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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Tinuvin 152

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals Pty Ltd (ABN 97 005 061 469)
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 Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Spectral Data, Purity, Hazardous and Non-hazardous Impurities, Additives/Adjuvants, Import Volume, and Identity of Manufacturer/Recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Part B: Vapour Pressure, Hydrolysis as Function of pH, Adsorption/Desorption, Dissociation Constant, and Flammability Limits.
Part C: Acute Inhalation Toxicity, In Vivo Genotoxicity, and Bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
US TSCA (June 1998), Italy (No. 98-00-0152-01), Japan ISHL (September 2002), and China.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Tinuvin 152

3. COMPOSITION

DEGREE OF PURITY
High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None are present at above the relevant cut off level for classification of the notified polymer as a hazardous substance

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Import, as an essentially pure solid.

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

Year	*1*	*2*	*3*	*4*	*5*

Tonnes	20	20	20	20	20

USE
A reactive hindered light stabiliser (HALS) used at levels of 0.5-2% to improve coating durability, mainly in the automotive OEM (Original Equipment Manufacturer) or metal finishing industry.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Ciba Specialty Chemicals Pty Ltd

TRANSPORTATION AND PACKAGING
Tinuvin 152 will be shipped into Australia in 20 kg polythene-lined fibreboard boxes, transported by road to the Ciba warehouse at Thomastown VIC for use in manufacturing surface coatings, or storage, and possibly repacking prior distribution to a number of customer coating production plants. Storage will be in a covered bunded area and in accordance with state legislation.

5.2. Operation description

At a customer formulation plant, a storeperson will deliver sealed packages of Tinuvin 152 by forklift to various work areas as required, for example, warehouse, batch making or repacking areas Formulation operators will weigh Tinuvin 152 and manually add all weighed stabilisers, pigments, and additives into a blending vessel (typically 5000 L capacity) with controlled systems for milling and screening. The laboratory technician will perform testing and adjustment to the formulation if necessary. The final UV protective coating containing 0.5-2% (typically 0.8%) notified chemical will be packed directly from the blender into 200 L drums for sending to industrial specialist automotive OEM or refinish coating applicators.

At the coating application plants, laboratory technician will match the colour and equipment operators will apply the final product onto plastic or metal substrates by either electrostatic or spraying process in purpose-designed spray booths. Fugitive spray will be trapped in the water curtain or knock-out labyrinth of the application room while residues in the air purification system will be filtered from the circulating water and sent for incineration or landfill disposal. The coating containing the notified chemical is not intended for use in air or mechanical atomisation. Car surface coatings will then be baked or UV cured to complete the cross-linking polymer matrix.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Coating formulation plant (4 sites)			
Storeperson	1	--	--
Weighing and charging worker	1	0.25 hour	60-120 days/year
Blending and transferring worker	1	1-2 hours	60-120 days/year
Milling and screening worker	1	2-4 hours	60-120 days/year
Packing worker	1	2-4 hours	60-120 days/year
Laboratory technician: sampling and in process/QC release	1	0.25 hour	60-120 days/year
Maintenance worker	1	4-8 hours	1-3 days/year
Coating application plant (10 sites)			
Storeperson	1	--	--
Colour matching, tinting and equipment charging worker	1	1-2 hours	60-120 days/year

Equipment controlling and monitoring worker	1	4-6 hours	60-120 days/year
Equipment cleaning/waste disposal worker	1	1-2 hours	60-120 days/year
Laboratory technician: sampling and in process/QC release	1	0.25 hour	60-120 days/year
Maintenance worker	1	4-8 hours	1-3 days/year

Exposure Details
During transport and storage, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached. Should a spill occur, it is expected to be contained and collected using dust binding materials, and placed into suitable containers for recovery or disposal in accord with the MSDS and official regulations.

Laboratory technicians may be potentially exposed to the notified chemical when sampling and testing formulation or coating samples containing it. However, they will handle only small quantities and will wear appropriate personal protective equipment. The testing of sprayed paint formulations will be carried out in a well-ventilated spray booth with a fume extraction system.

