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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

AZ-57-5328

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

Director
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 (P99-01082), Canada 2001 (NSN# 9380/10676

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
AZ-57-5328

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	IR Spectroscopy.
Remarks	Reference spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
Medium

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 0.24% 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 0.24% 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 0.062% 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 0.24%.

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 (0.062%) concentration in the coating solution.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa White granular solid

Melting Point/Melting Point

Remarks Not technically feasible; decomposed prior to melting from approximately 467 K. No report provided.

TEST FACILITY SafePharm Laboratories (2000a)

Relative Density 2417.1 kg/m^3 at 21±0.5ºC

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 25ºC (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 25ºC. 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 182 g/L at 20 ± 0.5ºC

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 5.0274 g of test substance with 20 mL glass double distilled water, shaking at 30ºC for 14.5 hours, standing at 20ºC for 6 hours, and filtering and analysing the solution. In the definitive test the mixtures of test substance glass double distilled water were added to 3 flasks shaken at approximately 30ºC and after standing at 20ºC 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 Solubility < 4 mg/100 g < HB 307 > at 37.0° ± 0.5°C

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

Remarks The fat solubility was examined by a simplified flask method. In a preliminary test, samples of ground test substance were mixed with a standard fat (HB 307) in flasks, shaken at approximately at 37°C for 17.25 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 3 or 21 h and filtered. The concentration of test substance in sample solutions was determined by atomic absorption spectroscopy.

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 =< -4.10 (Estimated)

Remarks The partition coefficient is based on the approximate solubilities of the test substance in n-octanol and water. Various mixtures of test substance and solvents were prepared. Following sonification, each mixture was visually assessed for the presence of undissolved material.

The estimated value was supported by the result of an experimentally determined (Shake Flask Method, OECD TG Method 107) log Pow value of <-2.12 for another water-soluble acid salt of the same metallic element as contained in the test substance. Further evidence to support the result was obtained by computer estimation of the partition coefficient of the test substance. The log Pow was estimated to be –4.34 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 log K_{oc} > 4.33 (Based on an analogue salt)

Screening test

METHOD OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.

Soil Type	*Organic carbon (%)*	*Mean metal adsorbed (% w/w)*	*Mean adsorption coefficient, K*	*Mean adsorption coefficient as a function of organic carbon content, Koc*
1	0.6	98.6	384	6.41×10^4
2	1.8	98.6	385	2.14×10^4
3	0.6	>99.0	>513	$>8.56 \times 10^4$

Soil Type	*% Metal desorbed*	*% Metal remaining on adsorbent after desorption step*
1	<2	>98
2	<2	>98
3	<2	>98

Remarks The adsorption/desorption characteristics for the metal ion were performed on another salt of the same metal. 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 high log K_{oc} value is inconsistent with the high water solubility and the low log P_{ow} of the test substance and indicate that the mobility of the notified chemical in soil is low. It is possible that ionic binding to charged soil particles is responsible for the mobility result.

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 ion 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	0.00

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 support combustion in the preliminary screening test.

TEST FACILITY SafePharm Laboratories (2001a).

Autoignition Temperature

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
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	severely irritating
Guinea pig, skin sensitisation - Maximisation test	no evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOEL 15 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 ground 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: All male animals had hunched posture and pilo-erection and recovered one day after dosing. There were no signs of systemic toxicity noted in females.
- Effects in Organs: None.
- Remarks - Results: None.

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

TEST FACILITY — SafePharm Laboratories Ltd (2001b).

7.2. Acute toxicity - dermal

TEST SUBSTANCE — Notified chemical.

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

- Species/Strain: Rat/Sprague-Dawley CD (Crl: CD).
- Vehicle: None.
- Type of dressing: Semi-occlusive.
- Remarks - Method: The test material was applied to an area of shorn skin and moistened with water. The animals were observed for deaths or overt sign 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	5 (male)	2000	0/5
II	5 (female)	2000	0/5

LD50 >2000 mg/kg bw.

Signs of Toxicity - Local Well defined erythema was noted at the treatment sites of all females one day after dosing with very slight to well defined erythema in three females three days after dosing. Other skin reactions noted at the treatment site of one female were superficial cracking of the epidermis, desquamation and crust formation, from day 2 to day 6. No signs of dermal irritation were noted in males during the study.

Signs of Toxicity - Systemic No signs of systemic toxicity were noted during the study.

Effects in Organs No abnormalities were noted at necropsy.

