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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

AZ-53-1326

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Director

Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
PPG Industries Australia Pty Limited,
McNaughton Road, Clayton. Victoria, 3168

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer, (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical name
CAS number
Structural formula
Molecular formula
Molecular weight
Spectral data
Purity
Identity of additives/adjuvants
Percentage weight of additives/adjuvants
Identity of sites

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Nil

NOTIFICATION IN OTHER COUNTRIES
USA 1999 (P00-0463), Canada 2001 (NSN# 9535/10675)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
AZ-53-1326

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	IR Spectroscopy
Remarks	Reference spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
Low

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None known.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

None known.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported as a component of an electrocoat resin (E6270) at a maximum concentration of 0.2% w/w.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonne	<1	<1	<1	<1	<1

USE
The notified chemical will be used as a component of mixture that is used in electrocoat resins to provide corrosion protection.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not stated.

IDENTITY OF MANUFACTURER/RECIPIENTS
PPG Industries Australia Pty Limited. The notified chemical will be processed at other industrial sites.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as a component of an electrocoat resin (E6270) in totes and will be transported by road from docks to the notifiers warehouse and then to customers.

5.2. Operation Description

The notified chemical is imported as a component of finished electrocoat resin (E6270) at a maximum concentration of 0.2% w/w. During electrocoating process, the electrocoat resin containing the notified chemical is transferred to an electrodeposition tank from totes through the use of pumping equipment to a fitting (2" banjo ball) at the base of the resin tote. The resin is then further diluted in the tank so that the final solution contains approximately 0.02% of the notified chemical.

Metal parts, which are suspended on a conveyor, are immersed in the tank and electrocoated. On leaving the tank, the parts are rinsed with an ultrafiltrate solution, which flows back to into the electrocoat tank utilising virtually 100% of the coating's solids. The coated parts are then passed through a heated zone to effect curing.

The notifier has stated that the entire electrocoating process is a closed system with recovery of rinse effluents and the eventual "cascade" of paint solids back into the electrocoat paint tank.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Waterside, transport and warehouse	not stated	not stated	not stated
Transfer operators	4	2 hr	250 days/year
Electrodeposition coating operators	4	2 hr	250 days/year
Oven curing operation	not stated	not stated	not stated

Exposure Details
Waterside, transport and warehouse workers will be exposed to the notified chemical only in the event of a spill. At the customer's facilities, worker exposure may occur on transfer from totes to an electrodeposition tank, during electrocoating operation if there is any obstruction to conveyor, and

during quality control testing when small test samples are withdrawn from the electrodeposition tank. The highest concentration of the notified chemical that workers may be exposed to is 0.2%.

The notifier specifies via MSDS and technical service advice, that workers at customers sites be trained in the proper handling of chemicals and provided with appropriate protective equipment (i.e. safety glasses, gloves, protective clothing etc). Furthermore, all activities are to be carried out in well-ventilated areas.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported and therefore no release due to manufacture will occur in Australia. Release during the electrocoating process is expected to be extremely small as the closed system ensures recovery and reuse of coatings material. Minimal waste chemical may be generated when the ultrafiltrate is disposed. Due to the transfer efficiency and material recovery systems inherent to the electrodeposition process, release of the chemical is not expected during the coating operation. Considering that the electrocoating systems are not cleaned very frequently (every 1 or 2 years), the loss via ultrafiltrate waste including any accidental spillage can be expected to be small.

Based on information provided by the notifier for a previous notification, electrodeposition baths are cleaned approximately every one or two years. The process involves transferring the bath contents to a fully enclosed storage tank via permanent piping. Water washing is used to rinse down the internal walls of the bath as the contents are being transferred. Residual washings and sludge from the bottom of the tank are removed by licensed waste contractors. After collection the waste is treated by flocculation, filtration and centrifugation, which separates the solids material from the water. The water is discharged to the sewer and the solids sludge is dried and sent to secure landfill. The large 1000 L totes in which the chemical is imported are expected to be returned to the USA.