Inhalation, dermal and ocular exposure due to splashes and spillages can occur during weighing, mixing, packaging, spray paint application, and equipment cleaning processes. A particle size distribution study for Tinuvin 152 indicates that although the majority of dust particles are in the range of 45-500 μm, the average particle size by microscopy for up to 18.8% of the particles is in the respirable range (2.3 to 6.2 μm), and therefore inhalation exposure to the pure notified chemical is possible during weighing and addition to the blending vessel. High dust concentrations within the formulation plant may also have a potential for combustion or explosion. Paint spraying at the coating application plant could result in problematic concentrations of the notified chemical. The notifier indicates that adequate ventilation will be in place to prevent workers from breathing mist, dust and particulates. Local exhaust ventilation will be employed at all work areas when required. Operators of the formulation and application plants will wear safety glasses with side-shields/chemical goggles, protective clothing, gloves, and appropriate respirators when required. Copies of the MSDS will be readily accessible in all work areas.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will be used in a small number of (up to 4) coating manufacturing plants. Washings from cleaning of formulation equipment will be kept for the next batch. Hence, it is anticipated that the industrial generation of wastes will be limited to traces remaining from clean-up of spills and trace residues in empty containers. Residual amount in the import containers is expected to be small (<20 g of the notified chemical per fibreboard box). Hence, the total waste chemical in empty containers is expected to be below 10 kg and will be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
The coatings will be applied using advanced electrostatic spraying techniques with less than 5% waste. It is estimated that up to 1000 kg of the notified chemical will be disposed of as coatings overspray annually which generally will be collected via aqueous scrubber/filters and the resultant solids will be drummed for disposal as hazardous waste, either through incineration or landfill. After application the coating will be either baked in an oven to ensure full cross-linking of the coatings polymer matrix or cured under UV radiation. Once the chemical is within a cured coating it is likely to share the fate of the substrate, which may involve recycling or landfill at the end of its useful lifetime.

5.5. Disposal

Wastes containing the notified chemical will either disposed of to landfill or incinerated.

5.6. Public exposure

The notified chemical is intended for use in industry only. There is likely to be significant dermal exposure to the finished surfaces. However, once cured the chemical is bound within the paint film and not bioavailable.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa White powder with no odour

Melting Range 83-90ºC

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Differential scanning calorimetry was used. The melting range describes a glass transition for the amorphous glass since the notified chemical is non-crystalline and does not have a true first-order melting point.
TEST FACILITY Ciba (1998b)

Boiling Point >140ºC at 101.3 kPa

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Differential scanning calorimetry was used. The notified chemical was determined to degrade before boiling as evidenced by an exothermic peak starting >140ºC.
TEST FACILITY Ciba (1998c)

Density 1.08 kg/m^3 at 24ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks A gas comparison pycnometer was used.
TEST FACILITY Ciba (1998d)

Vapour Pressure Not determined

Remarks Test was not conducted due to presence of volatile impurities. Vapour pressure is expected to be low due to the high MW of the notified chemical.

Water Solubility <10^{-4} g/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Due to the nature of the notified chemical (containing several minor components possibly up to 50% of the test sample), the shake flask method was used instead of the column elution method as recommended by the TG 105 for substances having a water solubility of <10^{-2} g/L. The samples of the notified chemical were filtered rather than centrifuged prior to HPLC analysis with its limit of quantitation claimed to be 10^{-4} g/L.
TEST FACILITY Ciba (1998e)

Hydrolysis as a Function of pH Not determined

Remarks Test was not conducted due to the low water solubility of the notified chemical.

Partition Coefficient (n-octanol/water) log Pow = 16.01 (calculated)

METHOD EC Directive 92/62/EEC A.8 Partition Coefficient - Fragmentation Calculation.
Remarks An estimate of the partition coefficient was determined using quantitative structure activity relationships (QSARs). The programme used was Clog P version 1.0.0 developed by BioByte Corp. The resulting value, 16.29, was corrected to take into account fragments not recognised by the computer program. The final value presented is 16.01.
TEST FACILITY Novartis (1998)

Adsorption/Desorption Not determined

Remarks Test was not conducted due to the low water solubility of the notified chemical. Given the high partition coefficient calculated it is anticipated that the notified chemical would adsorb strongly to soils and sediments.

Dissociation Constant Not determined

Remarks Test was not conducted due to presence of impurities together with the low water solubility of the notified chemical which could not be measured analytically. The notified chemical contains aromatic, secondary and tertiary amine nitrogen atoms which would display typical basicity, though noting that several are sterically hindered.

Particle Size

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

Range (μm)	*Mass (%)*
>500	0.4
45 - ≤500	80.8
≤45	4.4

Remarks During sieving, a significant amount of the notified chemical was lost as dust (14.4%), and approximately 4.4% of the particles were ≤45μm. The fraction lost as dust is expected to be predominantly smaller particles. By microscopic analysis, the average particle size ranged from 2.3 to 6.2 μm and 82% of the particles were circular in shape.

