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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Compound SF-4510

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NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
TCL Australia Pty. Ltd. (Trading as TCL Hofmann) (ABN 39 091 773 330)
150 Woodlands Drive
Braeside Victoria 3195

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name
Other Names
CAS Number
Molecular Formula
Structural Formula
Molecular Weight
Spectral Data
Methods of Detection and Determination
Non-Hazardous Impurities
Degree of Purity
Manufacture/Import Volume
Use Details
Site of Manufacturer/Recipients

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
EC, Italy, 03-84-8195-00

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Compound in Primid SF-4510

METHODS OF DETECTION AND DETERMINATION

METHOD	The notified chemical and its impurities are determined by HPLC.
Remarks	A HPLC chromatogram was provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported in sealed 25 kg cardboard boxes with polyethylene-liners as a powder component of the imported product Primid SF-4510 (<50% notified chemical).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<10	10-30	10-30	10-30	10-30

USE
The notified chemical is used as a cross-linking reagent in industrial spray-powder coating systems. Typical end-use applications include finished industrial and domestic metal wares such as architectural components as facades, window frames, doors, car parts, outdoor furniture and garden fences.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
TCL Hofmann
Breaside, Victoria

TRANSPORTATION AND PACKAGING
The notified chemical will be imported by sea and or air in 25 kg cardboard boxes with polyethylene (PE) liners and transported by road to the notifier's warehouse for storage prior to distribution, as required, to powder coating formulators.

Spray powder formulations containing the notified chemical (<10%) will be transported by road to industrial end-users in either 25 kg cardboard boxes with plastic liners or 800-1000 kg rigid plastic containers.

5.2. Operation description

The notified chemical is not manufactured in Australia. The notified chemical will be formulated into powder coatings for use by industrial applicators.

Blending and Extrusion
The bags (25 kg) of powdered product containing the notified chemical (<50%) will be transported by forklift, as required, from the spray coating plant's warehouse to the production area. All weighing, blending, extrusion operations are undertaken under local exhaust ventilation.

At the plant, the imported product (will be manually added directly with other coating additives to the blending hopper. Smaller amounts, if required, (<5 kg) will be weighed in a dedicated weigh booth

prior to addition to the hopper. Once loaded, the hopper is transferred to a dedicated and sealed dry blending area for blending of the spray coating components.

The resultant blend containing <10% notified chemical will be transferred in several ways (depending on the operation scale) from the hopper to a fully enclosed extruder machine. Large volume hoppers (1000 kg or more) are positioned directly over the extruder and the contents transferred to the extruder by gravimetric means. Smaller hoppers are positioned adjacent to the extruder and the contents suctioned into the extruder. Alternatively, the hopper contents are discharged either manually or by automated suction into separate smaller hoppers/containers before being transferred manually or by automated suction into the extruder. In the extruder, the blend is melted (by heating to the highest melting point of the components), and plastic pellets (<10% notified chemical) extruded. The plastic pellets are transferred by conveyor belt to an enclosed and automated mill machine for rolling, chipping grinding and milling. The resultant powdered coating (<10% notified chemical) is transferred by automated means to an enclosed and automated packing machine for packaging into 25 kg cardboard boxes with plastic liners or 800-1000 kg rigid plastic containers.

Powder Coating
The containers of formulated powder coating <10% notified chemical will be transferred by forklift, as required, from the warehouse to a dedicated spray-coating area. The containers will be opened manually and the spray gun injector hose placed directly into the container. The hose supplies the dry powder coating to the electrostatic spray gun. The dry powder electrostatic spray coating will be performed in enclosed spray booths. The articles to be coated will be passed through the spray booth on a conveyor. In automated plants, the spray guns are mounted on robotic arms. Touch-ups and small scale coating operations utilise manual spray equipment, which is hand held and used in a manual spray booth. The spray booths (both manual and automated) are generally self-cleaning. Over-spray (powder that does not stick the substrate) is automatically collected and recycled. After spraying, the articles are transported via a conveyor to a curing oven (which typically operate at approximately 200ºC).

End Use - industrial and domestic consumers
The notifier does not give specific details, however, it is expected that coated articles will be transported Australia-wide for use by industrial and domestic consumers.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Production Operators (weighing, loading, packing pellets)	2-3	2-4 hr	daily
Spray Powder Coaters	1	6-8 hr	daily
Cleaning Personnel	unknown	1-10 hr	52 days

Exposure Details

Transport and Warehousing
Transport, warehouse and stores personnel will wear protective equipment (overalls/ industrial clothing and gloves as appropriate) when receiving and handling consignments of the imported product containing the notified chemical (up to 50%). The product will be handled in the warehouse by forklift handling of pallets. During transport and warehousing, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached.

Blending and Extrusion
The main routes of exposure to the notified chemical (up to 50%) are dermal and accidental ocular and inhalation exposure during weighing and adding the imported powdered product to the automated batching and pellet-extruding machine.

Plant operators are involved in opening the imported packages containing the notified chemical and transferring the powder into the fully automated and enclosed batching machine which formulates and extrudes pellets (containing <10% notified chemical). It is possible that dermal, inhalation and accidental ocular exposure to the notified chemical by means of spillages may occur during transfer

operations.

