File No: LTD/1200

1 November 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Mirapol Surf S500

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Director
NICNAS

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Polymer in Mirapol Surf S500

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Rhodia Australia Pty Ltd (ABN 24 050 029 000) of 352 Ferntree Gully Road, Notting Hill VIC, 3168

NOTIFICATION CATEGORY
Limited: Polymer with NAMW > 1000

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

Chemical Identity
Spectral data
Polymer constituents and residual monomers
Identity of impurities
Additives/adjuvants
Estimated import volume
Detailed use
Formulation details
Identity of recipient

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 2004

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
The notified polymer is imported as an ingredient of Mirapol Surf S500.

METHODS OF DETECTION AND DETERMINATION

METHOD	Infrared (IR) Spectroscopy and Gel Permeation Chromatography (GPC)
Remarks	Spectra provided

3. COMPOSITION

DEGREE OF PURITY
>99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
All residual monomers and hazardous impurities are present below the relevant cut-offs for classification of the notified polymer as a hazardous substance.

DEGRADATION PRODUCTS
The notified polymer is expected to be stable under normal conditions of use and storage. On combustion or on thermal decomposition (pyrolysis), oxides of carbon, sulfur and nitrogen may be released.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The residual monomers are present with the notified polymer in solution and therefore may be released during use. The residual monomer content is very low.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as an ingredient (< 10%) in Mirapol Surf S500.

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

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

USE
The notified polymer will be used as an ingredient in a hard surface cleaner, such as a toilet bowel cleaner.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

IDENTITY OF RECIPIENTS
The hard surface cleaner formulation will occur at a site in New South Wales. Once formulated the hard surface cleaner will be distributed to retail outlets throughout Australia.

TRANSPORTATION AND PACKAGING
Mirapol Surf S500 containing the notified polymer will be imported and stored in 205 L metal drums and will be transported by road direct from the dockyard to the customer's warehouse in NSW for storage prior to reformulation into the end use product. It is envisaged that up to six shipments will be made per year. The formulated hard surface cleaner will initially be packaged in 500 mL screw-top plastic bottles but packsize may vary (typically up to 1 L) if the notified polymer is used in other hard surface cleaner products.

5.2. Operation description

Hard surface cleaner formulation and supply
During reformulation, the 205 L drums containing < 10% notified polymer will be taken from the warehouse to the blending room by forklift. The drum opening will be unscrewed and a dip tube will be inserted into the drum and the required amount of the polymer will be added to an enclosed 10,000 L stainless steel blending vessel using a diaphragm pump. The transfer line will be flushed with clean water at the end of the transfer operation.

Once blending has been completed, a sample containing < 1% notified polymer will be removed from a port hole in the blending tank and taken to the laboratory for analysis.

The finished product containing < 1% notified polymer will be pumped to the automated and enclosed filling line. The product will be filled into 500 mL plastic bottles using a multi-head filling machine. The screw caps are inserted onto the bottles within the filling machine. The closed bottles are then transferred to the packing area on a stainless steel conveyor. Workers will transfer the bottles into cardboard cartons. The cartons will be sealed by a packaging machine.

Maintenance workers will only be required during a breakdown or during routine maintenance. Maintenance work will only be conducted after the line has been flushed out.

The finished and packaged end use product will be transported to retail distribution centres. From there

it will be transported and stored in the supermarket warehouses. Supermarket workers will open the cartons, remove the plastic bottles and stack them on the supermarket shelves.

End use
There is potential for the formulated cleaning products (containing no more than 1% notified polymer) to be used occupationally.

Cleaning products are generally applied with a cloth or sponge, by mop or brush or by spray followed by wiping. Toilet bowl cleaners are usually applied directly from the bottle

In some cases, the cleaning product will be diluted with water prior to application. The dilution factor, which is often on the label, depends on the type of surface to be cleaned, the soil loading, and the type and method of application.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport to customer warehouse	2	2	6
Production mixer	1	2	40
Filling line operators	5	8	40
QC	2	0.5	40
Maintenance	2	2	5
Transport to supermarket warehouse	10	2	52
Supermarket workers	Approx. 5000	8	300

Exposure Details
Import, transport and distribution
During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached. Transport and warehouse workers will wear overalls and safety boots. In addition, warehouse workers will wear safety glasses and a hardhat.