TEST FACILITY Springborn Laboratories (1998a)

Flash Point Not applicable

Remarks The notified chemical is a solid at room temperature.

Flammability Limits Not determined

Remarks Not expected to be flammable.

Autoignition Temperature No self ignition to 90ºC

Remarks Test report not provided. The notified chemical had melted and decomposed into black tar during the test, therefore, it was considered not having an autoignition point below its melting point.

Explosive Properties Not a potential explosive

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

Remarks Mechanical friction and thermal sensitivity were negative, but the notified chemical was shown to have a strong mechanical sensitivity with respect to shock. However, it was considered not to be a potential explosive. It may be a dust explosion hazard.

TEST FACILITY Springborn Laboratories (1998b)

Reactivity Stable under normal environmental conditions

Remarks The notified chemical is not an oxidant. However, it may be incompatible with reactive chemicals and extremes of temperature. Thermal decomposition or burning may release noxious fumes such as oxides of carbon and nitrogen.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >5000 mg/kg bw	low toxicity
Rabbit, acute dermal LD50 >2000 mg/kg bw	low toxicity
Rat, acute inhalation	no data available
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation – adjuvant test	limited evidence of sensitisation (50% notified chemical)
Rat, repeated dose oral toxicity – 28 days	NOAEL = 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	non genotoxic
Genotoxicity – in vivo studies	no data available
Pharmacokinetic/Toxicokinetic studies	no data available
Developmental and reproductive effects	no data available
Carcinogenicity	no data available

7.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 401 Acute Oral Toxicity.
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).
EPA Acute Oral Toxicity 40 CFR 798.1175.

Species/Strain: Rat/Wistar Albino
Vehicle: Corn oil
Remarks – Method: No significant protocol deviations.

RESULTS

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

LD50: >5000 mg/kg bw
Signs of Toxicity: Red staining of the nose/mouth area was noted in the animal which died on day 1. Physical signs noted in the survivors included chromorhinorrhoea and diarrhoea (day 1), emaciation (day 8-9), and red staining of the nose/mouth. Body weight changes of male survivors were normal. Weight loss, associated with an obstructed water sipper, was noted in females but all returned to normal by day 14.
Effects in Organs: Necropsy results of the survivors were normal.
Remarks - Results: Necropsy results of the animal which died on day 1 revealed that the death was due to a dosing error which resulted in the test article deposited into the lungs.

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

TEST FACILITY: MB Research (1998a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 402 Acute Dermal Toxicity.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
EPA Acute Dermal Toxicity 40 CFR 798.1100.

Species/Strain: Rabbit/New Zealand White
Vehicle: Saline (moistened)

Type of dressing	Occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	0/10

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	No dermal reactions were noted to 72 h except some flaking skin observed at the treatment site of a female. Some animals were reclipped.
Signs of Toxicity - Systemic	Instances of diarrhoea, few faces, or soiling and wetness of the anogenital area were noted in two females during the 14-day observation period. Weight loss was also noted in these females, and in one male during the observation period. Other animals appeared normal.
Effects in Organs	Necropsy results were normal in 9/10 animals. Excess fluid in the peritoneal cavity was noted in one female.
Remarks - Results	None.

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

TEST FACILITY MB Research (1998b)

7.3. Acute toxicity – inhalation

Remarks Test was not conducted.

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).
EPA Primary Dermal Irritation 40 CFR 798.4470.

Species/Strain	Rabbit/New Zealand White
Number of Animals	5 males, 1 female
Vehicle	Distilled water (moistened)
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	Number of males/females were incorrectly selected, however it was unlikely to affect the study results or integrity.

RESULTS

Remarks - Results	Erythema and oedema were absent at all observation intervals. Primary irritation index = 0 (non irritating). There were no abnormal systemic signs noted during the observation period.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY MB Research (1998c)

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).
EPA Primary Eye Irritation 40 CFR 798.4500.

Species/Strain Rabbit/New Zealand White
Number of Animals 6 females
Observation Period 72 hours
Remarks - Method No significant protocol deviations.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.4	2	48 h	0
Conjunctiva: chemosis	0.2	1	48 h	0
Conjunctiva: discharge	0.3	2	48 h	0
Corneal opacity	0.1	2	24 h	0
Iridial inflammation	0.06	1	24 h	0

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

Remarks - Results Corneal opacity and iritis were noted in 1/6 eyes, cleared by 48 hours. Conjunctival irritation was noted in 6/6 eyes, cleared by 72 hours. There were no abnormal systemic signs noted during the observation period.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY MB Research (1998d)

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD EC Directive 96/54/EC B.6 Skin Sensitisation – Maximisation Test.
EPA Skin Sensitisation 40 CFR 792.105.

