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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

E96095

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
T. R. (Chemicals Australia) Pty Ltd (ABN 57 001 268 006)
195 Briens Rd
NORTHMEAD NSW 2152

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, CAS No., molecular and structural formulae, molecular weight, degree of purity and impurities.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: dissociation constant, in vivo mutagenicity and chronic toxicity to Daphnia.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
Europe.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
E96095

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Ultraviolet/visible light, infrared and proton nuclear magnetic resonance spectroscopy.
Remarks	Reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
High.

HAZARDOUS IMPURITIES
None.

NON HAZARDOUS IMPURITIES
One impurity at 11%.

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be introduced in 3-ply block ended paper sacks, capacity 15 – 20 kg, fitted with a pneumatically sealed external valve.

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

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

USE
Viscosity adjuster in solvent-based paints.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Unknown.

IDENTITY OF MANUFACTURER/RECIPIENTS
Notifier.

TRANSPORTATION AND PACKAGING
The paper sacks containing the notified chemical will be imported by air or sea and transported by rail or road. Paints are expected to be packaged in typical metal containers of 1 – 200 L volume.

5.2. Operation description

The solid ingredients are mixed and ground to the correct size in an enclosed bead mill. From there the mixture is transferred to a blender or high speed disperser and the final paint drummed off into suitable sized containers.

End use of the final paints will be by high pressure spraying or brushing after dilution with solvents.

5.3. Occupational exposure

Number and Category of Workers
At each site:

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Paint Formulation			
Process workers	4	5 hours/day	220 days/year
Laboratory staff	2	5 hours/day	220 days/year
End Use			
Paint application	~ 100	Up to 6 hours/day	Up to 250 days/year

Exposure Details
Exposure of workers during transport and storage should only occur as a result of breach of containers in the event of a transport accident.

The notified chemical is a fine powder. Inhalation of dust during weighing and addition to the bead mill is controlled by local exhaust ventilation. Local extraction is employed at various points to control inhalation exposure of dust and solvents particularly during additions to vessels and drumming off of final product. Exposure to drips and spills is possible particularly during cleaning and maintenance operations although such exposure will be low due to the low (< 2%) concentration of the notified chemical in formulated paint.

Once the notified chemical is mixed in paints exposure is low because of its low concentration (< 2%). As the notified chemical is contained in primers applied to large industrial structures by high pressure

spraying or brush and the primers are solvent-based, exposure to solvents requires the use of adequate personal protective equipment including overalls, gloves, goggles and respirator (if required). This personal protective equipment will reduce exposure to the notified chemical to very low levels.

5.4. Release

RELEASE OF CHEMICAL AT EMULSION MANUFACTURING SITE

The notified chemical will be manufactured overseas, imported into Australia and transported to various customer sites for storage and blending to form finished products containing < 2% of the notified chemical. Environmental release is unlikely during importation, storage and transportation, and spillage during a transport accident is the most likely reason for environmental release. Individual container capacity (15 - 20 kg), container specifications (3-ply, pneumatically sealed) and emergency spill response procedures would limit the extent of release.

RELEASE OF CHEMICAL FROM PAINT MANUFACTURING SITES

Paint preparation involves blending the notified chemical with various additives (eg. pigments, fillers, dispersing agents, resins, solvents) in either a mixing vessel or high speed disperser. Environmental release during paint manufacture is not expected due to the semi-closed or enclosed nature of the blending undertaken, semi- or fully automated metering systems, emergency spill response procedures (outlined in the MSDS), worker training, and the low concentrations of notified chemical used. Engineering controls (eg. bunding) are likely to contain spills and leaks of products containing the notified chemical. Equipment is cleaned with solvent and washings are recycled for use in subsequent batches. None of the paint manufacturing facilities are expected to dispose of wastewaters containing the notified chemical to municipal sewer.

RELEASE OF CHEMICAL FROM USE

Finished products will be contained in 1 - 200 L metal containers for distribution at retail outlets and use by consumers either by high pressure spraying or brushing after dilution with solvents. The heavy duty paints will be used to coat large industrial structures.

