File No: STD/1058

30 July 2004

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Pergafast 201

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Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

Pergafast 201

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals Pty Ltd of 235 Settlement Road THOMASTOWN VIC 3074.

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other name, CAS number, molecular and structural formula, molecular weight, spectral data, purity and impurity, import volumes, and manufacturing 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)
CEC/531, 2001.

NOTIFICATION IN OTHER COUNTRIES
UK/HSE, 2000.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Pergafast 201

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	UV/Vis, IR, NMR, HPLC
TEST FACILITY	RCC Ltd (1999a).

3. COMPOSITION

DEGREE OF PURITY
>90%.

4. INTRODUCTION AND USE INFORMATION

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

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

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

USE
The notified chemical is a non-phenolic colour developer for use in heat sensitive papers at less than 1% by weight.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not stated.

IDENTITY OF MANUFACTURER/RECIPIENTS
Ciba Specialty Chemicals Pty Ltd.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 50 kg metal drums and transported via road in Australia.

5.2. Operation Description

In Australia, the notified chemical will be formulated with other ingredients into a liquid paper-coating product containing <25% notified chemical. The paper-coating product is then applied onto the paper via an automatic coating machine. This heat-sensitive coating is then sealed under an impermeable topcoat to produce the final products, namely, event tickets for sale to the public.

The operating can be described as following:

Notified chemical (powder)	*Weigh and add* →	Blending vessel	*Transfer* → *(Liquid)*	Coating apparatus	*Apply* →	Heat-sensitive paper

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hour/day)*	*Exposure Frequency (day/year)*
Storeman	1	0.25	33
Weigher/charger	1	1.2	33
Blender/packer/machine operator	1	8	33
Laboratory technician	1	0.5	33

Exposure Details
The notified chemical will be formulated into industrial or consumer products in limited number sites in Australia.

Operations of weighing out the notified chemical from the import package and adding it to the blending vessel are under the control of local exhaust ventilation. Workers will wear personal protective equipment including a dust mask during these operations. The blending and coating application processes are enclosed with the only opportunity for dermal contact during product changeover and equipment maintenance. In these cases, the workers cleaning equipment and making pipe connections will wear PPE. Trained workers handling the notified chemical will have access to the MSDS and related personal protective equipment and training.

After application with the coating product containing the notified chemical, the paper will receive an impermeable topcoat. The final concentration of the notified chemical in paper products will be less than 1%. The notified chemical will be incorporated into the paper matrix under a topcoat and is hence unavailable for exposure.

During transport and storage, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured in Australia.

RELEASE OF CHEMICAL FROM USE
The notified chemical will be used in the formulation of a temperature sensitive paper coating. This will be done at a Melbourne plant and possibly one other plant in Australia. During this process the possible sources of release are:

- Spills.
  This may occur during transport, general handling and feeding of raw ingredients into the process and represents a loss of less than 1% (maximum of 100 kg of notified chemical annually). In the case of a spill it is likely that the material will be recycled back into the process if not contaminated. If contaminated then the material will be collected, stored in a labelled container and disposed of to landfill. The notifier has indicated that the site of the spill should be washed and any cleaning effluent absorbed and disposed of with the spilt material.
- Import drum residual.
  Up to 0.1% of the contents may remain in the empty drum (maximum of 10 kg of notified chemical annually).
- Equipment cleaning.
  Release due to this activity is expected to be minimal since all cleaning effluent is used as feed stock for the next batch of coating product.

5.5. Disposal

Any spilt material including clean-up material will be disposed of to landfill.

The drums may go to a licensed recycling operator, where any residual material will either be washed out and go to sewer or be incinerated in the cleaning process. If not, the drums with any residual material will go to landfill.

5.6. Public exposure

The notified chemical will not be sold to the public except in the form of finished paper products, namely, event tickets. There is potential for extensive dermal contact to paper products comprised <1% of the notified chemical.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa White odourless powder

Melting Point/Freezing Point 157.7°C

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	GLP & QA.
TEST FACILITY	RCC Ltd (1999b).

Boiling Point The notified chemical does not boil under atmospheric pressure and degradation occurs above 250°C

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	GLP & QA. The boiling point is calculated to be about 514°C using Meissner's method.
TEST FACILITY	RCC Ltd (1999c).

Density 1412 kg/m^3 at 20.9°C

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.

Remarks GLP & QA.
TEST FACILITY RCC Ltd (1999d).

Vapour Pressure 1.35 x10^{-15} kPa at 25°C

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks GLP & QA.
Vapour pressure is an estimate based on the calculated boiling point of 514°C using the Modified Watson Correlation (Lyman et al, 1990).

This estimation indicates that the notified chemical is very slightly volatile (Mensink, 1995).
TEST FACILITY RCC Ltd (1999e).

Water Solubility 34.7 mg/L at 20°C

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Analytical Method: HPLC

The water solubility was determined using the column elution method. Two experiments were undertaken, firstly with a flow rate of 0.52 mL/min and then at 0.26 mL/min, each with at least 5 successive samples. The column eluate was analysed every hour.

