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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

DP2009

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Director
NICNAS

FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
DuPont (Australia) Ltd (ABN 59 000 716 469), 168 Walker Street North Sydney NSW 2060;

Melbourne Powdercoating Company Ltd (ACN No. 069 802 580) of Lot 12 Tullamarine Park Road, Tullamarine Victoria 3043; and

Prima Furniture (Australia) Pty Ltd (ABN 42 006 219 549) of 30 Tullamarine Park Road Tullamarine Victoria 3043.

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Identity of chemical
Composition

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)
None

NOTIFICATION IN OTHER COUNTRIES
None

3. COMPOSITION

DEGREE OF PURITY
>90%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported as a component of a powder-coating product, at <5% (wt/wt) concentration.

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

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

USE
The notified chemical will be used in powder coatings for metal surfaces

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not stated

IDENTITY OF MANUFACTURER/RECIPIENTS
DuPont (Australia) Ltd;

Melbourne Powdercoating Company Ltd; and

Prima Furniture (Australia) Pty Ltd.

TRANSPORTATION AND PACKAGING
The coating products containing the notified chemical will be imported in 20 kg bags contained in boxes with plastic liners. The imported product will be stored and distributed by road from the notifier's site to various coating industry Australia-wide.

5.2. Operation description

The coating powder containing the notified chemical are typically produced by blending and extruding the resins, curing agents, pigments and additives using enclosed and automated systems. The resulting matrix is ground into a fine powder measuring approximately 90μm. The powder is stored in bags and sealed automatically for use as required.

Quality control personnel will collect samples of the flakes or finely milled powder. Flakes are milled into fine powder and sprayed onto test panels for curing and evaluation.

Maintenance workers are required to service the machinery periodically.

At the application facility, bags are opened and either emptied into a hopper with an automatic feeder to the production line, or the spray gun is connected directly from the bag. The coating powder is applied by automated or manual systems, with the work piece or substrate transported though a spray zone containing a number of spray guns and into an oven via an overhead conveyor for curing. The application of the powder is by electrostatic spray within a totally enclosed applications unit. The operator has the job of inspecting the coating and ensuring powder is continuously supplied to the sealed automatic applicator unit.

Some 3% of items require manual powder coat application, either to touch up or to achieve full spray with powder coat. Manual spraying is undertaken in a separate manual spray booth.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Applicator operator	2	8 hours/day	5 days/week; 48 weeks/year
Shift supervisor	1	8 hours/day	5 days/week; 48 weeks/year

Exposure Details
Warehousing and distribution of the notified chemical involves loading, moving and storing of packaged products containing the notified chemical. No exposure is expected except in the case of accident.

The possibility of inhalation, dermal and ocular exposure to the notified chemical exists when opening the bags containing the notified chemical, loading of powder coating into a hopper and application of powder coating and disposal of empty containers.

Over 97% of the powder coating is applied automatically and the rest is applied manually. Less than

3% of the items coated require manual touch up for complete coverage for odd shaped items. Exposure to the notified chemical may occur when manually spraying coated articles to achieve a complete coating. Both manual and automated booths have cyclone extraction fans to pull all residual airborne powder into capture filters. The equipment used is self-cleaning, minimising worker exposure Personal protective equipment used when handling uncured coated articles or spraying powder includes anti-static overalls, non-insulating gloves, anti-static footwear, and respirators or air fed respiratory equipment.

Upon curing, the chemical becomes an integral part of the article being produced. Excess coating powder is removed by exhaust extraction and collected for re-use or disposal.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured into Australia. Release of the notified chemical at the customer site is expected to be minimal because any excess neat material containing the notified chemical is normally collected and recycled. In the event of transport accident, any spilled material not reused would be collected for disposal.

RELEASE OF CHEMICAL FROM USE

The product will be used by Australian coating industry in a purpose-designed and built plant. Extraction fans are employed for capturing air-borne material. Dusts caught by the primary filter is recycled or sent to landfill for disposal. Spills of notified chemical in the spraying booth is collected and aggregated for waste disposal. The notifier estimates that total waste will form approximately 5% of the total annual import volume of the notified chemical.