It is possible that dermal and accidental ocular and inhalation exposure may occur if manual intervention is required during the automated transfer operations. It is possible that dermal and accidental ocular and inhalation exposure to the powder coating containing the notified chemical may occur if manual intervention is required during the milling/sieving and automated packaging operation or the powdered packages are accidentally breached. Production operators and supervisors will have intermittent exposure to the notified chemical when cleaning the equipment in general. Quality control personnel will have intermittent exposure when sampling batches of the reformulated powder coatings containing the notified chemical.

All workers involved in handling the imported product and formulated powder coatings will wear personal protective equipment (PPE) such as safety glasses, gloves, protective clothing and dust masks, if necessary. The weighing, batching, extruding and automated packaging operations occur under local exhaust ventilation (LVE). All production operators and supervisors are trained in the appropriate operational procedures and precautions.

Powder-Coating
The main routes of exposure to the product containing the notified chemical (< 10%) are dermal and accidental ocular and inhalation exposure during the manually opening of the product from boxes (25 kg) and placing the injector hose into the box. Workers may also be exposed when performing manual touch-ups with the most likely routes of exposure being inhalation, dermal and ocular exposure. Minimal exposure will occur during cleaning of spray-booths unless manual intervention is required as spray-booths are self-cleaning. Dermal and accidental ocular and inhalation exposure can also occur if the items being coated are moved manually to the oven for curing although in large-scale plants this is done automatically and therefore is only a consideration in small-scale plants.

Disposal
Workers may be involved in disposal of waste pelletised plastic or powder-coated products.

5.4. Release

RELEASE OF CHEMICAL AT SITE
Blending and Extrusion: The notified chemical is manufactured overseas and is imported into Melbourne in 25 kg PE lined bags. The notified chemical is subsequently transported to the reformulation site where the notified chemical undergoes mixing, heating, extruding, rolling, chipping, milling, sieving and subsequent packaging into similar 25 kg PE lined bags. Mix containing the notified chemical that does not pass through the sieving process is returned to the chipper for subsequent re-processing.

Environmental release is not expected during formulation apart from accidents during transport and handling. In these situations, the notified chemical is expected to be swept up, and if not contaminated, returned to the above process stream. Contaminated notified chemical is expected to be thermally decomposed in an incinerator. Import packaging is also expected to be incinerated or disposed of to secure landfill. It is estimate that up to 2% of the total import volume will be lost during formulation including from cleaning of equipment. However, 95% of this is expected to be recovered and returned to the processing stream.

RELEASE OF CHEMICAL FROM USE

Powder-Coating: The notified chemical is a component (< 10%) of powder coating. During use, the powder coating is mixed in a hopper and applied to metal surfaces by spray. Once applied, the powder coating is cured by heating, effectively binding the notified chemical within the coating matrix. Overspray, containing the notified chemical is expected to be swept up and be recycled by returning to the hopper and being reapplied. The loss of powder coating due to the spraying/recycling process is expected to be below 1% of the total import volume of notified chemical will be lost during end-use.

5.5. Disposal

Once cured, the notified chemical remains trapped within the surface-coating matrix. The fate of the notified chemical is therefore related to that of metal to which it is applied. It is expected that this will

either be disposed of to landfill, or to metal recycling programs. In landfill, the notified chemical is not expected to be mobile, should remain associated with the metal to which it is applied. Over time, the notified chemical may degrade by biotic and abiotic processes to form simple compounds. During metal recycling, the notified chemical is expected to be thermally decomposed in the metal furnace.

5.6. Public exposure

No manufacture of the notified chemical will take place in Australia. The notified chemical will only be imported as a component of the product Primid SF-4510 for use as a cross-linking agent in industrial powder coating systems. The imported product will not be available for use by the general public.

The notified polymer will not be sold to the public except in the form of finished metal wares. Members of the public, however, may come into contact with metal wares coated with the notified chemical. The powder coating will be applied to a variety of articles such as architectural components as facades, window frames, doors, car parts, outdoor furniture and garden fences. Once cured, the notified chemical is bound in an inert matrix and is not bioavilable. The notified chemical will be bound within the articles at a level of < 10%.

The potential for exposure of the general public to the notified chemical contained in Primid SF-4510 during normal industrial handling, transportation and manufacturing processes will be minimal. Only in extreme cases of inappropriate handling or accidents during transportation would there be any likelihood of the notified chemical being released from the packaging and the public being exposed or contamination of the environment occurring. During normal uses of the various articles that may by coated with the products containing the notified chemical, public exposure to such coatings would be low given the reported use patterns of such items.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa White powdered solid.