This result indicates the notified chemical to be moderately soluble (Mensink, 1995).
TEST FACILITY RCC Ltd (1999f).

Hydrolysis as a Function of pH

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

Analytical Method: HPLC

pH	*T (°C)*	*% hydrolysis after 5 days*	*$t_{½}$*
4	50	-	-
7	50	<10	> 1 year
9	50	<10	> 1 year

Remarks The study was conducted in the standard way with aqueous buffer solutions adjusted to pH 4.0, 7.0 and 9.0.

Solubility at pH 4 below the lowest calibration point of 1.191 µg/L, therefore no degradation curve could be determined.

These results indicate that the notified chemical is hydrolytically stable.
TEST FACILITY RCC Ltd (1999g).

Partition Coefficient (n-octanol/water) Log Pow at 20°C = 2.6

METHOD OECD TG 117 Partition Coefficient (n-octanol/water), HPLC Method.
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Analytical Method: HPLC + UV-VIS detector.

Reference Items: benzonitrile, nitrobenzene, anisole, 1,4-dichlorobenzene, benzophenone, bromobenzene and formamide.

The test solution (11.025 µg/L) was injected 3 times, while the reference solutions were injected 6 times. The log P_{ow} was determined by the relative retention time compared with the reference substances.

TEST FACILITY RCC Ltd (1999h).

Adsorption/Desorption estimated K_{oc} = 160–210 (log K_{oc} = 2.2-2.3)

METHOD QSAR estimation method of EC using the following equations:
Log K_{oc} = 0.81X Log K_{ow} + 0.1 for predominantly hydrophobic chemical class
Log K_{oc} = 0.49X Log K_{ow} + 1.05 for phenylureas chemical class

Remarks The notifier claims that the notified chemical is expected to be adsorbed by organic material in soil and sediments. However, McCall *et al* (1981) indicate that chemical's with K_{oc} between 150 and 500 have medium to high mobility.

TEST FACILITY Ciba (2000).

Dissociation Constant Not determined.

Remarks This was not attempted due to its solubility below pH 4. There are no dissociable groups.

Particle Size The particles are in the range between 0.5-20 µm, with 50% of them below 4.0 µm

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

Range (µm)	*Mass (%)*
<0.83	5
0.83-1.16	5
1.16-4.03	40
4.03-9.54	40
>9.54	10

Remarks GLP & QA.

TEST FACILITY RCC Ltd (1999i).

Flash Point Not applicable.

Flammability Limits Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).

Remarks GLP & QA.
In the preliminary test, the notified chemical melted immediately to give a clear brown-black substance. Therefore, no main test was conducted.

TEST FACILITY RCC Ltd (1999j).

Autoignition Temperature Not auto-flammable

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.

Remarks GLP & QA.
No exothermic reaction observed up to 400°C.

TEST FACILITY RCC Ltd (1999k).

Explosive Properties Non-explosive either by thermal or mechanical (shock and friction) stress.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.

TEST FACILITY Institute of Safety & Security (1999).

Reactivity Not expected to be an oxidising substance

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
Rat, acute inhalation	No study report was provided
Rabbit, skin irritation	non-irritating (not classified as an irritant)
Rabbit, eye irritation	slightly irritating (not classified as an irritant)
Guinea pig, skin sensitisation - adjuvant test	limited evidence of sensitisation (not classified as a sensitiser)
Rat, oral repeat dose toxicity - 28 days.	NOAEL=30 mg/kg/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	genotoxic
Genotoxicity – in vivo micronucleus test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE	The 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/WIST
Vehicle	PEG 300
Remarks - Method	GLP & QA.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity	One male died on day 3, and ruffled fur was observed in 1 male on day 3. No clinical signs were noted during the observation period in all other surviving animals.
Effects in Organs	None.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	RCC Ltd (1999l).

7.2. Acute toxicity - dermal

TEST SUBSTANCE	The notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/WIST
Vehicle	PEG 300
Type of dressing	Semi-occlusive.
Remarks - Method	GLP & QA.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	None.
Signs of Toxicity - Systemic	None.
Effects in Organs	None.

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

TEST FACILITY RCC Ltd (1999m).

7.3. Acute toxicity - inhalation

No study provided.

7.4. Irritation – skin

TEST SUBSTANCE The notified chemical

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

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Water
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	GLP & QA.

RESULTS Draize scores for erythema and oedema were zero for all animals during the study.

Remarks - Results The primary irritation index is 0.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY RCC Ltd (1999n).

7.5. Irritation - eye

TEST SUBSTANCE The notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	GLP & QA.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.3	0.3	0.7	1	48 h	0
Conjunctiva: chemosis	0	0	0.7	1	48 h	0
Conjunctiva: discharge	Not examined in the study					
Corneal opacity	Draize scores were zero for all animals during the study.					
Iridial inflammation						

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

Remarks - Results: Draize scores of redness and chemosis were 1 for all animals at 1 hour after administration.

