

File No LTD/1118

27 April 2004

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Polymer in Clear Tint PC Cyan 486

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
National Occupational Health and Safety Commission
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1161 or + 61 2 6279 1163.

This Full Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

**Director
Chemicals Notification and Assessment**

TABLE OF CONTENTS

FULL PUBLIC REPORT	4
1. APPLICANT AND NOTIFICATION DETAILS	4
2. IDENTITY OF CHEMICAL	4
3. COMPOSITION.....	4
4. INTRODUCTION AND USE INFORMATION	5
5. PROCESS AND RELEASE INFORMATION.....	5
5.1. Distribution, Transport and Storage.....	5
5.2. Operation Description.....	5
5.3. Occupational exposure.....	5
5.4. Release.....	6
5.5. Disposal	6
5.6. Public exposure	6
6. PHYSICAL AND CHEMICAL PROPERTIES	6
7. TOXICOLOGICAL INVESTIGATIONS	7
7.1. Acute toxicity – oral	7
7.2. Irritation – skin	8
7.3. Genotoxicity - bacteria.....	8
7.4. Genotoxicity – in vitro.....	9
8. ENVIRONMENT.....	12
8.1. Environmental fate	12
8.1.1. Ready biodegradability.....	12
8.1.2. Bioaccumulation	12
8.2. Ecotoxicological investigations.....	12
8.2.1. Acute toxicity to fish.....	12
8.2.3. Algal growth inhibition test.....	12
8.2.4. Inhibition of microbial activity	12
9. RISK ASSESSMENT	13
9.1. Environment.....	13
9.1.1. Environment – exposure assessment.....	13
9.1.2. Environment – effects assessment.....	13
9.1.3. Environment – risk characterisation.....	13
9.2. Human health	13
9.2.1. Occupational health and safety – exposure assessment.....	13
9.2.2. Public health – exposure assessment.....	14
9.2.3. Human health - effects assessment.....	14
9.2.4. Occupational health and safety – risk characterisation.....	14
9.2.5. Public health – risk characterisation.....	14
10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS	14
10.1. Hazard classification.....	14
10.2. Environmental risk assessment.....	14
10.3. Human health risk assessment.....	14
10.3.1. Occupational health and safety.....	14
10.3.2. Public health.....	15
11. MATERIAL SAFETY DATA SHEET	15
11.1. Material Safety Data Sheet.....	15
11.2. Label	15
12. RECOMMENDATIONS.....	15
12.1. Secondary notification	15
13. BIBLIOGRAPHY	16

FULL PUBLIC REPORT

Polymer in Clear Tint PC Cyan 486

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Nuplex Industries (Aust) Pty Ltd (ABN 25 000 045 572)

15 Park Rd

SEVEN HILLS NSW 2147

NOTIFICATION CATEGORY

Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, molecular and structural formulae, molecular weight, spectral data and purity.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None.

NOTIFICATION IN OTHER COUNTRIES

US.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Clear Tint PC Cyan 486 contains the notified polymer and will be imported already combined into polypropylene at less than 10%.

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	> 1000
--------------------------------------	--------

% of Low MW Species < 1000	0.2%
----------------------------	------

% of Low MW Species < 500	< 0.1%
---------------------------	--------

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Ultraviolet/Visible (UV/Vis) and Infrared (IR) spectroscopy.
-------------------	--

Remarks	Reference spectra were provided.
---------	----------------------------------

3. COMPOSITION

DEGREE OF PURITY

High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Three hazardous impurities at < 1% each.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

None.

ADDITIVES/ADJUVANTS

None.

DEGRADATION PRODUCTS

Stable.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

None known except for water content at < 2%.

4. INTRODUCTION AND USE INFORMATION

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

As a component of a polypropylene masterbatch at 10%.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	1.7	1.7	1.7	1.7	1.7

USE

Colourant for polypropylene.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY

Unknown.

IDENTITY OF MANUFACTURER/RECIPIENTS

Notifier.

TRANSPORTATION AND PACKAGING

In multiwall paper bags at 20 kg net weight, or alternatively in 100 kg fibre drums.

5.2. Operation Description

The masterbatch pellet is vacuum transferred from bags to the feeding hopper on the moulding machine and dispensed automatically at the desired rate into the hopper of an injection-moulding machine. Once heated, the melted pellets are moulded to form the shape of the plastic article, then cooled.