Use of paints containing the notified chemical would be widespread and diffuse throughout Australia, with concentrations at urban areas/cities. Most of the paint containing the notified chemical will be applied to surfaces where it will dry and harden to a film, with low potential for environmental release of the encapsulated notified chemical. Spills would also dry and harden to a film.

Emptied paint containers may potentially contain a residue of ~ 0.5% of the initial contents (0.0075% of the notified chemical or < 1 kg of the notified chemical). Waste generated due to overspray and cleaning of application equipment may potentially generate up to 500 kg/y of waste containing the notified chemical. This waste may be recycled, but is more likely to be sent to landfill for disposal. Overspray during application is likely to fall to the ground or onto drop sheets, and accidental washing of brushes and spray equipment may potentially result in some of the notified chemical entering the sewerage system. Air scrubbers, refrigeration units or local incinerators may be used at application sites to control emissions of dusts and solvent vapours.

In the long term the painted surface may be repainted or painted materials may be demolished and sent to landfill for disposal or a material recycling facility.

5.5. Disposal

Wastes generated during industrial application of paint products (eg. spray equipment/brushes) containing the notified chemical will be recycled (eg. solvent recovery) or disposed of through a licensed waste contractor for incineration (aqueous) or landfill disposal (dried wastes). Emptied containers will be allowed to dry and either recycled (metal) or sent to landfill for disposal.

5.6. Public exposure

The public will not normally be exposed to the notified chemical except in the final cured coating in which it will not be bioavailable. It is also possible that exposure could occur following a transport accident.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa White powder.

Melting Point 121 – 123.5ºC

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Melting block method.
TEST FACILITY Huntingdon Life Sciences (1999a).

Boiling Point > 144ºC

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Measured with differential scanning calorimeter. Decomposition observed at 144ºC.
TEST FACILITY Huntingdon Life Sciences (1999a).

Density 1020 kg/m^3 at 20ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Measured with pycnometer.
TEST FACILITY Huntingdon Life Sciences (1999a).

Vapour Pressure 3.26 x 10^{-10} kPa at 25ºC

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Measured with vapour pressure balance. No decomposition of the test material was noted during a stability test at ≤ 100°C. Very slightly volatile (Mensink *et al*., 1995).
TEST FACILITY Huntingdon Life Sciences (1999a).

Water Solubility < 0.1 mg/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Column Elution Method.). Classified as very slightly soluble in water (Mensink *et al*., 1995). Water solubility was determined by HPLC with spectrophotometric detection to determine dosages in a study on acute toxicity of E96095 to Rainbow Trout. It was estimated as 0.23 µg/L (Huntingdon Life Sciences, 1999l).
TEST FACILITY Huntingdon Life Sciences (1999a).

Fat (or n-octanol) Solubility < 0.72 g/kg standard fat HB307 at 37°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks Analytical Method: visual estimation.
TEST FACILITY Huntingdon Life Sciences (2001).

Hydrolysis as a Function of pH Not determined.

Remarks Not determined as very slightly water soluble (estimated as 0.23 µg/L (Huntingdon Life Sciences, 1999l)).

Partition Coefficient (n-octanol/water) log P_{ow} = 6.01 at 20°C

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).

EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks HPLC Method.
TEST FACILITY Huntingdon Life Sciences (1999a).

Adsorption/Desorption – screening test log K_{oc} = 6.26 at 20°C

METHOD OECD Draft Document TGP/94.75 (April 1994).
Remarks HPLC method.

The notified chemical is likely to be immobile in soils and sediments (McCall et al., 1980).
TEST FACILITY Huntingdon Life Sciences (1999a)

Dissociation Constant Not determined.
Remarks The low water solubility of the test substance limits the ability to measure the dissociation constant. There are no dissociable groups.

Particle Size Mass median aerodynamic diameter = 5.99 μm

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

Range (μm)	*Mass (%)*
≤ 2.01	13.51
≤ 10.09	73.54
2.01 – 199.8	86.44

Remarks Method: Coulter counter.
TEST FACILITY Huntingdon Life Sciences (1999a).

Flash Point Not determined.

Remarks Not determined as substance is a solid.