5.5. Disposal

All waste material containing the notified chemical generated during use is collected and placed in a receptacle and irradiated to cross-link into a solid reacted mass for landfill disposal as non-hazardous waste. At the completion of their useful life, materials coated with coating containing the notified chemical will be recycled and sent to landfill disposal or incinerated. Metal recycling is likely to result in destruction of the notified chemical through heating to produce simpler compounds of carbon.

5.6. Public exposure

The coating product containing the notified chemical will not be available to the public as the application is solely for industrial coatings application. The general public may have dermal contact to coated articles. However, at this stage the notified chemical will form part of the cured coating and will not be available for exposure.

The potential for exposure of the public to the notified chemical during normal industrial storage, handling and transportation is low. The coating products will be packaged in bags contained in cartons. This packaging will protect the contents from being released during normal handling.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Colourless solid

Melting Point 89-90ºC

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
TEST FACILITY E. Merck Central Analytical Laboratory (1988a)

Density 1284 kg/m^3

METHOD OECD TG 109 Density of Liquids and Solids.
TEST FACILITY Natec Institute (1988a)

Vapour Pressure 7.0×10^{-5} kPa at 25ºC

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
TEST FACILITY E. Merck Central Analytical Laboratory (1988b)

Water Solubility 7.6 g/L at 25ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks The water solubility was determined based on a modified flask method using UV absorbance to quantify the notified chemical.
TEST FACILITY E. Merck Central Analytical Laboratory (1988c)

Hydrolysis as a Function of pH $T_{1/2}$ at pH 4.0 > 1 year
$T_{1/2}$ at pH 7.0 > 1 year
$T_{1/2}$ at pH 9.0 > 1 year

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

pH	*T (°C)*	*t½ years*
4	50	>1
7	50	>1
9	50	>1

Remarks The abiotic degradation of the notified chemical was investigated over five days at 50°C at pH 4, 7 and 9. Concentrations were determined by HPLC. The report indicates that there was no evidence of hydrolytic loss of the notified chemical observed. Therefore, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely to occur

TEST FACILITY E. Merck Central Analytical Laboratory (1988d)

Partition Coefficient (n-octanol/water) $\log P_{ow} = 0.84$

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks The concentration of the notified chemical in the organic and aqueous phases was then determined using UV spectrophotometry. This method indicated that the partition coefficient of the notified chemical is 6.93, which is indicative of partitioning into the aqueous phase.
TEST FACILITY E. Merck Central Analytical Laboratory (1988e)

Adsorption/Desorption $\log K_{oc} = 1.05$

METHOD OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.
Remarks The adsorption coefficient, K_{OC} was obtained by a using a set of reference compounds with adsorption coefficients which had been determined using OECD TG 106. The capacity factor of the notified chemical was determined based on its HPLC retention time compared with the retention times of known substances. Using the relationship $\log K_{OC} = 2.239 \times \log k' + 2.874$ indicates that the log adsorption coefficient for the notified chemical is 1.05, classifying it as highly mobile in soil.

TEST FACILITY Fraunhofer-Institut fur Umweltchemie und Okotoxikologie (1996)

Dissociation Constant Not determined

Remarks The notified chemical contains no functional groups that are expected to dissociate.

Particle Size 84 % of particles are below 10μm (respirable)

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.
TEST FACILITY E. Merck Central Analytical Laboratory (1988f)

Flash Point Not determined

Remarks The notified chemical is solid at room temperature.

Flammability Limits Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
TEST FACILITY E. Merck Central Analytical Laboratory (1988g)

Autoignition Temperature No spontaneous ignition occurs up to the melting point

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
TEST FACILITY Natec Institut (1988b)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
TEST FACILITY E. Merck Central Analytical Laboratory (1988h)

Oxidising Properties Not oxidising

METHOD EC Directive 92/69/EEC A.17 Oxidising Properties (Solids).
TEST FACILITY E. Merck Central Analytical Laboratory (1988i)

Reactivity Not determined

Remarks The notified chemical is stable under normal conditions of use.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 = 3108 – 4082 mg/kg bw	Low toxicity
Rat, acute dermal LD50 > 5000 mg/kg bw	Low toxicity
Rat, acute inhalation	Test not provided
Rabbit, skin irritation	Slightly irritating
Rabbit, eye irritation	Non-irritating
Guinea pig, skin sensitisation - adjuvant test	No evidence of sensitisation.
Rat, oral repeat dose toxicity – 28 days.	NOAEL = 1000 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	Non mutagenic
Genotoxicity – in vitro mammalian chromosomal aberration test	Non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 401 Acute Oral Toxicity.