The notification for the new chemical did not indicate the amount likely to be released specifically due to cleaning of equipment, but it is estimated that this would be unlikely to exceed 5% of total imports (< 50 kg). If it is further estimated that spillage and samples withdrawn for quality testing results in losses of 1% and 0.02%, respectively, a maximum of 60 kg could be expected to be released to the environment.

In the event of an accidental spill, the spilled material should be contained and prevented from entering drains, streams or any water body. Material should be collected with sand, vermiculite or other non-combustible absorbent material and place in clean and suitable containers for disposal.

RELEASE OF CHEMICAL FROM USE

The notified chemical is used in electrodeposition of small metal automotive parts. Once electrocoated, the parts are passed through a heated zone to effect curing, which reduce the possibility of the chemical being released to the atmosphere. The chemical will be bound to the metal with the other components of the resin and form an inert layer.

5.5. Disposal

Minimal waste is expected during electrocoating. Ultrafiltrate waste is either combined with solvent and incinerated or undergoes other liquid waste treatment. Any solid residues are disposed of in hazardous waste landfills in accordance with federal, State and local environmental control regulations. Empty containers should be recycled or disposed of through an approved waste management facility.

5.6. Public exposure

The notified chemical is used in electrodeposition coating that is cured and overcoated prior to sale to consumers. Therefore, the notified chemical will not be available for exposure and consumers are not expected to come in direct contact with the new substance. Furthermore, the notified chemical will be present at a very low (0.02%) concentration in the coating solution.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Light tan granular solid

Melting Point/Freezing temperature and boiling temperature >359.85 °C at 100.70 kPa.

METHOD OECD TG 102 Melting Point/Melting Range and OECD TG 103 Boiling Point
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature and EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Determined by differential scanning calorimetry.
TEST FACILITY SafePharm Laboratories (2000a).

Relative Density 2183.9 kg/m^3 at 21±0.5°C

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Determined by gas comparison pycnometer.
TEST FACILITY SafePharm Laboratories (2000a).

Vapour Pressure < 7.2 X 10^{-8} kPa at 25°C (Based on an analogue salt)

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks The vapour pressure was determined using a vapour pressure balance system with measurements made at several temperatures and linear regression analysis used to calculate the vapour pressure at 25°C. The temperature of the sample was controlled electronically. Results were derived from the final run (maximum degassing) by imposing a regression slope of –1500 K on the value which under these circumstances gave the maximum estimated vapour pressure.

According to the results, the test substance is very slightly volatile (Mensink *et al* 1995).
TEST FACILITY SafePharm Laboratories (2000b).

Water Solubility 265 g/L at 20 ± 0.5°C

METHOD OECD TG 105 Water Solubility and EC Directive 92/69/EEC A.6 Water Solubility (Flask Method).
Remarks A preliminary test was conducted by diluting 7.5057 g of test substance with 20 mL glass double distilled water, shaking at 30°C for 3 hours, standing at 20°C for 20.5 hours, and filtering and analysing the solution. In the definitive test the mixtures of test substance and glass double distilled water were added to 3 flasks shaken at approximately 30°C and after standing at 20°C for a period of not less than 24 hours, the contents of the flasks were filtered.

The concentration of test substance was determined by atomic absorption spectroscopy (AAS).

It was not possible to prepare samples at 5 times the saturation concentration as recommended by the test guidelines as the unfilterable mixture would not have produced sufficient solution for analysis. This was considered to have no detrimental effect on the study results as significant amount of undissolved material remained in each flask ensuring saturation.

The test substance is readily soluble in water (Mensink *et al.* 1995).
TEST FACILITY SafePharm Laboratories (2000a).

Fat (or n-octanol) Solubility 5.0 X 10^{-2} g/100 g < Standard fat > at 37.0° ± 0.5°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks In a preliminary test, samples of ground test substance were mixed with standard fat in flasks, shaken at approximately at 37°C for 19 hours and assessed visually for the presence of undissolved material.

In the definitive test, samples of ground test substance were mixed with a standard fat in 8 flasks. Initial shaking was at either 30 or 50°C for 1 h and the final shaking was at 37°C for either 3 or 24 h. The samples were then equilibrated at 37°C for either 1 or 1.25 h and filtered. The concentration of test substance in sample solutions was determined by AAS.

