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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Mirapol Surf Products S110, S210 and S410

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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:	www.nicnas.gov.au

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NICNAS

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Polymer in Mirapol Surf Products S110, S210 and S410

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Rhodia Australia Pty Ltd (ABN 24 50 029 000)
352 Ferntree Gully Rd
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
Polymer constituents
Molecular weight
Spectral data
Purity and Identity of impurities
Formulation details
Identity of Recipient

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

Vapour Pressure
Hydrolysis as a function of pH
Partition Coefficient
Adsorption/Desorption
Flash Point
Flammability Limits
Autoignition Temperature

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
CEC/579

NOTIFICATION IN OTHER COUNTRIES
Canada (2004) NSN: 12881

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
The Polymer is a component of the following Mirapol Surf Products: S110, S210 and S410.

METHODS OF DETECTION AND DETERMINATION

METHOD	Gel Permeation Chromatography and Nuclear Magnetic Resonance (NMR) spectroscopy
Remarks	Spectra provided.
TEST FACILITY	Rhodia (2001)

3. COMPOSITION

DEGREE OF PURITY
97%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
All hazardous impurities or residual monomers are present at below the relevant cut offs for classification of the notified polymer as a hazardous substance on the basis of monomer impurity content.

DEGRADATION PRODUCTS
The polymer is not expected to degrade under normal conditions of use. Under extreme heat conditions e.g. fire, the polymer would degrade to oxides of carbon and nitrogen.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The polymer is stable under normal conditions of use. The very low monomer content may decrease a little on storage due to loss or oxidation.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as a component of the Mirapol Surf series S110, S210 and S410. Mirapol Surf S410 is a powdered product containing a maximum 20% notified polymer. Mirapol Surf S110, and S210 are aqueous products containing < 20% notified polymer.

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

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

USE
Mirapol Surf S410 (containing up to 20% notified polymer) is to be used as an additive in dishwasher powder or tablets especially 2 in 1 or 3 in 1 formulations to deliver rinse aid benefits. Recommended use level is 0.5-1% Mirapol Surf S410 on “as is basis”. At present, the Mirapol Surf 410 is not used for the manufacture of dishwasher tablets.

Uses for the other Mirapol Surf products (S110 and S210) include car wash, window wash, bathroom cleaning and other hard surface cleaning applications. Use levels of these other Mirapol products is limited to 4% in the formulation, however, the typical use level is 0.5-1% on “as is basis”.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Not specified

IDENTITY OF MANUFACTURER/RECIPIENTS
The dishwasher powder containing the notified polymer will be formulated at a site in NSW. At present, sites of formulation for the other end use products have not been identified.

TRANSPORTATION AND PACKAGING
Mirapol Surf S410 is imported in 25 kg polylined cardboard boxes. The formulated dishwasher powder is packed into 1 kg high density polyethylene (HDPE) bottles.

Mirapol Surf S110 and S210 are imported in 200 kg HDPE drums. Most car, window, bathroom and surface cleaners are packed in HPDE bottles. Although packsizes will vary, typical pack sizes for these products are 500 mL to 1 L.

5.2. Operation description

Use in dishwasher powders

Formulation

Dishwashing powders are manufactured in a continuous, dry blending process. Mirapol Surf S410 (containing up to 20% notified polymer) is manually dispensed into a hopper where it is automatically dosed onto a closed chamber conveyor from where it is conveyed to a closed, continuous rotary blender.

The finished blended dishwasher powder containing up to 1% Mirapol Surf S410 is then conveyed by bucket conveyor to a filling machine where it is packed into bottles for household consumer use.

Other potential uses

Formulation

At present, sites of formulation for the other end use products have not been identified and therefore specific operation descriptions cannot be provided. Formulation of these products will involve transfer of the Mirapol product (containing <20 % notified polymer), blending with other ingredients and filling the formulated product (containing no more than 4% of the Mirapol products (S110 and S210)) into bottles.

