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

**FULL PUBLIC REPORT**

**Mirapol FB2**

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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:	<a href="http://www.nicnas.gov.au">www.nicnas.gov.au</a>

**Director**

## **Chemicals Notification and Assessment**

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## **FULL PUBLIC REPORT**

<b>Mirapol FB2</b>
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### **1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Procter and Gamble Australia Pty Ltd (ABN: 91 008 396 245)  
320 Victoria Road  
RYDALMERE NSW 2116

NOTIFICATION CATEGORY

Limited: Polymer with NAMW  $\geq 1000$  (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical names

CAS Number

Molecular formula

Structural formula

Weight percentage and ingredients

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

Canada, USA

### **2. IDENTITY OF CHEMICAL**

MARKETING NAME(S)

Mirapol-FB2

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	10652
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Weight Average Molecular Weight (Mw)	29174
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Polydispersity Index (Mw/Mn)	2.74
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% of Low MW Species < 1000	<0.2
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% of Low MW Species < 500	<0.1
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## SPECTRAL DATA

ANALYTICAL METHOD	<sup>1</sup> H and <sup>13</sup> C NMR spectroscopy
Remarks	Spectroscopy undertaken with sample from Mirapol-FB2 Lot# MI1L1100859
	<sup>13</sup> C NMR Spectroscopy Peaks at 18.985, 43.732, 44.752, 65.483, 74.404, 176.258, and 179.672 ppm
	<sup>1</sup> H NMR Spectroscopy Peaks at 0.972, 0.989, 1.070, 2.541, 2.580, 2.642, 2.680, 2.767, 2.836, 3.391, 3.912, 4.630 ppm
TEST FACILITY	Rhodia (2003a)
ANALYTICAL METHOD	<sup>1</sup> H and <sup>13</sup> C NMR spectroscopy Lot SC-39-63
Remarks	Spectroscopy undertaken with sample from Mirapol-FB2 Lot #SC-39-63
	<sup>13</sup> C NMR Spectroscopy Peaks at 15.810, 18.924, 43.644, 44.700, 45.147, 55.865, 59.901, 64.262, 65.295, 65.450, 65.596, 69.962, 73.291, 74.302, 176.182, 176.802, 178.588 ppm
	<sup>1</sup> H NMR Spectroscopy Peaks at 1.1, 2.5, 2.6, 2.65, 2.7, 2.75, 2.8, 3.4, 3.5, 3.9, 4.25, 4.45, 4.55, 4.6, 4.75, 4.85 ppm
TEST FACILITY	Rhodia (2003b)
ANALYTICAL METHOD	Infrared spectroscopy
Remarks	Spectroscopy undertaken with sample from Mirapol-FB2 Lot# MI3100859
	Peaks at 624.9, 989.6, 1174.1, 1386.5, 1462.5, 1600.3, 1737.6, 2979.0, 3432.4 cm <sup>-1</sup>
TEST FACILITY	Rhodia (2003c)
ANALYTICAL METHOD	Infrared spectroscopy
Remarks	Spectroscopy undertaken with sample from Mirapol-FB2 Lot #SC-39-63
	Peaks at 619.5, 988.6, 1173.5, 1385.9, 1462.7, 1607.7, 1735.4, 2980.8, 3434.5 cm <sup>-1</sup>
TEST FACILITY	Rhodia (2003d)

## METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Infrared and NMR spectroscopy
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## 3. COMPOSITION

DEGREE OF PURITY  
35%

## HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

None

## NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (&gt;1% by weight)

None

## ADDITIVES/ADJUVANTS

<i>Chemical Name</i>	1,2,3-Propanetricarboxylic acid, 2-hydroxy-		
<i>CAS No.</i>	77-92-9	<i>Weight %</i>	10%
<i>Chemical Name</i>	3,5,7-Triaza-1-azoniatricyclo[3.3.1.1 <sup>3,7</sup> ]decane, 1-(3-chloro-2-propenyl)-, chloride		
<i>CAS No.</i>	4080-31-3	<i>Weight %</i>	<0.2%
<i>Chemical Name</i>	Carbonic acid, monosodium salt		
<i>CAS No.</i>	144-55-8	<i>Weight %</i>	<0.2%
<i>Chemical Name</i>	Water		
<i>CAS No.</i>	7732-18-5	<i>Weight %</i>	<62.4%

## DEGRADATION PRODUCTS

Under extreme heat conditions eg fire the product will burn and produce oxides of carbon and nitrogen.

## LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

The material is stable with respect to viscosity, solid, pH and molecular weight for at least a year under normal storage conditions.

#### 4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia. It will be imported as an ingredient of a finished consumer dishwashing liquid at concentration of 0.2%.