Since no significant test substance concentrations were detected, the fat solubility has been reported based on the concentration at which the method was validated.

TEST FACILITY SafePharm Laboratories (2000a).

Hydrolysis as a Function of pH Not determined.

Remarks The test substance is expected to be hydrolytically stable under the environmental pH range from 4 to 9.

Partition Coefficient (n-octanol/water) log Pow of the metal ion content at 21 ± 0.5°C < -2.25 (determined by AAS)
log Pow of the counter ion = -4.34 (estimated)

METHOD OECD TG 107 Partition Coefficient (n-octanol/water), EC Directive 92/69/EEC A.8 Partition Coefficient and OPPTS 830.7550.

Remarks

The partition coefficient of the metal ion was obtained by the Shake flask method. Six partitions were performed with the combined volume both phases not less than 90% of the total volume of the test vessel. The flasks were shaken (inverted through approximately 180°) for 5 minutes. Aliquots of both phases were analysed.

The partition coefficient of the counter ion was obtained by computer estimation using KOWWIN for windows (v1.65).

The low log P_{ow} is consistent with the high water solubility indicating a low affinity for the organic phase and component of soils and sediments.

TEST FACILITY SafePharm Laboratories (2000a).

Adsorption/Desorption Not determined.

Remarks The adsorption/desorption characteristics for the metal ion were not performed since the inorganic salts in the test solutions would mask those contributed by the notified chemical. No testing was done to monitor the counter ions since it was anticipated that approximately 2 mg/L of these ions would be undetectable due to interference from chloride ions in the test matrix and anions and organic acids from the soils.

The test substance can be expected to be mobile in soil due to its high water solubility and the low log P_{ow} but may bind in other ways.

TEST FACILITY SafePharm Laboratories (2000a).

Dissociation Constant pKa = 1.0 and 12.1 (Estimated)

Remarks The test substance is an inorganic salt. Two dissociation constants for the anion (when considered as its acid) were estimated using software supplied by Advanced Chemistry Development Inc, Toronto, Canada. The metal is not expected to show acidic properties in aqueous solution.

TEST FACILITY SafePharm Laboratories (2000a).

Surface Tension 72.7 mN/m at 20.0° ± 0.5°C

METHOD EC Directive 92/69/EEC A.5 Surface Tension and ISO 304 ring method.

Remarks The surface tension of a 1.03 g/L solution was determined using a interfacial

tension balance and the ISO 304 ring method. Measurements were made at recorded intervals until a constant reading was obtained along with a calibration reading of glass double-distilled water and temperature reading.

Once calibrated, the balance and ring assembly used gave a direct reading for surface tension within the required accuracy (± 0.5 mN/m).

The results indicate that the test substance is not surface active.

TEST FACILITY SafePharm Laboratories (2000c).

Particle Size

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

Range (μm)	*Mass (%)*
<100	0.20

Remarks The notified chemical is essentially non-inhalable.
TEST FACILITY SafePharm Laboratories (2000a).

Flash Point
Remarks Not determined.

Flammability Limits

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids)..
Remarks Not highly inflammable as failed to ignite in the preliminary screening test.
TEST FACILITY SafePharm Laboratories (2001a).

Autoignition Temperature >400ºC

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks Determined not to have a relative self-ignition temperature below 400 °C.
TEST FACILITY SafePharm Laboratories (2001a).

Explosive Properties
Remarks Not expected to be explosive based on structure.

Reactivity
Remarks Expected to stable under normal environmental conditions.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity
Guinea pig, skin sensitisation - Maximisation test	no evidence of sensitisation.
Rat, oral repeat dose toxicity - 14 days.	NOEL 500 mg/kg/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain: Rat/Sprague-Dawley CD (Crl: CD).
Vehicle: Distilled water.
Remarks - Method: The test material was grounded to fine powder and dispersed at a concentration of 200 mg/mL in distilled water. All animals were dosed once only by gavage. The animals were observed for deaths or signs of toxicity at ½, 1, 2 and 4 hours after dosing and subsequently once daily for fourteen days.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 (male)	2000	0/3
II	3 (female)	2000	0/3

LD50: >2000 mg/kg bw.
Signs of Toxicity: There were no signs of systemic toxicity.
Effects in Organs: No abnormalities were noted at necropsy.
Remarks - Results: None.

