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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Donor S1

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Donor S1

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Basell Australia Pty Ltd (ABN 42004327762)
Level 13, 90 Collins St
MELBOURNE VIC 3000

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer, (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS No., molecular formula, structural formula, molecular weight, spectral data, purity and impurities, manufacture/import volume, manufacturing process, identity of sites.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: flammability, reativity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
Italy.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Donor S1.

SPECTRAL DATA

METHOD	UV/visible, Infrared and NMR spectroscopy
Remarks	Reference spectra were provided.

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	UV/visible, Infrared and NMR spectroscopy, Mass spectroscopy

3. COMPOSITION

DEGREE OF PURITY
High.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

NON-HAZARDOUS IMPURITIES
Seven impurities at < 10% (w/w) total.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
As a component of a catalyst formulation at concentrations up to 20%.

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

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

USE
Catalyst used in polypropylene and polyethylene manufacture.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
A single site in Victoria.

TRANSPORTATION AND PACKAGING
The liquid formulation containing the notified chemical will be imported by ship in 200 L plastic or steel drums and transported to the manufacturing site. Polypropylene pellets produced using the notified chemical will be transported and stored in 25 kg bags or 500 kg bulk bags.

5.2. Operation Description

Transport & Storage
The notified chemical will be imported as a component of a liquid formulation used in the manufacture of polypropylene at concentrations up to 20%. It will be transported directly to the manufacturing site for storage and use.

Primary Manufacture
The liquid formulation containing the notified chemical will be uploaded from the import drum using nitrogen to displace the liquid into a dedicated enclosed mixing vessel. The notified chemical is gravity fed to the mixing vessel and then directly into the polypropylene reaction process.

Secondary Manufacture
Following polypropylene manufacture the resulting product is cooled, pelletised and bagged for transport to a secondary manufacturer. The polypropylene pellets are blended with additives and moulded into various items.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and storage	2	4 hours/day	6 days/year
Storage: drum handling	1	2 hours/day	240 days/year
Plastics manufacture: process workers	2	4 hours/day	48 days/year
Plastics manufacture: laboratory analysis	2	4 hours/day	3 days/year

Exposure Details
Transport & Storage
As the import drums will not opened during transport and storage, exposure is only likely in the event of a major spill involving breach of import containers. In this event, personal protective equipment

(PPE) such as impervious gloves, boots and face shield will limit exposure.

Primary Manufacture
The process for uploading the drum contents into the polypropylene reaction process is designed to minimise contamination of the contents with air and as a result, minimises spills. The mixing vessel is kept under nitrogen pressure. Once into the enclosed process exposure is unlikely except for quality control sampling involving small samples tested in fume cupboards. As the notified substance is consumed in the polymerisation process, no exposure is expected after this stage.

Secondary Manufacture
Exposure to the notified chemical is not considered to be possible, as the notified chemical will be wholly incorporated into the polypropylene matrix and thus biologically unavailable.

5.4. Release

The liquid formulation containing the notified chemical at a concentration of less than 20% will be transferred from the 200 L import drum to a dedicated enclosed mixing vessel. Exposure may occur if import containers are accidentally breached, or there may be minor release from maintenance of piping in bunded areas. Residues of chemical left in used import drums are another potential source of environmental exposure. The notifier has assumed that drum residues will be less than 24 kg per year.

The notified chemical is used as part the polymerisation process to create the polypropylene matrix. As the process is in a closed system, environmental release is unlikely except for quality control sampling involving small samples tested in fume cupboards. As the notified substance is consumed in the polymerisation process, no exposure is expected after this stage. However, washing of the mixing vessels may release some components to wastewater. Following polypropylene manufacture, the resulting product is pelletised and transported to a secondary manufacturer. The polypropylene pellets are subsequently blended with additives and then moulded into various items.

RELEASE OF CHEMICAL FROM USE
Because the notified chemical will be incorporated into the polypropylene matrix at concentrations below 50 ppb, it is expected to be biologically unavailable. It is assumed that any waste pellets will be disposed of to landfill.

5.5. Disposal

Any spills from maintenance operations will be adsorbed and disposed of to landfill. Following polyethylene/polypropylene manufacture, the resulting product is cooled, pelletised and bagged for transport to a secondary manufacturer. It is assumed that any remaining pellets will be disposed of to landfill, as will the bags used to transport the pellets.