Melting Point/Freezing Point 77.4°C ± 0.1 °C

METHOD	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Differential scanning calorimeter. No protocol deviations reported. Statement of GLP compliance.
TEST FACILITY	RCC (2001a)

Boiling Point 309°C at 101.3 kPa

METHOD	EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Capillary test. No protocol deviations reported. Statement of GLP compliance.
TEST FACILITY	RCC (2001b)

Density 1183 kg/m^3 at 20°C

METHOD	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	By gas comparison pyconometer. No protocol deviations reported. Statement of GLP compliance.
TEST FACILITY	RCC (2001c)

Vapour Pressure < 1 ×10^{-8} kPa at 25°C

METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Calculated using the Modified Watson Correlation using the calculated boiling point. In respect to the environment, the notified chemical is classified as very slightly volatile (Mensink et al, (1995)).
TEST FACILITY	RCC (2001d)

Water Solubility 50.8 g/L at 20ºC

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks No protocol deviations reported. Statement of GLP compliance.
Flask & Analytical Method. 5 g of notified chemical was added to 25 mL of water. After up to 96 hours at 20-35ºC, supernatant solutions were centrifuged (~2900 G), filtered (0.45 μm) and diluted in a 1:500 ratio with methanol/water (50:50 v/v) before analysis using a HPLC. The notified chemical was found to be readily soluble (Mensink et al, (1995)).
TEST FACILITY RCC (2001e)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*t½ days*
4	50	>8760
7	25	514
	50	31
	65	7.5
	75	2.8
9	25	253
	50	37
	65	4.9
	75	2

Remarks No protocol deviations reported. Statement of GLP compliance.
Hydrolysis was performed at 50.0ºC ± 0.1ºC. The test item was found to be stable at pH 4.0, and therefore, no further testing was performed at this pH value. Further testing was performed at different temperatures in order to calculate the rate constant (K_{25}) and the half-life time of the hydrolysis at pH 7.0 and pH 9.0 at 25ºC was extrapolated.
TEST FACILITY RCC (2001f)

Partition Coefficient (n-octanol/water) log Pow = 0.23 at 20ºC

METHOD OECD TG 107 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks No protocol deviations reported. Statement of GLP compliance.
Flask Method. A preliminary test was performed which determined the solubility in n-octanol to be approximately 136 g/L. Three main tests were carried out, each in duplicate, whose spike solution was prepared by dissolving 106.6 mg in 200 mL n-octanol (saturated with water). Six test vessels were prepared, and after shaking for 30 minutes, were centrifuged for 10 minutes at about 2900 g, to achieve phase separation. The concentration of notified chemical was then determined using HPLC.
TEST FACILITY RCC (2001g)

Adsorption/Desorption – screening test log K_{oc} = 32 at 20°C

METHOD Estimate – "Expert Statement on the adsorption coefficient for soils and sediment of the notified chemical"
Remarks The expert statement concluded that the notified chemical is mobile in soils, based on the regression equation: log K_{OC} = 0.544 log P_{OW} + 1.377, where log P_{OW} = 0.23.
TEST FACILITY RCC (2001h)

Dissociation Constant Does not dissociate or protonate in the environmentally relevant range from pH 4-9.

METHOD Estimate – "Expert Statement on the dissociation constant of the notified chemical"
Remarks The expert statement concluded that the notified chemical does not dissociate or protonate in the environmentally relevant.
TEST FACILITY RCC (2001i)

Particle Size

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (μm)	*Mass (%)*
<14.2	5
<17.4	10
<30.4	50
<68.3	90

Remarks No protocol deviations reported. Statement of GLP compliance.
Test conducted on a sparingly soluble/suspension of test substance in petroleum benzine. <10 μm, 3% inspirable; <100 μm 93% respirable. Mass median aerodynamic diameter: 30.4 μm.
TEST FACILITY RCC (2001j)

Flash Point Not applicable.

Remarks The notified chemical is a solid. The test is not applicable to solids.

Flammability Limits Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks No protocol deviations reported. Statement of GLP compliance.
The product failed to ignite with a flame during the preliminary test (contact time of about 2 minutes). In contact with the ignition source, the product melted and a colourless melt remained. No flame was observed. Therefore no main test was performed.
TEST FACILITY RCC (2001k).

Autoignition Temperature > 80°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks No protocol deviations reported. Statement of GLP compliance.
The notified chemical did not autoignite below its melting point and therefore is regarded as not auto-flammable according to this test.
TEST FACILITY RCC (2001l)

Explosive Properties Not explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks No protocol deviations reported. Statement of GLP compliance.
The absence of reactive groups and the oxygen balance (-219) indicates that experimental testing is not required for this product. However, exothermic decomposition energy was investigated (and could not be determined). There was no exothermic peak found under test conditions.
TEST FACILITY RCC (2001m).

Reactivity Not highly reactive.

Remarks Not readily oxidisable.
Stable in air under normal storage and environmental conditions. Hydrolyses slowly in water at neutral pH values.

ADDITIONAL TESTS

Fat (or n-octanol) Solubility 13,600 mg/100 g n-octanol at 20°C

METHOD See below
Remarks There is no specific report on the method of determination of this value. However, in the Partition Coefficient study (OECD 107 & 117), the figure above was given as "about" the solubility in n-octanol.