Species/Strain Guinea pig/Hartley-derived Albino
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: <0.1% test article in propylene glycol
topical: 100% test article in propylene glycol
MAIN STUDY
Number of Animals Test Group: 20 Control Group: 10
INDUCTION PHASE Induction Concentration:
intradermal (day 1): 3% test article in propylene glycol or in FCA
topical (day 7): 50% test article in propylene glycol
(FCA = Freund's Complete Adjuvant)
Signs of Irritation Not reported
CHALLENGE PHASE
1st challenge topical: 50% test article in propylene glycol
Remarks - Method The temperature and relative humidity of the animal room exceeded the preferred ranges, however they were considered not to be adverse on the outcome of the study.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	50%	4/20	2/20
Control Group	50%	0/10	0/10

Remarks - Results Dermal reactions (score 1) were noted in 4/20 and 2/20 test animals at

24 h and 48 h respectively. Also at 24 h, slight patchy erythema (scored as ±) were noted in 13/20 test animals and 9/10 control animals, and at 48 h, staining of test sites with or without desquamation was additionally observed in both test and control animals. A separate positive control study with alpha-hexylcinnamaldehyde confirmed the sensitivity of the test system.

CONCLUSION There was limited evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test (50% notified chemical).

TEST FACILITY Springborn Laboratories (1998c)

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).
Japan MHW Repeated Dose (28 Days) Toxicity in Mammalian Species.

Species/Strain	Rat/Sprague-Dawley Crl:CD BR VAF/Plus
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	Corn oil
Remarks - Method	None

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5 per sex	0	0/10
II (low dose)	5 per sex	50	0/10
III (mid dose)	5 per sex	250	0/10
IV (high dose)	5 per sex	1000	0/10
V (control recovery)	5 per sex	0	0/10
VI (high dose recovery)	5 per sex	1000	0/10

Mortality and Time to Death
No mortalities were noted during the study.

Clinical Observations
A slight increase in the incidence of increased activity was noted for males and females in the high dose group during the treatment and recovery phases. No other remarkable clinical signs of toxicity were observed in any of the study animals. There were no statistically significant or toxicologically meaningful differences among the treated and untreated groups with respect to the functional observation battery, body weight, and food consumption.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
There were no toxicologically meaningful differences in haematology, coagulation, biochemistry, and urinalysis among the groups during the treatment or recovery phases.

Effects in Organs
No treatment-related ocular abnormalities were noted in any of the study animals and no remarkable gross necropsy observations were noted for males or females at the end of the treatment or recovery phases. No treatment-related macroscopic or microscopic changes were observed in any of the organs or tissues examined. All microscopic changes were considered spontaneous and unrelated to treatment.

Remarks – Results

Changes recorded as statistically significant in globulin (day 29 - end of treatment phase), erythrocytes and mean absolute/relative kidney weights (day 42 - end of recovery phase) for high dose males or females were not considered toxicological meaningful since they were either within the historical range, observed only in one sex, occurred only at the end of the recovery phase, or have no correlative organ pathology or changes in related parameters observed.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day, which is the highest dose tested in this study.

TEST FACILITY Springborn Laboratories (1998d)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2uvrA.
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 10, 33.3, 100, 333, 1000, 5000 µg/plate b) Without metabolic activation: 10, 33.3, 100, 333, 1000, 5000 µg/plate
Vehicle	Ethanol
Remarks - Method	Two independent tests were conducted in triplicate.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>5000	>1000	Negative
Test 2	--	>5000	>1000	Negative
Present				
Test 1	>5000	>5000	>1000	Negative
Test 2	--	>5000	>1000	Negative

Remarks - Results In Test 1, a 2.1-fold increase in the number of revertants per plate was observed with WP2uvrA in the absence of S9 mix. However, due to the lack of a dose response, this increase was considered not to meet the criteria for a positive evaluation. The vehicle and positive controls responded appropriately.

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

TEST FACILITY Covance (1998a)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.

Cell Type/Cell Line	Chinese Hamster Ovary (CHO-WBL) cells
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.