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

TEST FACILITY: RCC Ltd (1999o).

7.6. Skin sensitisation

TEST SUBSTANCE: The notified chemical

METHOD: OECD TG 406 Skin Sensitisation – adjuvant test
EC Directive 96/54/EC B.6 Skin Sensitization

Species/Strain: Guinea pig/GOHI

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: <1%
topical: <1%

REMARKS: Draize scores were 1 at 15-50%, 0-1 at 1.0-10%, and 0 at 0.5%.

MAIN STUDY

Number of Animals: Test Group: 10 Control Group: 5

INDUCTION PHASE: Induction Concentration:
intradermal injection 5%
topical application 50%

Signs of Irritation: Draize scores at both 24 and 48 hours were 1 in all test animals after epidermal application.

CHALLENGE PHASE

1st challenge: topical application: 0.5% notified chemical
topical application: corn oil

Remarks - Method: GLP & QA.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	0.5% notified chemical	1/10	0/10		
	Corn oil	0/10	0/10		
Control Group	0.5% notified chemical	0/5	0/5		
	Corn oil	0/5	0/5		

Remarks - Results: Data of positive control group were provided.

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

TEST FACILITY: RCC Ltd (1999p).

7.7. 28-Day Repeat dose toxicity

TEST SUBSTANCE	The notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Wistar
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 14 days.
Vehicle	PEG 300
Remarks - Method	GLP & QA.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	30	0
III (mid dose)	5/sex	150	0
IV (high dose)	5/sex	750	4 females
V (control recovery)	5/sex	0	0
VI (high dose recovery)	5/sex	750	1 male and 4 females

Mortality and Time to Death

Four of the five high-dose females (group IV) died before scheduled necropsy (two on day 3, one on day 6 and one was killed in extremis on day 3). In the group VI, four of the five females died before scheduled necropsy (one on day 4 and three on day 29).

One high-dose male of group VI was found dead on the day 29.

Clinical Observations

High-dose animals had salivation, piloerection, hypothermia, hardened abdomen, hunched posture and sedation. The high-dose animals also had low bodyweight, and were less active in the locomotor activity test when compared with the controls.

One mid-dose female had salivation. No clinical signs were observed in low-dose animals.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology

At high-dose level, treatment-related changes were noted as lower red blood cell and lymphocyte counts, lower mean cell haemoglobin concentration, lower levels of plasma haemoglobin and hematocrit, higher mean cell volume, higher reticulocyte counts (with shift towards high fluorescence reticulocytes) with higher normoblast counts, increased methemoglobin concentration, higher white blood cell counts, higher segmented leukocyte counts and polychromatophilia.

At mid-dose level, treatment-related changes included lower red blood cell count, lower levels of plasma haemoglobin, and hematocrit; higher mean cell volume and shift towards high fluorescence reticulocytes.

No treatment-related changes were noted at low-dose level.

After the recovery period, the red blood cell counts of animals treated previously with 750 mg/kg/day remained lower than the controls, and the absolute and relative reticulocyte counts exceeded those of the controls. A shift toward low fluorescence reticulocytes was noted in the animals treated previously with 750 mg/kg/day when compared with the controls. These findings were considered to be late effects (incomplete recovery) of the notified chemical.

Clinical Chemistry

At high-dose level, treatment-related changes were noted as lower plasma glucose levels, higher creatinine levels (males only), higher uric acid levels, higher total bilirubin levels, lower cholesterol levels, lower phospholipids, higher creatine kinase levels, higher activities of aspartate and alanine aminotransferase, lactate dehydrogenase and alkaline phosphatase and gamma glutamyl transferase, higher globulin levels and lower albumin/globulin ratio (females only), higher phosphorus levels, lower sodium levels (males only) and lower chloride levels.

At mid-dose level, treatment-related changes were noted as lower phospholipids (males only) and increased activity of gamma glutamyl transferase.

No test article-related changes were noted at 30 mg/kg/day, and the clinical chemistry parameters of high-dose animals at the end of the recovery period compared favourably with those of the controls.

Urinalysis
Treatment-related differences to the control values were noted only in high-dose animals. These included higher urine production after 18 hours (females only) and lower pH. All other differences to the control values were considered to be unrelated to the treatment with the notified chemical, and the post recovery urinalysis results of treatment-treated animals were similar to those of the controls.

Effects in Organs
After 4 weeks treatment, higher liver weights were noted in males at all dose levels and in mid and high-dose females. Higher kidney weights were noted in mid and high-dose females, whereas adrenal weights were higher in both sexes at high-dose level. Thymus weights were lower in high-dose males and females. These changes were considered to be treatment-related. The lower thymus weights were also noted after the recovery period in high-dose males.

All other organ weights compared favourably with the control values.

Macroscopic Findings
Terminal Sacrifice and Decedents
At a dosage of 750 mg/kg/day:
Size reduction of the thymus was observed in all males and 2 females, and one male had thickening of the thyroid gland. Stomach foci were found in 5 females and 1 male, and size reduction of the spleen in 2 females.