5.6. Public exposure

The general public will come into contact with a wide range of finished articles moulded from polypropylene manufactured using the notified chemical as part of a catalyst. The notified chemical is expected to be consumed in the polymerisation reaction, and therefore not biologically available in finished articles such as automotive components and parts, pipes, bathroom fittings, furniture and stadium seating. Therefore, public exposure is expected to be negligible.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Clear liquid.

Melting Point/Freezing Point -70ºC

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
TEST FACILITY LCG Bioscience (2001a).

Boiling Point Not determined.

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Decomposition begins at 52ºC.
TEST FACILITY LCG Bioscience (2001a).

Density 961.8 kg/m^3 at 20ºC

METHOD EC Directive 92/69/EEC A.3 Relative Density.
TEST FACILITY LCG Bioscience (2001a).

Vapour Pressure 4.2 x 10^{-4} kPa at 25ºC
3.7 x 10^{-4} kPa at 20ºC.

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Two tests performed at 32 °C (305 K) and 40 °C (313 K) using the gas saturation method. Used Clausius-Clapeyron equation to calculate vapour pressure at lower temperatures.
TEST FACILITY LCG Bioscience (2001a)

Water Solubility 150 mg/L at 25ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks GC with FID. Flask method: Donor S1 mixed with analytical grade water at 10 g/L. Filtered at 24 h, 48 h and 72 h at 30°C. Solution of filtered water + acetone + internal standard analysed using GC/FID. Peak areas calculated as mean of two injections. Standard deviation of water solubility = 0.0019 mg/mL.
TEST FACILITY LCG Bioscience (2001a)

Hydrolysis as a Function of pH Abiotic degradation hydrolysis as a function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.
Remarks GC/FID. Preliminary test then full test conducted at 50 ± 0.5°C, to test for pseudo-first order behaviour. Two replicates of each treatment combination. Values at 20°C are extrapolated using the empirical Arrhenius equation

pH	*T (°C)*	*t½ hours*
4	25	600
7	25	523
9	25	438
4	50	43
7	50	44
9	50	39
4	20	1044
7	20	905
9	20	733

Remarks The test substance is slightly hydrolysing (United Nations 2003).
TEST FACILITY LCG Bioscience (2001c)

Partition Coefficient (n-octanol/water) Log P_{ow} at 20ºC > 3.0

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient – Shake Flask Method
Remarks Solutions in ratios of 1:1, 1:2, and 2:1 were shaken for 2 hours, then concentrations were measured using GC/FID
TEST FACILITY LCG Bioscience (2001d)

Adsorption/Desorption log K_{oc} = 2.23 at room temperature.
– screening test only

METHOD OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.
Remarks Since less than 25% of test substance was retained in 16 hours at room temperature by the three soils, no further testing was considered necessary

Soil Type	*Organic Carbon Content (%)*	*K_{oc} (mL/g)*	*Comments*
I	1.71	-	Lower than test solution without soil, therefore cannot calculate K_{oc}
II	1.3	-	As above
III	0.9	171	-

TEST FACILITY LCG Bioscience (2001e)

Dissociation Constant Not applicable.

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks Notified chemical has no groups that could dissociate.

Surface Tension 28.8 mN/m at 20°C

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Ring method, determined directly on sample at 20°C (no dilution).
TEST FACILITY LCG Bioscience (2001a).

Flash Point 108°C

METHOD EC Directive 92/69/EEC A.9 Flash Point.
TEST FACILITY LCG Bioscience (2000a).

Flammability Limits Not determined.

Autoignition Temperature 384°C

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
TEST FACILITY LCG Bioscience (2001a).

Explosive Properties Not explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Tests performed with respect to thermal and mechanical shock.
TEST FACILITY LCG Bioscience (2001a).

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral, LD50 >2000 mg/kg bw	low toxicity
Rat, acute dermal, LD50 >2000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test/non-adjuvant test.	no evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOAEL = 300 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration in human lymphocytes	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical.

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

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3/sex	2000	None

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

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

TEST FACILITY LCG Bioscience (2000b).

7.2. Acute toxicity - dermal

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain Rat/Sprague Dawley.
Vehicle None.
Type of dressing Semi-occlusive.
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 - Local	None.
Signs of Toxicity - Systemic	None.
Effects in Organs	None.
Remarks - Results	None.

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

TEST FACILITY LCG Bioscience (2001f).

7.3. Irritation – skin

TEST SUBSTANCE Notified chemical.