## 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>	2	2	2	2	2

## USE

The notified polymer will be used as a suds stabiliser in consumer dishwashing liquid. The notified polymer will be present at 0.2% in the dishwashing liquid formulation.

#### 5. PROCESS AND RELEASE INFORMATION

##### 5.1. Distribution, Transport and Storage

## PORT OF ENTRY

Sydney

## IDENTITY OF MANUFACTURER/RECIPIENTS

The product will be transported from the dockside by road to the Procter and Gamble warehouse in Arndell Park, NSW.

## TRANSPORTATION AND PACKAGING

The notified chemical will be imported as an ingredient in finished consumer product. It will be imported in 375 mL and 750 mL plastic bottles. No repackaging will occur. The bottles of product will be transported in cartons.

## 5.2. Operation Description

The notified chemical will be imported as an ingredient of a finished consumer dishwashing liquid.

The product will be transported from the dockside by road to a warehouse, where it will be stored. The product will then be transported, as required to various retail outlets such as supermarkets, pharmacies, and department/variety stores. The cartons containing the product will be unpacked and products placed on the shelves.

## 5.3. Occupational exposure

*Number and Category of Workers*

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Waterside and transport	50	8 hours/day	12 times/year
Warehouse	20-30	4 hours/day	100 times/year
Retail workers	10,000	1 hour/day	100 times/year

*Exposure Details*

Waterside and transport workers will transfer cartons containing the sealed finished product containing the notified chemical from the ships to truck. The cartons will be performed using cranes and forklifts. The product will then be transported to warehouse facilities, at which storage and distribution will occur. Transport and warehouse workers will manually lift the cartons between the truck and storage areas. Once the product is distributed to retail sites, the product will unpack the cartons and place the products onto shelves.

Exposure will only occur in the event of an accident, when the packaging is breached.

## 5.4. Release

RELEASE OF CHEMICAL AT SITE

No release is expected as the notified polymer will not be manufactured in Australia.

RELEASE OF CHEMICAL FROM USE

As the notified polymer will be used as an ingredient in household dishwashing liquid, it is expected that almost all of the notified polymer will end up in the sewer. The applicant indicates that removal of the notified chemical in activated sludge treatment plants is expected to exceed 90%. A small amount of the finished product (approximately 20 kg/year) of the notified polymer will remain in the plastic bottles, which will be disposed of to landfill via household garbage collection. The polyethylene bottle can be recycled.

## 5.5. Disposal

Most the notified polymer will ultimately be disposed of to sewer from use some will go to landfill as container residue.

## 5.6. Public exposure

The public will be exposed to notified polymer during the use of the dishwashing liquid. The concentration of the notified polymer in the dishwashing liquid will be 0.2% and further dilution will occur on adding the liquid to dish washing water. Exposure to the notified polymer from washed dishes is not expected to occur as the chemical is expected to be rinsed from the washed articles prior to drying.

The applicant has suggested that exposure may occur via the consumption of drinking water containing the notified polymer following the use and disposal of the dishwashing detergent.

The public are unlikely to be exposed to the notified polymer during transport, storage, manufacture, and commercial use, except in the accident of an accidental spillage.

## 6. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance at 20°C and 101.3 kPa** The notified polymer is clear yellow solution

**Boiling Point** 100.7°C at 101.3 kPa

METHOD In house method  
 Remarks Mirapol-FB2 is a solution containing about 35% solids and 65% water. Mirapol-FB2 (lot #MI1L100859) was used to determine the boiling point. The boiling point was similar to that of water.  
 TEST FACILITY Rhodia (2003e)

**Density** 1000-1100 kg/m<sup>3</sup>

Remarks For Mirapol-FB2, test report not available.

**Vapour Pressure** Approx 3.6 kPa at 25°C .

METHOD In house method  
 Remarks Mirapol-FB2 is a solution containing about 35% solids and 65% water. Mirapol-FB2 (lot #MI1L100859) was used to determine the vapour pressure. The sample followed the vapour pressure for water. The vapour pressure of the water appears not to have been disturbed by the non-volatile solids present in the sample.  
 TEST FACILITY Rhodia (2003e)

**Water Solubility** 426-771 g/L at pH 7, at 20°C

METHOD Modified shake flask method.  
 Remarks Triplicate test samples were prepared in pH 1, 7 and 10 by adding approximately 5 g of test substance to 40 mL culture tubes. The temperature of each solution was measured. Observations of each test samples were then made to determine if all of the test substance had dissolved. The sample solutions were then placed on a shaker in a 20°C environmental chamber for at least 2 h to confirm that the test substance was completely dissolved at that concentration level. The solubility of the test substance was determined to be 293-363 and 426-771 mg/mL at pH 1 and 7. For pH 10, the solubility could not be determined due to the formation of an emulsion.  
 TEST FACILITY The notified polymer is readily soluble in water (Mensink et al 1995). ABC Laboratories Inc. (2001a)