5.3. Occupational exposure

Number and Category of Workers (per site)

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Storage	1	Up to 8 hours per day	Up to 240 days per year
Equipment maintenance	1	“	“
Manufacture	2	“	“

Exposure Details

The manufacture of plastic articles involves a highly automated process. Skin contact may occur when opening containers and manually charging the polymer masterbatch into the heat-moulding machine. However, worker exposure is not anticipated since the notified polymer is encapsulated within the polypropylene masterbatch and would not be available for exposure.

Workers handling the masterbatch pellets containing the notified polymer will wear protective equipment including gloves, safety glasses and overalls. The moulding machines are enclosed and the process areas are fitted with local exhaust ventilation to capture fugitive vapours from the heated resin.

Handling of finished articles made from resin granules would not result in exposure to the notified polymer for workers as it will be encapsulated in the polymer matrix and not separately available for exposure.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Spills or leaks of the pellets containing the notified polymer would be collected and reused in further batches, or if contaminated, sent to landfill for disposal. Residues in emptied imported containers would also be sent to landfill for disposal (eg. <1% of total import quantity).

RELEASE OF CHEMICAL FROM USE

Limited release of the notified substance is expected from products containing the notified polymer due to its polymeric encapsulation.

5.5. Disposal

Since the notified chemical will be used in a range of consumer plastic products, the majority will eventually be sent to landfill for disposal or recycled at commercial recycling facilities. The use pattern would indicate that this disposal pattern would be widespread. The nature of the encapsulated substance would indicate a low potential for environmental release.

5.6. Public exposure

During manufacture of plastic products, any spillage will be contained within bunded areas. Public exposure during the manufacturing process is negligible.

Extraction studies indicate that the polymer will not leach from the waste product. Public exposure through waste is negligible.

The notified polymer in finished articles is expected not to be biologically available and extraction studies indicate no release of the polymer from the articles. Public exposure through contact with products is expected to be negligible.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Viscous dark blue liquid.
Melting Point/Freezing Point	> 200°C
Density	1200 kg/m ³
Vapour Pressure	Not expected to be volatile due to high molecular weight.
Water Solubility	>2 g/L (counter ion)

METHOD	Spectrophotometric
Remarks	Four concentrations (100, 200, 1000, 2000 mg/L) were prepared by mixing Cyan 486 (0.0101 g, 0.0202 g, 0.1000, 0.2001 g) in 100 mL flask in deionised water and diluting to the mark with ethanol. Cyan 486 dissolved completely in water. 1 mL of each concentration was pipetted into 100 mL and diluted to the mark with ethanol. Following mixing, the absorbance of each solution was measured spectrophotometrically.
TEST FACILITY	Not stated

Hydrolysis as a Function of pH	Not determined.
---------------------------------------	-----------------

Remarks Hydrolysis is unlikely to occur at environmentally relevant pH range. There are no groups generally considered as hydrolysable.

Partition Coefficient (n-octanol/water) Log Pow at room temperature = -1.1

METHOD Spectrophotometric
TEST FACILITY Not stated

Adsorption/Desorption Not determined.
Remarks May be expected to be mobile based on high water solubility and low Log Pow. However, the notified substance has a very low potential to leach when blended and encapsulated into polyethylene.

Dissociation Constant Not determined.
Remarks Substance contains strongly acidic sulphonic acid groups that will remain ionised throughout the environmental pH range.

Flash Point > 100°C

Flammability Limits > 230°C

Autoignition Temperature > 350°C

Explosive Properties None expected based on structure.

Reactivity Stable under normal environmental conditions.

7. TOXICOLOGICAL INVESTIGATIONS

The notified polymer has been tested for acute oral toxicity in rats, skin irritation in rabbits, mutagenicity in bacteria and clastogenicity in human lymphocytes. In addition, a close analogue of the dye counter ion component of the notified polymer was of low acute oral toxicity in rats and rabbits and a SIDS dossier exists for the analogue. These are also summarised below.

Notified polymer

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral LD50 > 5000 mg/kg bw	low toxicity
Rabbit, skin irritation	moderately irritating
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations in human lymphocytes	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified polymer.