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

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None.
Observation Period	72 hours.
Type of Dressing	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	0	-	0
Oedema	0	0	0	0	-	0

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

Remarks - Results	None.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY LCG Bioscience (2001g)

7.4. Irritation - eye

TEST SUBSTANCE Notified chemical.

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

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
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			
Conjunctiva: redness	0.33	0.33	0.33	2	24 hours	0
Conjunctiva: chemosis	0	0	0	0	-	0

Conjunctiva: discharge	Not reported					
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 None.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY LCG Bioscience (2001h)

7.5. Skin sensitisation

TEST SUBSTANCE Notified chemical.

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

Species/Strain Guinea pig/Dunkin Hartley albino

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 0.5%
topical: 100%

MAIN STUDY

Number of Animals Test Group: 10 Control Group: 5

INDUCTION PHASE Induction Concentration:
intradermal injection 5%
topical application 100%

Signs of Irritation Slight erythema and/or oedema after intradermal injections.

CHALLENGE PHASE

1st challenge topical application: 100%

Remarks - Method None.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	100%	0	0
Control Group	100%	0	0

Remarks - Results Six monthly tests verified the sensitivity of test animals used in this facility.

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

TEST FACILITY LCG Bioscience (2001i)

7.6. Repeat dose toxicity

TEST SUBSTANCE Notified chemical.

METHOD Not specified.

Species/Strain Rat/Sprague Dawley Crl:CD (SD) BR

Route of Administration Oral – gavage

Exposure Information Total exposure days: 28 days;
Dose regimen: 7 days per week;
Post-exposure observation period: None.

Vehicle	Corn oil.
Remarks - Method	Similar to OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0/10
II (low dose)	5/sex	100	0/10
III (mid dose)	5/sex	300	0/10
IV (high dose)	5/sex	1000	0/10

Clinical Observations

Salivation was observed in high dose animals from 15-60 minutes after dosing. Fur loss was also observed in 2/5 high dose females.

No other adverse clinical signs, including neurophysiological changes were observed.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No treatment-related changes were observed in haematological or urinalysis parameters. Statistically significantly higher serum total protein was observed in all treated females.

Effects in Organs

Organ Weights

Statistically significantly higher liver weights were observed in high dose animals of either sex. Relative liver weights were also statistically significantly higher in mid-dose animals of either sex, and in low-dose males.

Histopathology

High dose animals showed slight centrilobular hypertrophy in the liver, associated in females with more severe periportal vacuolation consistent with fatty change, compared to controls. High dose males showed increased hyaline droplet formation in the renal tubules, foci of gastric glandular mucosa erosion/degeneration and the presence of sinus haemorrhage and pigments in the mesenteric lymph nodes.

Some mid-dose animals showed slight centrilobular hypertrophy in the liver, associated in females with more severe periportal vacuolation consistent with fatty change.

One low dose female also showed more severe periportal vacuolation consistent with fatty change.

In the stomach foci of slight glandular mucosa erosion/degeneration were observed in males at 1000 mg/kg bw/day and one female showed a focus of gastric mucosa degeneration.

Remarks – Results

Hepatic hypertrophy was considered consistent with adaptive metabolic effects of xenobiotics on the liver. Hyaline droplet accumulation in the kidneys is a known species- and sex-specific change of the male rat.

CONCLUSION

No No Observed Effect Level (NOEL) was established in this study. The No Observed Adverse Effect Level (NOAEL) was established as 300 mg/kg bw/day in this study, based on irritative effects in the stomach of animals treated with a higher dose.

TEST FACILITY LCG Bioscience (2001j)

7.7. Genotoxicity - bacteria

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test

	using Bacteria. Plate incorporation procedure/Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102.
Metabolic Activation System	Phenobarbital and beta-naphthoflavone induced rat S9 liver fraction.
Concentration Range in Main Test	a) With metabolic activation: 50-5000 µg/plate. b) Without metabolic activation: 50-5000 µg/plate.
Vehicle	Dimethyl sulfoxide
Remarks - Method	

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	5000		None reported	None observed
Test 2		5000	None reported	None observed
Present				
Test 1	5000		None reported	None observed
Test 2		5000	None reported	None observed

Remarks – Results	Positive controls confirmed the reversion properties of the tester strains and the metabolic activity of the liver fractions.