Hard surface cleaner formulation and supply
The production mixer will open the drums and connect/disconnect the pumping equipment. This worker will also operate the blending vessel. Dermal and possibly ocular exposure to the notified polymer at a concentration of < 10% could occur from accidental spills or splashes and from contact with contaminated pumping equipment. This worker will wear protective overall and a rubber apron, safety boots, elbow length impervious gloves, safety glasses and a hardhat.

As maintenance work will only be conducted after the line has been flushed out, these workers are not expected to be exposed to the notified polymer.

QC staff may be exposed to the notified polymer at a concentration of < 1% during sampling and analysis. Workers will wear a lab coat, safety boots and safety glasses.

Filling line workers will only be exposed to formulated product where the notified polymer is in a diluted form (< 1% concentration). Since the filling line is automated and the filling machine is enclosed, these workers are only likely to come into contact with accidentally spilt material or from damaged plastic bottles.

Supermarket workers will only be exposed to the notified polymer at a concentration of < 1% in the event of a leak from damaged containers. The likely route of exposure will be dermal.

End use
Exposure to no more than 1% of the notified polymer could occur during final application of the cleaning products or during their addition to water if dilution is required. The main route of exposure

is expected to be dermal, although ocular exposure to splashes is possible and inhalation of aerosols could occur when using a spray-on pump. The level of exposure will vary depending on the method of application and work practices employed to minimise splashes and spills. Workers will usually wear rubber gloves.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Reformulation

The notified polymer will be imported as an aqueous solution and will be reformulated locally into a consumer end use product. During reformulation release to the environment could occur as a result of:

- Accidental spills (17.5 kg/year)
- Residues in empty 205 L drums (25 kg/year)
- Cleaning of blending equipment and transfer lines (25 kg/year)
- Damaged end use bottles (25 kg/year)

Empty drums are rinsed and sent to drum recycling, with the rinsate going to the onsite treatment plant. Any spilt material will be collected using a suitable adsorbent material and placed in a container sealed ready for disposal. Residues which cannot be collected will be washed into the onsite treatment plant. The rinsate from cleaning equipment and transfer lines will be sent to the onsite waste water treatment plant. The contents of the damaged end use bottles will be collected and added to subsequent batches.

Overall, it is estimated that up to 50 kg of the notified polymer will be sent to the onsite wastewater treatment plant. Due to the cationic nature of the polymer it is likely to adsorb to dissolved organic matter or suspended solids in the effluent or treatment plants, thus become part of the resultant sludge. Similarly, due to the anionic functionality present, there will be some binding to some metal cations, such as divalent calcium ions, within the waste stream. Thus, in the worst case, it could be assumed that 50% of the waster polymer would be removed within the treatment plant and end up in the sludge, which equates to approximately 25 kg. The sludge would be collected periodically and disposed of to landfill. The remaining 50% of the waste polymer, approximately 25 kg, is expected to be released to sewer.

RELEASE OF CHEMICAL FROM USE

End-use

It is anticipated that almost all of the notified polymer will enter the sewer as a result of use. When used as a toilet bowl cleaner, approximately, 0.05 g will be used per application. Based on a water volume of 7.5 L for a toilet bowl, the concentration of the polymer in the toilet bowl, assuming no adsorption to the ceramic walls, will be 6.7 mg/L. This will be diluted further (1:20) with waste water from other sources in the home and then enters the domestic sewer at a concentration of 0.335 mg/L as a point source release.

Approximately 1% of the volume of the end use product is expected to remain in empty containers and will be disposed of along with the container to landfill in the domestic garbage collection. This equates to up to 30 kg/year of the notified polymer.

5.5. Disposal

Effluent, containing up to 25 kg of the notified chemical, from the on-site treatment plant will be released to sewer. While the resultant sludge, containing up to 25 kg of the notified chemical, will be collected and disposed of to landfill on an as needed basis.

Collected spilt material will be disposed of to landfill. Any damaged product containers will be emptied, leaving up to 1% of residue, will then be disposed of to landfill.