Vehicle	Ethanol
Remarks - Method	The test guideline is stated as 437 OECD. This has been assumed to be a typographical error. Due to a technical oversight, an in-life critical phase was not audited, and one of the cultures treated with 2.48 µg/mL was not harvested due to leaking of culture medium. However, these were considered to have no impact on the study.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0.854, 1.22, 1.74, 2.48, 3.54, 5.05, 7.21, 10.3, 14.7, 21.0, 30.0, 42.9*, 61.3*, 87.5*, 125*	3 h	20 h
Test 2	14.7, 21.0, 30.0, 42.9*, 61.3*, 87.5*, 125*	17.8 h	20 h
Present			
Test 1	0.854, 1.22, 1.74, 2.48, 3.54, 5.05, 7.21, 10.3, 14.7, 21.0, 30.0, 42.9*, 61.3*, 87.5*, 125*	3 h	20 h
Test 2	30.0, 42.9, 61.3*, 87.5*, 105*, 125*	3 h	20 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	Not performed	>125	≥61.3	Negative
Test 2	Not performed	≥125	>61.3	Negative
Present				
Test 1	Not performed	≥87.5	≥61.3	Negative
Test 2	Not performed	≥125	>61.3	Negative

Remarks - Results

The following reductions in the mitotic indices were observed as compared with the solvent controls:
- without metabolic activation: 3% in cultures with 125 µg/mL (Test 1), and 2%, 19%, 19%, and 32% in cultures with 42.9, 61.3, 87.5, and 125 µg/mL, respectively (Test 2);
- with metabolic activation: 15%, 33%, 33% in cultures with 61.3, 87.5, and 125 µg/mL, respectively (Test 1), and 8%, 9%, 23%, and 22% in cultures with 61.3, 87.5, 105, and 125 µg/mL, respectively (Test 2).

With metabolic activation, the increased chromosomal aberration seen in Test 1 (8% vs 0% and 38% for the solvent and positive controls, respectively) at 125 µg/mL was not repeated in Test 2, and this was considered probably confounded by the precipitate.

CONCLUSION

The notified chemical was not clastogenic to CHO cells treated in vitro under the conditions of the test.

TEST FACILITY

Covance (1998b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 301 B Ready Biodegradability: CO_2 Evolution (Modified

	Sturm Test).
Inoculum	Activated sludge from wastewater plants treating municipal sewage
Exposure Period	29 days
Auxiliary Solvent	None
Analytical Monitoring	Back titration of unreacted $Ba(OH)_2$ in CO_2 traps with HCl
Remarks - Method	Test was conducted in duplicate using a nominal concentration of approx. 10 mg carbon/L.

RESULTS

Test Substance		*Reference Substance – Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
28	2.48	28	90.5

Remarks – Results	The rapid degradation (90.5% in 28 days) of the reference compound (sodium benzoate) confirmed the viability of the bacteria used in the test. The toxicity controls on Day 11 exhibited 37.5% degradation, which met the OECD criteria of at least 25% degradation within the first 14 days, indicating that the material was not toxic to sewage bacteria.
CONCLUSION	The notified chemical is not readily biodegradable under the conditions of the test. While the degradation figures above appear to be small, it is probable that the compound would be ultimately degraded after prolonged residence in landfill.
TEST FACILITY	Springborn Laboratories (1998e)

8.1.2. Bioaccumulation

No bioaccumulation data was submitted, but the low water solubility and expected high Log Pow indicate high potential for bioaccumulation (Connell 1989). However, the relatively high molecular weight and large molecular size would reduce the bioaccumulation potential. In addition, little of the notified chemical is expected to enter the water compartment during either manufacturing activities or use of finished products containing the chemical.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – static conditions.
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	48 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	The test was conducted at 14-16ºC over a 96 h period under static conditions. The stock solution (nominally 10 mg/L) was prepared by suspending a known amount of the test substance in the test medium and stirring (about 18 h). This stock solution was allowed to settle for 1 h. The test was conducted on the water accommodated fraction (WAF) which was collected from below the surface, with further dilutions of the WAF also being used. Water quality parameters of pH (7.1-7.6), temperature (14-16ºC), O_2 content (8.0-9.4 mg/L) were within normal limits throughout study. The observed decrease in concentration with time is attributed to the settling out of ultra-fine particulate or undissolved material which settles out over time or otherwise becomes unavailable.