No treatment-related changes were noted in animals given 150 or 30 mg/kg/day.

Recovery Sacrifice
Stomach foci were found in 1 male and 1 female, and size reduction of thymus in 3 males and 1 female.

Microscopic Findings
Terminal Sacrifice and Decedents
At a dosage of 750 mg/kg/day:
- Minimal or slight hypertrophy of the zona fasciculata in the adrenal glands in both sexes;
- Minimal or slight hypertrophy of centrilobular hepatocyte in the liver in both sexes; greater incidence and severity of periportal fat vacuolation in the liver in both sexes;
- Single cell death in the renal proximal convoluted tubules of females only;
- Greater incidence and severity of extramedullary haemopoiesis in the spleen of both sexes; minimal to marked lymphocyte depletion of the splenic marginal zones in both sexes;
- Focal erosion of the gastric glandular mucosa in both sexes;
- Minimal or slight bilateral degeneration of the germinal epithelium of the testes;
- Minimal to moderate lymphocyte depletion in the thymus in both sexes;
- Minimal or slight foci of alveolar macrophages in the lungs of females.

At a dosage of 150 mg/kg/day:
- Minimal hypertrophy of centrilobular hepatocyte in the liver of both sexes;
- Greater incidence and severity of extramedullary haemopoiesis in the spleen of females only.

No treatment-related changes were present in animals given 30 mg/kg/day.

Recovery Sacrifice

In males allowed 14 days without treatment at the end of the dosing period, there was full reversibility of the changes seen in the adrenal glands, liver, spleen and stomach and evidence of partial recovery from the lymphocyte depletion seen in the thymus. Degeneration of the germinal epithelium in the testes was still present in all the recovery males. However, this may have been a consequence of the short recovery period rather than a lack of reversibility of the finding.

Only one female survived to the recovery sacrifice, with no treatment-related changes present in this animal.

Remarks – Results

Oral administration of the notified chemical to Wistar rats at doses of 30, 150 and 750 mg/kg/day, for 28 days resulted in evidence of toxicity at 750 mg/kg/day and 150 mg/kg/day. No treatment-related changes were evident at the dose level of 30 mg/kg/day.

At 750 mg/kg/day, the premature deaths of one male and seven females (as well as euthanasia of a further female), clinical signs (salivation, piloerection, hypothermia, hardened abdomen, hunched posture and sedation), reduced locomotor activity, reduced body weight development, changes in haematology parameters suggestive of haemolytic anaemia, changes in clinical biochemistry parameters suggestive of differences in lipid metabolism, electrolytes and serum proteins, as well as liver enzyme activation. Additional treatment-related changes included higher urine production after 18 hours (females only) and lower pH (males only). Organ weight changes were noted as higher liver weights, higher kidney weights, higher adrenal weights and lower thymus weights. Treatment-related gross macroscopic changes included stomach foci (males and females), thickening of the thyroid gland (males) and size reduction of the spleen (females) and thymus (males and females), whereas microscopic differences to the control animals were noted in the adrenal glands, liver, spleen, thymus and glandular stomach of both sexes, in the kidneys and possibly the lungs of females and in the testes.

At 150 mg/kg/day, clinical signs (salivation), changes in haematology suggestive of haemolytic anaemia, changes in clinical biochemistry indicating differences in lipid metabolism and liver enzyme activation, higher liver weights and higher kidney weights, microscopic changes in the liver of both sexes and in the spleen of females.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 30 mg/kg bw/day in this study, based evidence of haemolytic anaemia and organ effects at 150 mg/kg/d.

TEST FACILITY RCC Ltd (1999q).

7.8. Genotoxicity - bacteria

TEST SUBSTANCE The notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure/Pre incubation procedure

Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, and TA100.
E. coli: WP2 uvrA.

Metabolic Activation System Mammalian microsomal fraction S9 mix

Concentration Range in Main Test
a) With metabolic activation: 0-5000 µg/plate.
b) Without metabolic activation: 0-5000 µg/plate.

Vehicle

Remarks - Method GLP & QA.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				

Test 1 (incorporation)	Not observed	Not observed	Not observed
Test 2 (pre-incubation)	Not observed	Not observed	Not observed
Present			
Test 1 (incorporation)	Not observed	Not observed	Not observed
Test 2 (pre-incubation)	Not observed	Not observed	Not observed

Remarks - Results: In Test 1, a slight toxic effect was observed in strain TA1537 at 5000 µg/plate with and without S9 mix.