Species/Strain	Rat/Emd: Wi-AF/HAN
Vehicle	0.25 % aqueous Methocel K4M Premium solution
Remarks - Method	10 rats from another study were used as controls for bodyweight development.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 rats per sex	0	Not presented
2	5 rats per sex	1500	1/10
3	5 rats per sex	2000	1/10
4	5 female rats	2500	4/5
5	5 rats per sex	3000	6/10
6	5 male rats	3500	1/5

LD50	
Day 1	Male & female: 4082 mg/kg bw Male: 4986 mg/kg bw Female: 2502 mg/kg bw
LD50	
Days 8 + 15	Male & female: 3108 mg/kg bw Male: 4032 mg/kg bw Female: 2098 mg/kg bw
Signs of Toxicity	Intoxication symptoms started within 0-15 minutes after treatment and subsided after 5 days. Symptoms included dyspnea, locomotor disturbances, tremor, piloerection, salivation, abdominal position, increased lacrimation, tonic-clonic convulsions, retention of faeces, blood crusted snout, abnormal tail posture and wet anal region. A transient reduction in body weight was observed on days 2 and 4.
Effects in Organs	6/13 rats that died had haemorrhages and/or erosions in the glandular stomach. In 4/13 rats that died dark red contents were seen in parts of the small intestine. In one rat the small intestine was completely empty, while in the colon and rectum smaller amounts of grossly inspissated and moulded faeces were observed. The liver of three female rats treated with 3000 mg/kg bw showed yellow-brownish colour. Peripheral fatty degeneration of liver cells (fine droplets) was observed histologically in these rats. Two rats had yellow-tinged, partly reddish mucous contents in parts of the small intestine.
Remarks - Results	All deaths occurred on days 1 and 2 of the study.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	E. Merck Central Analytical Laboratory (1987a).

7.2. Acute toxicity - dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rat/Emd: Wi-AF/HAN
Vehicle	Water
Type of dressing	Occlusive
Remarks - Method	24 hour exposure time

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	0	0/10
2	5 per sex	5000	0/10

LD50	>5000 mg/kg bw
Signs of Toxicity - Local	None
Signs of Toxicity - Systemic	None
Effects in Organs	None
Remarks - Results	On the day of administration the general condition and motility of the rats were obviously affected. As it was difficult to distinguish between reactions due to the fixation of the rubber sleeve and symptoms possible due to the test material, certain reactions may have been masked.

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

TEST FACILITY E. Merck Central Analytical Laboratory (1987b)

7.3. Acute Inhalation Toxicity

A study on acute inhalation toxicity was not provided.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Water
Observation Period	
Type of Dressing	Occlusive
Remarks - Method	0.5 g of the chemical was applied for 4 hours.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.125	0.125	0	1	2 days	0
Oedema	0	0	0	0	NA	0

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

Remarks - Results No signs of systemic toxicity were observed.

CONCLUSION The notified chemical is slightly irritating to skin.

TEST FACILITY E. Merck Central Analytical Laboratory (1987c)

7.5. Irritation - eye

TEST SUBSTANCE Notified chemical

METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White

Number of Animals	3
Observation Period	8 days
Remarks - Method	0.1 g of the chemical was applied to the conjunctival sac of the left eye. The eyes were not flushed afterwards.

RESULTS

Remarks - Results	All Draize scores were zero. No signs of systemic toxicity were observed. Individual animal data were not presented.