### Hydrolysis as a Function of pH

METHOD	OECD TG 111 Hydrolysis as a Function of pH			
<i>pH</i>	% hydrolysis at 20 °C for 5 days		% hydrolysis at 50 °C for 5 days	
	% DMEA	%propanediol	% DMEA	%propanediol
4a	1.5	0		6.3
4b	-	0		6.4
4c	0.4	0		7.9
7a	2.1	0.8	5.8	5.4
7b	3.3	1.1	3.1	7.3
7c	4.5	2.5	1.42	4.9
9a	11.5	6.8	21.5	11.8
9b	-	2.3	0.7	4.3
9c	11.6	6.7	21.3	9.1

a, b, c = replicates

Remarks Test solutions were stored at 20 and 50°C for five days in the dark. After this period, the expected hydrolysis products (N,N dimethylethanolamine (DMEA) and propanediol) were analysed by gas chromatography. The amount of hydrolysis



products appear to increase with pH and temperature. However, even at pH 9 the half-life at 20°C appears to be in excess of 20 days.

TEST FACILITY Euro-analytical microbiology Technology & Research Department (2002)

**Partition Coefficient (n-octanol/water)**  $\log K_{ow} \cong -4.8$

METHOD New substances notification regulations of the Canadian Environmental Protection Act (CEPA)

Remarks Triplicate test samples were prepared at the nominal concentrations of 10, 100, and 1000 µg/mL by adding approximately 2.5, 25 and 250 mg of the notified polymer, respectively, in 250 mL of octanol. A control sample was prepared by adding 250 mL of octanol in a flask. The flasks were capped and placed on orbital shakers in the environmental chamber for 72 h. Observations of the test samples were made after 3, 6, 24, 48 and 72 h of shaking. It was observed that particulate matter was present in all test samples at each timepoint at 19.6°C. Therefore, the solubility of the notified polymer in octanol was visually determined to be <10 µg/mL. As the substance is at least 70,000x more soluble in water than octanol, Kow is approximately  $1/70,000 = 1.4 \times 10^{-5}$  and  $\log Kow = -4.8$ .

TEST FACILITY ABC Laboratories, Inc. (2001b)

**Adsorption/Desorption** Not determined

Remarks The test was not conducted. The applicant has indicated that the resultant biodegradation products of the polymer are likely to include polyacrylates, short chain ethanolamines and propanediol following release to a sewage treatment plant. The resulting polycarboxylates adsorb readily to sewage and are precipitated during sewage treatment. The removal of the notified polymer in wastewater treatment plants is predicted to be >90% based on CAS removal data from the structurally related poly(dimethylaminoethyl methacrylate) homopolymer. Removal would be attributed to sorptive process onto activated sludge

**Dissociation Constant**  $pK_{a1} = 5.9$  and  $pK_{a2} = 9.3-9.7$

METHOD OECD TG 112 Dissociation Constants in Water.

Remarks Mirapol FB2 is a water solution of the polymer containing 35% solids and 65% water. The pKa values for two samples were measured by potentiometric titration. Two end points were observed for each sample. The first end point was at pH 5.9 and the second end-point was between 9.3-9.7. The first corresponds to citric acid, and the second to the amine.

TEST FACILITY Rhodia Inc. (2003f)

**Particle Size**

Remarks Not applicable the notified polymer is in an aqueous solution.

**Flash Point**

Remarks Not determined  
Aqueous solution of polymer is not flammable.

**Flammability Limits**

Remarks Not determined  
The notified polymer is in an aqueous solution

**Autoignition Temperature**

Remarks Not determined  
The aqueous solution containing polymer will not autoignite.

**Explosive Properties**

Remarks Not sensitive to mechanical impact. The aqueous solution has no explosive properties.

**Reactivity**

Remarks	Sample is stable under normal conditions and has no oxidising properties. The sample is an inert polymer solid dissolved in water. Hazardous polymerisation will not occur.
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## 7. TOXICOLOGICAL INVESTIGATIONS

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity

### 7.1. Acute toxicity – oral

TEST SUBSTANCE	SS0953.01 (27% active ingredient)
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Sprague-Dawley
Vehicle	None
Remarks - Method	

#### RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5 animal/sex	7407	0/10

LD50	>7407 mg/kg bw
Signs of Toxicity	The only notable clinical sign of toxicity observed during the study was dark material around the nose of one male on day 3 of the observation period. Body weight gain was observed in all animals during the observation period.
Effects in Organs	At necroscopy, a thin area of the diaphragm was observed in two males. Constriction of the spleen was observed in one male. Thoracic adhesion was observed in one female.
Remarks - Results	The LD <sub>50</sub> for the active ingredient is > 2000 mg/kg bw.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
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TEST FACILITY	SLI (2001a)
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## 7.2. Results of analogue toxicity testing

The applicant has provided the results of toxicity testing carried out on several structurally and size related homopolymers and copolymers (Table One). These analogues are used widely in personal care products or detergents.