Remarks - Results None.

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

TEST FACILITY SafePharm Laboratories Ltd (2000d).

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 None

Observation Period 7 days

Type of Dressing Semi-occlusive.

Remarks - Method 0.5 g of the test material, moistened with 0.5 mL of distilled water was applied. The patch was removed after 4 hrs.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1	0	1.33	2	72 hrs	0
Oedema	0	0	0.67	1	48 hrs	0

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

Remarks - Results All treated skin sites appeared normal at the 7 day observation.

CONCLUSION The notified chemical is slightly irritating to skin.

TEST FACILITY SafePharm Laboratories Ltd (2000e).

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 One

Observation Period	48 hrs
Remarks - Method	Only one rabbit was used. 0.1 mL of the test material was placed into the conjunctival sac of the right eye. The left eye remained untreated and was used for control purposes. Assessment of the ocular damage/irritation was made approximately 1, 24 and 48 hrs following treatment.

RESULTS None

Lesion	*Time after treatment*		
	1 hr	24 hrs	48 hrs
Cornea			
Degree of opacity	0	1	2
Area of opacity	3	3	3
Iris	1	1	1
Conjunctiva:			
Redness	3	3	3
Chemosis	2	2	2
Discharge	2	2	3

Remarks - Results	Sloughing of the nictitating and lower conjunctival membranes and white appearance of the lower nictitating and conjunctival membranes were noted at the 48-hour observation. The animal was killed for humane reasons immediately after 48-hour observation in accordance with the UK Home Office guidelines. Due to the severity of the ocular responses, the notified chemical was classified as severely irritating and no further animals were treated.

CONCLUSION The notified chemical is severely irritating to the eye.

TEST FACILITY SafePharm Laboratories Ltd, Derby (2000f)

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 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: 0.1% 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: 50% in distilled topical application: 25% 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 Ltd (2000g).

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/Sprague-Dawley CD (Crl: CD)
Route of Administration: Oral – gavage.
Exposure Information: Total exposure days: 28 days;
Dose regimen: 7 days per week;
Post-exposure observation period: Nil
Vehicle: Distilled water
Remarks - Method: None

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	15	0/10
III (mid dose)	5/sex	150	0/10
IV (high dose)	5/sex	1000	0/10

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

Clinical Observations
No treatment-related clinical sings were detected in 15 and 150 mg/kg/day. Animals of both sex treated with 1000 mg/kg/day showed increased salivation up to ten minutes after dosing from Day 7 onwards. Females from this dose group developed hunched posture and prolonged salivation (up to one hour after dosing) at this time, which continued throughout the study. In addition, noisy respiration was reported in a number of high dose females continuing throughout the study whilst tiptoe gait and wet fur occasionally observed in this group. Increased hindlimb grip strength in both sexes and forelimb grip strength for males was seen for high dose animals. Slight reduction in body weight gain was seen in high dose animals.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Clinical Chemistry: No treatment-related blood chemical changes were detected.
Haematology: A slight reduction in group mean haemoglobulin, haematocrit, erythrocyte count, mean corpuscular volume and mean corpuscular haemoglobulin, as compared with controls, was found in high dose females; however, the reduction in the group means can be ascribed to abnormal values in a single animal. No such effects were detected for 1000 mg/kg/day males or for animals of either sex treated with 150 or 15 mg/kg/day.

Effects in Organs
No treatment-related organ weight changes were noted. Nine of the ten animals treated with 1000 mg/kg/day showed gastric changes at necropsy, which include a raised limiting ridge and thickened and/or reddened glandular gastric epithelium. No macroscopic abnormalities were detected at 150 or 15 mg/kg/day.

No treatment-related microscopic changes were observed at 15 mg/kg/day. An increased incidence of centrilobular hypertrophy was observed for animals of either sex treated with 1000 mg/kg/day and for males treated with 150 mg/kg/day. Mucosal apoptosis and submucosal ridge acute inflammation in the glandular stomach and acantosis of the limiting ridge was observed for animals of either sex at 1000 mg/kg/day.

Remarks – Results
None.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 15 mg/kg bw/day in this study, based on liver changes observed in males at 150 mg/kg bw/day.

TEST FACILITY SafePharm Laboratories (2001c).

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.

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: 15, 50, 150, 500, 1500 & 5000 µg/plate. b) Without metabolic activation:15, 50, 150, 500, 1500 & 5000 µg/plate.
Vehicle	DMSO
Remarks - Method	Two independent assays were performed triplicate.

