formulated product)	0.5-5 mg/day	5-25 mg/day	25-75 mg/day
Internal dose (assuming 10% dermal absorption)	<10 mg/day (neat)			
	< 0.05 mg/day (formulated product)	0.05-0.5 mg/day	0.5-2.5 mg/day	2.5-7.5 mg/day
MOE	7000 (neat)			
	>1 400 000 (formulated product)	140 000-1 400 000	28 000-140 000	9 333-28 000

The EASE program did not include the scenario of occupational exposure with personal protective equipment (PPE). If workers wear overalls, gloves, safety boots and eye protection, the MOE is expected to be even higher with the industrial controls. Taking into account that exposure estimates were worst-case, the risk of adverse health effects in workers exposed to the notified chemical is considered to be low particularly when industrial control is in place and PPE is worn.

9.2.5. Public health – risk characterisation

There is potential for public exposure arising from its use in sealant/adhesive and surface coating products, but the low concentrations in these final products indicates a low risk to public health. From the above estimation of margin of exposure, the MOE for the public is expected to be very high, i.e. low risk.

After drying and curing, the sealant/adhesive and surface coating products containing the notified chemical will not be bioavailable.

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* (NOHSC, 1999b). The classification and labelling details are:

Sensitisation by skin contact (Xn).

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***
Skin sensitisation	1	May cause an allergic skin reaction
Acute hazards to the aquatic environment	3	Harmful to aquatic life

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, the notified 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 Low Concern to public health based on its reported use pattern.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and products containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). There are 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 and products containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The NOHSC should consider the following health hazard classification for the notified chemical:
  - Sensitisation (Xn): R43 (May cause sensitisation by skin contact)

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - concentration cut-off ≥ 1%: R43 (May cause sensitisation by skin contact)

- Products containing equal and more than 1% notified chemical and available to the public must carry the following safety directions on the label:
  - S24 (Avoid contact with skin)
  - S37 (Wear suitable gloves)

Health Surveillance

- The notified chemical should be considered by NOHSC for development of health surveillance guidelines.

- As the notified chemical is a health hazard, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of the health effect.

- Sensitised workers should be advised not to further handling the notified chemical.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - enclosure of mixing tanks during formulation
  - local exhaust ventilation during transfer of notified chemical from drum to mixing tank.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - during transfer to mixing tank, avoid splashing
  - during formulation of products containing the notified chemical, minimise spray use during cleaning operations

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during formulation:
  - Industrial overalls
  - Protective gloves
  - Safety eye protections

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

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public Health

- The following measures should be taken to minimise public exposure to the notified chemical:
  - The risk and safety phrases should be displayed on the labels of products containing ≥1% notified chemical for public uses.

Environment

Disposal

- The notified chemical should be disposed of in accordance with State/Territory waste management guidelines.
- Wastes generated during industrial application of surface coatings containing the notifier polymer should be disposed of through a licensed waste contractor to an approved landfill or by special means, eg. incinerated, in accordance with regulations.
- In domestic applications unused/unwanted surface coating should be kept in the original container and collected by Local Government programs for recycling and/or left to dry and sent to landfill.
- Overspray wastes on drop sheets should be allowed to dry and sent to landfill for disposal.

Emergency procedures

- Large spills of the notified chemical should be contained and pumped into resealable labelled containers for disposal. Residues should be absorbed using inert materials (eg. sand, earth).
- Small spills should be flushed with copious amounts of water but only if waters are able to be collected for specific wastewater treatment, otherwise cleanup as for large spills residues.
- Keep spills and cleaning runoff out of municipal sewers, stormwater or open bodies of water.

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 Subsection 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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