Table One

Analogue	Molecular Weight	Identity
A	>100000	Dimethyl amino ethyl methacrylate (DMAEMA) homopolymer
B1	<100000	Vinylpyrrolidone & (DMAEMA) copolymer
B2	>100000	Vinylpyrrolidone & (DMAEMA) copolymer

Acute oral toxicity data are available for analogues A, B1, and B2. All analogues had LD<sub>50</sub> >2000 mg/kg bw and thus have low acute oral toxicity. No mortality or clinical signs of toxicity were observed for any of the analogues.

Primary skin irritation data are available for analogues A, B1, and B2. Analogue A caused slight irritation (Primary Irritation Index <1); the remaining analogues did not cause skin irritation under the test conditions.

Primary eye irritation data were provided for analogues A, B1, and B2. Analogues A, B1, and B2 did not cause eye irritation.

Data on skin sensitisation potential of analogues A, B1, and B2, were provided. Commercial samples containing the analogues in the tests and would be expected to contain low level residual monomers similar to the levels present in the notified polymer. There was no evidence of reactions indicative of skin sensitisation to the analogues under the conditions of the test

Water-soluble compounds such as notified polymer will readily dissolve in nasal mucous and it is expected that these will be eliminated before reaching the respiratory tract.

Analogue B2 was tested in 13-week inhalation study, as a component of hair conditioner formulation at concentration of 1.5%. Groups of 12 hamster and 12 rats were exposed in a dynamic chamber for 4 hours per day, 5 days per week for 13 weeks to a mean product concentration of 9.9 mg/m<sup>3</sup>, the final effective concentration of analogue B2 was approximately 0.03 mg/m<sup>3</sup>. There were no deaths or adverse effect in either species. There were no gross histopathologic observations in the lungs or other tissues compared to control animals.

The available analogue data demonstrate a lack of mutagenicity. There was no evidence of point mutation induction for analogue A, in the Ames test. The ability for analogue A to induce chromosomal aberrations was tested *in vitro* using CHL cells. Analogue A did not induce a significant increase in numerical or structural chromosome aberrations *in vitro*.

## 8. ENVIRONMENT

### 8.1. Environmental fate

#### 8.1.1. Biodegradability

No test results or report has been provided. The applicant has indicated that following release to a sewage treatment plant, the notified polymer is expected to undergo primary biodegradation by the biochemical hydrolysis of the ester groups pendant to the acrylate/methacrylate backbone. The degradation products are likely to include polyacrylates, short chain ethanolamines and propanediol. The latter short chain organics are expected to mineralise completely while any further biodegradation of the polycarboxylate would occur very slowly. The notified polymer is not expected to be inherently biodegradable under aerobic nor anaerobic conditions, consistent with literature data on structurally analogous polymers.

#### 8.1.2. Bioaccumulation

Given the high water solubility and the high molecular weight, the notified polymer is unlikely to bioaccumulate.

### 8.2. Ecotoxicological investigations

#### 8.2.1. Acute toxicity to fish

TEST SUBSTANCE	SS0953.01 (27% active ingredient)
METHOD	OECD TG 203, EC Directive 92/69/EEC C.1 and US EPA TSCA Environmental Effects Testing Guideline 797.1400
Species	Fathead minnow ( <i>Pimephales promelas</i> )
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	160-166 mg CaCO <sub>3</sub> /L
Analytical Monitoring	None
Remarks – Method	Based on the range finding tests, nominal concentrations of 1.3, 2.5, 5.0, 10 and 20 mg/L were used for the definitive flow-through test. Two glass aquaria per control and treatments were used. Each test chamber contained 10 fish for a total of 20 fish per control and treatments. Observations for mortality and sublethal responses were made at approximately 3, 24, 48, 72 and 96 h after test initiation. Water quality parameters of temperature, dissolved oxygen and pH were measured throughout the test and were within acceptable limits.