Flammability Limits Not highly flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks Flame test was negative.
TEST FACILITY Huntingdon Life Sciences (1999a).

Autoignition Temperature > 450°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
TEST FACILITY Huntingdon Life Sciences (1999a).

Explosive Properties Not explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Thermal and mechanical sensitivity were tested.
TEST FACILITY Huntingdon Life Sciences (1999a).

Oxidising Properties Not oxidising.

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
TEST FACILITY Huntingdon Life Sciences (1999a).

Reactivity

Remarks Expected to be stable under normal environmental conditions.

7. TOXICOLOGICAL INVESTIGATIONS

The toxicological data were generated with E96095 which is used as a component of the primers and contained a high concentration of the notified chemical and less than 20% of a related chemical.

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 LC50 = 5.08 mg/L/4 hour	low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test.	no evidence of sensitisation.
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 1000 mg/kg/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE E96095.

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat/Sprague-Dawley.
Vehicle Corn oil.
Remarks - Method None.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	None.

LD50 > 2000 mg/kg bw
Signs of Toxicity Piloerection, accompanied by hunched posture in all animals, ungroomed appearance and soft to liquid faeces resolved by day 3.
Effects in Organs None.
Remarks - Results Bodyweight gain was satisfactory throughout the study.

CONCLUSION The test substance is of low toxicity via the oral route.

TEST FACILITY Huntingdon Life Sciences (1999b).

7.2. Acute toxicity - dermal

TEST SUBSTANCE E96095.

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain Rat/Sprague-Dawley.
Vehicle Corn oil.
Type of dressing Semi-occlusive.
Remarks - Method The humidity was lower than stated in the protocol but was thought not to have affected the result.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	None.

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	A slight to moderate dermal response evident in 9/10 rats following removing dressing resolved by day 7
Signs of Toxicity - Systemic	None.
Effects in Organs	None.
Remarks - Results	Body weight gain was largely unaffected by treatment.

CONCLUSION The test substance is of low toxicity via the dermal route.

TEST FACILITY Huntingdon Life Sciences (1999c).

7.3. Acute toxicity - inhalation

TEST SUBSTANCE E96095.

METHOD OECD TG 403 Acute Inhalation Toxicity.
EC Directive 92/69/EEC, 93/21/EEC B.2 Acute Toxicity (Inhalation).
US EPA Test Guidelines OPPTS 870.1300, Acute Inhalation Toxicity, 1998.

Species/Strain	Rat/Sprague-Dawley.
Vehicle	None.
Method of Exposure	Oro-nasal exposure.
Exposure Period	4 hours.
Physical Form	Solid aerosol (particulate).
Particle Size	The mass median aerodynamic diameter was 4.7, 3.5 or 3.4 μm for groups receiving dosages of 5.3, 0.77 or 2.26 mg/L, respectively.
Remarks - Method	No significant deviations from protocol.

RESULTS

Group	*Number and Sex of Animals*	*Concentration (mg/L)*		*Mortality*
		Nominal	*Actual*	
1	5/sex	2.3	0.77	None.
2	"	5.9	2.26	No males/1 female.
3	"	13.0	5.30	4 males/2 females.

LC50	5.08 mg/L/ 4 hours.
Signs of Toxicity	Exaggerated breathing was observed for all treated rats during exposure. Noisy breathing was observed in animals exposed to the mid or high dose and a fast breathing rate was noted in mid dose rats throughout the observation period. Other signs noted post exposure in the mid and high dose groups included lethargy and eyes partially closed, awkward gait and ataxia. Staggering was noted in the high dose group and piloerection in the mid dose group. There were treatment related signs evident in the low and mid dose groups from days 4 and 8, respectively. Bodyweight loss occurred in high dose females for the first week post exposure and the mean bodyweight gain for mid and high dose males and low and mid dose females were lower than control values following

exposure. Thereafter, the mean bodyweight gain of mid and high dose females were higher than control values. Food consumption in mid and high dose animals was lower than controls during the first week following exposure.

Effects in Organs: The lung weights of decedents were higher than controls for mid and high dose animals as were the lung weights of surviving high dose females.