Surface Tension 67.4 mN/m at 19.6ºC

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks No protocol deviations reported. Statement of GLP compliance. .
Concentration: "About 0.1%" 200.8 mg in 200 mL distilled water using a ring tensiometer. The notified substance was found to be not surface active.
TEST FACILITY RCC (2001n)

Oxidizing Properties

METHOD Estimate – "Expert Statement on the oxidising properties of the notified chemical"
Remarks The expert statement concluded that the notified chemical is incapable of causing fire or enhancing the risk of fire when in contact with combustible material due to the negative oxygen balance, which implies a surplus of carbon atoms.
TEST FACILITY RCC (2001o)

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	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test/non-adjuvant test.	no evidence of sensitisation
Rat, repeat dose <route of exposure> toxicity – 28 days.	NOEL 200 mg/kg bw/day, NO(A)EL 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro <test type>	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE

METHOD
OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 96/54/EEC B.4 tris Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain	Rat/ HanBrl: Wist (SPF)
Vehicle	Bi-distilled water
Remarks - Method	No significant protocol deviations. Statement of GLP included.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 males	2000	0/3
2	3 females	2000	0/3

LD50	> 2000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	No adverse macroscopic observations at necropsy
Remarks - Results	There were no deaths or notified chemical related clinical signs or remarkable body weight changes during the study period.

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

TEST FACILITY RCC (2001p)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

METHOD
OECD TG 402 Acute Dermal Toxicity.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).

Species/Strain	Rat/ HanCrl: Wist Han (Glx. BRL)BR
Vehicle	Bi-distilled water
Type of dressing	Occlusive/Semi-occlusive.
Remarks - Method	No significant protocol deviations. Statement of GLP included.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 males	2000	0/5
2	5 females	2000	0/5

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Slight focal erythema was noted in five animals (two males and three females) at the second observation day but on no other days and was considered a test item-related effect. Slight scale skin was noted in one female on the third observation day and was considered to be incidental.
Signs of Toxicity - Systemic	There were no notified chemical-related systemic reactions.
Effects in Organs	No macroscopic findings were observed at necropsy.
Remarks - Results	No significant protocol deviations. There were no deaths or notified chemical related clinical signs or remarkable body weight changes during the study period.

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

TEST FACILITY RCC (2001q)

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Bi-distilled water
Observation Period	72 h
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. Statement of GLP included.

RESULTS

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

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

Remarks - Results There were no deaths or test substance related clinical signs or remarkable body weight changes during the study period. There were no dermal reactions.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY RCC (2001r)

7.5. Irritation – eye

TEST SUBSTANCE: 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 (1 male, 2 females)
Observation Period: 72 h
Remarks - Method: No significant protocol deviations.
Statement of GLP included.
pH of 1% aqueous solution = 5–6

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	1.67	2.33	2.00	3	3 days	2
Conjunctiva: chemosis	0.33	1	0.33	2	2 days	0
Conjunctiva: discharge[†]	-	-	-	-	-	-
Corneal opacity	0	1	0	1	3 days	1
Iridial inflammation	0	0	0	0	-	-

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
[†] A slight to moderate mucus discharge was observed in both females at the 1-,24- and 48-hour readings but no scores were given.

Remarks - Results: A slight corneal opacity was observed in one female from 24 to 72 hours after treatment.
Slight to moderate reddening of the conjunctivae was observed in the male from 1 hour to 7 days after treatment. Slight to marked reddening was also noted in both females from 1 to 72 hours after treatment.
Slight swelling of the conjunctivae was evident in the male at the 1- and 24- hour readings. Slight to obvious swelling (with partial eversion of lids) was also observed in both females from either 1 to 24 hours or 1 to 48 hours after treatment.
Moderate reddening of the sclera was noted in the male from 1 to 24 hours after treatment. Slight to moderate reddening was observed in both females during the observation period but cleared by day 7.
No abnormal findings were noted in the treated eye of any animal on the test day 10 at termination.

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

TEST FACILITY: RCC (2001s)

7.6. Skin sensitisation

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 406 Skin Sensitisation - Magnusson and Kligman.
EC Directive 96/54/EC B.6 Skin Sensitisation - Magnusson and Kligman.

Species/Strain: Guinea pig/Ibm: GOHI; SPF-quality
PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: 3%
topical: 15% (at 50% concentration resulted in discrete and patchy erythema in 2/2 test animals)
MAIN STUDY

Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 3% w/v in corn oil and in Freund's Complete Adjuvant topical: 50% w/v in corn oil
Signs of Irritation	Intradermal injection: The intradermal injections using Freund's Complete Adjuvant (with and without notified chemical) caused oedema, necrotizing dermatitis, encrustation and exfoliation of encrustation. The administration sites treated with notified chemical in corn oil showed no signs of irritation. Intradermal injections of the vehicle alone exhibited no signs of irritation. Topical Induction: The administration sites treated with corn oil only or the notified chemical at 15% in corn oil showed no signs of irritation. At 50% the administration sites treated with notified chemical in corn oil showed discrete/patchy erythema 4/10 animals at the 24- and 48-hour reading.
CHALLENGE PHASE	
1st challenge	topical: 15% (w/v in corn oil)
Remarks - Method	No significant protocol deviations. Statement of GLP included.
RESULTS	No dermal reactions were seen in either the control or the test groups at 24 or 48 hours after patch removal
Remarks - Results	There were no deaths during the course of the study. There were no signs of systemic toxicity observed in the animals. No toxicologically significant changes in body weights were observed in the test animals.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	RCC (2001t)

7.7. Repeat dose toxicity

TEST SUBSTANCE	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, HanBrl:WIST (SPF)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days for recovery groups
Vehicle	Bidistilled water
Remarks - Method	No significant protocol deviations. Statement of GLP included.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0/10
II (low dose)	5/sex	50	0/10
III (mid dose)	5/sex	200	0/10
IV (high dose)	5/sex	1000	0/10
V (control recovery)	5/sex	0	0/10
VI (high dose recovery)	5/sex	1000	0/10

All animals survived until scheduled necropsy.