5.6. Public exposure

Exposure to the notified polymer at a concentration of < 1% could occur during final application of the cleaning products or during their addition to water if dilution is required. The main route of exposure is expected to be dermal, although ocular exposure to splashes is possible and inhalation of aerosols

could occur when using a spray-on pump. The level of exposure will vary depending on the method of application and measures taken to avoid splashes and spills. Toilet bowl cleaners are usually applied directly from the bottle to the internal surface of the toilet bowel, minimizing the possibility of exposure. Typical use information for some applications is provided below (European Commission, 2003a):

Product	*Grams of Product/Task*	*Use Frequency (tasks per week)*	*Duration of Task*
Surface cleaners liquid	30 – 110 (per 5 litre of water)	1-7	10 – 20 min
Surface cleaner spray	5 – 30	1-7	2 – 10 min
Toilet cleaner (liquid)	30	1-2	< 1 min

Since cleaning products are stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

6. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer is not isolated from solution. Limited physicochemical data has been provided for Mirapol Surf S500.

Appearance at 20ºC and 101.3 kPa Colourless Liquid

Boiling Point 100ºC at 101.3 kPa (estimated)

Remarks The boiling point of Mirapol Surf S500 is expected to be similar to that of water.

Density 1120 kg/m^3 at 20ºC

Remarks Data from MSDS. Study report not reviewed.

Vapour Pressure 3.17 kPa at 25ºC

Remarks Based on the high molecular weight and structure of the notified polymer, the vapour pressure is expected to be low. Aqueous solutions of the notified polymer are expected to have a vapour pressure corresponding to no more than that of water i.e. 3.17 kPa at 25 ºC.

Water Solubility >240 g/L at 20ºC

Remarks The water solubility of the notified polymer has not been determined. A 24% aqueous solution of the notified polymer is clear indicating that the water solubility of the polymer is at least 240 g/L.

Hydrolysis as a Function of pH Not determined

Remarks The manufacturer specifies a shelf life of 6 months for the aqueous polymer solution at pH 4-5. Thus, the polymer is stable in water for this period at this pH range. Furthermore, the polymer is resistant to biodegradation.

Partition Coefficient (n-octanol/water) Not determined

Remarks The notified polymer is amphoteric and has high water solubility under acidic conditions. Thus, it is expected to have a low Log Pow.

Adsorption/Desorption Not determined

Remarks The notified polymer is amphoteric and has high water solubility under acidic conditions. Thus, it is expected to have a low Log Pow and low affinity for organic matter in soil. However. the polymer is expected to bind strongly to silicates in soil via ion exchange mechanisms.

Dissociation Constant Not determined

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks Although the notified polymer contains functional groups which have the potential to undergo dissociation, the overall charge (anionic) of the notified polymer is not expected to change under environmental conditions (pH 4-9). The pH of Mirapol Surf S500 is 4-5.

Particle Size Not determined

Remarks Notified polymer is not isolated from solution

Flash Point Not determined

Remarks The notified polymer is imported in aqueous form and therefore is unlikely to be combustible in this form.

Flammability Limits Not determined

Remarks The notified polymer is imported in aqueous form. The notified polymer does not react upon contact with water.

Autoignition Temperature Not determined

Remarks The notified polymer is imported in aqueous form and therefore is unlikely to self ignite in this form.

Explosive Properties Not determined

Remarks The notified polymer is imported in aqueous form and therefore is unlikely to be explosive in this form. There are no chemical groups that would imply explosive properties.

Reactivity

Remarks The notified polymer is manufactured as an aqueous solution which is stable under normal conditions for at least 6 months.

7. TOXICOLOGICAL INVESTIGATIONS

The following toxicological studies were conducted using an aqueous solution of the notified polymer and Mirapol Surf S500.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	low toxicity, LD50 >2000 mg/kg bw
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Skin Sensitisation - LLNA	evidence of sensitisation
Genotoxicity – bacterial reverse mutation	non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Aqueous solution of the notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Sprague Dawley
Vehicle	Purified water
Remarks - Method	No significant protocol deviations. The dose-level of the test item was adjusted taking into account the % concentration of the notified polymer.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 females	2000*	0
II	3 females	2000*	0

* notified polymer.

LD50	>2000 mg/kg bw (notified polymer)
Signs of Toxicity	Hypoactivity, piloerection and dyspnea were observed in the first three treated females on day 1; hypoactivity and dyspnea persisted on day 2. In the three other treated females, piloerection and dyspnea were noted on day 1 only. The overall bodyweight gain was not affected by treatment.
Effects in Organs	No apparent abnormalities noted at necropsy.
Remarks - Results	
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	CIT (2003a)

7.2. Irritation – skin

TEST SUBSTANCE	Aqueous solution of the notified polymer
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	Test substance administered as supplied
Observation Period	72 hours

Type of Dressing Semi-occlusive.
Remarks - Method No significant protocol deviations

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	N/A	0
Oedema	0	0	0	0	N/A	0

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

Remarks - Results

CONCLUSION The notified polymer as tested is non-irritating to the skin.