Transfer: Depending on the site of formulation, the notified polymer may be transferred manually, semi-automatically, e.g. by dip pipe or automatically by dedicated pipework. Smaller quantities may be pre-weighed into smaller drums or buckets before addition to the blending vessel.

Blending: Depending on the site of formulation, blending vessels may be open or closed

Filling: Typically, the bottle filling process will be automated, however, some manual input may be involved such as capping.

End use

There is potential for the formulated cleaning products (containing no more than 4% of the Mirapol products (S110 and S210)) to be used occupationally, for example in car wash facilities and by cleaners and window cleaners.

Cleaning products are generally applied with a cloth or sponge, by mop or brush or by spray followed by wiping.

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 (hours per day)*	*Exposure Frequency (days per year)*
Use in dishwasher powder			
Blender – Dispensing	1	0.25	50
Blender – Operating blending plant	3	1.5	50
Filling	4	8	110

At present, sites of formulation for the other end use products have not been identified, therefore specific information on the number and category of workers is not available. However, it is likely that this data will be similar to that provided above. Occupational end use of the cleaning products is expected to occur five days a week.

Exposure Details
Use in dishwasher powder
Formulation
Dermal and possibly ocular and inhalation exposure to the notified polymer may occur during the transfer of Mirapol Surf S410 to the hopper. Exposure to the notified polymer during blending is unlikely due to the automated nature of this process. Blenders are fully equipped with gloves, glasses and respiratory protection.

Packaging operators may have some limited respiratory or dermal exposure to up to 1% Mirapol Surf S410 containing the notified polymer through contact with spills or dust. The wearing of safety glasses and gloves by packaging operators is mandatory. Respiratory protection is available to all staff.

Other potential uses
Formulation
Workers involved with the transfer, blending and filling operations have the potential for exposure to the notified polymer, although the potential for exposure is usually greatest during the initial transfer. The main route of exposure is expected to be dermal although ocular exposure is possible. Workers could be exposed to Mirapol Surf S110 or S210 containing the notified polymer or these Mirapol products up to a concentration of 4% prior to and post formulation respectively. The level of exposure would vary from site to site depending on the level of automation of the formulation process.

Other workers that may be exposed to the notified polymer include quality control workers and workers involved in cleaning process equipment and waste disposal.

End use
Exposure to no more than 4% of the Mirapol products (S110 and S210) containing 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
Since the notified polymer will not be manufactured locally, there will be no environmental exposure associated with this process in Australia. Environmental release of the notified polymer is unlikely during importation, storage and transportation, and an accidental spill/leak is the most likely reason for environmental release. The concentration of the notified polymer (a maximum of 20%) will also limit the impact on the environment of such incidents. Any significant spillage will either be salvaged for use or collected using dry absorbent material and disposed of via a licensed waste contractor.

The reformulating facility is fully bunded and isolated from storm water drains by automatic control systems. Release of the notified polymer during blending of the dishwashing products is expected to be minimal due to the use of a continuous dry blending and mostly automated and closed systems. The formulation of other potential end use products (not identified yet) may be semi-automated with open or closed blending vessels.

The formulation equipment is cleaned via a dry cleaning process and the extracted dust is re-used in subsequent batches. The release of the notified polymer during formulation is expected to be a maximum of 14 kg per annum (including the container residues, which are estimated to be 50 g per container).

RELEASE OF CHEMICAL FROM USE
Since the notified polymer will be used in dishwashing products, almost all of the imported polymer will enter the sewer during use. This will also apply if the notified polymer is to be used in other cleaning products.

The percentage of notified polymer remaining in emptied consumer product containers is not specified but will vary depending on the size and type of the containers and the type of consumer product. This could be assumed to be about 1% of the imported polymer (50 kg per annum).

5.5. Disposal

Spilled material during the formulation process that is not re-used will be collected using dry absorbent material and disposed of via a licensed waste contractor. The end product containers are expected to be collected through domestic garbage and then disposed of to landfill.