#### RESULTS

Concentration mg/L Nominal	Number of Fish in duplicate	Number Dead				
		3 h	24 h	48 h	72 h	96 h
1.3	10, 10	0, 0	0, 0	0, 0	0, 0	0, 0
2.5	10, 10	0, 0	0, 0	0, 0	0, 0	0, 0
5.0	10, 10	0, 0	0, 0	0, 0	2, 0	2, 0
10	10, 10	0, 0	0, 0	5, 9	7, 10	7, 10
20	10, 10	0, 0	1, 0	9, 10	9, 10	9, 10

LC50	7.7 mg/L at 96 hours (CL 6.4 and 9.3 mg/L)
NOEC (or LOEC)	2.5 mg/L at 96 hours.
Remarks – Results	All results were expressed as nominal concentrations. The control and all treatments were murky in appearance on day 0 and for the remainder of the test with particulate matter on bottom of the test chambers. After 96 h of exposure, 10, 85 and 95% mortality was observed in the 5, 10 and 20 mg/L treatments, respectively. No mortality was observed in the control or treatments $\leq 2.5$ mg/L.

#### CONCLUSION

The notified polymer is moderately harmful to fathead minnow.

TEST FACILITY

ABC Laboratories Inc. (2001c)

**8.2.2. Acute/chronic toxicity to aquatic invertebrates**

TEST SUBSTANCE

SS0953.01 (27% active ingredient)

METHOD

OECD TG 202 *Daphnia* sp. Acute Immobilisation Test and Reproduction TestEC Directive 92/69/EEC C.2 Acute Toxicity for *Daphnia*

US EPA TSCA guideline 797.1300 (3)

Species

*Daphnia magna*

Exposure Period

48 h

Auxiliary Solvent

None

Water Hardness

138-140mg CaCO<sub>3</sub>/L

Analytical Monitoring

None

Remarks - Method

Based on the range finding results, nominal concentrations of 6.5, 13, 25, 50 and 100 mg/L were used for the definitive flow-through test. 1 L glass chambers were used for exposure chambers. Illumination was provided by fluorescent bulbs of a 16 h light:8 h dark photoperiod. Ten daphnids were transferred to each of the two replicate beakers in each treatment resulting in a total of 20 daphnids per treatment. Observations for immobilisation and sublethal responses were made at test initiation and once every 24 h after test initiation. Water quality parameters of temperature, dissolved oxygen and pH were measured throughout the test and were within acceptable limits.

## RESULTS

Concentration mg/L	Number of <i>D. magna</i> in duplicate	Number Immobilised		
		0 h	24 h	48 h
Nominal				
6.5	10, 10	0, 0	0, 0	0, 0
13	10, 10	0, 0	0, 0	0, 1
25	10, 10	0, 0	0, 0	1, 2
50	10, 10	0, 0	0, 0	0, 5
100	10, 10	0, 0	0, 0	8, 4

LC50

86 mg/L at 48 hours (CI: 59-170 mg/L)

NOEC (or LOEC)

13 mg/L at 48 hours

Remarks - Results

All results are expressed as nominal concentrations. The control and all treatments were murky in appearance on day 0 and for the remainder of the test with particulate matter on bottom of the test chambers. After 48 h of exposure, 20, 50 and 80% mortality were observed in the 25, 50 and 100 mg/L treatments, respectively. No mortality was observed in the control (except one at 48 h) or treatments ≤6.5 mg/L.

CONCLUSION

The notified polymer is harmful to fathead minnow

TEST FACILITY

ABC Laboratories Inc. (2001d)

### 8.2.3. Algal growth inhibition test

TEST SUBSTANCE	SS0953.01 (27% active ingredient)
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test. US EPA TSCA guideline 797.1050
Species	Unicellular green alga, <i>Scenedesmus subspicatus</i>
Exposure Period	96 hours
Nominal Concentration Range	0.0, 0.85, 1.70, 3.3, 6.5, 13, 25, 50 and 100 mg/L
Auxiliary Solvent	None
Water Hardness	130-160 mg CaCO <sub>3</sub> /L
Analytical Monitoring	None
Remarks - Method	The test medium was a freshwater algal nutrient medium. The microbial activity of the test medium used during the definitive test was determined using a bacterial plate count method. Based on the results of the unsuccessful definitive attempt, nominal concentrations of 0.85, 1.7, 3.3, 6.5, 13, 25, 50 and 100 mg/L were used for the definitive test. 4 replicates were used for the positive control, natural surface water control and each test concentrations. The flasks were incubated at 24°C for 96 h in an environmental chamber. The definitive test was conducted for 96 h when the algae were inoculated to the test chambers. Cell counts were made on three of the four replicates using a light microscope and a hemacytometer at 0 h for each positive and natural surface water control replicate, and on each control and treatment replicate once every 24 h thereafter until test termination. Water quality parameters of temperature and pH were measured throughout the test and were within acceptable limits.