TEST FACILITY CIT (2003b)

7.3. Irritation – eye

TEST SUBSTANCE Aqueous solution of the notified polymer

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 No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	0	0	0	N/A	0
Conjunctiva: chemosis	0	0	0	0	N/A	0
Conjunctiva: discharge	0	0	0	0	N/A	0
Corneal opacity	0	0	0	0	N/A	0
Iridial inflammation	0	0	0	0	N/A	0

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

Remarks - Results

CONCLUSION The notified polymer as tested is non-irritating to the eye.

TEST FACILITY CIT (2003c)

7.4.1. Skin sensitisation

TEST SUBSTANCE Mirapol Surf S500

METHOD OECD TG 406 Skin Sensitisation – Magnusson and Kligman
EC Directive 96/54/EC B.6 Skin Sensitisation - Magnusson and Kligman
Species/Strain Guinea pig/Hartley Crl: (HA) BR
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: Irritation observed up to 25% test substance
topical: 100% test substance
MAIN STUDY

Number of Animals	Test Group: 20 Control Group: 10
INDUCTION PHASE	Induction Concentration: intradermal: 25% test substance in 0.9% NaCl topical: 100% test substance
Signs of Irritation	Marked local reactions (unspecified) at the intradermal injection sites were noted in a few animals (unspecified) of the treated group between days 16 and 20.
CHALLENGE PHASE	
1st challenge	topical: 100% test substance
Remarks - Method	No significant protocol deviations As the test item was shown to be non-irritating during the preliminary test, the animals of both groups were treated with 0.5 mL of sodium lauryl sulfate at a concentration 10% prior to the topical induction phase.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100% test substance	1/20	1/20	-	-
Control Group	100% test substance	0/10	0/10		

Remarks - Results	In the treated group, a discrete erythema as noted in one animal at the 24-hour observation and in another at the 48-hour observation.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.
TEST FACILITY	CIT (2004a)

7.4.2. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Aqueous solution of the notified polymer
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/CBA/J
Vehicle	Methyl ethyl ketone
Remarks - Method	No significant protocol deviations.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	139.33	-
0.6%*	82.15	0.59
1.2%*	203.14	1.46
2.4%*	175.89	1.26
6%*	789.54	5.67
12%*	757.69	5.44
Positive Control		
A-hexacinnamaldehyde	4026.59	28.90

* Concentration of notified polymer

Remarks - Results	There were no deaths or test substance-related clinical signs or

remarkable body weight changes during the study period.

Residual test item was noted in all animals treated with 12% notified polymer on days 2, 3 and 6, in all the animals treated with 6% notified polymer on days 2 and 3 and in 1/4 animals treated with 6% on day 6 and in 2/4 animals treated with 2.4% notified polymer on days 3 and 6.

Less than 5% increase in ear thickness was noted in the animals treated with 0.6, 1.2 or 2.4% notified polymer. At the concentration of 6% a slight increase in ear thickness (14.56%) was noted between day 1 and day 6: however, as this was caused by a single animal in which residual test item was noted, it was not considered biologically relevant. At the concentration of 12%, a slight increase in ear thickness (16.98%) was recorded between day 1 and day 6. As it was associated with alopecia around the ears in all animals, the 12% concentration was considered as slightly irritating.

In the treated groups, a positive lymphoproliferative response (maximal SI=5.67%), which exceeded the threshold value of 3 for the SI, was noted at concentrations ≥6%. As the increase in ear thickness noted at the concentration of 6% was not ascribed to an irritant effect of the test item, the lymphoproliferative response observed at this concentration was attributed to delayed contact hypersensitivity.

CONCLUSION — There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.

TEST FACILITY — CIT (2004b)

7.5. Genotoxicity – bacteria

TEST SUBSTANCE — Aqueous solution of the notified polymer

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 and preincubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 312.5 -5000 µg/plate b) Without metabolic activation: 312.5 -5000 µg/plate
Vehicle	Water
Remarks - Method	No significant protocol deviations.

The test item was tested in a preliminary test and two mutagenicity experiments. The preliminary test, both experiments without metabolic activation and the first experiment with metabolic activation were performed according to the direct plate incorporation method. The second experiment with metabolic activation was performed according to the preincubation method.