5.6. Public exposure

Since the notified polymer will be in products sold to the general public, widespread public exposure is expected.

Use in dishwasher powders

Incidental dermal exposure to up to 1% Mirapol Surf S410 could occur during the addition of the powder or tablet to the dishwasher. Typical use information is as follows (European Commission, 2003a):

Product	*Grams/Task*	*Use Frequency (tasks per week)*	*Duration of Task*
Dishwasher Powder	20-46	3-7	< 1 min
Dishwasher Tablet	20-50	3-7	< 1 min

Since the dishwasher powder will be stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

Other potential uses

Exposure to no more than 4% of the Mirapol products containing 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 measures taken to avoid splashes and spills. Frequency of exposure will vary depending on the end use of the formulated products, for instance surface cleaners would be expected to be used more frequently than car and window cleaners. Typical use information for some applications is provided below (European Commission, 2003a):

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

Limited physicochemical data were available for the notified polymer itself. Some data has been provided for the Mirapol Surf Products.

Appearance at 20°C and 101.3 kPa Solid, white powder (notified polymer)
Colourless liquid (Aqueous solution of the notified polymer)

Melting Point 212°C (notified polymer)

Remarks Value provided by notifier. No study report provided.

Density 1.05 to 1.13 kg/m^3 at 20°C (Aqueous solution of the notified polymer)

Remarks Data taken from MSDS. Study report not provided

Vapour Pressure Not determined

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 °C.

Water Solubility >500 mg/L at 22°C (pH2, 7 or 10) (notified polymer)

METHOD OECD TG 120 Solution/Extraction Behaviour of Polymers in Water.
Testing of Water Availability for Polymers Submitted for Assessment under the Canadian Environmental Protection Act (2001).

Remarks The results were obtained from the Environment Canada New Substances Evaluation Report (Environment Canada, 2004). The study report was not provided. A preliminary test was conducted to determine the water solubility of the notified polymer. The solubility tests were conducted at pH 2 (buffered), pH 7 (unbuffered) and pH 10 (buffered) at 22ºC.

n-Octanol Solubility < 46 mg/L at 22ºC (notified polymer)

METHOD Based on OECD TG 105 Water Solubility.

Remarks The results were obtained from the Environment Canada New Substances Evaluation Report (Environment Canada, 2004). The study report was not provided. The test sample was stirred in n-octanol for 5 days at 22º ± 1ºC. Some undissolved sample was observed at the end of stirring.

Hydrolysis as a Function of pH Not determined.

Remarks In the water solubility study summarised above the solutions were tested at pH 2, 7 and 10 but no information was available on the stability. However, there are no groups generally recognisable as hydrolysing.

Partition Coefficient (n-octanol/water) Not determined.

Remarks Based on the n-octanol solubility of < 46 mg/L and the water solubility of > 500 mg/L the log K_{ow} was calculated to be < -1.0.

The estimated low log K_{ow} is consistent with the high water solubility indicating that the notified polymer is likely to favour the aqueous phase.

Adsorption/Desorption Not determined.

Remarks The notified polymer is highly water-soluble. However, due to its cationic character, it has strong affinity to negatively charged material. The notifier indicates that test data for its affinity to adhere to glass and metal has indicated that the polymer at its use level binds to the surface within sixty seconds. Therefore, it can be expected to bind to silicates in soil and sediments through ion exchange mechanisms.

The affinity of cationic polymers to negatively charged material is also supported in literature. Boethling and Nabholz (1997) state that cationic polymers with a number average molecular weight greater than 1000 are assumed to partition mainly to the solids phase and to be 90% removed relative to the total influent

concentration. The remaining 10% is assumed to be discharged to receiving waters although much of this material is likely to be in the form of polymer sorbed to suspended solids.