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

TEST FACILITY LCG Bioscience (2001k)

7.8. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
EC Directive 2000/32/EEC B.10 Mutagenicity – In Vitro Mammalian Chromosome Aberration Test

Cell Type/Cell Line	Freshly drawn human peripheral blood lymphocytes.
Metabolic Activation System	Phenobarbital and beta-naphthoflavone induced rat S9 liver fraction.
Vehicle	Dimethyl sulfoxide
Remarks - Method	None.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	5, 10, 20*, 41*, 81*, 163, 325, 650, 1300, 2600	4 hours	22 hours
	5, 10, 20*, 41*, 81*, 163, 325, 650, 1300, 2600	22 hours	22 hours
Test 2	25, 50*, 100, 150*	4 hours	46 hours
Present			
Test 1	87.5, 175*, 350*, 525*, 700*	4 hours	22 hours
Test 2	50, 87, 152*, 266*, 465*, 814, 1425, 2493	4 hours	46 hours

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1		≥ 81	≥ 163	±
Test 2		≥ 150		-
Present				
Test 1	≥ 650	≥ 525	≥ 650	-
Test 2		≥ 465		-

Remarks - Results

In Test 1 after 22 hours continuous treatment without metabolic activation, a statistically significant increase in the frequency of chromsosomal aberrations was observed. However, this was not dose dependent and the solvent control was abnormally low so this observation was ascribed to chance.

The positive controls gave the expected increases and the negative controls were within historical limits.

CONCLUSION

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

TEST FACILITY

LCG Bioscience (2001l)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

Modified sturm test

TEST SUBSTANCE	DONOR S1
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test. EEC Directive 92/96 Method C4C
Inoculum	250 mL of activated sludge from "La Fouillouse"
Exposure Period	28 days
Auxiliary Solvent	No
Analytical Monitoring	Not reported for notified chemical. CO_2 measured in test.
Remarks - Method	Two replicates, 1 toxicity control flask and 1 reference control flask Concentration of test item in media = 15.6 mg/L Temp: 20.9-23.3°C pH: 7.66-8.28 (8.28 in reference control, highest pH in test medium = 7.8)

RESULTS

Test substance		*Reference Substance (sodium acetate trihydrate)*	
Day	*% degradation*	*Day*	*% degradation*
2	2	2	9
7	3	7	43
14	4	14	67
28	5	28	89

Remarks - Results	Test item not toxic to inoculum, since 35% degradation in 14 d (i.e., higher than 25%)
CONCLUSION	Not readily biodegradable
TEST FACILITY	LCG Bioscience (2001m)

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	DONOR S1
METHOD	In compliance with EEC Directive 92/69/EEC C.1 Acute Toxicity for Fish. – semi-static In accordance with the requirements of directives 87/18/EEC and 88/320/EEC
Species	*Danio rerio* (Zebra Fish)
Exposure Period	96 h
Auxiliary Solvent	No (tap water)
Water Hardness	100 mg $CaCO_3$/L (tap water)
Analytical Monitoring	GC/FID
Remarks – Method	Test species is one of the recommended species listed in the EEC method. Water hardness within required hardness of 10-250 mg/L. Reference item was potassium dichromate. pH: 7.86 – 8.16 (variation less than 1 unit). DO: 94%. Temperature range: 19.7°C – 22.5°C. Max temperature variation per concentration 2.6°C (greater than method requirement of ± 1 °C within test). Concentrations NOT maintained within 80% of initial concentration,

therefore geometrical means calculated.
7 day acclimation period for fish (as per EEC method), however, only held for 7 days (instead of required 12) before commencement of test.
Feeding stopped 28 h before test.
No replicates.
Loading = 1.05 g/L (1.0 g/L recommended in EEC method)
Media refreshed every 24 h.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	10	0	0	0	1	1
10	6.84	10	0	0	0	0	1
15	7.93	10	0	0	0	0	0
22.5	16.49	10	0	1	1	3	5
33.8	30.15	10	0	9	10	10	10
50.6	46.67	10	5	10	10	10	10

96 h LC_{50}	16.49 mg/L (geometrical mean)
NOEC	Presumed to be 7.93 mg/L
Remarks – Results	DEH cannot calculate EC50 using ToxCalc™ because two or more partial responses are required and are not present. Reference test (used to demonstrate response of tested species) not conducted in conjunction with this test, instead done separately 19 days earlier. LC_{50} = 241.8 mg/L. Variations to EEC guidelines are not considered to invalidate the results.

CONCLUSION The test substance is harmful to fish (United Nations 2003).

TEST FACILITY LCG Bioscience (2001n).