The lungs of all mid and high dose decedents were severely congested. Pale and/or raised areas were also evident in high dose animals. A white frothy fluid was seen in the lungs of high dose animals. The stomach and small intestines of decedents were gas filled and the intestines of one high dose male were yellow in colour in addition to a pale liver being observed.

Pale and/or raised areas were evident on the lungs of surviving high dose females. Areas of severe/moderate congestion were noted on the lungs of 2/4 surviving high dose rats.

CONCLUSION: The test substance is of low toxicity via inhalation.

TEST FACILITY: Huntingdon Life Sciences (1999d).

7.4. Irritation – skin

TEST SUBSTANCE: E96095.

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

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None.
Observation Period	3 days.
Type of Dressing	Semi-occlusive.
Remarks - Method	None.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0.3	2	24 hours	0
Oedema	0	0	0	1	1 hour	0

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

Remarks - Results: No effects were seen in 2/3 animals.

CONCLUSION: The test substance is slightly irritating to the skin.

TEST FACILITY: Huntingdon Life Sciences (1999e).

7.5. Irritation - eye

TEST SUBSTANCE: E96095.

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 3 days.
Remarks - Method Low value for humidity.

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	0	0	1	1 hour	0
Conjunctiva: chemosis	0	0	0	2	1 hour	0
Conjunctiva: discharge						
Corneal opacity	0	0	0	0		0
Iridial inflammation	0	0	0	0		0

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

Remarks - Results Conjunctival effects were seen in all animals at 1 hour.

CONCLUSION The test substance is slightly irritating to the eye.

TEST FACILITY Huntingdon Life Sciences (1999f).

7.6. Skin sensitisation

TEST SUBSTANCE E96095.

METHOD OECD TG 406 Skin Sensitisation – maximisation test.
EC Directive 96/54/EC B.6 Skin Sensitisation – maximisation test.
EPA Health Effects Test Guidelines OPPTS 870.2600 "Skin Sensitisation" EPA 712-C-98-197, 1998.

Species/Strain Guinea pig/Dunkin-Hartley.

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: < 5% (w/v)
topical: 10% (w/v)

MAIN STUDY

Number of Animals Test Group: 10 Control Group: 5

INDUCTION PHASE Induction Concentration:
intradermal: 5% (w/v)
topical: 70% (w/v)

Signs of Irritation Slight irritation was observed at injection sites of animals receiving test substance and vehicle and necrosis occurred at sites receiving Freund's Complete Adjuvant. No reactions to topical induction were observed.

CHALLENGE PHASE

1st challenge intradermal:
topical: 5% and 10% (w/v)

Remarks - Method Humidity was outside the normal range on occasions.

RESULTS

Animal	*Challenge Concentration*	*Number of animals showing skin reactions after challenge*	
		24 h	*48 h*
Test Group	5%	0/10	0/10
	10%	2/10	0/10
Control Group	5%	0/5	0/5
	10%	0/5	0/5

Remarks - Results Two of the test animals exhibited equivocal responses to challenge with 10% (w/v) test substance 24 hours after patch removal.

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

TEST FACILITY Huntingdon Life Sciences (1999g).

7.7. Repeat dose toxicity

TEST SUBSTANCE E96095.

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	
Route of Administration	Oral – gavage.
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 2 weeks.
Vehicle	Corn oil.
Remarks - Method	None.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	None
II (low dose)	"	200	"
III (mid dose)	"	600	"
IV (high dose)	"	1000	"
V (control recovery)	"	0	"
VI (high dose recovery)	"	1000	"

Clinical Observations
None.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Clinical chemistry: Non dose related increase in alanine aminotransferase in all treated female groups. Slight elevation of urea nitrogen and lowering of albumin/globulin (A/G) ratio in recovery high dose females and slightly elevated A/G ratio was observed in high dose recovery males.
Haematology: A slightly higher packed cell volume was observed in recovery high dose females.
Urinalysis: Slight increase in urinary volume in high dose females.

Effects in Organs
Slight increase in relative kidney weights was observed in recovery high dose females and a slight lowering of relative kidney weights was observed in high dose females and recovery high dose males. Slightly lower liver weights were observed in recovery high dose males. There were no macroscopic or microscopic findings in organs.