RESULTS

Concentration				Number of Fish	Mortality				
Nominal (% WAF)	Actual (µg/L)				1 h	24 h	48 h	72 h	96 h
	Initial	Final	Mean						
0	<0.89	<0.77	NA	10	0	0	0	0	0
6.3	8.2	3.1	5.6	10	0	0	0	0	0
13	16	6.3	11	10	0	0	0	0	0
25	31	10	21	10	0	0	0	0	0
50	79	25	52	10	0	0	0	0	0
100	130	44	85	10	0	0	0	0	0

LC50	>85 µg/L at 96 hours.
NOEC	85 µg/L at 96 hours.
Remarks – Results	No mortalities were observed during the test. After 96 h two fish were observed with partial loss of equilibrium. One of these fish was in the highest test concentration and the other in the control, suggesting that this was not a treatment related response.

CONCLUSION The test material is not toxic to fish up to the limit of its water solubility.

TEST FACILITY Springborn Laboratories (1998f)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – static conditions.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	180 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	The test was conducted at 20ºC over a 48 h period under static conditions The stock solution (nominally 10 mg/L) was prepared by suspending a known amount of the test substance in the test medium and stirring (about 18 h). This stock solution was allowed to settle for 1 h. The test was conducted on the water accommodated fraction (WAF) which was collected from below the surface, with further dilutions of the WAF also being used. Water quality parameters of pH (8.1-8.2), temperature (20ºC), O_2 content (8.3-8.8 mg/L) were within normal limits throughout study. The observed decrease in concentration with time is attributed to the settling out of ultra-fine particulate or undissolved material which settles out over time or otherwise becomes unavailable.

RESULTS

Concentration				Number of D. magna	Number Immobilised	
Nominal (% WAF)	Actual (µg/L)				24 h	48 h
	Initial	Final	Mean			
0	<0.82	<0.83	NA	20	0	0
6.3	2.1	1.4	1.8	20	0	0
13	3.9	2.7	3.3	20	0	0
25	7.6	4.5	6.0	20	0	1
50	16	8.7	12	20	0	0
100	20	18	19	20	0	0

LC50	>19 µg/L at 48 hours
NOEC (or LOEC)	19 µg/L at 48 hours
Remarks – Results	The single observed immobile daphnia in the 6.0 µg/L mean measured concentration was not considered to represent an adverse response to the test material and was ascribed to naturally occurring variability.
CONCLUSION	The test material is not toxic to daphnia up to the limit of its solubility.
TEST FACILITY	Springborn Laboratories (1998g)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	96 hours
Concentration Range	
Nominal	6.3, 13, 25, 50, 100
Actual - initial	64, 120, 250, 510, 950 µg/L
- final	16, 39, 60, 140, 320 µg/L
- mean	40, 78, 160, 330, 640µg/L
Auxiliary Solvent	None
Water Hardness	Not specified
Analytical Monitoring	HPLC
Remarks – Method	The test was conducted at 24ºC over a 96 h period under static conditions The stock solution (nominally 10 mg/L) was prepared by suspending a known amount of the test substance in the test medium and stirring (about 18 h). This stock solution was allowed to settle for 1 h. The test was conducted on the water accommodated fraction (WAF) which was collected from below the surface, with further dilutions of the WAF also being used. Water quality parameters of pH (7.3-9.8), temperature (24ºC) were within normal limits throughout study. The observed decrease in concentration with time is attributed to the settling out of ultra-fine particulate or undissolved material which settles out over time or otherwise becomes unavailable.

RESULTS

Biomass		*Growth*	
EbC50	*NOEC*	*ErC50*	*NOEC*
µg/L at 72 h	*µg/L at 72 h*	*µg/L at 72 h*	*µg/L at 72 h*
>640	640	>640	640

Remarks – Results	The results of the study showed little inhibitory effect on the growth of *Pseudokirchneriella subcapitata*. Based on these results, the 72 h NOEC for biomass would be 330 µg/L and for growth rate 640 µg/L. However, the 96 h results had shown the lack of a consistent concentration-response suggesting that the significant response observed for biomass at 330 µg/L may not be treatment related. Hence, the 72 h NOEC value is 640 µg/L. Since <50% inhibitory effect was observed on the test algae up to the highest concentration which could be achieved in the test media, both the 72 h E_bC50 and E_rC50 are >640 µg/L.
CONCLUSION	The notified chemical is not toxic to algae up to and exceeding the limit of its water solubility in the test media.
TEST FACILITY	Springborn Laboratories(1998h)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Activated domestic sewage sludge
Exposure Period	3 hours
Concentration Range	
Nominal	10, 32, 102, 328, 1050 mg/L
Remarks – Method	Test was conducted using activated sludge obtained from sewage treatment plant in Wareham, USA. The reference material was 3,5-dichlorophenol.
RESULTS	
EC50	>1050 mg/L
NOEC	1050 mg/L
Remarks – Results	When compared to the control vessels, 0.00, 14.7, 4.00, 6.13 and 1.33% inhibition was observed for the concentrations tested (10, 32, 102, 328, 1050 mg/L, respectively). Since these values were close to the controls an EC50 was not determined, but expected to be >1050 mg/L, the highest nominal test concentration. The EC50 of the reference substance was 9.6 mg/L, which is within the acceptable range of 5-30 mg/L, confirming the suitability of the activated sludge.
CONCLUSION	The ecotoxicity data indicates the notified chemical is not inhibitory to activated sludge up to 1050 mg/L suspension, the highest concentration tested.
TEST FACILITY	Springborn Laboratories(1998i)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Coatings containing the notified polymer will be applied to metal or plastic surfaces by OEMs or metal finishers. No environmental exposure is expected at end use once the coating has dried to form a hard and durable paint matrix. The notified polymer in paints is fully encapsulated in the coatings matrix and as such is not likely to be released to the environment.