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. The notified chemical was toxic at and above 1500 µg/plate as indicated by reduction in background lawn. 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 (2001d)

7.9. 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 in triplicate.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	30, 60, 120*, 240*, 480*, 720	4	20
Test 2	15, 30, 60, 120*, 240*, 480*, 720	24	0

Present			
Test 1	30, 60, 120*, 240*, 480*, 720	4	20
Test 2	15, 30, 60, 120*, 240*, 480*, 720	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. In both experiments, the level of precipitate present at 720 µg/mL excluded this dose from selection for metaphase analysis in the presence or absence of metabolic activation. Appropriate positive controls were used and led to statistically significant increases in frequency 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 (2001e).

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	Adjusted to 50 mg $CaCO_3$/L
Analytical Monitoring	Samples from test solutions and control medium were drawn at the beginning and end of each renewal period (every 24 hours) and analysed using flame Atomic Absorption Spectrophotometry (AAS) and Inductively Coupled Plasma-Atomic Emission Spectrophotometry (ICP-AES) after filtration.
Remarks – Method	Pre-study solubility tests showed that the test substance precipitated in test media after approximately 24 to 48 hours. This effect was more severe with higher total hardness values (up to 100 mg/L as $CaCO_3$). This precipitation was considered to be due to a reaction with the salts in the water forming an insoluble precipitate and/or a pH dependent effect. Based on further solubility test results, the use of a test medium of dechlorinated tap water with the hardness of approximately 50 mg/L as $CaCO_3$ was considered appropriate to minimise precipitation losses. Based on a range finding test, which resulted in mortalities at 10 and 100 mg/L concentrations but no sub-lethal effects at any concentration, a definitive test was conducted with 5 test concentrations. 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	20	0	0	0	0	0	0
1.8	20	0	0	0	0	0	0
3.2	20	0	0	0	0	0	0
5.6	20	0	0	0	0	0	0
10	20	0	0	2	12	14	14
18	20	0	0	20	20	20	20

LC50	
Based on nominal concentrations	8.9 mg/L at 96 hours (95% confidence limits 7.9-10 mg/L).
Based on time-weighted mean measured concentrations	0.14 mg/L at 96 hours (95% confidence limits 0.093-0.20 mg/L).
NOEC	
Based on nominal	5.6 mg/L at 96 hours

concentrations	
Based on time-weighted mean measured concentrations	0.025 mg/L at 96 hours
Remarks – Results	Microscopic inspection showed that test substance had not adhered to the surface of the gill filaments of the dead fish (at the 10 and 18 mg/L concentrations). Sub-lethal effects were observed at concentrations of 10 mg/L and above. These were increased pigmentation, swimming at the bottom of the vessels, swimming at the bottom with increased pigmentation, loss of equilibrium with increased pigmentation and the presence of moribund fish. The majority of results obtained using flame AAS were less than the limit of quantification (LOQ) or low and variable, therefore, frozen samples from the control, 5.6, 10 and 18 mg/L test groups were analysed using ICP-AES. The ICP-AES results were low but consistent. The low values were considered to be due to precipitation but these were considered also to reflect the amount of test substance in solution and bioavailable to test organisms. In a 'worst-case' analysis the LC50 and NOEC values based on the time-weighted mean measured concentrations of the filtered test media were calculated. Where a value was less than the LOQ, a value equal to one half of the LOQ was substituted into the equation.
CONCLUSION	Based on the time-weighted mean measured concentrations, the test substance is very toxic to fish.
TEST FACILITY	SafePharm Laboratories (2001f).

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test and EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Adjusted to approximately 100 mg $CaCO_3$/L
Analytical Monitoring	Samples from test solutions and control medium were drawn at 0 and 48 hours and analysed with using AAS.
Remarks - Method	Pre-study solubility tests showed that the test substance precipitated in test media after approximately 24 to 48 hours. This effect was more severe with higher total hardness values (up to 250 mg/L as $CaCO_3$). This precipitation was considered to be due to a reaction with the salts in the water forming an insoluble precipitate. Based on further solubility test results, a test medium of reconstituted water with the hardness of approximately 100 mg/L as $CaCO_3$ was used for the definitive test. A 100 mg/L test concentration was observed to be clear and colourless at 0 hours with only a slight precipitate visible after 24 hours. Based on a range finding test, which resulted in mortalities at 10 and 100 mg/L concentrations, a definitive test was conducted with 9 test concentrations. Oxygen content, pH and temperature were all satisfactorily maintained.
RESULTS	

Concentration mg/L Nominal	*Number of D. magna*	*% Immobilised*	
		24 h	*48 h*
Control	10	0	0
1.0	10	0	0
1.8	10	0	0
3.2	10	0	0
5.6	10	0	0
10	10	2	35
18	10	9	60
32	10	12	90
56	10	20	100
100	10	20	100

EC50

Based on nominal concentrations: 15 mg/L at 48 hours (95% confidence limits 12-18 mg/L).