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

TEST FACILITY: SafePharm Laboratories (2000d).

7.2. Skin sensitisation

TEST SUBSTANCE: Notified chemical.

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

Species/Strain: Guinea pig/ Dunkin-Hartley

MAIN STUDY

Number of Animals: Test Group: 20 Control Group: 10

INDUCTION PHASE: Induction Concentration:
Intradermal injection: 1% in a 1:1 preparation of FCA plus distilled water
topical application: 75% in distilled water

Signs of Irritation: No significantly different signs of irritation were present in the treatment group, as compared to the control.

CHALLENGE PHASE

1st challenge: topical application: 75% in distilled water
topical application: 50% in distilled water

Remarks - Method The concentrations applied were determined in a preliminary study.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	50%	0	0
	25%	0	0
Control Group	50%	0	0
	25%	0	0

Remarks - Results No skin reactions were noted at the challenge site of the test or control group animals at the 24 or 48-hour observations.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY SafePharm Laboratories (2000e).

7.3. Repeat dose toxicity

TEST SUBSTANCE Notified chemical.

METHOD The study was conducted as a 14-day screening test using a protocol (provided) based on OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

Species/Strain Rat/Sprague-Dawley CD (Crl: CD)

Route of Administration Oral – gavage.

Exposure Information Total exposure days: 14 days;
Dose regimen: 7 days per week;
Post-exposure observation period: Nil

Vehicle Arachis oil.

Remarks - Method Limited clinical chemistry, haematology, organ weight and histopathological data were collected.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	3/sex	0	0/6
II (low dose)	3/sex	500	0/6
III (high dose)	3/sex	1000	0/6

Mortality and Time to Death

There were no deaths during this study.

Clinical Observations

Increased salivation was seen in high dose animals from day 6 onwards. No other clinically observable signs of toxicity were detected in treated or control animals throughout the study. Normal bodyweight gains were seen in all animals.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

A reduction in plasma potassium concentration was detected on animals of either sex treated with 1000 mg/kg/day, but in isolation the toxicological significance of this intergroup difference was limited. Females treated with 1000 mg/kg/day also showed an increase in plasma cholesterol. No convincing blood chemical changes were noted at 500 mg/kg/day.

A slight reduction in haemoglobulin, haematocrit and erythrocyte count was detected for males treated with 1000 mg/kg/day, as compared with controls. Erythrocyte count was also reduced for 1000 mg/kg/day females.

Effects in Organs

No treatment related effects were noted on organ weights and also on macroscopic appearance.

Remarks - Results	Based on the results of the screening test, it was decided that the 28-day study should be performed using the analogue subject of LTD/1121.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 500 mg/kg bw/day in this study, based on blood chemical changes at 1000 mg/kg/day.

TEST FACILITY	SafePharm Laboratories (2001b).

7.4. Genotoxicity - bacteria

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.14 Mutagenicity – Reverse Mutation Test using Bacteria.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2 uvrA.
Metabolic Activation System	S9 fraction from livers of phenobarbitone/β-naphthoflavone induced rats.
Concentration Range in Main Test	a) With metabolic activation: 50, 150, 500, 1500 & 5000 µg/plate. b) Without metabolic activation: 50, 150, 500, 1500 & 5000 µg/plate.
Vehicle	DMSO
Remarks - Method	Two independent assays were performed in triplicate. No test material precipitate was observed by eye on the plates at any of the doses tested in either the presence or absence of S9-mix although a clear, globular precipitate was observed under an inverted microscope at 5000 µg/plate.

RESULTS

Remarks - Results	No significant increases in the numbers of revertants were seen for any strain either in the presence or absence of metabolic activation. No signs of toxicity were observed. Appropriate positive controls were used and led to large increases in revertants, indicating that the test system responded appropriately.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm Laboratories (2000f).