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE DONOR S1

METHOD EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – semi static.

Species	*Daphnia magna*
Exposure Period	48 hours.
Auxiliary Solvent	No.
Water Hardness	220 mg $CaCO_3$/L (LC medium)
Analytical Monitoring	GC/FID
Remarks - Method	Concentrations NOT maintained within 80% of initial concentration, therefore geometrical means calculated (maintenance within 80% a requirement of the EEC method). Minimum dissolved O_2 = 8.1 mg/L (complies with EEC method requirement of above 2 mg/L). pH 7.93-8.02. Temp: 19.8-21.1°C. One concentration contained 19 *Daphnia* instead of 20. Number of batches not stated (EEC method prefers four batches of 5 animals or two batches of 10).

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	0	20	0	0
4.3	2.1	20	1	1
9.4	6.2	19	0	6

20.7	11.5	20	2	5
45.5	21.3	20	0	1
100	47.1	20	20	20

48 h EC_{50}	Between 21.3-47.1 mg/L
NOEC (or LOEC)	Not calculatable
Remarks - Results	The DEH cannot calculate an EC50 with confidence because there is no clear dose response. However, the EEC method accepts a range if the consecutive concentrations are at a ratio of 2.2 (data fulfil this requirement).

CONCLUSION The test substance is harmful to *Daphnia* (United Nations 2003).

TEST FACILITY LCG Bioscience (2001o)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE DONOR S1

METHOD EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range Nominal	0, 3.2, 7, 15.5, 34.1, 75 mg/L
Concentration Range Actual	0, 1.0, 2.4, 3.4, 15.5, 41.5 mg/L
Auxiliary Solvent	No.
Water Hardness	50 mg $CaCO_3$/L
Analytical Monitoring	GC/FID
Remarks - Method	Concentrations NOT maintained within 80% of initial concentration, therefore geometrical means calculated. Maximal pH variation: 0.44. Test medium not specified. Three replicates at each test concentration. Minimum lighting 5320 lux instead of 6000 lux.

RESULTS

Biomass		*Growth*	
EC_b (I) 50 mg/L at 72 h	*$NOEC_b$ mg/L*	*EC_r (I) 50 mg/L at 72 h*	*$NOEC_r$ mg/L*
4.4	1	22.8	2.4

Remarks - Results	Growth curves not presented. Study fulfilled the requirement of the EEC method that cell density in control cultures increase by factor of at least 16 within 3 days, as it increased by 225. The deviation in concentrations are not expected to invalidate the results.

CONCLUSION Using lowest EC of 4.4 mg/L, the substance is toxic to algae (United Nations 2003)

TEST FACILITY Report: LCG Bioscience (2001p).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The proposed use and disposal patterns for the notified chemical indicate that release to the environment is minimal.

Exposure may occur if import containers are accidentally breached, or there may be minor release from maintenance of piping in bunded areas. The former scenario is considered unlikely, and any spills from maintenance operations will be adsorbed and disposed of to landfill. Residues of chemical left in used import drums are another potential source of environmental exposure. The notifier has assumed that drum residues will be less than 24 kg per year. In the absence of information to the contrary, it may be assumed that these residues are released to wastewater from the manufacturing plant.

As the polymerisation process is in a closed system, release is unlikely except for quality control sampling involving small samples tested in fume cupboards. Because the notified substance is consumed in the polymerisation process, no exposure is expected after this stage. However, washing of the mixing vessels may release some components to wastewater.
Because the notified chemical will be incorporated into the polypropylene matrix at concentrations below 50 ppb, it is expected to be biologically unavailable in finished products. It is assumed that any waste polypropylene pellets will be disposed of to landfill.

9.1.2. Environment – effects assessment

Aquatic toxicity data were submitted for 3 taxa (fish, *Daphnia* and algae). These data indicate that the notified chemical is harmful to fish and aquatic invertebrates, and toxic to algae. Although these studies did not fully comply with the EEC test guidelines, in that the test concentrations varied by more than 20% of the nominal value, actual test data are usually preferred to modelling data. Modelling data using PBT profiler, based on the chemical structure of the notified chemical, indicate that the 48 h LC_{50} for Daphnids is 2.86 mg/L, the 96 h EC_{50} for green algae is 0.27 mg/L, and the 96 h EC_{50} for fish is 3.17 mg/L. According to the actual toxicity studies, the most sensitive species of the three tested was the alga *Selenastrum capricornutum,* with a reported EC_b (I) 50 at 72 h of 4.4 mg/L.