The dose-level of the test item was adjusted taking into account the % concentration of the notified polymer.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate)* Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*

Absent	>5000			
Test 1		>5000	>5000	negative
Test 2		>5000	>5000	negative
Present	>5000			
Test 1		>5000	>5000	negative
Test 2		>5000	>5000	negative

* Concentration of notified polymer

Remarks - Results: No toxicity or precipitation was observed. The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of metabolic activation. Positive controls confirmed the sensitivity of the test system.

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

TEST FACILITY: CIT (2004c)

8. ENVIRONMENT
8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Aqueous solution of the notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO2 Evolution Test (modified Sturm).
Inoculum	Aerated sludge from a treatment plant that treats predominantly domestic effluent
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Barium hydroxide and then titration with 1M hydrochloric acid
Remarks - Method	Reference substance – sodium acetate Treatments: - inoculum (12 mg/L SS) only – 2 flasks - test substance (at 10 mg/L TOC) and inoculum (12 mg/L SS) – 2 flasks - reference substance (at 10 mg/L TOC) and inoculum (12 mg/L SS) – 1 flask - Toxicity control: test substance (at 10 mg/L TOC), reference substance (at 10 mg/L TOC) and inoculum (12 mg/L SS) – 1 flask Temperature was maintained between 20 and 24°C. Aeration was at 30-10 mL/min. Dissolved oxygen and pH were measured daily.

RESULTS

Test substance		*Sodium Acetate*		*Toxicity control*	
Day	*% Degradation*	*Day*	*% Degradation*	*Day*	*% Degradation*
3	0	3	17.23	3	9.57
5	0	5	36.42	5	20.31
7	0	7	50.35	7	27.43
10	0	10	63.04	10	31.52
14	0	14	68.24	14	33.42
17	0	17	72.53	17	33.42
21	0	21	74.98	21	33.42
25	0	25	76.08	25	33.42
28	0	28	78.03	28	33.42

Remarks - Results	By day 14, the reference substance reached 68% degradation and the toxicity control had reached 33 %, thereby satisfying the greater than 60% and greater than 25% validity criteria. Throughout, the test substance duplicates did not differ from each other. All the study conditions were validated by the satisfaction of all criteria.
CONCLUSION	Under the conditions of the study, the test substance was not readily biodegradable.
TEST FACILITY	CIT (2003d)

8.1.2. Bioaccumulation

No studies undertaken.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Aqueous solution of the notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test – semi-static test.
Species	Zebra fish (*Danio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	150± 20 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks – Method	Solutions were changed after 24, 48 and 72 hours. During the study, fish were not fed and there was no aeration (unless required). Environmental conditions (including a light/dark cycle, temperature, pH and dissolved oxygen) were measured at the start and end and every 24 hours and were maintained at desired levels. The dose-level of the test item was adjusted taking into account the % concentration of the notified polymer.

RESULTS

*Concentration mg/L**		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*2 h*	*24 h*	*48 h*	*72 h*	*96 h*
0		7	0	0	0	0	0
0.01		5	0	0	0	0	0
0.1		5	0	0	0	0	0
1		5	0	0	0	0	0
10		5	0	0	0	0	0
100		7	0	0	0	0	0

*concentration of notified polymer

LC50	>100 mg/L at 96 hours.
NOEC (or LOEC)	100 mg/L at 96 hours.
Remarks – Results	No mortality or abnormal behaviour were observed. LC_{50} calculated via geometric mean. All validity criteria were met.
CONCLUSION	Under the study conditions, the notified polymer was not toxic to fish.
TEST FACILITY	CIT (2003e)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Aqueous solution of the notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test – static test.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	255 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks - Method	During the study, daphnid were not fed and there was no aeration (unless required). Environmental conditions (including a light/dark cycle, temperature, pH and dissolved oxygen) were measured at the start and end and were maintained at desired levels. The test solution was clear and colourless.

The dose-level of the test item was adjusted taking into account the % concentration of the notified polymer.

RESULTS

*Concentration mg/L**		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	20	0	0
0.01	-	20	0	0
0.1	-	20	0	0
1	-	20	0	0
10	-	20	0	0
100	-	20	0	0

*concentration of notified polymer

LC50	> 100 mg/L at 48 hours
NOEC (or LOEC)	100 mg/L at 48 hours
Remarks - Results	No immobilization or abnormal behaviour were observed. LC_{50} calculated via geometric mean. All validity criteria were met.