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

TEST FACILITY E. Merck Central Analytical Laboratory (1987c)

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation – Maximisation test

Species/Strain	Guinea pig/Iva: PDH
MAIN STUDY	
Number of Animals	Test Group: 10/sex Control Group: 10/sex
INDUCTION PHASE	Induction Concentration: *Intradermal*: Pairs of intradermal injections (0.1 mL) to the scapular region as follows: • 1:1 Freund's Complete Adjuvant (FCA) and water; • 5% Notified chemical in water; • 5% Notified chemical in 1:1 FCA and water. *Topical:* 20 % DP2009 in water under occlusive dressing for 48 hours.
Signs of Irritation	During the induction phase, all injection sites were swollen and red up to day 2 of the study. Thereafter, open wounds, formation of scab and epithelization of tissue at the injection sites were observed in the guinea pigs of the test and control groups.
CHALLENGE PHASE	
1st challenge	*Topical application:* 5 % DP2009 in water under occlusive dressing for 24 hours.
Remarks - Method	A preliminary study was not described in this report.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	5%	0/20	0/20
Control Group	5%	0/20	0/20

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

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

TEST FACILITY E. Merck Central Analytical Laboratory (1988j)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Wistar
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: Not stated
Vehicle	Methocel K4M Premium
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5 rats/sex	0	0/10
II (low dose)	5 rats/sex	64	0/10
III (mid dose)	5 rats/sex	160	0/10
IV (high dose)	5 rats/sex	400	0/10

Mortality and Time to Death
No animals died during the study

Clinical Observations
Rats in groups 3-5 showed a dose dependent increase in the incidence of non-specific symptoms, such as pushing through the bedding or salivation, immediately after treatment. Some animals in group 5 showed a brown discoloration of the saliva. These effects may have been caused by the catheter during dosing or the bitter taste of the test material.

One animal in the control group and one from group 2 displayed limited hair loss from the third week of treatment.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No remarkable peripheral haematological changes were observed. Isolated significant differences in mean values relative to controls were within in-house laboratory biological variation limits.

A significant increase in serum alanine aminotransferase (ALAT) activity was observed in group 5. This increase was within the upper limit of the normal range.

Effects in Organs
Signs of increased liver metabolism, such as a slightly increased incidence of eosinophilic degenerated hepatocytes and single cell necrosis, were observed in 4/5 male rats in group 5. These effects are typically reversible.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was the top dose of 1000 mg/kg bw/day.

TEST FACILITY	E. Merck Central Analytical Laboratory (1988k)

7.8. Genotoxicity - bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 and 472 Bacterial Reverse Mutation Test. EC Directive 2000/322/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.

Species/Strain	*S. typhimurium*: strains TA1535, TA1537, TA1538, TA98, TA100, *E. coli*: strainsWP2 and WP2*uvrA*
Metabolic Activation System	Induced rat liver microsomal fraction (S9).
Concentration Range in Main Test	a) With metabolic activation: 0 – 10000 µg/plate. b) Without metabolic activation: 0 – 10000µg/plate.
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks - Method	No significant protocol deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 10000 µg/plate	> 10000 µg/plate	Not stated	Negative
Present				
Test 1	> 10000 µg/plate	> 10000 µg/plate	Not stated	Negative

Remarks - Results	The negative controls were within normal limits and the positive controls (1-ethyl-2-nitro-3-nitrosoguanidine, methyl methanesulfonate, 2-nitrofluorene, 4-nitro-1,2-phenylene diamine, sodium azide and 9-aminoacridine (-S9); 2-aminoanthracene (+S9) demonstrated the sensitivity of the test.

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY E. Merck Central Analytical Laboratory (1987d and 1991)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.

Cell Type/Cell Line	V79 Chinese hamster cells
Metabolic Activation System	Induced rat liver microsomal fraction
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks - Method	No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	150, 300,600,1200 and 2400	5 hours	18 hours
Test 2	1200 and 2400	5 hours	7 hours
Test 3	1200 and 2400	5 hours	28 hours
Present			
Test 1	150, 300, 600 and 1200	5 hours	18 hours
Test 2	1200	5 hours	7 hours
Test 3	1200	5 hours	28 hours

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity in Main test	*Precipitation*	*Genotoxic Effect*
Present			
Test 1	2400	> 2400	Negative
Test 2	2400	> 2400	Negative
Test 3	> 2400	> 2400	Negative
Absent			
Test 1	> 1200	> 1200	Negative
Test 2	1200	> 1200	Negative
Test 3	> 1200	> 1200	Negative

Remarks - Results: In a preliminary range finding study it was determined that concentrations of the notified chemical 2959 at 2400 mg/mL without metabolic activator and 4800 mg/ml with metabolic activator resulted in a significant inhibition of cell growth. Positive controls demonstrated the sensitivity of the test.