### RESULTS

Biomass		Growth	
<i>E<sub>b</sub></i> C50 (mg/L) at 72 h	NOEC (mg/L)	<i>E<sub>r</sub></i> C50 (mg/L) at 72 h	NOEC (mg/L)
28 (CI: 23-32 mg/L)	1.7	420 (CI: 240-610 mg/L)	1.7

Remarks - Results	The positive control solution turned from clear to green after 48 h of exposure. The natural surface water control and all treatment solutions were murky in appearance at test initiation. For the remainder of the exposure, the natural surface water control was murky in appearance with particulate matter. After 48 h of exposure, the natural surface water control and all treatments ≤50 mg/L were green in colour. After 72 h the 100 mg/L treatment was also green in colour, however, algal clumps were also observed. The green colour was resulted from the increase in algal biomass while the particulate matter observed appeared to be related to the suspended solids present in the test medium.
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CONCLUSION	The notified polymer is considered to be slightly toxic to unicellular green algae
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TEST FACILITY	ABC Laboratories Inc. (2001e)
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## 9. RISK ASSESSMENT

### 9.1. Environment

#### 9.1.1. Environment – exposure assessment

Based on the release in Section 5.4, virtually all of the notified polymer will be discharged to sewer. Using a worst-case scenario, it has been assumed that all 2000 kg of the notified polymer used is discharged through sewerage systems throughout Australia and none is attenuated within these systems. Assuming a national population of 19,500,000 and that each person contributes an average 200 L/day to overall sewage flows and all partitioned into water, the predicted concentration in sewage effluent on a nationwide basis is estimated as  $(2000 \text{ kg} / (200 \text{ L} \times 365 \text{ days} \times 19,500,000 \text{ persons})) = 1.4 \text{ } \mu\text{g/L}$ .

Based on the respective dilution factors of 1 and 10 for inland and ocean discharges of effluents, the PECs of the notified polymer in freshwater and marine water may approximate 1.4 or 0.14  $\mu\text{g/L}$ .

In the absence of vapour pressure data for the notified polymer, DEH was not able to perform calculations for partitioning and losses in sewage treatment plants (European Commission, 1996) based on the SIMPLETREAT model. However, based on the information for structural analogues of the notified polymer, it may be assumed that 90% of the notified polymer will be adsorbed to the sludge and the remaining 10% may stay in solution, passing through the STP.

Assuming 2000 kg of the notified polymer would be discharged to sewer per year and based on the assumption that 0.1 tonnes of biosolids is generated for each ML of STP effluent, this may result in an average biosolid concentration of 12.6 mg/kg  $[(0.9 \times 2000 \text{ kg}) \times 1000 / (1.42 \times 10^6 \text{ ML} \times 0.1 \times 1000 \text{ kg})]$  assuming 90% attenuation in sludge during the STP process. Biosolids are applied to agricultural soils, with an average rate of 10 tonnes/ha/year. Assuming a bulk density of 1000 kg/m<sup>3</sup> and a soil mixing zone of 0.1 m, the concentration of the notified polymer may approximate 1.26 mg/kg in the applied soil, assuming accumulation of the notified polymer in soil for 10 years under repeated biosolids application. Thus an estimated worst case PEC for the notified polymer in soils following application of biosolids would be 1.26 mg/kg.

The effluent re-use (eg irrigation purposes) concentration of the notified chemical may potentially approximate 1.4  $\mu\text{g/L}$ , assuming no attenuation during the STP process. STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m<sup>2</sup>/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m<sup>3</sup>). Using these assumptions, irrigation with a concentration of 1.4  $\mu\text{g/L}$  may potentially result in a soil concentration of approximately  $1.4 \times 10^{-1} \text{ mg/kg}$  assuming accumulation of the notified chemical in soil for 10 years under repeated irrigation. Thus, 1.4 mg/kg is an estimated worst case PEC for the notified chemical in soils following effluent irrigation.

#### Fate

Following release to sewer, the notified polymer is expected to largely move to sludge where abiotic or slow biotic processes are largely responsible for the degradation of the notified polymer. In view of its high water solubility and high molecular weight, the bioaccumulation potential is considered to be low (Connell 1990). Based on literature data on structural analogues, leaching in landfill is unlikely to occur as it is predicted that the notified polymer will form complexes with humic acid as well as other soil matrix components.