Up to 1000 kg of waste may be generated during coating application each year as a result of overspray. The majority of this waste will be sent to landfills for disposal. In landfill, the notified chemical in solid wastes is expected to be immobile, and eventually will degrade through biotic and abiotic processes, and consequently, should not pose a significant exposure hazard to the environment.

A minimal amount of residual chemical (<10 kg per annum) will be disposed of to landfill as residues in the import containers. Spills of notified chemical to land are expected to bind to soil and are not expected to be mobile or affect groundwater due to very low water solubility. Spills of notified polymer to waters are not expected to dissolve, and may settle to sediment due to the low water solubility.

The majority of the notified chemical will incorporated into coatings and is expected to remain bound within cured coatings at low levels on metal or plastic substrates. Once the chemical is within a cured coating it is likely to share the fate of the substrate, which may involve recycling or landfill at the end of its useful lifetime.

According to the general characteristics of bioaccumulative organic chemicals (Connell 1989) the notified chemical has a moderate to high potential to bioaccumulate. However, low exposure expected to the aquatic environment would further reduce any potential for bioaccumulation.

9.1.2. Environment – effects assessment

The notified chemical is non-toxic to fish, daphnia, algae and sewage micoorganisms up to the limit of its water solubility. Hence accurate LC50 and EC50 levels could not be determined and consequently the estimation of a PNEC is not possible.

9.1.3. Environment – risk characterisation

No aquatic exposure is anticipated during reformulation and normal use of the notified chemical. During application of coatings, up to 1000 kg/annum of notified chemical wastes could be generated. It is expected that practically all of this waste will be disposed of in approved landfills as inert solid waste. In landfill, the solid wastes should be contained and not pose a significant risk to the environment.

Very little will be released to water and it is not possible to calculate a reasonable predicted environmental concentration (PEC). However, as the notified chemical is not toxic to aquatic organisms up to the limit of its water solubility, it is estimated the risk quotient (PEC/PNEC) should be very small.

The above considerations indicate minimal risk to the environment when the notified chemical is used in the manner and levels indicated by the notifier.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

During transport and storage, workers are unlikely to be exposed to the notified chemical. In the event of an accident, spills will be removed in accord with the MSDS and government regulations.

Although formulation of the coating products will take place in closed vessels, several groups of workers at the formulation plants may receive transient dermal, inhalation and/or ocular exposure to the notified chemical during routine operations. Exposure may occur from inadvertent leaks and spills during weighing and loading ingredients, packaging from the blending vessel into 200 L transport drums, and cleaning equipment. QC sampling and maintenance of transfer lines/pumps will be conducted under exhaust ventilation so inhalation exposure is unlikely. The plant personnel will wear chemical resistant gloves, goggles, coveralls and respirators (where appropriate) to minimise exposure to the notified chemical and other components of the coating formulations. Employers are responsible for maintaining the level of atmospheric nuisance dust and organic vapours below the relevant NOHSC exposure standards (NOHSC 1995). In addition, the engineering controls, industrial hygiene and good work practices will help further limit worker exposure to the notified chemical.