Remarks – Results
All of the slight changes listed above were not considered toxicologically significant as they were not corroborated by dose dependence or pathological changes. All other observed effects were either slight and within the historical control ranges or scattered observations.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on a lack of significant findings at this dose level.

TEST FACILITY Huntingdon Life Sciences (1999h).

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	E96095.
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, TA100. *E. coli*: WP2uvrA (pKM101).
Metabolic Activation System	Aroclor 1254-induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 0 - 5000 µg/plate. b) Without metabolic activation: 0 - 5000 µg/plate.
Vehicle	Suspension in purified water containing 0.15% agar.
Remarks - Method	Plate incorporation used in first test, pre incubation in second test.

RESULTS

Remarks - Results	No increase in revertant numbers was observed in either of two experiments in the treated plates. Negative controls were within expected limits and positive controls demonstrated the sensitivity of the test. No thinning of the background lawn on the treated plates was seen, indicating the test substance was not substantially toxic.
CONCLUSION	The test substance was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Huntingdon Life Sciences (1999i).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	E96095.
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. US EPA (1998) Health Effects Test Guidelines OPPTS 870.5375 In vitro Mammalian Chromosome Aberration Test. EPA 712-C-98-223.
Cell Type/Cell Line	Human lymphocytes.
Metabolic Activation System	Aroclor 1254-induced rat liver S9 fraction.
Vehicle	Suspension in culture medium.
Remarks - Method	None.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 36.09, 78.13, 156.25, 312.5, 625, 1250*, 2500*, 5000*	3 hours	20 hours
Test 2	0*, 313, 625*, 1250*, 2000*, 2500, 3500, 5000	20 hours	20 hours
Present			
Test 1	0*, 36.09, 78.13, 156.25, 312.5, 625, 1250*, 2500*, 5000*	3 hours	20 hours
Test 2	0*, 313, 625, 1250, 2000, 2500*, 3500*, 5000*	3 hours	20 hours

*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		None		None
Test 2		2000		"
Present				
Test 1		None		"
Test 2		3500		"

Remarks - Results

No significant reductions of mitotic index were seen in test 1 either in the presence or absence of metabolic activation; reduction below 50% was seen in test 2. Positive controls indicated the sensitivity of the test system and negative controls were within historical limits.

CONCLUSION

The test substance was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY

Huntingdon Life Sciences (1999j).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: E96095.

METHOD: OECD TG 301 B Ready Biodegradability: Modified Sturm Test. (CO_2 Evolution)

Inoculum	Mixed microbial population from activated sewage sludge, Oakley sewage treatment works, UK.
Exposure Period	30 days.
Auxiliary Solvent	None.
Analytical Monitoring	None.
Remarks – Method	Test substance was added to 2 vessels containing mineral salts medium inoculated with activated sludge (30 mg solids/L) to give a nominal test concentration of 39.9 mg/L (10 mg C/L). Control vessels included inoculated mineral salts and a reference substance (sodium benzoate 10 mg C/L). An additional mixture contained sodium benzoate (10 mg C/L) and test substance (10 mg C/L). Test chambers were incubated for 29 days with CO_2-free air. CO_2 produced during the test period was collected in Dreschel bottles containing $Ba(OH)_2$ and the residual $Ba(OH)_2$ was measured by titration.

RESULTS

Day	*Test substance % TCO_2*	*Sodium benzoate % TCO_2*
1	4.5	7
3	7.5	40
9	8	70
14	8	75
21	9	78
28	9	79
29	9	80

Remarks – Results: The reference substance achieved 64% of TCO_2 after day 7, 80% after 29 days, and 65% after 29 days in the presence of the test substance, thereby validating that the test conditions (eg. viable inoculum) and indicating that the test substance did not inhibit the sewage sludge microbes.

CONCLUSION: The test material at a nominal exposure concentration of 39.9 mg/L achieved only 9% of the TCO_2 generation after 28 d (< 60% of TCO_2 criterion) and is not readily biodegradable.