Dissociation Constant pKa = 1.3

METHOD In House – Titration Method
Remarks The dissociation constant was determined by reverse and forward titration using HCl and NaOH respectively. An aqueous solution of the notified polymer (0.1 weight %) was used.
TEST FACILITY Rhodia (2004)

Particle Size

Range (μm)	*Mass (%)*
>1000	10 (max)
500-1000	50 (min)
<250	10 (max)

Remarks The notified polymer is only available in powdered form in the product Mirapol Surf S410. The above information was taken from the technical datasheet for Mirapol Surf S410 which contains 16 – 20% notified polymer.

Flash Point Not determined

Remarks The notifier reports that the flashpoint of the polymer in aqueous solution is expected to be more than 93°C.

Flammability Limits Not determined

Remarks Mirapol Surf S410 (~20% notified polymer) is considered to be non-flammable. The notified polymer is present in all other formulations as an aqueous solution.

Autoignition Temperature Not determined

Remarks No information is available for autoignition of the polymer or product Mirapol Surf S410. It is expected that the autoignition temperature is likely to be above 93°C. The notified polymer is present in all other formulations as an aqueous solution and is unlikely to self ignite in this form.

Explosive Properties Not predicted to be explosive

Remarks There are no chemical groups that would imply explosive properties, therefore the result has been predicted to be negative

Reactivity

Remarks The Mirapol Surf series containing the notified polymer is reported to be stable at ambient temperatures and under normal conditions of use. This series of products are reported to decompose with an increase in temperature.

7. TOXICOLOGICAL INVESTIGATIONS

The following toxicological studies were conducted using an aqueous solution containing approximately 20% notified polymer.

Endpoint and Result	*Assessment Conclusion*
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL 300 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	mutagenic
Genotoxicity – in vivo mouse micronucleus test	non genotoxic

7.1. Skin sensitisation

TEST SUBSTANCE	Aqueous solution of the notified polymer (18% notified polymer)
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/Dunkin-Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 50% test substance (~9% notified polymer) topical: 50% test substance (~9% notified polymer)
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 50% test substance in sterile water (~9% notified polymer) topical: tested as supplied (~18% notified polymer)
Signs of Irritation	Intradermal injection: Well defined erythema was apparent at the sites of intradermal injection following administration of Freunds complete adjuvant (test and control animals) and the vehicle mixed with Freunds complete adjuvant (control group). A slight erythema was noted at sites treated with the test item in the vehicle (test group) and a severe reaction was noted at sites treated with the test item in Freunds complete adjuvant (test group). Topical induction: The test sites were pre-treated with 10% sodium lauryl sulphate 24 hours before topical induction. No erythema was observed in test or control animals following topical induction.
CHALLENGE PHASE	
1st challenge	topical: 50% test substance in sterile water (~9% notified polymer)
Remarks - Method	No significant protocol deviations.

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	50% test substance (~9% notified polymer)	0/10	0/10	-	-
Control Group	50% test substance (~9% notified polymer)	0/10	0/10	-	-

Remarks - Results	There were no deaths or test substance-related clinical signs of toxicity or remarkable body weight changes during the study. There were no reactions indicative of sensitisation to the test substance following the challenge exposure.

CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.
TEST FACILITY	RTC (2002)

7.2. Repeat dose toxicity

TEST SUBSTANCE	Aqueous solution of the notified polymer (19% notified polymer)
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: Not applicable
Vehicle	Purified water
Remarks - Method	No significant protocol deviations. Dose levels were based on a 7-day range-finding study during which there were no relevant signs of toxicity. All dose levels were prepared taking into account the purity of the test substance and are therefore expressed as concentration of notified polymer.

RESULTS

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

Mortality and Time to Death

No deaths occurred during the treatment period.