Clinical Observations

Salivation was noted in some males and females treated with 1000 mg/kg/day during daily observations. This finding, although slight in degree, was considered to be a test item related, and was no longer seen during the 14-day recovery period. No treatment related effects in daily food consumption and mean body weights were observed compared to the controls during the treatment and recovery periods.

No clinical signs were evident during the weekly behavioural observations performed during weeks 1-3.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No treatment-related adverse effects were observed in haematological, biochemical or urinalysis parameters after 28 days (non-recovery groups) or 42 days (recovery groups).

Clinical Chemistry

After four weeks, treatment, males treated with 1000 mg/kg/day had significantly lower glucose levels ($p<0.1$). Although the glucose levels exceeded the 95% tolerance limits of the historical control data, a dose-response relationship was absent and therefore this difference was considered to be incidental.

Significantly higher phospholipid ($p<0.01$) and sodium levels ($p<0.01$) were also noted in males treated with 1000 mg/kg/day, but these differences remained within the 95% tolerance limits of the historical control data and therefore considered to be fortuitous.

Male rats also showed significant differences in the lactate dehydrogenase activity at all dose levels ($p<0.01$), in creatine kinase levels at 50 mg/kg/day ($p<0.05$) and 1000 mg/kg/day ($p<0.05$), and in the phosphorous levels at 50 mg/kg/day ($p<0.01$) and potassium levels at 50 mg/kg/day ($p<0.05$) after four weeks treatment. In the absence of dose-response relationships, these differences were considered to be incidental.

Differences noted after the two-week recovery period in males previously treated with the test item included higher sodium levels ($p<0.01$) and lower potassium levels ($p<0.05$). The differences, however, compared favourably with historical control data and were therefore considered to be incidental differences in control values

All differences noted after four weeks' treatment in the test-item treated females (increased bilirubin at 50 mg/kg/day, $p<0.01$ and 1000 mg/kg/day, $p<0.01$; increased total cholesterol at 1000 mg/kg/day, $p<0.01$; increased phospholipids at 1000 mg/kg/day, $p<0.01$; reduced activity of aspartate aminotransferase at 1000 mg/kg/day, $p<0.05$; increased calcium at 200 mg/kg/day and 1000 mg/kg/day, both $p<0.05$) were not supported by a dose-response relationship or remained within the 95% tolerance limits of the historical control data and therefore considered to be incidental. Likewise, the few differences noted after two weeks' recovery in the females previously treated with the test item at 1000 mg/kg/day (increased phosphorous, $p<0.05$; increased globulin, $p<0.05$) remained within the 95% tolerance limits of the historical control data and considered to be incidental.

Haematology

After four weeks' treatment a significant increase in the ratio of middle fluorescent reticulocytes was noted in males treated with 50 mg/kg/day ($p<0.01$) or 200 mg/kg/day ($p<0.05$), and a significant reduction in the number of low fluorescent reticulocytes was noted in males treated with 1000 mg/kg/day ($p<0.05$). The latter finding ($p<0.05$) persisted after the two-week recovery period, and the number of high fluorescent reticulocytes was increased in the males previously treated with 1000 mg/kg/day, although this finding was considered to be due to a low control value. The results were within historical control data limits.

After four weeks, treatment the mean levels of methemoglobin were significantly elevated in test item-treated males ($p<0.01$) when compared with the controls. This finding persisted after the two-week recovery period in the males ($p<0.05$) previously treated with 1000 mg/kg/day. This finding was not seen in females, remained within the 95% tolerance limits of the historical control data and was considered to be caused by a low mean value in the control males (0.8 in the historical data and 0.4 in the control males). All values remained within the 95% tolerance limits of the historical control data and a clear dose-response relationship was not present.

Slight but statistically significant elevations of the absolute and relative reticulocyte counts ($p<0.01$) were noted in the females treated with 1000 mg/kg/day after four weeks, treatment, and the ratio of high fluorescent reticulocyte was increased when compared with the controls. Although statistically significant, these changes

remained within the 95% tolerance limits of historical control data, were not seen in males, were not dose-dependant and were not accompanied by indications of anaemia and therefore considered to be incidental.

Urinalysis
In males and females treated with 1000 mg/kg/day for four weeks, the urinary output (18hr) was increased when compared with the controls. The difference to the control values attained statistical significance in males ($p<0.01$). Significant increases in the specific gravity of the males ($p<0.05$) and females ($p<0.01$) treated with 1000 mg/kg/day was noted, and the urinary pH of males treated with 200 mg/kg/day and 1000 mg/kg/day was decreased significantly (both $p<0.05$). All values remained within the 95% tolerance limits of the historical data and were considered fortuitous.