7.5. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test. EC Directive 92/69/EEC B10.
Cell Type/Cell Line	Human lymphocytes
Metabolic Activation System	Liver Homogenates (S-9mix) from phenobarbitone and β-naphthoflavone induced rats
Vehicle	DMSO
Remarks - Method	Two separate experiments were performed. The highest final concentration, with no precipitate after incubation at 37°C, was 580 µg/ml.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			

Test 1	145, 290, 580*, 1160* & 2320*	4	20
Test 2	72.5, 145, 290, 580*, 1160* & 2320*	24	0
Present			
Test 1	145, 290, 580*, 1160* & 2320*	4	20
Test 2	72.5, 145, 290, 580*, 1160* & 2320*	4	20

*Cultures selected for metaphase analysis.

RESULTS

Remarks - Results	No significant increases in the numbers of cells with chromosome aberrations or polyploidy was seen at any dose either in the presence or absence of metabolic activation. No signs of toxicity as measured by mitotic index were seen in Experiment 1, but in Experiment 2, in the absence of metabolic activation, a dose dependent reduction in metabolic index to 36% was seen. Appropriate positive controls were used and led to statistically significant increases in frequencies of cells with chromosome aberrations, indicating that the test system responded appropriately.
CONCLUSION	The test substance was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	SafePharm Laboratories (2001c).

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test, EC Directive 92/69/EEC C.1 Acute Toxicity for Fish and US EPA Draft Ecological Test Guidelines OPPTS 850.1075 - semi-static.
Species	Rainbow trout (*Oncorhynchus mykiss)*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	111 mg $CaCO_3$/L
Analytical Monitoring	Samples from test solutions were drawn at 0, 24 and 96 hours and analysed using AAS.
Remarks – Method	Based on a range finding test (at 1, 10 and 100 mg/L concentrations), which resulted in no mortalities or sub-lethal effects at any concentration, a limit test was conducted at a test concentration of 100 mg/L. Oxygen content, pH and temperature were all satisfactorily maintained.

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*Mortality*					
		3 h	*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0	0	0
Control	10	0	0	0	0	0	0
100	10	0	0	0	0	0	0
100	10	0	0	0	0	0	0
100	10	0	0	0	0	0	0

LC50	> 100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	There were no sub-lethal effects of exposure in the fish exposed to any test solution. Test concentrations measured at 0, 24 and 96 hours varied from 82% to 95% of the nominal except in one replicate which showed a concentration of 79% of the nominal. This low value was attributed to instrument variation. The corresponding old media test sample showed a concentration of 93% of nominal at 24 hours indicating that the actual concentration at 0 hours was greater than 80% of nominal. Due to these variations in measured test concentrations, the results were based on the nominal concentrations.
CONCLUSION	The test substance is practically non-toxic to fish.
TEST FACILITY	Safepharm Laboratories (2001d).

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test, EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia and

	OPPTS 850.1010 - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	103 mg $CaCO_3$/L
Analytical Monitoring	
Remarks - Method	Based on a range finding test (at 0.1, 1.0, 10 and 100 mg/L concentrations), which resulted in no immobilisation at any concentration, a limit test was conducted at a test concentration of 100 mg/L. Oxygen content, pH and temperature were all satisfactorily maintained.

RESULTS

Concentration mg/L	*Number of D. magna*	*% Immobilised (Initial population: 10 per replicate)*	
Nominal		*24 h*	*48 h*
Control	20	0	0
100	40	0	0

EC50	> 100 mg/L at 48 hours.
NOEC	100 mg/L at 48 hours.
Remarks - Results	The measured test concentrations at 0 and 48 hours ranged from 82% to 98% of nominal value. The results are based on the nominal concentrations.

CONCLUSION — The test substance is practically non-toxic to daphnia.

TEST FACILITY — Safepharm Laboratories (2001e).

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 and OPPTS 850.5400.

Species	*Selenastrum capricornutum (Pseudokirchneriella subcapitata)*
Exposure Period	96 hours
Concentration Range	
Nominal	6.25, 12.5, 25, 50, 100 and 200 mg/L
Auxiliary Solvent	None
Water Hardness	The test substance was dissolved directly in culture medium with the aid of high shear mixing.
Analytical Monitoring	Samples of control and test solutions were obtained at 0 and 96 hours and analysed by AAS.
Remarks - Method	The test concentrations were based on two preliminary range finding studies conducted at concentrations ranging from 0.10 to 200 mg/L, which showed no effect on growth up to 50 mg/L but reduced growth at 100 and 200 mg/L. The temperature and pH were satisfactorily maintained. A regrowth experiment was performed after 96 hours. The sub-cultures with test concentrations reduced to below the inhibiting level were incubated for 72 hours.