Clinical Observations

The general clinical observations were restricted to areas of hair loss and exophthalmos. These were observed in both control and test animals and were considered to be incidental (as they only occurred in 1-2 animals) and not to be related to administration of the test substance. There was no evidence of disturbance of either autonomic or physiological functions at any dose level. The functional test battery showed no treatment-related changes in any neurotoxicological parameter. There were no relevant differences in motor activity and body weight gain between control and treated animals. There was a slight reduction (0 - 23%) in food consumption in group IV male animals compared with control group animals. This was statistically significant ($P<0.05$) only at day 15, was not accompanied by any significant decrease in bodyweight and is considered to be incidental.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry

A statistically significant reduced glucose level was noted in group III (7 - 27% reduction, $P<0.05$) and group IV males (12 – 25% reduction, $P<0.01$) when compared to controls, however, this was not considered to be treatment related as individual values were within the range of historical background data, no similar effect was observed in females and glucose levels were relatively high in a few control animals. Other changes noted compared to controls included inorganic phosphorus, calcium and chloride levels. Such changes were mainly slight (<5%), not dose related and of opposite trend between the two sexes and as such were not considered to be treatment related.

Haematology
A statistically significant reduction in the white blood cells (WBC) count was observed in group IV males (34% reduction, P<0.05) and females (41% reduction, P<0.05) compared to controls. This was essentially due to a lower lymphocyte count. The individual lymphocyte and WBC count values were below the lowest value in the respective control animals. A trend towards lowered WBC counts was evident in all treatment groups. Differential WBC counts in male treatment animals revealed a dose related trend in decreased neutrophils, eosinophils, basophils and leukocytes. Treatment females only showed a dose related trend in decreased leukocytes. No other toxicologically significant changes were observed in any other haematological parameter that was tested. The effect on white blood cells is considered to be treatment related.

Urinalysis
Not conducted

Effects in Organs
Organ Weight
Lower thyroid weights were observed in group IV females. However, this was not considered to be of toxicological importance, as the trend was not observed in both sexes, there were no associated histopathological abnormalities and it mainly was due to the contribution of one individual low value. Dose related reductions (not statistically significant) in adrenal weights (12 - 37% overall reduction) and liver weights (5 – 72% overall reduction) were seen in 4/5 males and 2/5 females respectively, compared to controls. This was not considered to be of toxicological importance as the trend was not observed in both sexes and there were no associated histopathological abnormalities.

Gross Pathology
The thyroids were reduced by 60% in one group IV female. As this was not associated with relevant histopathological abnormalities, it was considered to be of no toxicological importance. The few other macroscopic findings such as exophthalmia, alopecia and uterus dilation were those which are commonly observed in rats of this strain and age.

Histopathology
There were no significant differences between the microscopic findings in control and group IV animals. Therefore it was considered that there were no treatment related histopathological abnormalities.

Remarks – Results
The effect on white blood cells is indicative of distribution of the notified polymer to the bone marrow in this study.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 300 mg/kg bw/day in both sexes in this study, based on a statistically significant (P<0.05) and biologically significant (>10%) reduction in lymphocyte and white blood cell count observed in animals dosed at 1000 mg/kg bw/day.

TEST FACILITY CIT (2002a)

7.3. Genotoxicity – bacteria

TEST SUBSTANCE	Aqueous solution of the notified polymer (19.1% 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 Pre incubation 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	Distilled Water (Millipore, CIT)

Remarks - Method

No significant protocol deviations.
Tests conducted: A preliminary toxicity test (strains TA98, TA100 and TA102), two independent experiments (all strains) with and without metabolic activation and a third confirmatory experiment (TA98 and TA 100) in the presence of S9 using a concentration range of 1000 – 5000 µg/plate. All experiments were performed in accordance with the direct plate incorporation procedure except for the second and third experiments with S9, which were performed according to the preincubation procedure.

All dose levels were prepared taking into account the purity of the test substance and are therefore expressed as concentration of 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	positive
Test 3		>5000	>5000	positive

Remarks - Results

No toxicity or precipitation was observed in any of the experiments.

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 under plate incorporation method conditions. Negative and positive controls gave appropriate responses.

Under preincubation method conditions and in the presence of metabolic activation, 2.9 fold and 3.4 fold increases in the number of revertants were induced in the TA100 and TA98 strains, respectively, at 5000 µg/plate. In a confirmatory study under the same conditions but with a closer range of dose-levels, a dose related increase in the number of revertants was induced in these tester strains, with 2.7 fold and up to 2.8 fold increases in the number of revertants in the TA98 and TA100 strains respectively.