#### 9.1.2. Environment – effects assessment

In summary the aquatic toxicity indicate:

Fathead minnow ( <i>Pimephales promelas</i> ): 96 h LC50	7.7 mg/L
<i>Daphnia magna</i> : 48 h EC50	86 mg/L
Unicellular Green alga, <i>Scenedesmus suspicatus</i> : E <sub>b</sub> C50	28 mg/L

Using the lowest 96 h LC50 of 7.7 mg/L for fathead minnow, a predicted no effect



concentration (PNEC) of 77 µg/L has been derived by dividing the LC<sub>50</sub> value by a safety factor of 100 since toxicity data are available for three trophic levels.

#### 9.1.3. Environment – risk characterisation

On the basis of its low volume use (2000 kg/year) and the nationwide diffuse use of the notified polymer, it is not considered to pose an unacceptable risk to the health of the aquatic life. The worst case PEC/PNEC ratio for the aquatic environment assuming nationwide use is (1.4/77) 0.018 and (0.14/77) 0.0018 for fresh water and marine water, respectively. These values are significantly less than 1, further indicating no immediate concern to the aquatic compartment. The PEC/PNEC will be further reduced by the adsorption to sludge.

Leaching in landfill is unlikely to occur as it is predicted that the notified polymer will form complexes with humic acid as well as other soil matrix components with further possibility of abiotic or slow biotic processes largely responsible for the degradation of the notified polymer.

### 9.2. Human health

#### 9.2.1. Occupational health and safety – exposure assessment

The notified polymer will be imported as an ingredient of a finished household dishwashing liquid. The notified polymer will be present at a concentration of 0.2% in the product. No reformulation or repackaging of the finished product will occur. Occupational exposure to notified polymer will only occur in the case of an accident, in which the packaging is breached.

#### 9.2.2. Public health – exposure assessment

Direct public exposure during transport and storage is unlikely, and therefore, public exposure will be restricted to those persons using the dishwashing liquid. The concentration of the notified polymer in the dishwashing liquid will be 0.2%. It is expected the dishwashing product will be used in two ways; firstly diluted with water in the sink and secondly by application directly on to sponge/washing clothes. The applicant has suggested that on average the product will be used approximately once a day. Persons using the final product will be dermally exposed to the notified polymer primarily through the hands and the lower arms. Accidental direct ocular exposure and ingestion of the notified polymer may also occur.

### ANTICIPATED HUMAN EXPOSURE TO THE NOTIFIED POLYMER

#### A) Dermal exposure via the use of dishwashing liquid

- a) Via washing dishes in the sink; and
- b) Via washing by direct application to a sponge or dishcloth.

#### B) Ingestion of drinking water containing the notified polymer after use and disposal of the dishwashing liquid.

#### C) Ingestion of residue of the dishwashing liquid after dishwashing in sink without rinsing

A)

General equation:

$$= \frac{(\text{task/day}) \times (\text{solution volume}) \times (\% \text{ absorption}) \times (\text{level substance}) \times (\text{task concentration})}{\text{body weight}}$$

Average daily product use (dish washing in sink) = 1.1/day

Average daily product use (dish washing by hand) = 1.1/day

Thickness of wash solution on skin = 0.0024 cm

Surface area exposed during dish washing in sink = 1680 cm<sup>2</sup>

Surface area exposed during dish washing by hand = 720 cm<sup>2</sup>

Assumed dermal absorption = 10%

Assumed concentration of notified polymer in finished product = 0.2%

Use concentration for dish washing liquid in sink (task concentration) = 1.3 mg/cm<sup>3</sup>  
 Use concentration for dish washing liquid by hand (task concentration) = 50 mg/cm<sup>3</sup>  
 Average adult body weight 71.8 kg  
 Solution volume (dish washing in sink) = 4.032 cm<sup>3</sup>  
 Solution volume (dish washing by hand) = 1.728 cm<sup>3</sup>  
 Solution volume = volume if the solution on the skin.  
 = (thickness of wash solution on the skin) x (surface area exposed)

For washing dishes in the sink

$$\begin{aligned}
 &= \frac{(\text{task/day}) \times (\text{solution volume}) \times (\% \text{ absorption}) \times (\text{level substance}) \times (\text{task concentration})}{\text{body weight}} \\
 &= \frac{(1.1) \times (4.032 \text{ cm}^3) \times (10\%) \times (0.2\%) \times (1.3 \text{ mg/cm}^3)}{71.8 \text{ kg}} \\
 &= 1.6 \times 10^{-5} \text{ mg/kg bw/day}
 \end{aligned}$$

For washing dishes via direct application to sponge/dishcloth

$$\begin{aligned}
 &= \frac{(\text{task/day}) \times (\text{solution volume}) \times (\% \text{ absorption}) \times (\text{level substance}) \times (\text{task concentration})}{\text{body weight}} \\
 &= \frac{(1.1) \times (1.728 \text{ cm}^3) \times (10\%) \times (0.2\%) \times (50 \text{ mg/cm}^3)}{71.8 \text{ kg}} \\
 &= 2.64 \times 10^{-4} \text{ mg/kg bw/day}
 \end{aligned}$$

B)

Oral exposure via the consumption of drinking water containing the notified polymer following the use and disposal of the dishwashing liquid was calculated to be  $3.0 \times 10^{-7}$  mg/kg bw/day. The following exposure parameters were used:  
 High end surface water concentration of  $1.55 \times 10^{-2}$  µg/L,  
 Drinking water intake of 1.4L/day,  
 Absorption 100% was assumed  
 Adult body weight of 71.8kg.