CONCLUSION: The notified chemical was not clastogenic under the conditions of the test.

TEST FACILITY: E. Merck (1988l)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 301 D Ready Biodegradability: Closed Bottle Test.

Inoculum: Mixed inoculum Activated sewage sludge and effluent, Heuenfelde sewage farm, Hamburg).

Exposure Period: 28 d

Auxiliary Solvent: None

Analytical Monitoring: Oxygen demand was measured at 0, 5, 18 and 28 days.

Remarks - Method: Oxygen consumption was measured by oxygen electrode and Theoretical oxygen demand calculated using the elemental composition (TOD = 2.0 mg O_2/mg active substance).

RESULTS

Test substance		*Sodium-n-dodecylsulfate*	
Day	*% degradation*	*Day*	*% degradation*
5	3.5%	5	50.3
18	26.7%	18	52.5
28	24.3%	28	62.5

Remarks - Results: The biodegradability of the reference substance was 62.5% after 28 days, indicating that the activity of the inoculum used in the test was confirmed.

CONCLUSION: The test substance is not readily biodegradable under the test conditions. The test substance weakly inhibited the biodegradation of the reference substance.

TEST FACILITY NATEC Institut (1988c).

8.1.2. Bioaccumulation

A bioaccumulation report was not provided. However, the high water solubility and low partition coefficient value of the notified chemical indicate that it has a low bioaccumulation potential (Connell, 1990).

8.2. Ecotoxicological investigations

Test	Species	Results
Acute Toxicity	Zebra Fish	LC50 (96 h) = 340 mg/L
OECD TG 203	*Brachydanio rerio*	
Acute Immobilisation	Water Flea	EC50 (48 h) = 615 mg/L
OECD TG 202	*Daphnia magna*	
Growth Inhibition	Algae	E_bC50 (72 h) = 9.1 mg/L
OECD TG 201	*Scenedesmus subspicatus*	E_rC50 (72 h) = 97.6 mg/L
		Pre-illumination E_bC_{50} (72 h) = 34.9 mg/L
		Pre-illumination E_rC_{50} (72 h) > 100 mg/L
Growth Inhibition	Algae	EC50 (72 h) = 2.6 mg/L
	Scenedesmus subspicatus	NOEC < 1.0 mg/L

The acute toxicity tests on fish (Natec Institut, 1987a) were performed using a static methodology and observations were performed at 3, 6, 24, 48, 72 and 96 hours. The test was performed using ten specimen fish per loading rate at a temperature range of 21-25 ºC. The tests were conducted using the test substance at nominal concentrations of 1, 10, 100, 198, 296, 444, 667 and 1000 mg/L. The results of the definitive study showed that no mortalities were observed in the test vessels with less than 198 mg/L of the notified chemical. After 96 h, 20% mortality was observed at a test concentration of 296 mg/L while 100% was observed at test substance concentrations above 444 mg/L. The 96-hour LC50 for the notified chemical to *Brachydanio rerio* is 340 mg/L.

The immobilisation tests with *Daphnia* (Natec Institut, 1987b) were also performed under static conditions with observations performed at 24 and 48 hours. The test was performed using 20 daphnids per flask at a temperature of 20 ºC. The tests were conducted using the test substance made up at nominal concentrations of 50, 100, 250, 300, 400, 500, 600, 800, 900, 1000 and 1200 mg/L. No immobilised daphnids were observed in the test vessels with less than 250 mg/L. After 48 h, 15, 25, 30, 35, 50, 70, 95 and 100 % mortality was observed after at test substance concentrations of 300, 400, 500, 600, 800, 900, 1000 and 1200 mg/L, respectively. The 48-hour EC50 for the notified chemical to *Daphnia magna* is 615 mg/L as determined by probit analysis. Analysis of the raw data using the Toxcal program gave an EC50 of 642 mg/L.