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain Rat/Crl:CD®(SD)BR
Vehicle Distilled water.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5/sex	5000	None
LD50	> 5000 mg/kg bw		
Signs of Toxicity	None.		

Effects in Organs	None.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Covance Laboratories (1998a).

7.2. Irritation – skin

TEST SUBSTANCE	Notified polymer.
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. USEPA Health Effects Test Guidelines, 40 CFR 798.4470, 1989.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None.
Observation Period	14 days.
Type of Dressing	Semi-occlusive.

RESULTS

<i>Lesion</i>	<i>Mean Score* Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	1	2	1.33	2	7 days	0
<i>Oedema</i>	0.33	2	1.33	2	7 days	0

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

CONCLUSION	The notified polymer is moderately irritating to skin.
TEST FACILITY	Covance Laboratories (1998b).

7.3. Genotoxicity - bacteria

TEST SUBSTANCE	Notified polymer.
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure.
Species/Strain	<i>S. typhimurium</i> : TA1538, TA1535, TA1537, TA98, TA100. <i>E. coli</i> : WP2 uvrA.
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	Deionised water.

RESULTS

Remarks - Results	No increases in induced mutant frequency were observed in any strain at any dose level were observed with the notified polymer. Positive and negative controls confirmed the validity of the test. Cytotoxicity was observed with TA 100 at either 100 (-S9) or 333 µg/plate (+S9) and above and with WP2 <i>uvrA</i> at 1000 µg/plate (±S9).
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Covance Laboratories (1998c).

7.4. Genotoxicity – in vitro

TEST SUBSTANCE Notified polymer.

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
EC Directive 2000/32/EEC B.10.
Cell Type/Cell Line Human lymphocytes.
Metabolic Activation System Phenobarbitone/β-naphthoflavone-induced rat liver S9 fraction.
Vehicle Culture medium.

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL)</i>	<i>Exposure Period</i>	<i>Harvest Time</i>
<i>Absent</i>			
Test 1	0*, 80, 160*, 320*, 480*, 640, 800	4 hours	24 hours
Test 2	0*, 80*, 160*, 240*, 320, 480, 560	24 hours	24 hours
<i>Present</i>			
Test 1	0*, 80, 160*, 320*, 480*, 640, 800	4 hours	24 hours
Test 2	0*, 160*, 320*, 480*, 560*, 640, 800	4 hours	24 hours

*Cultures selected for metaphase analysis.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	> 625	≥ 640	-	-
Test 2	> 312.5	≥ 320	-	-
<i>Present</i>				
Test 1	> 2500	≥ 640	-	-
Test 2		≥ 560	-	-

Remarks - Results Positive controls demonstrated the sensitivity of the test.

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

TEST FACILITY Safepharm (2002).

7.5 Toxicology of copper phthalocyanine – dye counter ion analogue

7.5.1 Acute oral toxicity

The OECD/SIDS document reported that acute oral LD50 in rats was > 10000 mg/kg bw; in rabbits it was > 16000 mg/kg bw (OECD/SIDS, 1993). Other studies have reported the acute oral toxicity in rats to be > 6400 mg/kg bw, > 10000 mg/kg bw and > 15000 mg/kg bw (European Commission, 2000).

7.5.2 Repeated dose toxicity

A 13-week feeding study was conducted in mice at > 5000 mg/kg bw. No toxic signs or pathological changes were found after 13 weeks (OECD/SIDS, 1993).

A 28-day repeated dose toxicity test was conducted in Wistar rats (10/sex/group) administered doses of 0, 40, 200 and 1000 mg/kg per day by oral gavage. After 28 days administration there was a significant decrease of red blood cell count and a tendency to decrease in haemoglobin and packed cell volume in the 200 and 1000 mg/kg males. After recovery there was a slight increase in these parameters in 1000 mg/kg females. There was

an increase in the weights of lung, spleen, adrenals and salivary glands in 1000 mg/kg males. The NOAEL for rats was 200 mg/kg/day (OECD/SIDS, 1993).

A 13-week feeding study (concentrations of test substance: 0.3 – 5.0% in food) was conducted in rats and mice. No signs of toxicity were observed after 13 weeks of feeding (OECD/SIDS, 1993).