C)

Oral exposure via the ingestion of residue of the dishwashing liquid if no rinsing occurs following washing in sink  
 Exposure parameters:  
 Absorption 100% was assumed  
 Adult body weight = 71.8kg  
 Estimated volume remaining on articles = 0.5mL  
 Use concentration for dish washing liquid in sink (task concentration) = 1.3 mg/mL  
 Level substance = 0.2%

$$\begin{aligned}
 &= \frac{(\% \text{ absorption}) \times (\text{level substance}) \times (\text{task concentration}) \times (\text{est. vol. remaining on article})}{\text{body weight}} \\
 &= \frac{(100\%) \times (0.2\%) \times (1.3 \text{ mg/mL}) \times (0.5 \text{ mL})}{71.8} \\
 &= 1.81 \times 10^{-5} \text{ mg/kg bw/day}
 \end{aligned}$$

### 9.2.3. Human health - effects assessment

Limited toxicological testing has been carried out on the notified polymer. The notified polymer was found to have low acute oral toxicity. Due to its large molecular weight, the notified

polymer is not expected to be absorbed and cause systemic toxicity. The applicant has stated that the notified polymer was found to be non mutagenic in a bacterial reversion mutation study. The study was not provided, as the English translation was not available.

The analogue toxicity data indicates that the notified polymer is not likely to cause eye irritation, and skin sensitisation. The analogue data suggests that the notified polymer may cause slight skin irritation. Overall, the analogue data demonstrates that the notified polymer is not likely to be mutagenic. The results of a repeated dose inhalation study using an analogue indicates that the notified polymer, if inhaled, as component of a product is not likely to cause adverse effects.

The applicant has stated that the use of alternative counterions is not expected to alter the hazard properties of the notified polymer.

Based on the available data the notified chemical is not classified as hazardous under the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC, 1999).

#### **9.2.4. Occupational health and safety – risk characterisation**

No manufacture, reformulation or repackaging will occur in Australia. The notified polymer will be imported as component of a finished product at a low concentration (0.2%). Exposure to the notified polymer will only occur in the case of an accident when packaging is breached. Thus occupational health and safety risk will be minimal.

#### **9.2.5. Public health – risk characterisation**

The primary source of exposure to the notified polymer will be by dermal exposure. Other routes of accidental or incidental exposure will be ocular or oral exposure. These exposures are expected to be low and infrequent. The notified polymer has low acute oral toxicity and its large size and low concentrations in the finished product are unlikely to cause any observable toxicity. Products containing the notified polymer are expected to be emetic or cause transient nausea and diarrhoea. These effects are attributable to the other chemicals within the product matrix.

Based on the analogue data the notified polymer may cause slight skin irritation but these hazards are likely to be offset by the low concentration of the notified polymer in dishwashing liquid. The dishwashing liquid containing the notified polymer may if splashed into the eye, cause mild transient stinging or redness. Again these effects are likely to be due to other chemicals in the products.

Based on the toxicity data provided for the notified polymer and analogues, and current exposure estimates, overall, the notified polymer poses a low public health regulatory concern.

## **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

The notified polymer can not be classified using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) as testing has only been carried out to a limited dose at 2000 mg/kg bw. 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 PEC/PNEC ratio:

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

## 10.3. Human health risk assessment

### 10.3.1. Occupational health and safety

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

### 10.3.2. Public health

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

## 11. MATERIAL SAFETY DATA SHEET

### 11.1. Material Safety Data Sheet

The MSDS of the products containing the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

It is noted that the ecotoxicity data in the MSDS are different from those in this report. The notifier should correct the ecotoxicity data in the MSDS accordingly.

### 11.2. Label

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

## 12. RECOMMENDATIONS

### CONTROL MEASURES

#### Occupational Health and Safety

- 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 to landfill.

#### Emergency procedures

- Spills/release of the notified chemical should be recovered as much as possible. Absorb non-recoverable liquid with sand or inert absorbent. Wash contaminated area with large amount 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:

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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