Algae were exposed to the test substance at nominal concentrations of 1, 3.2, 10, 32 and 100 mg/L for 72 h without pre-illumination and for 72 h with 24 h pre-illumination under static test conditions and constant illumination (RCC, 1998). The test substance at a concentration of 10 mg/L was also tested without pre-illumination for 120 h and constant illumination (RCC, 1998). Analysis of the test media indicated that approximately 80% of the test substance had degraded in the 24 h pre-illumination period and was completely degraded after 72 h of constant illumination. The results (based on nominal concentrations) indicate that both biomass and the growth rate of *Scenedesmus subspicatus* are adversely affected by the test substance and its photolysis degradation products. The notifier indicates that in the 120 h without pre-illumination test the algal cell densities reached those of the control after approximately 96 h and cell growth was inhibited by nutrient limitation in the static test.

In the second test, algae were exposed to the test substance at nominal concentrations of 1.0, 10 and 100 mg/L for 72 h at 24˚C under constant illumination and shaking (ABC, 1993). Three replicate test flasks were prepared for the test substance and three controls. No abnormalities were detected in any of the replicate test samples. Both biomass and growth rate of *Scenedesmus subspicatus* was adversely affected by the test substance, giving a 72 h EC50 of 2.6 mg/L and NOEC of < 1.0 mg/L.

It should be noted that while there is no apparent difference between the two 72 h (without pre-illumination) algal toxicity tests conducted above, the results obtained differ considerably for unclear reasons.

The ecotoxicity data indicates the notified chemical is moderately toxic to algae, but appears to be practically non-toxic to fish and daphnia.

During a 28 d biodegradation study (Natec Institut, 1988c), the notified chemical weakly inhibited biodegradation of the reference substance.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

A limited quantity (<5% of import volume) of the notified chemical is expected to be generated in waste materials during use in coating of various materials. Wastes generated are recycled or stabilised into a matrix for landfill disposal. A low potential for environmental release is expected. Air extraction filters from application areas are sent to incineration for disposal.

The reacted overcoat forms a solid cross-linked mass. The notified chemical is not readily biodegradable; however, in water the notified chemical is expected to degrade photochemically.

9.1.2. Environment – effects assessment

The ecotoxicity data indicate the notified chemical is moderately toxic to algae, but appears to be practically non-toxic to fish and daphnia. A PNEC of 26 ug/L may be assigned based on the most sensitive algal result and an assessment factor of 100.

9.1.3. Environment – risk characterisation

A low potential for environmental release of the notified chemical is expected, with most wastes generated either being recycled, incinerated or landfilled. Within the landfill environment, the notified chemical is likely to degrade over time to simpler compounds of carbon. There will be limited release to the aquatic environment and a meaningful PEC cannot be calculated for comparison with the PNEC. However, the safety margin is expected to be high.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and Storage

Transport and storage workers will handle sealed bags containing the notified chemical. Workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached.

Coating application

The potential for inhalation, dermal and ocular exposure to the notified chemical exists when opening the bags containing the notified chemical, loading of powder coating into a hopper and application of powder coating and disposal of empty containers. All spraying is performed in a spray booth fitted with local exhaust and dust extraction system to prevent dust build-up. Where manual application is in use, the direction of airflow comes from behind the operator. Application plant operators will wear similar protective equipment (anti-static overalls, non-insulating gloves, anti-static footwear, and respirators or air fed respiratory equipment) to those required during formulation of powder coatings.

Upon curing, the notified chemical is incorporated into the chemical matrix and becomes inaccessible for exposure.

9.2.2. Public health – exposure assessment

There are no consumer uses for the notified chemical and therefore, it is not available to the public. The notified chemical becomes cross-linked and immobilised on the surface of the coated article. Therefore, the distribution of coated articles is not expected to cause adverse health effects to the public. Members of the public are unlikely to be in contact with the notified chemical and the potential for public exposure is minimal.

Public exposure to the notified chemical during storage and transport is expected to be low.