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

TEST FACILITY: RCC Ltd (1999r).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE: The notified chemical

METHOD: OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
- Cell Type/Cell Line: Chinese hamster V79 cells
- Metabolic Activation System: Mammalian microsomal fraction S9 mix
- Vehicle: DMSO
- Remarks - Method: GLP & QA.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	18.8, 37.5*, 75*, 150*, 225 and 300	4	18
Present			
Test 1	18.8*, 37.5*, 75*, 150, 200 and 250	4	18

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	>39.1		≥312.5	
Test 1		≥150		Observed at 150
Present	>156.3		≥312.5	
Test 1		≥75		Observed at 75

Remarks - Results: The notified chemical induced structural chromosome aberrations in the study. However, the increases of aberrant cells were observed only in the presence of cytotoxicity. Therefore, a non-genotoxic DNA damaging mechanism cannot be excluded.

CONCLUSION: The notified chemical was clastogenic to Chinese hamster V79 cells treated in vitro under the conditions of the test.

TEST FACILITY: RCC Ltd (1999s).

7.10. Genotoxicity – in vivo

TEST SUBSTANCE	The notified chemical
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test. EC Directive 2000/32/EC B.12 Mutagenicity Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mouse/NMRI
Route of Administration	Oral – gavage
Vehicle	Corn oil
Remarks - Method	GLP & QA.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
1	5/sex	0	24
2	5/sex	200	24
3	5/sex	670	24
4	5/sex	2000	24
5	5/sex	2000	48
6 (control)	5/sex	40 (CP)	24

CP=cyclophosphamide.

RESULTS	
Doses Producing Toxicity	Toxic effects were observed including reduction of spontaneous activity, closure of eyelid and apathy at 2000 mg/kg..
Genotoxic Effects	The number of normochromatic erythrocytes (NCEs) was not substantially increased compared to the mean NCE number in controls. Also, there was no statistically significant or biologically relevant enhancement in the frequency of the detected micronuclei at any preparation interval and dose level after administration of the notified chemical.
Remarks - Results	
CONCLUSION	The notified chemical was not clastogenic in this in vivo mammalian erythrocyte micronucleus test under the conditions of the test.
TEST FACILITY	RCC Ltd (1999t).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	The notified chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Aerobic activated sludge from wastewater treatment plant that treats mainly domestic effluent.
Exposure Period	28 days
Auxiliary Solvent	No emulsifiers or solvents used.
Analytical Monitoring	Electrochemical analysis – converts pressure change into oxygen consumption.
Remarks - Method	Reference Substance: sodium benzoate. Ultrasound dispersion for 15 minutes used to obtain homogeneous suspension. Treatments: • Test flasks (two flasks) 100 mg/L of test substance (not completely

soluble) + 30 mg dry/L activated sludge
- Inoculum control (two flasks): 30 mg dry/L activated sludge
- Procedure control (two flasks): 104 mg/L reference substance only + 30 mg dry/L activated sludge
- Abiotic control (one flask): 100 mg/L and 10 mg/L mercury dichloride
- Toxicity control: 100 mg/L test substance, 100 mg/L reference substance + 30 mg dry/L activated sludge

The flasks were maintained in darkness at 22°C.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% degradation*	*Day*	*% degradation*
1	1	1	9.5
7	2.5	7	69.5
14	1	14	72.5
21	1	21	73.5
28	1.5	28	74.5

Remarks - Results

Since the reference substance reached greater than 60% day 14, the study was valid.

Degradation in the toxicity control was 42 and 38% by day 14, thus satisfying the validity criteria of > 25% within 14 days.

No degradation of the test substance occurred in the abiotic control during the study.

CONCLUSION

The test substance is not readily biodegradable.

TEST FACILITY

RCC (1999u)

8.1.2. Inherent biodegradability

Remarks

The notifier has indicated that the notified chemical is inherently biodegradable with 73% total elimination after 28 days.

This cannot be confirmed since a study report was not provided.

8.1.3. Bioaccumulation

Remarks

No studies were attempted. However, the notifier has provided a BCF of 30 that had been calculated in the EU report. This indicates that the chemical is slightly bioaccumulative (Mensink, 1995).

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE

The notified chemical

METHOD

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

Species

Zebra fish (*Brachydanio rerio*)

Exposure Period

96 hours

Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC + U/VIS detector
Remarks – Method	A preliminary test indicated that only one test concentration need to be investigated – nominal concentration of 100 mg/L. The test solution was prepared by mixing 450 mg in 4.5 L of test water by ultrasonic treatment for 15 minutes. The solution was stirred with a magnetic stirrer for 96 hours at room temperature in the dark to achieve maximum possible dispersion. The solution was then filtered and the filtrate used as the test solution, which may have contained some very finely dispersed particles. A control with 7 fish was run throughout the study. Both tanks were slightly aerated during the study and the fish were not fed. Oxygen concentration and pH were measured daily in a single test concentration and the control. Temperature was maintained at 22ºC and a 16 hour light and 8 hour dark photoperiod was maintained.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
100	63	7	0	0	0	0	0

LC50	> 63 mg/L at 96 hours.
NOEC (or LOEC)	63 mg/L at 96 hours.
Remarks – Results	pH range during study: test substance 7.6-7.9, control 7.9. Oxygen concentration during study: test substance 8.0-8.4 mg/L, control 8.2-8.6 mg/L. Temperature during study: test substance 22 ºC, control 22ºC.