CONCLUSION

The notified polymer was mutagenic to bacteria (*S. typhimurium* strains TA100 and TA98) in the presence of metabolic activation under preincubation method conditions.

TEST FACILITY

CIT (2002b)

7.4. Genotoxicity – in vivo

TEST SUBSTANCE

Aqueous solution of the notified polymer (19.2% notified polymer)

METHOD

OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.

Species/Strain: Mice/Swiss Ico: OF1
Route of Administration: Oral – gavage
Vehicle: Purified Water

Remarks - Method

No significant protocol deviations.

Test animals received two treatments separated by 24 hours. The positive control was administered only once.

All dose levels were prepared taking into account the purity of the test substance and are therefore expressed as concentration of notified polymer

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5 per sex	0	48
II (low dose)	5 per sex	500	48
III (mid dose)	5 per sex	1000	48
IV (high dose)	8 per sex*	2000	48
V (positive control, CP)	5 per sex	50	24

CP=cyclophosphamide.
*Only 5 animals per sex were subjected to bone marrow analysis.

RESULTS

Doses Producing Toxicity

The high dose (2000 mg/kg bw) reached the limit dose for a non-toxic test substance. There were no deaths, test substance related clinical findings or remarkable bodyweight changes during the study.

Genotoxic Effects

There was no statistically significant decrease in the ratio of Polychromatic Erythrocytes/Normochromatic Erythrocytes (PCE/NCE), demonstrating the test substance was not cytotoxic to the bone marrow. The test substance did not induce a statistically significant increase in the frequency of micronucleated PCE over the levels observed in the vehicle controls.

Remarks - Results

The frequency of micronucleated PCE in the positive control was significantly higher (7 - 20 fold increase, $P<0.001$) than the vehicle control.

CONCLUSION

The notified polymer was not clastogenic under the conditions of this in vivo mouse micronucleus test.

TEST FACILITY

CIT (2003)

8. ENVIRONMENT

8.1. Environmental fate

Only a summary of the following test on ready biodegradation was provided (also reported in the Environment Canada NSN Assessment Summary (Environment Canada 2004).

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Remarks - Results	The results indicated a biodegradation rate of 6.3% in 28 days.
CONCLUSION	The notified polymer is not readily biodegradable.
TEST FACILITY	Stantec (2003)

8.1.2. Bioaccumulation

No bioaccumulation data were provided. However, the potential for bioaccumulation is considered to be low due to the high molecular weight and the high water solubility of the notified polymer.

8.2. Ecotoxicological investigations

The following ecotoxicological studies were conducted using an aqueous solution containing approximately 20% notified polymer.

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Aqueous solution of the notified polymer (17.8% notified polymer)
METHOD	OECD TG 203 Fish, Acute Toxicity Test –Semi static.
Species	Zebrafish (*Danio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not stated but reconstituted water (ISO 7346) was used as dilution water.
Analytical Monitoring	None
Remarks – Method	Based on the results of a range finding test (resulting in no mortalities at 1000 mg/L of the test substance) a limit test was performed at a nominal test concentration of 562 mg/L of test substance (corresponding to 100 mg/L dry matter). Some brown coloured particles were observed in the sample of test substance. A stock solution of the test substance was prepared by direct dispersion of 2247 mg in 1000 mL of dilution water, which was then diluted to obtain the test concentration. The test solutions were renewed every 24 hours. Whether these were clear (given the above observation) was not stated. Prior to medium renewal, the dissolved oxygen contents were 6.0 to 6.6 mg/L in control and 5.9 to 6.3 mg/L in the test substance solutions and the pH ranged from 7.1 to 7.2 in control and 7.1 to 7.2 in test solutions. After medium renewal, the dissolved oxygen contents were 8.4 to 8.5 mg/L in both the control and test substance solutions and the pH ranged from 7.8 to 8.0 in control and 7.8 to 7.9 in test solutions. The temperature was maintained between 22 and 23°C. The sensitivity of the selected batch of fish was validated using potassium

dichromate.