TEST FACILITY: Huntington Life Sciences (1999k)

8.1.2. Bioaccumulation

Based on the partition co-efficient (log P_{ow} ~ 6), the notified chemical may bioaccumulate. However, due to the low water solubility, low affinity to fat and industrial use pattern, predicted environmental concentrations will be minimal.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE E96095.

METHOD
- Species: Rainbow trout (*Oncorhynchus mykiss*); 4.2 cm length, 1.25 g wet wt.
- Exposure Period: 96 hours.
- Auxiliary Solvent: None.
- Water Hardness: ~150 mg/L (as $CaCO_3$)
- Analytical Monitoring: Analysis of saturated solution by HPLC.
- Remarks – Method: Test substance was added directly to diluent water to give a nominal solution concentration of 100 mg/L. Diluent water consisted of filtered, dechlorinated water. After stirring for 24 h, the test solution was filtered to remove excess test substance. The resulting solution was assumed to be 100% saturated. Test solution temperature: 13°C; photoperiod 16 h light: 8 h dark; dissolved oxygen: 8.8-9.3 mgO_2/L; pH: 7.8. Observations of mortalities and adverse effects were made at 0.25, 2, 4, 24, 48, 72 & 96 h.

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*Mortality %*				
		1 h	*24 h*	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0	0
100% saturation (~ 0.23 µg/L)	10	0	0	0	0	0

- LC50: > 100% saturation at 96 hours.
- NOEC (or LOEC): 100% saturation at 96 hours.
- Remarks – Results: Exposure to the test substance in solution at 100% saturation produced no mortalities or observable adverse effects. A stock solution containing the test substance was prepared for analysis by HPLC/spectrophotometric detection to determine its water solubility. Concentration peaks detected were below the limit of quantitation (0.5 µg/L), and estimated to be 0.23 µg/L.

CONCLUSION E96095 produced no observed acutely adverse effects in trout up to the limit of its water solubility.

TEST FACILITY Huntingdon Life Sciences (1999l)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE E96095.

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test – static and EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia.
- Species: *Daphnia magna*; 1st instar (< 24 h old)
- Exposure Period: 48 hours.
- Auxiliary Solvent: None.
- Water Hardness: ~ 140 - 250 mg/L (as $CaCO_3$)
- Analytical Monitoring: Analysis of saturated solution by HPLC.
- Remarks - Method: Range finding (1.0%, 10% and 100% saturation) and definitive (100% saturation) tests were performed. Test substance was added directly to diluent water to give a nominal solution concentration of 100 mg/L. Diluent water consisted of reconstituted medium Elendt M4, prepared using analytical grade reagents and deionised water. After stirring for 24 h, the test solution was filtered to remove excess material before use. Test vessels consisted of 250 mL glass beakers each containing 100 mL

test solution. The resulting solution was assumed to be 100% saturated. Test solution temperature: 20 - 24°C; photoperiod 16 h light: 8 h dark; dissolved oxygen: 7.8 - 8.4 mgO_2/L; pH: 7.8 - 7.9. Observations of mortalities and adverse effects were made at 0.25, 2, 4, 24, 48, 72 & 96 h. Loading: 20 mL per test organism.

RESULTS

Concentration mg/L Nominal	*Number of Daphnia*	*Mortality %*	
		24 h	*48 h*
Control	20 (4 replicates of 5)	0	0
100% saturation (~ 0.23 µg/L)	"	0	0

EC50 > 100% saturation at 48 hours.
NOEC 100%.
Remarks - Results No mortalities or adverse effects were noted at the highest test concentration (assumed to be 100% saturation) of the notified chemical.

CONCLUSION E96095 produced no observed acutely adverse effects in Daphnids up to the limit of its water solubility.

TEST FACILITY Huntingdon Life Sciences (1999m)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE E96095.