CONCLUSION — This indicates that the test substance is not toxic to fish at its limit of water solubility.

TEST FACILITY — RCC (1999v)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE — The notified chemical

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

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC + U/VIS detector
Remarks - Method	The test solution was prepared by mixing 450 mg in 4.5 L of test water by ultrasonic treatment for 15 minutes. The solution was stirred with a magnetic stirrer for 96 hours at room temperature in the dark to achieve maximum possible dispersion. The solution was then filtered and the filtrate and the dilutions 1:2.2, 1:4.6, 1:10, 1:22 and 1:46 were tested. Again these solutions may have contained some very finely dispersed particles. Oxygen concentration and pH were measured and the start and at the end

of the study. Temperature was maintained at 20ºC and a 16 hour light and 8 hour dark photoperiod was maintained.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
100 (Filtrate)	89	20	20	20
46 (1:2.2)	36	20	0	0
(1:4.6)	-	20	0	0
(1:10)	-	20	0	0
(1:22)	-	20	0	0
(1:46)	-	20	0	0
control		20	1	1

EC50	89 mg/L at 24 hours 57 mg/L at 48 hours (calculated)
NOEC (or LOEC)	36 mg/L at 48 hours
Remarks - Results	The pH before and after the study were the same for the test substance concentration and the control - before 7.8 after 7.9. The oxygen concentration during study for the test substance concentrations and the control were 8.6 and 8.1 mg/L, before and after respectively.

CONCLUSION — This result indicates that the test substance is slightly toxic to daphnia.

TEST FACILITY — RCC (1999w)

8.2.2. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE — The notified chemical

METHOD — OECD TG 212 Daphnia magna and Reproduction Test – semistatic.

Species	*Daphnia magna*
Exposure Period	21 days
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC + UV/VIS detector
Remarks - Method	The test solution was prepared by mixing 56, 49 and 35 mg of test substance in 1600, 1400 and 100 mL, respectively, by ultrasonic treatment for 15 minutes. The solution was stirred with a magnetic stirrer for 2 hours at room temperature in the dark to achieve maximum possible dispersion. The solution was then filtered and the filtrate and the dilutions 1:3.2, 1:10, 1:32 and 1:100 were tested along with a control. Test medium was renewed on days 2, 5, 7, 9, 12, 14, 16 and 19. The test animals were transferred out of the test vessels during the renewal. The daphnia were fed on the five consecutive week days and over the weekend. The mortality and the number of young were recorded 3 times a week prior to medium renewal. Oxygen concentration and pH were measured and the start and at the end of the study. Temperature was maintained at 20-21ºC and a 16 hour light and 8 hour dark photoperiod was maintained.

RESULTS

Concentration mg/L		*Initial Number of D. magna*	*Number surviving*		*Number of offspring*	
Nominal	*Actual*		12 d	21 d	12 d	21 d
35 (filtrate)	34.5	10	0	0	0	0
(1:3.2)	10.2	10	9	9	317	756
(1:10)	-	10	10	10	311	798
(1:32)	-	10	10	10	326	812
(1:100)	-	10	10	9	321	839
Control		10	10	10	318	859

EC50	21 mg/L at 21days
NOEC	10.2 mg/L at 21 days
LOEC	34.5 mg/L at 21 days
Remarks - Results	The pH ranged 7.8 to 8.0, the oxygen concentration ranged from 7.9 to 9.0 mg/L and the water temperature ranged from 20 to 21°C. The test solutions remained clear throughout the study.
CONCLUSION	With a NOEC > 1 mg/L, the test substance would be very slightly toxic to Daphnia (Mensink, 1995).
TEST FACILITY	RCC (1999x)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	The notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range Nominal	0.22, 0.46, 1.0, 2.2, 4.6 and 10 mg/L
Concentration Range Actual	0.18, 0.39, 0.84, 1.79, 3.80 and 8.44 mg/L
Auxiliary Solvent	None
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	HPLC + UV/VIS detector
Remarks - Method	There were 3 replicates per test concentration and 6 control replicates. The concentration of algal cells was 10 000 per mL of test medium. The experimental flasks were covered with glass dishes and incubated in a water bath at 23°C, under continuous illumination (8600 Lux). The solutions were continually stirred by magnetic stirrers. pH was measured at the beginning and end of the study.

RESULTS

Biomass		*Growth*	
EC_{50}	NOEC	*EC_{50}*	NOEC
mg/L at 72 h		*mg/L at 72 h*	
0.77 (95% C.L. 0.3-1.5)	0.22	3.0 (95% C.L. 1.5-9.1)	0.29

Remarks - Results	The pH ranged from 7.9-8.1 at the beginning of the study and at the end the range was the same.
CONCLUSION	With an EC_{50} of 0.77 mg/L, the test substance is highly toxic to algae.