7.5.3 Skin irritation

A skin irritation test was conducted in an unspecified species in accordance with a method of The Consumer Product Safety Commission of the USA in the Code of Federal Regulations, Title 16, section 1550.41. The test substance was negative for skin irritation (OECD/SIDS, 1993). Skin irritation was negative in 4 other studies in rabbits (European Commission, 2000).

7.5.4 Eye irritation

The test substance was not irritating to the eye in rabbits in one test and in two unidentified species in 2 further tests (European Commission, 2000).

7.5.5 Bacterial mutagenicity

A preincubation assay conducted in *Salmonella typhimurium* strains TA 98, TA 100, TA 102 and TA 97 with or without metabolic activation was negative. A preincubation assay and spot test conducted in *S. typhimurium* strains TA 1535 and TA 1538 with or without metabolic activation was negative. A suspension assay conducted in *S. typhimurium* strains TA 98 and TA 100 with or without metabolic activation was negative (OECD/SIDS, 1993).

Several other studies were negative as follows: *S. typhimurium* strains TA 1535, TA 1537, TA 1538 and TA 100 and *Escherichia coli* WP2uvrA with and without metabolic activation; *S. typhimurium* strains TA 100, TA 98, TA 102 and TA 97 with and without metabolic activation; *S. typhimurium* strains TA 1535, TA 100, TA 1537 and TA 98 at doses of 20 – 10000 µg/plate with and without metabolic activation ; *S. typhimurium* strain TA 98 with and without metabolic activation; *S. typhimurium* strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100 with and without metabolic activation and *Escherichia coli* WP2uvrA with and without metabolic activation (European Commission, 2000).

7.5.6 Chromosomal aberrations in mammalian cells in vitro

Chinese Hamster lung cells were incubated in the test substance (dissolved in dimethyl sulfoxide) at 0, 0.75, 1.50 and 3.0 mg/mL with or without metabolic activation (S9). The lowest concentrations producing toxicity were 1.3 mg/mL (-S9) or > 2.0 mg/mL. The test was conducted in accordance with the Japanese Guideline for Screening Mutagenicity Testing of Chemicals (OECD/SIDS, 1993).

7.5.7 Mammalian cell gene mutation

Two studies on mutation in mouse lymphoma L5178Y TK+/- cells were conducted with and without metabolic activation and were both negative (European Commission, 2000).

7.5.8 Unscheduled DNA synthesis

The test substance was negative in 2 studies of unscheduled DNA synthesis in rat hepatocytes (European Commission, 2000).

7.5.9 Cell transformation

The test substance was negative in two cell transformation assays in C3H/10T1/2 CL8 cells (European Commission, 2000).

7.5.10 Toxicity to reproduction and teratogenicity

Groups of Crj, CD(SD) rats (12/group/sex) were administered the test substance at doses of 0, 40, 200 or 1000 mg/kg/day for 42 days (males) or for 14 days prior to mating to day 3 of lactation for females. Blue discolouration of faeces was observed at doses > 40 mg/kg/day and blue-green or greyish blue discolouration of the contents of the stomach and intestines were noted in a few animals at 200 mg/kg/day and in all animals at the high dose. The NOAEL for the parental generation was 1000 mg/kg/day and for the F1 generation was 1000 mg/kg/day maternal exposure. The test substance was negative for reproductive toxicity in parental animals (fertility, gestation, reproductive organ toxicity). No teratogenic effects were observed (OECD/SIDS, 1993).

7.5.11 Carcinogenicity

Mice were administered the test substance via the oral route for 8 months. No tumours were found (OECD/SIDS, 1993).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

Not tested

8.1.2. Bioaccumulation

Remarks

No bioaccumulation test data or comments were provided in the notification dossier. With a high water solubility and low affinity for octanol, the notified substance has a low potential to bioaccumulate in exposed organisms. Together with the high MW, the polymeric encapsulation of the notified substance and very limited potential for leaching indicates a low rate for release to the aquatic compartment.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

Not tested

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE

Notified polymer.

METHOD

OECD TG 202 *Daphnia* sp. Acute Immobilisation Test and Reproduction Test – static test.

Species

Daphnia magna

Exposure Period

48 hours

Auxiliary Solvent

Not stated.

Water Hardness

Not stated.