9.2.3. Human health - effects assessment

The notified chemical was of very low acute oral toxicity and low acute dermal toxicity in rats (each LD50 > 3000 mg/kg). It was a slight skin irritant in rabbits, was not an eye irritant in rabbits and was not a skin sensitiser in guinea pigs.

Reversible signs of increased liver metabolism, such as a slightly increased incidence of eosinophilic degenerated hepatocytes and single cell necrosis, were observed in a 28-day oral repeated dose study in rats (NOAEL = 1000 mg/kg bw/day). The notified chemical was neither mutagenic in bacteria nor clastogenic in Chinese hamster cells in vitro.

Based on the toxicological data provided, the notified chemical would not be classified as hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

9.2.4. Occupational health and safety – risk characterisation

Transport and storage

Except in the event of accident, the risk of adverse health effects during transport and storage is limited, since workers are only expected to handle sealed bags containing the notified chemical.

Coating application

The notified chemical will be imported as a component of a ready to use powder coating product, at <5% w/w concentration.

Applicators will potentially be exposed to the notified chemical in the coating product when manually loading the hoppers, which automatically feed the spray gun, on disposal of empty bags and when collecting oversprayed coating. However, exhaust ventilation is used in the loading area, and oversprayed powder is collected using dust-tight vacuum cleaners. In addition, workers involved in manual spraying will be clad with anti-static overalls, non-insulating gloves, anti-static footwear, and respirators or air fed respiratory equipment to minimise exposure to the notified chemical. All coating application is carried in spray booths with exhaust extraction system. Adequate ventilation systems are in place to maintain exposure levels below the relevant occupational exposure standards.

There is a NOHSC exposure standard of 10 mg/m^3 TWA for nuisance dust. Employers should ensure that the exposure standard should be observed during all phases where worker exposure to dust may occur. Spray painting should be in accordance with the NOHSC *National Guidance Material for Spray Painting*.

The largely enclosed and automated operations involved, the low concentration of the chemical in the coating produycts and the use of personal protective equipment when handling the coating products, would ensure that the occupational risk posed by the notified chemical is low when used as specified in the notification.

9.2.5. Public health – risk characterisation

There are no consumer uses for the coating product containing the notified chemical and it is not available to the public. The spray operation ensures that the sprayed-on powder layer becomes an integral part of the coated article. After curing, the notified chemical becomes inaccessible to human contact. The public health risk posed by the notified chemical is expected to be low because the notified chemical is likely to be bound within a cured paint, from which it is unlikely to be bioavailable.

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

10.1. Hazard classification

Based on the toxicological data provided, the notified chemical would not be classified as hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

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.

Acute Toxicity Category 5
Symbol: No symbol
Signal word: Warning
Hazard statement: May be harmful if swallowed.

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is No Significant Concern to public health when used as a component of powder coatings.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifiers were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical provided by the notifiers were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical when used in powder coatings:
  - Local exhaust ventilation during spraying, filling of hoppers, reclaiming powder and clean-up.
  - Enclosed and automated spray application.

  - Spray painting booths and equipment should be in accordance with Australian

Standard AS3754-1990, *Safe Application of Powder Coatings by Electrostatic Spraying.*

- Employers should implement the following safe work practices to minimise occupational exposure to the notified chemical when used in powder coatings:
  - Avoid generating dusts, when opening powder coating packages, loading hoppers, reclaiming powder and cleaning equipment.
  - Precautions must be taken to avoid sources of ignition, e.g. use of earthing leads.
  - NOHSC exposure standard for nuisance dust should not be exceeded in the workplace

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical when used in powder coatings:
  - anti-static overalls
  - non-insulating gloves
  - anti-static footwear
  - dust respirators or air fed respiratory equipment

  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.

Disposal

- The notified chemical should be disposed of by controlled incineration in accordance with local and national regulations.

Storage

- Store and handle in accordance with recommendation in the MSDS.

Emergency procedures

- Spills/release of the notified chemical should be contained and placed in suitable containers that must be tightly sealed and properly labelled for disposal. Use mechanical handling equipment. The notified chemical should not be flushed into surface waters, sanitary sewer or groundwater system.

12.1. Secondary notification

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

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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