Effects in Organs
Elevated absolute and relative liver weights were noted in males ($p<0.05$) and females ($p<0.01$) treated with the test item at 1000 mg/kg/day, and elevated absolute kidney weights were slightly higher in males and females treated with 1000 mg/kg/day for four weeks. These changes were considered to be test item related.

All other differences in organ weights (increased absolute adrenal weights in males treated with 200 mg/kg/day, $p<0.05$; increased adrenal to-body weight ratio in males treated with 50 mg/kg/day, $p<0.05$; decreased testes-to-body weight ratio in males treated with 200 mg/kg/day, $p<0.05$) were, in the absence of dose-response relationships, considered to be incidental.

All other organ weights were within the normal range of variation. No differences of toxicological relevance were noted in absolute or organ weights after the recovery period.

Macroscopic/Microscopic Findings
A number of macroscopic findings were observed in rats of all groups. No findings were observed that there were considered to be related to the administration of the test item at the end of the 28-day treatment period and at the end of the 14-day recovery period. All findings diagnosed either did not distinguish test item treated rats from controls or were considered to be of no toxicological relevance.

A number of microscopic findings were observed in rats of all groups after the 28-day treatment period and after the 14-day recovery period. Except for the histopathologic finding noted in the liver of rats treated with 1000 mg/kg/day, the incidence and severity of these findings did not distinguish test item treated rats from controls or were considered to be of no toxicological significance.

At the 28-day treatment period, the following change in the liver was considered to represent a test item related effect: minimal to slight centrilobular hepatocellular hypertrophy diagnosed in rats (5/5 females and 5/5 males) treated with 1000 mg/kg bw/day. In males the mean severity grade for this change was 1.4, while in females the mean severity grade was 1.0.

Remarks – Results

CONCLUSION
The No Observed Effect Level (NOEL) was established as 200 mg/kg bw/day The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day in this study, based on the effects observed in the treated groups.

TEST FACILITY RCC (2001u)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure (experiment 1) and Pre incubation procedure (experiment 2) for all strains
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	Phenobarbital and β–Naphthoflavone induced rat liver S9 fraction
Concentration Range in Main Test	a) With metabolic activation: 33–5000 µg/plate b) Without metabolic activation: 33–5000 µg/plate
Vehicle	Deionised water
Remarks - Method	No significant protocol deviations. Statement of GLP included.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000 µg/plate	> 5000 µg/plate	> 5000 µg/plate	None
Test 2	> 5000 µg/plate	> 5000 µg/plate	> 5000 µg/plate	None
Present				
Test 1	> 5000 µg/plate	> 5000 µg/plate	> 5000 µg/plate	None
Test 2	> 5000 µg/plate	> 5000 µg/plate	> 5000 µg/plate	None

Remarks - Results	No precipitation was observed. Concurrent positive controls demonstrated the sensitivity of the assay and metabolising activity of the liver preparations. Negative controls were within historical limits.
CONCLUSION	The notified chemical was not mutagenic to *S. typhimurium* under the conditions of the test.
TEST FACILITY	RCC (2001v)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	Chinese Hamster lung fibroblast Cell line V79
Metabolic Activation System	Phenobarbital and β–Naphthoflavone induced rat liver S9 fraction
Vehicle	Minimal Essential Medium
Remarks - Method	No significant protocol deviations. Statement of GLP included.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	78.1, 156.3, 312.5, 625*, 1250*, 2500*	4	18
Test 2	156.3, 312.5, 625*, 1250*, 2500*	18	18
Test 3	625, 1250, 1875, 2500*	28	28
Present			
Test 1	78.1, 156.3, 312.5, 625*, 1250*, 2500*	4	18
Test 2	148.4, 297, 594*, 1188*, 1875, 2375*	4	28

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>2500	>2500	>2500	Negative
Test 2	>2500	>2500	>2500	Negative
Test 3	>2500	>2500	>2500	Negative
Present				
Test 1	>2500	>2500	>2500	Negative
Test 2	>2375	>2375	>2375	Negative

Remarks - Results	Cytotoxicity was not observed at any test concentration. No statistically or biologically significant increases in the percentage of aberrant cells above the vehicle control levels, were recorded for any cultures treated with the notified chemical in either the presence or absence of metabolic activation. Positive controls confirmed the sensitivity of the test system.
CONCLUSION	The notified chemical was not clastogenic to Chinese Hamster lung fibroblast Cell line V79 treated in vitro under the conditions of the test.
TEST FACILITY	RCC (2001w)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical.
METHOD	EC Directive 92/69/EEC C.4-A Biodegradation: Determination of the "Ready" Biodegradability: Dissolved Organic Carbon (DOC) Die-Away Test.
Inoculum	Aerobic activated sludge from a city waste water treatment plant.
Exposure Period	45 Days
Auxiliary Solvent	Nil
Analytical Monitoring	DOC analyses were performed on a Shimadzu TOC-500 Analyser.
Remarks - Method	Since the biodegradation of the test substance started at 21 days, the test was extended to 45 days. An abiotic, reference, and toxicity control were also tested.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
3	0	3	98
10	0	7	100
14	7	14	100
21	6	21	100
28	21	28	100