Analytical Monitoring

Nominal concentrations were also determined analytically, with minor losses within 48 h. Photoperiod: Light:dark 16:8, with transition periods. Due to losses, time-weighted mean concentrations were used.

Remarks - Method

Tests performed under Good Laboratory Practice. Range finding and definitive tests were performed. Test concentrations were nominally 0.10, 0.18, 0.32, 0.56, 1.0, 1.8, 3.2, 5.6 and 10 mg/L (actual at 48 hrs 0, 0.072, 0.126, 0.249, 0.408, 0.789, 1.41, 2.51, 4.46 and 8.07 mg/L. Temperature 20°C. Water and dissolved oxygen concentration were monitored with no treatment-related differences observed. The full report on the study was not provided.

RESULTS

EC50 (time-weighted mean)

6.9 mg/L at 48 hours (95% CI 6.3-7.6)

NOEC (time-weighted mean)

3.2 mg/L

Remarks - Results

Immobilisation numbers at 24 and 48 hours were not provided.

CONCLUSION

The test substance is toxic to freshwater waterfleas (*D. magna*)

TEST FACILITY

SafePharm Laboratories (1998)

8.2.3. Algal growth inhibition test

Not tested. Expected to be toxic to algae.

8.2.4. Inhibition of microbial activity

Not tested

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer will be imported as a 10% blend in polypropylene in solidified pellet form for use as a masterbatch for the plastics industry.

Environmental release is unlikely during importation, storage and transportation, and spillage during a transport accident the most likely reason for environmental release. Individual container capacity (20 kg multi-wall paper bags or 100 kg fibre drums), container specifications, the pelletised form of the imported product and very low water solubility of the polymer-encapsulated form would limit the extent of release if spilled.

Customers of the notifier will blend the notified polymer into various polypropylene and polyethylene plastic products such as packaging, storage containers, protective packaging, medical devices, blow moulding bottles, and thin-walled containers. Release from the plastics manufacturing facilities is anticipated to be limited given the colorant is in a pelletised form; however, spilled pellets are likely to be collected and recycled into further batches. Pellet residues in emptied containers (eg. 1% of the total annual import volume) are likely to be sent to landfill for disposal.

The majority of the notified polymer will eventually be sent to landfill for disposal or recycled at commercial recycling facilities. A small proportion of the plastic materials containing the notified polymer may occur as litter, with landfill disposal of collected wastes most likely. The use pattern would indicate that this disposal pattern would be widespread. The nature of the encapsulated substance would indicate a low potential for environmental release.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity test available indicate an EC50 for *Daphnia magna* of 6.9 mg/L (95% CI. 6.3-7.6). A predicted no effect concentration for aquatic organisms (PNEC_{aquatic}) of 0.007 mg/L (7 µg/L) has been derived by dividing this EC50 value by a safety factor of 1000, used to account for the availability of data for only one taxa, interspecies sensitivity, acute to chronic effects ratio and other adverse factors that may potentially arise in the environment if organisms are exposed to the substance. In the absence of ecotoxicity data for marine species, the freshwater PNEC has been adopted as a marine species PNEC. No sediment toxicity data were available for the notified polymer. No soil toxicity data are available for the notified substance or formulation. Environmental release to the aquatic and terrestrial compartment is unlikely to be significant based on the use pattern.

9.1.3. Environment – risk characterisation

The use pattern indicates that the notified polymer poses a very low risk to the aquatic environment due primarily to the limited potential for release to the aquatic environment and polymer-encapsulated solid form in which it would be imported and formulated. With an acute oral LD50 in rats of >5 g/kg bw, incidental ingestion of pellets by wildlife (eg. granivores) is unlikely to pose an unacceptable health risk. Following its useful life, the manufactured product containing the notified chemical is likely to be recycled or sent to landfill for disposal, with landfill the final disposal location. The notified substance is expected to be stable in the longterm in the landfill environment, eventually breaking down to simpler compounds of C, H, N, O and copper.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Exposure (mainly dermal) may occur intermittently to masterbatch pellets and finished plastic articles. The notified polymer is encapsulated at these stages and will not be bioavailable. In the intermediate stage when the masterbatch is liquid, it is in the moulding machine and the process is fully enclosed. Exposure to fumes is controlled by the use of local exhaust ventilation.