At the coating application plant, the coating formulations will be unloaded from the drums through enclosed transfer lines to a tank where it is mixed with other paint components prior to application to automotive bodies and parts. Spray painting will take place in enclosed spray booths or cabinets. Subsequent curing of the paint by oven baking will occur under the influence of exhaust ventilation, also in an enclosed space. Although these are fully enclosed and automated processes, the spray equipment controlled by workers will be subject to periodic change-over of coating material into the spray process and to occasional maintenance activity. Workers will not be exposed to problematic concentrations of the notified chemical as a result of spraying processes because it is carried out in an enclosed space nor via accidental drips and spills because of the PPE required to be used. Maintenance and QC personnel may also experience exposure during routine operations. Mixing tank operators, application/curing operators and maintenance personnel will wear chemical resistant gloves, goggles, and coveralls. Organic vapour respirators may also be used. QC personnel will wear laboratory coats, gloves and safety glasses. Considering the PPE worn, the engineering controls and good work practices, exposure of these workers is determined to be minimal.

After curing, the notified chemical will be locked in a paint matrix and not bioavailable.

9.2.2. Public health – exposure assessment

Members of the public may be exposed to the notified chemical or coating formulations containing the notified chemical following transport accidents en route. Such accidents are unlikely. The formulation and application of the coatings will be conducted in an enclosed and controlled industrial environment. The well engineered processes and regulated disposal of wastes mean that public contact with the notified chemical through environmental releases is also unlikely. The coatings containing the notified chemical are not available to the public. During its end use, the notified chemical becomes an integral part of a hard durable coating on motor vehicles and is not accessible to human contact. The potential for public exposure to the notified chemical therefore is assessed as negligible.

9.2.3. Human health – effects assessment

The notified chemical has a low acute oral and dermal toxicity in rats (LD50>2000 mg/kg bw). It is not an irritant to rabbit skin, but slightly irritating to the rabbit eyes. It shows limited evidence of sensitising activity at up to 50% solution in an adjuvant study in guinea pigs. Besides a slight increase in the incidence of increased activity which was noted for males and females at 1000 mg/kg/day during the treatment and recovery phases, no clinical or microscopic changes were considered toxicologically meaningful in a 28-day repeated dose oral study in rats. The NOAEL was established to be 1000 mg/kg bw/day, which is the highest dose tested in this study. The notified chemical was not mutagenic in a bacterial reverse mutation assay, and did not reveal any genotoxic potential in vitro.

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

9.2.4. Occupational health and safety – risk characterisation

The notified chemical will be used only at industrial sites where operatives are familiar in using such products and good handling procedures and housekeeping are the norm. Little exposure by the dermal route is expected given the work practices and PPE worn. The significant amount of respirable particles present presents a potential inhalation risk. However, the low toxicity by other routes and the low bioavailability of the notified chemical due to its high molecular weight indicates a likely low inhalation hazard, and handling of the powder will take place in a dispensary equipped with local exhaust ventilation for handling fine pigments. Therefore, the OHS risk presented by the notified chemical is expected to be low, given the engineering controls, the good work practices and safety measures including use of appropriate personal protective equipment by workers. Following curing of the paint, the chemical will be cross-linked with other paint components to form a stable film. In this form, the chemical is essentially unavailable for absorption and thus the health risk to workers after paint curing would be negligible.

The notified chemical may be present in formulations containing hazardous ingredients. If these formulations 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.

9.2.5. Public health – risk characterisation

Members of the public may make dermal contact with painted surfaces containing the notified chemical. However, the risk to public health will be negligible because the chemical is present at low concentrations, bound within a matrix and not 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.

According to the criteria of the GHS, the notified chemical would be classified as Chronic Category IV (aquatic environment). This applies to chemicals which are poorly soluble, have no acute toxicity and lack potential to rapidly degrade and/or have the potential to bioaccumulate (BCF ≥500 or if absent, log Kow ≥4).

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 in the proposed manner.

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

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in the pure powder form:
  - Use of enclosed systems at the blending and packaging sites, including enclosed blending vessels equipped with local exhaust ventilation, and closed transfer lines/pumps for charging and emptying of the blending and auxiliary processes and for the packing off equipment;
  - Adequate ventilation for the plant operators, including use of local exhaust ventilation on weighing and addition to the blending vessel and on QC testing.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in the pure powder form:
  - Adequate training for staff in handling paint products, including enforcing the adherence of industrial spray painters to the NOHSC *National Guidance Material*

for Spray Painting;
- Implementation of general health surveillance and monitoring programs as required.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in the pure powder form:
  - Industrial standard protective clothing and gloves;
  - Safety glasses with side-shields/chemical goggles;
  - Particulate respirators if required.

  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

- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified chemical:
  - Do not allow the notified chemical or contaminated packaging to enter drains, sewers or water courses.

Disposal

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

Emergency procedures

- Spills/release of the notified chemical should be handled by dampening down to avoid dust and scoop into marked containers for disposal as chemical waste.

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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