RESULTS

	E_bC50 (mg/L)	E_rC50 (mg/L)	NOEC (mg/L)
72 h	170	-	-
96 h	130	-	50
0-96 h	-	> 200	-

Remarks - Results

No cell abnormalities were observed in any of the test cultures after 96 hours. The pH values in the control cultures increased during the study period. This was attributed to the increase in cell numbers and the associated increase in CO_2 required for photosynthesis and growth.

Test concentrations measured at 0 hours ranged from 104% to 120% of nominal with the exception of the 6.25 and 12.5 mg/L solutions, which showed measured test concentrations of 130% and 122% of nominal, respectively. The high variation was considered to be due to instrument variation. Measured concentrations varied from 86% to 114%.

Regrowth occurred in all test cultures after 24 hours, which showed that the test substance was algistatic in effect.

CONCLUSION

The test substance is practically non-toxic to algae.

TEST FACILITY

Safepharm Laboratories (2001f).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Once used in electrocoating, the notified chemical will be bound to the metal surface with the other components of the resin and form an inert layer and it is unlikely to pose a risk to the environment. Up to 60 kg per year of the notified chemical is expected to be disposed of to landfill as waste, and an extremely small amount to the sewer.

The fate of the chemical will be therefore related to that of the metal parts. This is likely to be either recycling for recovery of the metals, or deposition into landfill. During the recovery of the metals the paint coatings would be destroyed as a result of the high temperatures in the blast furnaces, and the chemical would be decomposed to water vapour and oxides of carbon, sulphur and nitrogen and the metal would go to the remaining ash. Any material incinerated as a consequence of trade waste disposal operations would be destroyed in a similar manner.

Information on biodegradability was not provided, however it is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified polymer due to abiotic or slow biotic processes to give water vapour and oxides of carbon, sulphur and nitrogen.

No bioaccumulation data were provided. However, if there is any release to the aquatic compartment, bioaccumulation is not expected due to the high water solubility and the low Log Pow and fat solubility of the notified chemical (Connell, 1990). The very limited exposure to the aquatic compartment makes it very difficult to calculate a meaningful predicted environmental concentration (PEC).

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below (all end points are based on nominal concentrations).

Organism	*Duration*	*End Point*	*mg/L*
Fish	96 h	LC50	>100
Daphnia	48 h	EC50	>100
Algae	72 h	E_bC50	170
	96 h	E_bC50	130
	0-96 h	E_rC50	>200

A predicted no effect concentration (PNEC - aquatic ecosystems) of >1 mg/L has been derived by dividing the lowest end point value of >100 mg/L by a worst-case scenario uncertainty (safety) factor of 100, as toxicity data are available for three trophic levels.

9.1.3. Environment – risk characterisation

Almost all of the notified chemical imported will eventually be disposed of to landfill. In landfill, the notified chemical bound to the metal surfaces can be expected to be immobile and eventually degrade to give water vapour and oxides of sulphur and nitrogen as well as metal salts.

It is not possible to determine a realistic PEC value in order to assess the risk to aquatic organisms, as the use pattern of the notified chemical will result in very low exposure to the aquatic environment. However, due to the limited release to water, it is unlikely that the chemical would exist at levels which could pose a threat to aquatic organisms, noting the low aquatic toxicity. Based on the proposed use pattern, the release of the notified chemical to the environment is expected to be very low. Abiotic or slow biotic processes are expected to be largely responsible for the eventual degradation of the notified chemical, although the metal ions will be unaffected.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be imported in totes as a component of finished electrocoat resin (E6270) at a maximum concentration of 0.2% w/w. The exposure for importation and distribution workers is expected to be negligible except in the event that the packaging is breached.