CONCLUSION — Under the study conditions, the notified polymer was not toxic to daphnid.

TEST FACILITY — CIT (2003f)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE — Aqueous solution of the notified polymer

METHOD — OECD TG 201 Alga, Growth Inhibition Test.

Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 0.01, 0.1, 1.0 and 10 mg/L Actual: Not determined
Auxiliary Solvent	None
Water Hardness	34±07 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks - Method	Test solutions were agitated throughout the study. Cell growth was recorded every 24 hours. The dose-level of the test item was adjusted taking into account the % concentration of the notified polymer.

RESULTS

Biomass		*Growth*	
E_bC_{50} mg/L at 72 h	NOEC mg/L	E_rC_{50} Mg/L at 72 h	NOEC mg/L
>100*	100*	>100*	100*

*concentration of notified polymer

Remarks - Results

CONCLUSION — Under the conditions of the study, the notified polymer is not toxic to algae.

TEST FACILITY — CIT (2003g)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer is highly water soluble. It is expected to bind strongly to silicates in soil, metal ions and negatively charged particles in wastewater. Once bound, the polymer is expected to flocculate and settle. The polymer may degrade slowly under abiotic conditions.

9.1.2. Environment – effects assessment

The notified polymer meets the PLC criteria. Furthermore, the results of toxicity studies in fish, daphnia and algae demonstrate that the polymer is of low aquatic hazard. Using the EC_{50} > 100 mg/L the predicted no effect concentration (PNEC) can be estimated using a safety factor of 100, since there are data for three trophic levels, to be >1 mg/L.

The polymer was also tested for biodegradation potential and found not to degrade under biotic conditions to any extent over a 28-day period under the conditions of the test.

Given that the notified polymer has a high molecular weight it is unlikely to cross biological membranes and bioconcentrate within aquatic organisms.

9.1.3. Environment – risk characterisation

Liquid effluent generated on the formulation site will go to an onsite treatment plant with effluent going to sewer and sludge going to landfill. As indicated previously up to 50% of the waste notified polymer will be removed, thus the following PEC due to reformulation can be calculated:

Amount of polymer sent to onsite treatment plant	50 kg/y
Daily polymer concentration in inffluent	0.137 kg/day
Daily polymer concentration after 50% removal	0.069 kg/day
Daily flow rate through treatment plant	80000 L/day
Average concentration in treatment plant effluent	0.86 mg/L
Average inflow to North Head STP	336 ML/day
PEC_{STP}	0.002 ng/L
PEC_{ocean}	0.0002 ng/L

The notified polymer is highly water soluble. The notified polymer is expected to bind strongly to silicates in soil, metal ions and negatively charged particles in wastewater. Once bound, the polymer is expected to flocculate and settle.

For nation-wide use of the end product, a worst case scenario is where all of the imported notified polymer will be released to sewer. Therefore, a PEC can be estimated as follows, on the assumption that there is no removal in the STP.

Amount of polymer released	3000 kg/yr
Population of Australia	20 million
Amount of water used per person per day	200 L
Number of days used	365
PEC_{STP}	$\frac{3000\ 000\ 000}{365X200X20\ 000\ 000}$
	= 2 μg/L
PEC_{ocean}	0.2 μg/L

However, there is likely to be at least 50% removed in the STP, which means the PEC_{STP} and PEC_{ocean} will be 1 μg/L and 0.1 μg/L, respectively.

Using the above PNEC estimation (>1 mg/L) and the estimated worst case PEC (0.002 mg/L),

the risk quotient (RQ = PEC/PNEC) is <0.002. With Q significantly less than 1 and based on the proposed use pattern of the notified polymer, the amount being imported and the nationwide use of the products and subsequent diffuse release, it is not expected to pose risk to the health of aquatic life.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Hard surface cleaner formulation and supply

Only transport and storage workers and the production mixer have the potential for exposure to the notified polymer as introduced (concentration < 10%).

Transport and storage worker exposure to the notified polymer is expected to be negligible except in the case of an accidental spill.

Although the production mixer may be exposed to the notified polymer from accidental spills and from contact with contaminated pumping equipment, exposure is expected to be low due to the low concentration and the use of PPE.