METHOD OECD TG 201 Alga, Growth Inhibition Test and EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species Green alga *Selenastrum capricornutum* Strain CCAP 278/4.
Exposure Period 72 hours.
Concentration Range
Nominal 100% saturation in water
Actual ~0.23 µg/L
Auxiliary Solvent None
Water Hardness Not reported
Analytical Monitoring Analysis of saturated solution by HPLC.
Remarks - Method Algal cultures were exposed to a saturated solution of E96095 plus one untreated control (6 replicates of each) in sterile nutrient medium. Test substance was added directly to diluent water to give a nominal solution concentration of 100 mg/L. Diluent water consisted of filtered, dechlorinated water. After stirring for 24 h, the test solution was filtered to remove excess material. The resulting solution was assumed to be 100% saturated. Cultures were incubated (23 - 24°C) in 250 mL flasks with 100 mL of test solution (shaken) under continuous illumination (7000 lux). Cell numbers were counted daily. Initial and final cell densities were 1.1 x 10^4 cell/mL and 1.3 x 10^6 cells/mL in the control. Solution pH was 7.7 - 8.2.

RESULTS

Biomass		*Growth*	
EbC50 mg/L at 72 h	*NOEC mg/L*	*ErC50 mg/L 0-72 h*	*NOEC mg/L*
> 100% saturation	Not determined	> 100% saturation	Not determined

Remarks - Results When compared to the control, some biomass (19.5%) and growth (3.6%) inhibition was reported at the concentration tested (significant $p < 0.05$). Consequently, the reported NOEC values are not considered

	appropriate. No cell abnormalities were observed after inspection microscopically at 72 h. No cultures showed any signs of contamination by foreign fungi cells or protozoa.
CONCLUSION	The test substance produced some toxicity at the test concentration of 100% saturation (19.5% biomass; 3.6% growth inhibition); however, the EC50 values were > 100% saturation.
TEST FACILITY	Huntingdon Life Sciences (1999n)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical.
Remarks – Results	Assessed during the ready biodegradability test (Huntington Life Sciences, 1999k). The reference substance achieved 65% of TCO_2 after 29 days in the presence of the test substance (~ 40 mg/L nominal and well above the limit of water solubility of 0.23 μg/L), indicating that the test substance did not inhibit the sewage sludge microbes.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is likely to be moderately persistent in the environment as it is not readily biodegradable (9% TCO_2 degradation in 29 days), probably hydrolytically stable and very slight soluble in water (0.23 μg/L) . The notified chemical is very slightly volatile and migration to the atmosphere is unlikely to be significant. With an estimated adsorption coefficient (Log Koc) of 6.26, the notified chemical in soil is likely to adhere to soils particulates and is unlikely to be mobile.

Based on the lifecycle assessment of the notified chemical, release to the aquatic or terrestrial environment is unlikely. No aqueous wastes are expected to be released to sewer or natural waterways during the manufacture of the solvent-based finished paint products, and the use and disposal pattern indicates that the notified chemical would not be released to sewer or natural waterways during application or disposal. There may be minor release to the sewer through inappropriate washing of brushes and spray equipment with water.

9.1.2. Environment – effects assessment

Aquatic ecotoxicity data are available for four taxonomic groups (a freshwater fish, an invertebrate, green alga and sewage sludge microbes). No aquatic toxicity data are available for marine species or soil or sediment-dwelling organisms.

Aquatic ecotoxicity data indicate that the notified chemical is practically non-toxic to aquatic animals up to the limit of its water solubility (estimated by HPLC at 0.23 μg/L); however, some (< 20% compared to control) inhibitory effect on biomass and growth of algae was evident at a test concentration of 100% saturation. No NOEC for alga could be determined based on the statistically significant effects observed at the single test concentration used. No aquatic predicted no effect concentration (PNEC) can be derived due to the uncertainty of this endpoint. No adverse effects on activated sewage sludge microbes was evident at ~40 mg/L; however, such concentrations are unlikely in the sewerage system.

9.1.3. Environment – risk characterisation

Most of the notified chemical will be applied at a low level in paint to surfaces, where upon drying, it will be encapsulated within the paint film with minimal potential for environmental release. Most wastes containing the notified chemical are likely to be incinerated or sent to landfill for disposal. Incineration of the notified chemical is expected to produce oxides of

carbon and nitrogen. Within the landfill environment, the notified chemical is not expected to be mobile (based on log K_{oc}) and is expected to degrade over time by abiotic and biotic processes to simple compounds of carbon and nitrogen. Although potentially bioaccumulative, the very low water solubility and expected limited release of the notified chemical to the aquatic environment indicates that bioaccumulation is unlikely to occur.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Exposure to the notified chemical during transport and storage should only occur in the event of accidental rupture of the paper sacks in which it is imported and this can be considered to be a rare occurrence.