9.2.2. Public health – exposure assessment

Public exposure through the manufacturing process and via waste disposal is negligible. The public may come into contact with the plastic articles containing the notified polymer but the polymer will not be bioavailable.

9.2.3. Human health - effects assessment

The notified polymer was of low acute oral toxicity in rats and was a moderate skin irritant in rabbits. It was not mutagenic in bacteria.

A close analogue of the dye counter ion component of the notified polymer was of low acute oral toxicity in rats and rabbits. It was not a skin or eye irritant in rabbits and was not mutagenic in bacteria or in mouse lymphoma cells in vitro. It did not induce unscheduled DNA synthesis in rat hepatocytes in vitro, chromosomal aberrations in mammalian cells in vitro or cell transformation in mammalian cells. It was not reprotoxic or teratogenic in rats or mice at doses up to 1000 mg/kg/day and was not carcinogenic in mice up to 8 months of treatment. In repeated dose studies, no significant systemic toxicity was identified.

9.2.4. Occupational health and safety – risk characterisation

The notified polymer is introduced at less than 10% encapsulated in polypropylene. As such it is unlikely to be bioavailable at any point where contact is possible. Toxicity studies on the notified polymer or an analogue of the anion indicate only a potential for skin irritancy. Therefore, there is a low risk of adverse health effects to workers involved in transport, storage, plastic article manufacture or disposal.

9.2.5. Public health – risk characterisation

The public are likely to come into contact with the notified polymer only in the form of finished plastic articles. In this form the notified polymer is not bioavailable and the risk of adverse health effects 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*.

and

As a comparison only, the classification of the notified substance 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.

- Chronic Hazard Category 2: Toxic to Aquatic Life

The formulation containing the notified substance is not expected to be readily biodegradable and is toxic to aquatic organisms (ie. L(E)C50 1-10 mg/L). This system is not mandated in Australia and carries no legal status but is presented for information purposes.

10.2. Environmental risk assessment

On the basis of the reported use pattern, the notified polymer is not considered to pose an unacceptable 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 a [product containing the 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 a [product containing the 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

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

Disposal

- The notified substance will be a component of a polymerised polypropylene pellet or polypropylene or polyethylene plastic consumer product. It should be disposed of by recycling as plastic recyclable materials or sent to landfill for disposal in accordance with approved State or Territory waste management regulations.

Emergency procedures

- Spills/release of the notified polymer should be cleaned up and handled in accordance with procedures described in the Material Safety Data Sheet. Contain spill and do not allow spilled pellets to enter soils or waterways. Take up spilled pellets and place in to container for re-use or disposal.

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(1) of the Act; if
 - the notified polymer is to be imported in a form where it is not encapsulated in a masterbatchor
- (2) 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.

13. BIBLIOGRAPHY

Covance Laboratories (1998a) Acute Oral Toxicity Study of 10522-75 in Rats. Project No. 71200632. Covance Laboratories Inc, WI, USA (unpublished report submitted by notifier).

Covance Laboratories (1998b) Primary Dermal Irritation Study of 10599-53 in Rabbits. Project No. 80404880. Covance Laboratories Inc, WI, USA (unpublished report submitted by notifier).

Covance Laboratories (1998c) Mutagenicity Test with 10522-75 in the *Salmonella-Escherichia coli*/Mammalian Microsome Reverse Mutation Assay with a Confirmatory Assay. Project No. 19078-0-409OECD. Covance Laboratories Inc, VA, USA (unpublished report submitted by notifier).

European Commission (2000) IUCLID Dataset reported by the European Chemicals Industry in accordance with Council Regulation No. 793/93 on the Evaluation and Control of the Risks of Existing Substances. European Chemicals Bureau.

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Australian Government Publishing Service, Canberra.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

OECD/SIDS (1993) Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme.

SafePharm Laboratories (1998) 10522-75: Acute Toxicity to *Daphnia magna*. SPL No. 656/013. SafePharm Laboratories Limited, Derby UK (unpublished report submitted by notifier).

SafePharm Laboratories (2002) Experimental 12014-70: Chromosome Aberration Test in Human Lymphocytes in vitro. SPL Project No. 656/175. SafePharm Laboratories Limited, Derby UK (unpublished report submitted by notifier).

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.