Remarks - Results	After 45 days, the notified chemical biodegraded by an average of 74%. Consequently, the notified chemical is biodegradable, but not ready biodegradable. In the abiotic control, containing the test item and poisoned mineral medium, no degradation was noted after 45 days of exposure (based on DOC-measurements). The reference item, sodium benzoate, was completely biodegraded within 7 days of exposure, confirming the suitability of the activated sludge. In the toxicity control, containing the test item, the reference item sodium benzoate, and activated sludge (inoculum), the initial DOC decreased by 56% within 14 days of exposure. Thus, according to the test guidelines, the test item can be assumed to not be inhibitory to activated sludge because degradation was >35% within 14 days.
CONCLUSION	The notified chemical is classed as biodegradable.
TEST FACILITY	RCC (2001x)

8.1.2. Bioaccumulation

No specific study is available for bioaccumulation. Other studies have shown that the notified chemical has a log P_{OW} of 0.23. Values of log P_{OW} below 3 indicate no bioaccumulation tendency. Aquatic exposure will also be limited.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE

METHOD
OECD TG 203 Fish, Acute Toxicity Test – 96 hour static test.
EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – 96 hour static test.

Species	Zebra Fish (*Brachydanio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	Nil
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	pH was 8.0 throughout and oxygen concentration was always 8.2 mg/L or higher. Temperature ranged from 22 to 23ºC.
Remarks – Method	The analytically determined test item concentration (by HPLC) in the analysed test medium at the start and the end of the test was 101 and 107% of the nominal value, respectively. Consequently, the test item was stable during the test period of 96 hours under the test conditions, and the reported biological results are based on the nominal concentrations of the test item.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0		7	0	0	0	0	0
4.6		7	0	0	0	0	0
10		7	0	0	0	0	0
22		7	0	0	0	0	0
46		7	0	0	0	0	0
100		7	0	0	0	0	0

LC50	>100 mg/L at 96 hours.
NOEC	=100 mg/L at 96 hours.
Remarks – Results	No remarkable observations were made concerning the appearance of the test media. All test media were clear solutions throughout the entire test duration. In the control and in the test media up to and including the highest concentration, all fish survived until the end of the test and no signs of intoxication were observed.

CONCLUSION The notified chemical is very slightly toxic to fish.

TEST FACILITY RCC (2001y)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical.

METHOD
OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – 48 h Immobilisation Test.
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - 48 h Immobilisation Test.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Nil
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	pH was 8.0 throughout and oxygen concentration was always 8.3 mg/L or higher. Temperature was constantly 21ºC.
Remarks - Method	The analytically determined test item concentration (by HPLC) in the

analysed test medium at the start and the end of the test was 94 and 91% of the nominal value, respectively. Consequently, the test item was stable during the test period of 48 hours under the test conditions, and the reported biological results are based on the nominal concentrations of the test item. No significant protocol deviations were noted.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		20	0	0
100		20	0	0

EC50 >100 mg/L at 48 hours
NOEC =100 mg/L at 48 hours
Remarks - Results No remarkable observations were made concerning the appearance of the test media. All test media were clear solutions throughout the entire test duration. In the control and in the test concentration of 100 mg/L, no immobilised or dead test organisms were observed during the test period of 48 hours.

CONCLUSION The notified chemical is very slightly toxic to *Daphnia*.

TEST FACILITY RCC (2001z)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species *Scenedsemus subspicatus*
Exposure Period 72 hours
Concentration Range Nominal: 4.6, 10, 22, 46 and 100 mg/L
Auxiliary Solvent Nil
Water Hardness 24 mg $CaCO_3$/L
Analytical Monitoring
Remarks - Method No significant protocol deviations. The analytically determined test item concentration (by HPLC) in the analysed test medium at the start and the end of the test was 101 and 103% of the nominal value, respectively. Consequently, the test item was stable during the test period of 72 hours under the test conditions, and the reported biological results are based on the nominal concentrations of the test item.

RESULTS

Biomass		*Growth*	
NOEC	*EC_b50*	*NOEC*	*EC_r50*
mg/L at 72 h	*... mg/L*	*mg/L at 72 h*	*... mg/L*
46	>100	46	>100

Remarks - Results The notified chemical was observed to have a statistically significant inhibitory effect on the growth of the test organism after 72 hours at 100 mg/L. The 72 hour NOEC was determined to be 46 mg/L, since up to this test concentration both the mean biomass and the mean growth rates were not significantly different from the control. The inhibition of the growth rate was less than 10% at a concentration of 100 mg/L.

CONCLUSION	The notified chemical is very slightly toxic to algae.
TEST FACILITY	RCC (2001aa)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Aerobic activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 10-1000 mg/L
Remarks – Method	
RESULTS	
IC50	>1000 mg/L
NOEC	>1000 mg/L
Remarks – Results	The oxygen consumption rates of the two controls differed by 14% (guideline recommended maximum variation of 15%). The 3,5-dichlorophenol positive control results fell within the guideline-recommended range, confirming the suitability of the activated sludge used in the experiment. The 3-hour EC_{20}, EC_{50}, and EC_{80} values could not be calculated but were clearly higher than 1000 mg/L.
CONCLUSION	The notified chemical does not significantly inhibit sewerage microbial activity.
TEST FACILITY	RCC (2001ab)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be imported into Melbourne, then distributed to a reformulation site, whereby the notified chemical will be mixed with other ingredients to form a powder coating mix. It is estimated that up to 2% of the total import volume will be lost during formulation, however, 95% of this is expected to be recovered and returned to the processing stream. After repackaging, the notified chemical will be transported to two powder coat applicators. The notified chemical is expected to be applied to metal substrate, where it will be held in an inert coating matrix bound to the substrate once cured by heating. Spilt and oversprayed powder coating material, containing the notified chemical, is expected to be returned and reapplied. The loss of powder coating due to the spraying/recycling process is expected to be below 1% of the total import volume of notified chemical.