Paint manufacture initially involves transfer of the notified chemical as a solid powder to a bead mill together with other solid ingredients after weighing out. Local exhaust ventilation is typically employed at these stages to reduce atmospheric concentrations and the time taken for addition would be expected to be a small fraction of that required for the manufacture of a paint batch. A line from the bead mill is normally connected to the paint mixing vessel for enclosed transfer. Once in the mixing vessel the notified chemical is at a concentration of less than 2% and exposure will normally be limited to small samples removed for QC testing. Drum filling is typically automatic and subject to local exhaust ventilation to remove solvent vapours.

Application of the coating containing the notified chemical is by high pressure spray onto industrial structures. Therefore, there is a high potential for dermal, ocular and inhalation exposure to the paint although exposure to the notified chemical would be low even in the absence of the personal protective equipment required to prevent exposure other paint components.

9.2.2. Public health – exposure assessment

The paint containing the notified chemical will not be available to the public. The public is only likely to be exposed to the notified chemical in the event of a transport accident or in the cured paint film in which it is not bioavailable.

9.2.3. Human health – effects assessment

E96095, containing a high proportion of the notified chemical was of low acute toxicity via the oral, dermal and inhalation routes in rats. It was a slight skin and eye irritant in rabbits, was not a skin sensitiser in guinea pigs, did not induce mutations in bacteria and did not induce chromosomal aberrations in human lymphocytes in vitro. E96095 did not exhibit organ toxicity in rats in a 28-day repeated dose oral toxicity study up to a dose of 1000 mg/kg/day.

The notifier has classified E96095 as harmful via the inhalation route on the basis that the observed 4-hour LC50 of 5.08 mg/L absolute chamber concentration equated to 3.6 mg/L for the respirable component (particles < 7μm in aerodynamic diameter).

9.2.4. Occupational health and safety – risk characterisation

E96095 has been classified by the notifier as harmful via the inhalation route. Although the majority of particles of E96095 as imported are in the respirable range, exposure is likely to be minimal except if there is a transport or warehousing accident. Therefore, apart from the possibility of slight skin and eye irritation during weighing and mixer loading of the powdered notified chemical during paint manufacture, the risk to workers handling the notified chemical is low.

9.2.5. Public health – risk characterisation

Exposure of the public to the notified chemical is only possible in the event of a transport accident or when it is in a cured paint film. Therefore, there is a low risk of adverse health effects.

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

10.1. Hazard classification

The notifier has classified E96095 as harmful via the inhalation route.

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its proposed use and disposal pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is Negligible Concern to public health when used as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of E96095 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 E96095 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:
  - Local exhaust ventilation should be used when weighing out the imported powder containing the notified chemical and adding it to the bead mill. The atmospheric concentration should be maintained below the NOHSC exposure standard of 10 mg/m^3 TWA for total dust (NOHSC, 1995). Respirable dust levels should be kept below the ACGIH standard of 3 mg/m^3 TWA.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- The notified chemical should be disposed of in accordance with State/Territory waste management guidelines to landfill or incinerator.
- Wastes generated during industrial application of paint products containing the notified chemical should be disposed of through a licensed waste contractor. Unused/unwanted paint should be kept in the original container for recycling and/or left to dry and sent to landfill. Overspray wastes on drop sheets should be allowed to dry and sent to landfill for disposal.

Emergency procedures

- Spills/release of the notified chemical (powder) should be swept and collected into labelled sealable containers for reuse or disposal to landfill or incineration.
- Spills/release of solvent-based paints containing the notified chemical should be contained and adsorbed into inert material. The adsorbent should be placed into labelled sealable containers for disposal. Avoid spills entering waterways or sewer.
- Keep spills and cleaning runoff out of municipal sewers, stormwater or open bodies of water.

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 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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