The main potential for occupational exposure is during transfer operation at the customer's facilities when the electrocoat resin is transferred to an electrodeposition tank from totes through the use of pumping equipment. Worker exposure may occur during electrocoating operation if there is any obstruction to the conveyor, and during quality control testing when small test samples are withdrawn from the electrodeposition tank.

Minimal exposure is expected at the electrocoating process, as the entire process is a closed system. However, the possibility of exposure to drips and spills exists during the processes of connection and disconnection of totes, preparation, cleaning, and maintenance. Dermal exposure would be the predominant route of occupational exposure to workers during these activities. The notifier specifies, via MSDS and technical service advice, that workers at customers sites be trained in the proper handling of chemicals and provided with appropriate protective equipment (i.e. safety glasses, gloves, protective clothing etc). Furthermore, all activities are to be carried out in well-ventilated areas.

9.2.2. Public health – exposure assessment

The notified chemical will not be available for public exposure as the notified chemical is cured and overcoated prior to sale to consumers. Therefore, consumers are not expected to come in direct contact with the notified chemical. Furthermore, the notified chemical will be present at a very low (0.02%) concentration in the coating solution.

The public will only be exposed during the transport and handling of the notified chemical if there is an accident resulting in spillage. Therefore, the overall public exposure to the notified chemical will be low, due to the low concentration of the notified chemical handled and its use pattern.

9.2.3. Human health - effects assessment

The notified chemical was shown to be of low acute toxicity via the oral route in rats. It was not a skin sensitiser. The notified chemical was not mutagenic in bacteria, and was not genotoxic in *in vitro* chromosome aberration test. In a 14-day oral repeat dose study, the NOEL was 500 mg/kg/day.

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (1999).

9.2.4. Occupational health and safety – risk characterisation

The main occupational exposure is expected for workers handling the notified chemical during electrocoating operation at the customer manufacturing facilities. However, for these workers, the risk of exposure is expected to be low, as electrocoating will be a closed system except for QC testing.

The opportunity for skin exposure exists during product transfer to electrodeposition tank and equipment cleaning/maintenance. In these cases, workers handling connections or equipment will be properly protected with PPE as recommended in the MSDS. Furthermore, all activities are to be carried out in well-ventilated areas. Eye contact is only likely in the case of accidental splashes and is controlled by the use of safety glasses or goggles.

During transport, storage and distribution of the products containing the notified chemical, there is unlikely to be any worker exposure, except in the event of an accidental spill. Exposure after a spill should be controlled by the recommended practices for cleaning up of spills stated in the

MSDS.

Overall, the occupational risk is low for handlers of the notified chemical, as the notified chemical is expected to have low hazard at the concentration used. The occupational risk would be further reduced due to the use of enclosed system for electrodeposition coating, and the wearing of protective clothing during product transfer, equipment cleaning and maintenance.

9.2.5. Public health – risk characterisation

The public will be mainly exposed to the notified chemical through industrial use of cured and overcoated coatings. The notified chemical is expected to have low hazard at the low concentration used in these coatings. Furthermore, exposure of the general public to the notified chemical as a result of its transport or through its use is assessed as being low. Therefore, the risk to the public resulting from the use of the notified chemical is expected to be very low.

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

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (1999).

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.

It is not possible to classify the notified chemical according to the criteria of the GHS (United Nations, 2003).

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 as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the 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, 1994b). 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 engineering controls to minimise occupational exposure to the notified chemical as introduced and as diluted for use:
  - Enclosed electrocoating operation.
  - Local exhaust ventilation during product transfer and electrocoating operation.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and diluted for use:
  - Protective gloves, safety glasses or goggles, industrial clothing and footwear

  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.

Environment

Disposal

- The solid residues of the notified chemical should be disposed of in accordance with federal, State and local environmental control regulations.

- Empty containers should be recycled or disposed of through an approved waste management facility.

Emergency procedures

- Spills/release of the notified chemical should be contained and prevented from entering drains, streams or any water body.
- The spilled material should be collected with sand, vermiculite or other non-combustible absorbent material and place in clean and suitable containers for disposal.
- Spilled material may be placed in a suitable container for later recycling.

12.1. Secondary notification

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

(1) Under Section 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical;

or

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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