The notified chemical is classified as moderately volatile and moderately soluble in water (United Nations, 2003).

9.1.3. Environment – risk characterisation

In order to evaluate the environmental risk, data on measured concentrations in the environment, or alternatively, predictions of environmental concentrations (PEC), are compared with predicted no effect concentrations (PNEC). The PNEC is a concentration that is expected to cause no harm to organisms. The PNEC value of the notified chemical is 44 µg/L, using the algal endpoint of 4.4 mg/L and a safety factor of 100. A safety factor is used to account for intra and inter-species variability, and it decreases from 1000 as more data for different taxa are provided. A risk quotient (RQ) is calculated where RQ = PEC/PNEC. Any RQ greater than 1 (that is, where the concentration in the environment is less than the concentration that would cause harm) is considered safe for the environment.

Discharge of residues from used import drums to the local wastewater plant and then to the aquatic environment can be estimated. It is assumed that wastewater goes to a treatment plant (STP), which receives 50 million litres of wastewater a day. If 24 kg are released to the STP per year, then the PEC to rivers is 1.32 µg/L, and the RQ = 0.03. This indicates a low risk to aquatic ecosystems from residues in import drums.

Once formulated, the majority of the chemical will be bound within the polypropylene matrix, and is therefore expected to eventually end up in landfill. For this reason there will be no release to water as a result of use. Although considered moderately volatile, its presence in a liquid formulation, together with use in a closed system, means that release to air is expected to be minimal.

If the notified chemical is used according to the reported use pattern, the risk to the environment is expected to be low.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport & Storage

As the import drums will not be opened during transport and storage, exposure is only likely in the event of a major spill involving breach of import containers.

Primary Manufacture

The process for uploading the drum contents into the polypropylene reaction process is designed to minimise contamination of the contents with air and as a result, minimises spills. The mixing vessel is kept under nitrogen pressure. Once into the enclosed process exposure is unlikely except for quality control sampling involving small samples tested in fume cupboards. As the notified substance is consumed in the polymerisation process, no exposure is expected after this stage.

Secondary Manufacture

Exposure to the notified chemical is not considered to be possible, as the notified chemical will be wholly incorporated into the polypropylene matrix and thus biologically unavailable.

9.2.2. Public health – exposure assessment

The general public will come into contact with a wide range of finished articles moulded from polypropylene manufactured using the notified chemical as part of a catalyst. The notified chemical is expected to be consumed in the polymerisation reaction, and therefore is not biologically available in finished articles. Therefore, public exposure is expected to be negligible.

9.2.3. Human health - effects assessment

The notified chemical exhibited low acute oral and dermal toxicity in rats, was not a skin irritant and was a slight eye irritant in rabbits. No evidence of skin senstisation was found in guinea pigs. The NOAEL in a 28-day repeat dose oral toxicity study in rats was 300 mg/kg bw/day based on local irritation to the stomach. No NOEL was established. The notified chemical was not genotoxic in 2 short term in vitro tests.

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is unlikely to be acutely or chronically toxic, irritant, sensitising or genotoxic on the basis of results from animal bioassays or short term in vitro genotoxicity screening tests. In addition control of exposure during transport and storage prior to manufacture, during polypropylene manufacture and moulding suggests exposure is unlikely. Therefore, the risk of adverse health effects to workers is low.

9.2.5. Public health – risk characterisation

As the public exposure is expected to be negligible and the notified chemical is unlikely to be acutely or chronically toxic, irritant, sensitising or genotoxic on the basis of results from animal bioassays or short term in vitro genotoxicity screening tests, the risk to the public is low.

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

10.1. Hazard classification

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

The classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is Chronic Category 2. While this system is not mandated in Australia, the classification for this notified chemical is presented for comparative purposes.

10.2. Environmental risk assessment

The PEC/PNEC ratio is 0.03, and therefore use of the notified chemical in accordance with its reported use pattern is not considered to pose a significant risk to the environment.

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 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 safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoidance of contact with eyes.
- 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

- Use of the chemical must remain within the parameters specified by this notification.

Disposal

- The notified chemical should be disposed of by incineration.

Emergency procedures

- Spills/release of the notified chemical should be handled by adsorption on to an inert material, and then disposed of via a licensed waste disposal operator to a suitable landfill. Do NOT allow any amount of product to reach ground water, water bodies or

sewage systems.

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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