Based on time-weighted mean measured concentrations: 12 mg/L at 48 hours (95% confidence limits 9.8-14 mg/L).

NOEC

Based on nominal concentrations: 5.6 mg/L at 48 hours.

Based on time-weighted mean measured concentrations: 6.0 mg/L at 48 hours.

Remarks - Results: Microscopic examination showed that test substance had not adhered to the antennae or thoracic appendages of immobilised daphnids. Test concentration analysis showed variable results as did the analysis of frozen samples. Some values were below the LOQ. The general trend to decline in concentration observed over the study period was considered to be due to further precipitation of test substance. The overall variability in results was considered to be linked to precipitation at different rates throughout the concentration range and the inherent variability of the method of analysis at the very low concentrations used.

In a 'worst-case' analysis the EC50 and NOEC values based on the time-weighted mean measured concentrations were calculated using measured concentrations determined at 48 hours for 5.6 mg/L (nominal) and above.

CONCLUSION: Based on the time-weighted mean measured concentrations, the test substance is harmful to daphnia.

TEST FACILITY: SafePharm Laboratories (2001g).

8.2.3. Algal growth inhibition test

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 201 Alga, Growth Inhibition Test and EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species: *Pseudokirchneriella subcapitata*

Exposure Period: 96 hours

Concentration Range

Nominal: 0.625, 1.25, 2.5, 5.0 and 10 mg/L (based on the results of a range finding test)

Auxiliary Solvent: None

Water Hardness	The test substance was dissolved directly in culture medium with no EDTA.
Analytical Monitoring	Samples of control and test solutions were obtained at 0 and analysed by AAS.
Remarks - Method	Preliminary solubility tests showed resulted in no visible precipitation for 96 hours when the chelating agent EDTA was removed from the culture medium. The temperature and pH were satisfactorily maintained

RESULTS

	E_bC50 (mg/L		E_rC50 (mg/L)		NOEC (mg/L)	
	Nominal	*Time-weighted mean measured*	*Nominal*	*Time-weighted mean measured*	*Nominal*	*Time-weighted mean measured*
72 h	1.5	0.66	-	-	-	-
96 h	1.4	0.62	-	-	0.625	0.45
0-96 h	-	-	3.9	1.3	-	-

Remarks - Results	At 96 hours, no cell abnormalities detected in the control or test solutions except at 10 mg/L, where no intact cells were observed. No precipitate was observed in test cultures after 96 hours. Test concentrations measured at 0 hours ranged from 90 to 121% of nominal. A marked decline in measured concentrations was observed at 96 hours to below the LOQ. This was considered due to removal of the precipitated material formed when the test substance reacted with culture medium to form a salt, although no precipitate was noted visually. In a 'worst-case' analysis the LC50 and NOEC values based on the time-weighted mean measured concentrations were calculated. Where a value was less than the LOQ, a value equal to one half of the LOQ was used in the calculation. The results of a regrowth experiment after 96 hours of exposure showed that the test substance was algistatic in effect.
CONCLUSION	Based on the time-weighted mean measured concentrations, the test substance is very toxic to algae
TEST FACILITY	SafePharm Laboratories (2001h).

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test, EC Directive 87/302/EEC and US EPA Draft Ecological Test Guidelines OPPTS 850.6800.
Inoculum	A mixed population of activated sewage sludge from the aeration stage of a treatment plant, which treats predominantly domestic sewage.
Exposure Period	3 hours
Concentration Range Nominal	100, 180, 320, 560 and 1000 mg/L (based on a preliminary range finding study).
Remarks – Method	Test concentrations of the reference substance (3,5-dichlorophenol) were 3.2, 10 and 32 mg/L.
RESULTS	
EC50	460 mg/L
NOEC	180 mg/L (This is based on the inhibition of the respiration after 3 hours of contact as it was not possible to preform statistical analysis due to lack of replication).