Following formulation of the hard surface cleaner, filling line operators, QC staff, transport and storage workers, and supermarket workers have the potential to be exposed to the notified polymer (concentration < 1%)

Transport and storage worker, filling line workers and supermarket workers are not expected to be exposed to the notified polymer except in the event of an accident.

Exposure to the notified polymer by QC chemists is expected to be low due to low concentration of the notified polymer, the small samples involved and the limited exposure time. Exposure would be limited by the use of PPE.

End use

Workers may be exposed to no more than 1% of the notified polymer during final application of the formulated cleaning products or during their addition to water if dilution is required. Although the level of exposure will vary depending on the method of application and work practices employed, exposure is considered to be low due to the low concentration of the notified polymer.

9.2.2. Public health – exposure assessment

Hard surface cleaners containing the notified polymer will be sold to the public and as such widespread public exposure is expected. Although the level of exposure will vary depending on the method of application and measures taken to avoid splashes and spills, public exposure is considered to be low due to the low concentration of the notified polymer.

Since these products will be stored and used in a domestic environment, there is also the possibility for children to be exposed to the notified polymer by accidental ingestion.

9.2.3. Human health – effects assessment

Acute toxicity.

The notified polymer was of low acute toxicity in rats.

Irritation and Sensitisation.

An aqueous solution of the notified polymer was non-irritating to eyes and skin. Although the irritation potential of the notified polymer itself cannot be ascertained from this study, the notified polymer is not introduced to Australia in this form. The concentration of the notified polymer as introduced is an order of magnitude less than the concentration in the aqueous solution which was tested in the skin and eye irritation studies and therefore the notified polymer as introduced is also considered to be non-irritating to skin and eyes.

In a mouse local lymph node assay (LLNA), an aqueous solution of the notified polymer induced delayed contact hypersensitivity and as such the notified polymer is considered to be a potential skin sensitiser. The EC_3 value for the notified polymer is equal to approximately 4%. However, Mirapol Surf S500 was negative in a skin sensitisation adjuvant test in guinea pigs, and therefore the notified polymer as introduced is unlikely to induce a skin sensitisation reaction.

Mutagenicity.
The notified polymer was negative in an Ames bacterial reverse mutation test.

Hazard classification for health effects.
Based on the results of the LLNA sensitisation assay, the notified polymer is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

The notified polymer is only introduced into Australia in Mirapol Surf S500. Based on the results of a skin sensitisation adjuvant test, Mirapol Surf S500 is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

9.2.4. Occupational health and safety – risk characterisation

The risks to workers who have the potential to come into contact with the notified polymer is considered to be low due to the limited exposure predicted and the expected low toxicity of the notified polymer as introduced. However, as the notified polymer itself is classified as a skin sensitiser, as a precaution workers handling the notified polymer prior to formulation should wear impervious gloves and avoid skin contact.

9.2.5. Public health – risk characterisation

The risk to public health is considered to be low due to the expected low toxicity of the notified polymer at the concentrations supplied.

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

10.1. Hazard classification

Based on the available data, the notified polymer is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004). The classification and labelling details are:

R43 May cause sensitisation by skin contact

The notified polymer is only introduced into Australia in a mixture. Based on the available data, this mixture is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

and

As a comparison only, the classification of notified polymer 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.

	Hazard category	***Hazard statement***
Skin sensitiser	1	May cause allergic skin reaction

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 No Significant Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of Mirapol Surf S500 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 Mirapol Surf S500 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

REGULATORY CONTROLS

Hazard Classification and Labelling

- The ASCC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified polymer:
  - R43 May cause sensitisation by skin contact
  - S24 Avoid contact with skin
  - S37 Wear suitable gloves

- Use the following risk phrases for products/mixtures containing the notified polymer (unless the product/mixture has been tested for its sensitisation potential as a whole):
  - Conc >1%: R43 May cause sensitisation by skin contact

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
  - Avoid contact with skin

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Impervious gloves

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

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

- If products and mixtures containing the notified 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.

Environment

- The following control measures should be implemented by the reformulator to minimise environmental exposure during formulation of the notified polymer:
  - All process areas should be bunded with drains going to the on-site treatment plant.

Disposal

- The notified polymer should be disposed of by landfill.

Emergency procedures

- Spills/release of the notified polymer should be handled by containment with absorbent material and then placed in a sealable labelled container and disposed of to landfill.

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 introduced into Australia in products other than Mirapol Surf S500

or

(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.

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