Nearly all imported notified chemical will be contained in an inert matrix bound to metal. Its fate will be linked to that of the metal to which it has been applied, which will eventually be either recycled or disposed of to landfill. In landfill it is expected that the notified chemical will remain within the powder coating matrix associated with the metal, and over time, slowly degrade by biotic and abiotic processes. During metal recycling, it is expected that the notified chemical will be thermally decomposed.

As there is expected to be nil release to the aquatic compartment, a Predicted Environmental Concentration (PEC) cannot be derived.

Residual notified chemical remaining in packaging will either be thermally decomposed in

incinerators or be disposed of to landfill. Potential for environmental exposure is very low due to the nature of the product and its expected use.

9.1.2. Environment – effects assessment

The results of the ecotoxicological studies indicate that the notified chemical is not expected to be acutely toxic to aquatic life. All EC50 values were >100 mg/L, and all NOECs were also >100 mg/L, with the exception of algae with a NOEC of 46 mg/L. A Predicted No Effect Concentration (PNEC) was derived, using a safety factor of 100, as being >1 mg/L.

9.1.3. Environment – risk characterisation

Due to the limited potential for environmental release of the notified chemical, a PEC could not be derived. However, the notified chemical is clearly not toxic to aquatic organisms. Therefore, the environmental risk from the reported use pattern of the notified chemical is expected to be low.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical is imported as a fine powder in 25 kg lined cardboard boxes. Transport or warehouse workers can be exposed in the event of accidental breach of the containers.

The main operation during which inhalation exposure could occur will be after slitting the inner polyethylene bag and transferring the powder to the mixing vessel or weighing out smaller amounts of the product containing the notified chemical during both reformulation and end-use. Exposure during manual powder-coating spray operations is also possible. This exposure is controlled by the use of LEV and dust masks as required. Some dermal and ocular exposure can occur and will be controlled by the use of impervious gloves and safety goggles. Exposure during end-use applications will be lower due to a decreased concentration of notified chemical in the end product (< 10%). After application of the powder coating to various items, materials are placed in an oven for curing by automated means. After curing the notified chemical is trapped within an inert matrix and is not bioavilable.

9.2.2. Public health – exposure assessment

Under normal circumstances the public should only contact the notified chemical when it is incorporated in an inert solid matrix. Given the wide application of the product containing the notified chemical public exposure is possible but as it is used primarily for structural supports exposure would most likely be low and intermittent. The main route of public exposure would most likely be through release of the chemical after a transport accident.

9.2.3. Human health – effects assessment

The notified chemical was of low acute oral and dermal toxicity in rats, was not a skin irritant and was a slight eye irritant in rabbits and was not a skin sensitiser in guinea pigs. In a 28-day repeat dose toxicity study in rats, a NOEL of 200 mg/kg bw/day was determined. No adverse effects were found up to the highest dose tested, thus the NO(A)EL was established to be 1000 mg/kg bw/day. The notified chemical was neither mutagenic in *S. typhimurium* nor clastogenic in Chinese Hamster V79 cells in vitro.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Given the limited opportunity for exposure (limited to transfers of the imported notified chemical in the imported product and manual powder-coating spraying) the personal protective equipment and engineering controls in place combined with the low hazard indicated by the data set for this standard notification, there is virtually no risk of adverse health effects to workers involved in the reformulation and spraying of powder-coatings. There is low probability that nuisance dust levels could exceed the NOHSC exposure standard of 10 mg/m^3 (NOHSC, 1995) and this would be unlikely to occur.

9.2.5. Public health – risk characterisation

Based on the notified use, the notified chemical will not pose a significant hazard to public health when used in the proposed manner. The notified chemical is not available to the general public and nil residue of the notified chemical is expected in the applied coating because the notified chemical is incorporated into a polymeric structure as a result of the thermal curing process used during the application process. Consequently, the notified chemical is not bioavailable and as such unlikely to penetrate biological membranes.

As the notified chemical is of low hazard and public exposure will be low, the risk to the public from importation of the notified chemical and use and disposal in the manner described is considered to be negligible. .

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

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

As a comparison only, the classification of the 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.

Based on the available data, the notified chemical does not meet the criteria for classification under the GHS system.

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is Negligible Concern to public health when used under the public settings described.

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 was (were) in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is (They 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 product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - In handling the notified chemical avoid contact with eyes
  - In handling coatings containing the notified chemical avoid contact with eyes

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

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

Disposal

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

Emergency procedures

- Spills/release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

12.1. Secondary notification

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

(1) Under Section 64(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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