Remarks – Results	The 3 hour EC50 of the reference substance was 7.3 mg/L, thus validating the test. The pH of test media at concentrations of 320, 560 and 1000 mg/L were significantly lower than for other concentrations. This was considered as a contributing factor to the toxic nature of the test substance but not to have affected the integrity of the study. Slight foaming was observed in the test solutions at 560 and 1000 mg/L concentrations and small particles of test substance were observed in all test solutions after the 30 minutes and 3 hour contact time. This was considered to be due to precipitation of the test substance in dechlorinated tap water as the preliminary solubility tests indicated. Any precipitation in the lowest 3 concentrations were thought to have been obscured by the dark grey activated sewage sludge.
CONCLUSION	The test substance was not toxic to bacteria in activated sludge.
TEST FACILITY	SafePharm Laboratories (2001i).

8.2.5. Sediment-water chironomid toxicity test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 218 Sediment-Water Chironomid Toxicity Test using Spiked Sediments - Static
Species	Sediment dwelling larvae of *Chironomus riparius*
Exposure Period	28 days
Auxiliary Solvent	None
Water Hardness	Standard medium used.
Analytical Monitoring	None
Remarks - Method	Nominal concentrations of 0.10, 1.0, 10, 100 and 1000 mg/kg were tested in a range finding study. After aeration, the sediment was left for 7 days to allow settlement and equilibration of test concentrations between the sediment and water phases before the larvae were placed in test vessels.

RESULTS

Concentration mg/kg Nominal	*Number of Fully Emerged Midges after 28 Days*
Control	10
0.10	10
1.0	8
10	11
100	11
1000	10

EC50(emergence)	> 1000 mg/kg at 28 days
NOEC (or LOEC)	1000 mg/kg at 28 days (highest concentration tested).
Remarks - Results	The estimate of the EC50 (emergence) value was obtained by inspection of the data. No definitive study was conducted as the EC50 value was greater than 1000 mg/kg. The pH, temperature and oxygen content were all maintained satisfactorily.
CONCLUSION	The test substance when introduced in spiked sediment is practically non-toxic to larvae of *Chironomus riparius*
TEST FACILITY	SafePharm Laboratories (2001j).

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 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 time-weighted mean measured concentrations).

Organism	*Duration*	*End Point*	*mg/L*
Fish	96 h	LC50	0.14 (95% confidence limits 0.093-0.20 mg/L)
Daphnia	48 h	EC50	12 (95% confidence limits 9.8-14 mg/L).
Algae	72 h	E_bC50	0.66
	96 h	E_bC50	0.62
	0-96 h	E_rC50	1.3

A predicted no effect concentration (PNEC - aquatic ecosystems) of 1.4 X 10^{-3} mg/L (1.4 µg/L) has been derived by dividing the lowest end point value of 0.14 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. 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 0.24% 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 (0.062%) 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 and dermal routes in rats. It was not a skin sensitiser and was slightly irritating to rabbit skin. The notified chemical was severely irritating to the eye in a limited study carried out in one rabbit. The animal was killed at 48-hour observation due to humane reasons, as sloughing of the nictitating and lower conjunctival membrane was noted.

The notified chemical was not mutagenic in bacteria, and was not genotoxic in vitro chromosome aberration test. In a 28-day oral repeat dose study, the NOEL was 15 mg/kg/day.

The notified chemical is classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) and is assigned the risk phrase R41: Risk of Serious Damage to Eyes. While the notified chemical in powder form would have an exposure standard, this does not apply to the solutions being brought into Australia.

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 classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). The classification and labelling details are:

R41: Risk of serious eye damage

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.

According to the OECD (2003) Globally Harmonised System for the Classification and Labelling of Chemicals, the notified chemical is categorised as:

	Hazard category	***Hazard statement***
Serious eye damage/ eye irritation	1 Irreversible effects	Causes serious eye damage

According to the criteria of the GHS (United Nations, 2003), the notified chemical is classified as Chronic I (very toxic to aquatic life with long lasting effects).

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 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

REGULATORY CONTROLS

Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R41: Risk of serious eye damage

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - $\geq$ 10%: R41 Risk of serious eye damage
  - 5% $\leq$ conc $\leq$ 10%: R36 Irritating to eyes

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 as 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 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.

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.

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 of 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. However, due to the high aquatic toxicity, if new uses with higher aquatic exposure are proposed, a separate risk assessment may need to be carried out.

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