TEST FACILITY	RCC (1999y)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	The notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Aerobic activated sludge from wastewater treatment plant which mainly treats domestic effluent.
Exposure Period	3 hours
Concentration Range Nominal	10, 32, 100, 320 and 1000 mg/L
Remarks – Method	The reference substance used was 3,5-dichlorophenol at 5, 16 and 50 mg/L and there were two inoculum controls. All treatments had 200 mL of activated sludge and were continuously aerated at 1 L/minute. The pH and oxygen were measured in all treatments at the start and end of the study.
RESULTS	
EC50	356 mg/L
NOEC	74 mg/L
Remarks – Results	The EC_{50} of the reference substance was 9 mg/L (95% C.L. 5-12 mg/L). This is within the guideline criteria of 5-30 mg/L and indicates the study was valid. The pH at the beginning of the study ranged from 7.5-7.7 and at the end ranged from 8.3-8.5. The oxygen consumption rates of the two controls differed by 13.6%, which is below the guideline maximum of 15%.
CONCLUSION	This result indicates that the test substance is not toxic to microbial activity.
TEST FACILITY	RCC (1999z)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The main potential for environmental exposure would arise from release of the notified chemical during storage or transport. The use of bunded containment minimises the risk of release at storage sites. Up to 100 kg of notified chemical may be released to landfill annually via spills, with the possibility a small portion of this may enter the sewer via the clean-up process. A small amount of the notified chemical (up to 10 kg) may be disposed of to landfill in the empty import containers. The chemical's water solubility, it's partition coefficient and adsorption/desorption value indicate that the chemical will be moderately to highly mobile in soil and sediments. While it is not readily biodegradable, it is expected that over time it degrades via biotic and abiotic mechanisms. If it does leach from landfill it will be at very low concentrations and in a diffuse manner.

Very little of the notified chemical will be released to water under normal operation conditions, since the coating plants are 'no release' plants (ie feeding effluent back into the process/plant). In order to calculate a risk quotient, it is presumed, on a worst case basis, that 1% of the notified chemical will be reach the aquatic compartment due to the coating process. Since the coating

plants will be located in Melbourne the following PEC can be calculated:

Amount released	100 kg
Least number of day it will be used	33 days
Melbourne population	3 million
Amount of effluent entering sewer per person	150 L
PEC in sewer	$\frac{100x1000x1000}{33x3000000x150}$ = 0.007 mg/L (7 μg/L)
Dilution factor	1:10
PEC in ocean	0.7 μg/L

The notified substance will ultimately suffer the same fate as the finished article at the end of its useful life, ie be mostly disposed of to landfill or incinerated or some may be included in paper recycling. Incineration of waste paper will destroy the compound with the generation of water vapour and oxides of sulphur, nitrogen and carbon. The amount that will enter the recycling process is likely to be very small considering the types of paper articles (heat sensitive) that will use the coating containing the notified chemical.

Based on the import volume and low concentration of the notified chemical on the paper, release of the notified chemical to the environment is expected to be low and widespread.

Taking into account the notified chemical's molecular weight and environmental availability, it is unlikely to bioaccumulate.

9.1.2. Environment – effects assessment

The notified chemical is non-toxic to fish and sewage micoorganisms, slightly acutely toxic to Daphnia and very slightly chronically toxic, and highly toxic to algae. The PNEC, using the EC_{50} for the most sensitive species (Algae EC_{50} = 0.77 mg/L) and assessment factor of 100, is 7.7 μg/L.

9.1.3. Environment – risk characterisation

The majority of the notified chemical will share the fate of the articles into which it is incorporated. It is anticipated that these will be disposed of to landfill or incinerated at the end of their useful lifetime. In landfill it is expected that the notified chemical will remain immobile within the coating. Incineration of the notified chemical will result in the formation of water vapour and oxides of carbon and sulfur.

Using the above-calculated worst case PEC_{ocean}, the risk quotient (PEC/PNEC) is estimated to be 0.1 (=0.7/7.7). This indicates that the risk associated with the use of this chemical is minimal.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical is a very fine powder when imported. Inhalation, dermal and ocular exposure may occur during weighing and charging processes during formulation of the coating material. However, exposure to significant amounts of the notified chemical is limited because of the engineering controls, namely, local exhaust ventilation.

The notified chemical will be in liquid form after blending. As the blending and coating processes are closed systems, low occupational exposure is expected. However, some dermal exposure to coated paper during the packaging process may occur.

Dermal and inhalation exposure of maintenance workers to the notified chemical is possible during routine maintenance but is expected to be low due to the low concentration of the notified chemical in the formulation. However, due to the probable fine nature of the powder with 50% of particles <4 μm, and 91% <10 μm, respiratory exposure may occur. The national exposure standard for nuisance dusts is 10 mg/m^3 TWA (NOHSC, 1995). Australia has no exposure standard for respirable dust, however, the ACGIH TLV of 3 mg/m^3 TWA is

recommended (ACGIH, 2001).

After coating application, the notified chemical on the paper products is covered by an impermeable topcoat. Hence it is unavailable for exposure.

During transport and storage, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached.

Occupational exposure during weighing and charging is also estimated by the EASE (Estimation and Assessment of Substance Exposure) program developed by the Health and Safety Executive, UK (1997).

In the calculation of occupational exposure, the respiratory volume is based on a respiratory rate of 1.3 m^3/hour and a default value of 75% inspired amount was absorbed. The notifier indicated that the work duration for weigher/charger is 1.2 hours per day. The surface area of occupational exposure is selected to be 1000 cm^2 (NICNAS, 1996) and the contact is controlled at intermittent level.

	EASE Prediction
Physical state	Solid powder
Temperature	25°C
The operation	Dry manipulation
Inhalation exposure	
The particle size	Respirable
The dust type	Non-fibrous
The pattern of control	Local exhaust ventilation
The predicted exposure	2-5 mg/m^3 or 2.34-5.85 mg/day
Dermal exposure	
The use-pattern	- Closed system
The contact-level	- Direct handling Intermittent
The predicted dermal exposure	0.1-1 mg/cm^2/day or 100-1000 mg/day

9.2.2. Public health – exposure assessment

The notified chemical will not be sold to the public except in the form of finished articles, namely, event tickets. There is potential for extensive public exposure to paper products comprised partly of the notified chemical. However, exposure will be negligible because the notified chemical is sealed under an impermeable topcoat and present at low concentrations.

9.2.3. Human health - effects assessment

The notified chemical was of low acute oral and dermal toxicity in rats. It was not a skin irritant but a slight eye irritant in rabbits. Although some positive results in guinea pigs from the skin sensitisation study were observed (10% positive after challenged with 0.5% notified chemical), the notified chemical would not be classified as a skin sensitiser in accordance with the NOHSC Approved Criteria (NOHSC, 1999).

The NOAEL from a 28-day repeat dose study was established as 30 mg/kg/day based on the evidence of haemolytic anaemia and toxic effects mainly in the livers at the higher doses.

The notifier provided three genotoxicity study reports. The notified chemical was not mutagenic to bacteria in an Ames test, but was clastogenic to Chinese hamster V79 cells in vitro. However,

since the notified chemical was not found to be clastogenic in an in vivo micronucleus test in mouse, on weight of evidence, the chemical was not considered to be clastogenic from the genotoxicity studies.

9.2.4. Occupational health and safety – risk characterisation

Based on the assessment of health effects, the NOAEL of 30 mg/kg/day is used in the risk characterisation. The absorption rate from dermal exposure is assumed to be 10% and a bodyweight of 70 kg is used for estimation.

From the exposure estimates, the following margins of exposure (MOEs) are calculated for the various scenarios (MOE = NOAEL/internal dose).

	Industrial control	
Inhalation exposure	- Local exhaust ventilation	2.35-5.85 mg/day
Dermal exposure	-Closed system	100-1000 mg/day
Total exposure (inhalation + 10% dermal)		12.34-105.85 mg/day
Margin of Exposure (MOE) (NOAEL*70 kg/Total exposure)		19.8-170

The EASE program did not include the scenario of occupational exposure with personal protective equipment (PPE). If workers wear overalls, gloves, safety boots and eye protection, the MOE is expected to be well over 100 with the industrial controls. Taking into account that exposure estimates were worst-case, the risk of adverse health effects in workers exposed to the notified chemical is considered to be low particularly when industrial control is in place and PPE is worn.

9.2.5. Public health – risk characterisation

The notified chemical will not be available to the public. Members of the public may make dermal contact with paper products containing the notified chemical. However, the risk to public health will be negligible because the notified chemical is sealed under an impermeable topcoat and present at low concentrations, and unlikely to be bioavailable.

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

10.1. Hazard classification

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

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Acute hazards to the aquatic environment	1	Very toxic to aquatic life.

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern, limited release to the aquatic environment and the estimated risk quotient.

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 based on its reported use pattern.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

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

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to powder form of the notified chemical:
  - closed system for formulation
  - local exhaust ventilation during weighing and transfer the notified chemical powder.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - gloves
  - protective clothing
  - eye protection
  - dust mask or respirator when sufficient ventilation is not available.

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

- Atmospheric monitoring should be conducted to measure workplace dust concentrations during formulation of the notified chemical.

- 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

- The following control measures should be implemented by the coating manufacturer and paper coating plant to minimise environmental exposure during use of the notified chemical:

- Use and storage of the chemical in sealed and bunded areas.
- Loading of raw materials should be undertaken in an enclosure which is under the control of local exhaust ventilation.

Disposal

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

Emergency procedures

- Spills/release of the notified chemical should be handled by containment, collection via vacuum or sweeping, then placing material in sealable labelled containers. The spill area should be cleaned with a minimal amount of water, which is collected via an absorbent material which will then be disposed of with the spilt notified chemical. All drains and access points to nearby water causes should be blocked immediately.

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:

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

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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