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*% Mortality*			
		24 h	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0
561.8*	10	0	0	0	0

* 100 mg/L dry matter

LC50	>562 mg/L (100 mg/L dry matter) at 96 hours.
NOEC (or LOEC)	>562 mg/L (100 mg/L dry matter) at 96 hours (highest concentration tested).
Remarks – Results	No mortalities were observed in the control or test media and sub-lethal effects have not been reported.

CONCLUSION The notified polymer is practically non-toxic to fish at 100 mg/L dry weight.

TEST FACILITY INERIS (2002a)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Aqueous solution of the notified polymer (17.8% notified polymer)

METHOD International Standard NF EN ISO 6341 (May 1996) - Static

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	267 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks - Method	Based on the results of a range finding test (resulting in no mortalities at 100 mg/L dry matter) a limit test was performed at a nominal test concentration of 562 mg/L of test substance (corresponding to 100 mg/L dry matter). Some brown coloured particles were observed in the sample of test substance. The test solution was prepared by direct dispersion of 562 mg of test substance in 1000 mL of dilution water, to obtain the test concentration. Whether these were clear (given the above observation) was not stated. At the beginning of the test, the dissolved oxygen content of the test solution was 8.7 mg/L and the pH was 7.1. At 48 hours, the dissolved oxygen contents were 8.5 mg/L in the control and 8.4 mg/L in the test substance solution and the pH was 7.5 in the control and 7.4 in the test solution. The temperature was maintained between 20 and 21°C. The sensitivity of the test organisms was validated using potassium dichromate.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*% Immobilised*	
		24 h	*48 h*
Control	20	0	0
561.8*	20	0	0

* 100 mg/L dry matter

LC50	>562 mg/L (100 mg/L dry matter) at 96 hours.
NOEC (or LOEC)	>562 mg/L (100 mg/L dry matter) at 96 hours (highest concentration tested).
Remarks - Results	No sub-lethal effects have been reported.
CONCLUSION	The notified polymer is practically non-toxic to Daphnia at 100 mg/L dry weight.
TEST FACILITY	INERIS (2001)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Aqueous solution of the notified polymer (19.2% notified polymer)
METHOD	OECD TG 201 Alga, Growth Inhibition Test - Static
Species	Unicellular green alga (*Pseudokirchneriella subcapitata*)
Exposure Period	72 hours
Concentration	Nominal: 100 mg/L dry weight
Auxiliary Solvent	None
Water Hardness	Standard solution was used.
Analytical Monitoring	None
Remarks - Method	Based on the results of a range finding test a limit test was performed at a nominal test concentration of 521 mg/L of test substance (corresponding to 100 mg/L dry weight). The test solution was prepared by direct dispersion of 579 mg of test substance in 1000 mL of dilution water, which was then diluted to obtain the test concentration. The initial algal cell concentration was 10^4 cells/mL. The test flasks were incubated at 23 ± 2°C. The pH values of the controls were 8.14 (at the start) and ranged from 9.8 to 10.0 (at termination) while that of the exposure solutions were at 8.1 (at the start) and 9.6 (at test termination). The sensitivity of the strain of algae was validated using potassium dichromate.
RESULTS	
Remarks - Results	It was not possible to determine the EC50 and NOEC values for growth and biomass for algae as the results showed no inhibition of algal growth.
CONCLUSION	The notified polymer is practically non-toxic to algae at 100 mg/L dry weight.
TEST FACILITY	INERIS (2002b)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Up to 14 kg of the notified polymer is expected to be released to the environment during the formulation process. Nearly all of the imported notified polymer would eventually be released into the aquatic environment via the sewerage systems through use of dishwashing (and cleaning) products. A small amount of the polymer is also expected to be disposed of to landfill as residue in empty consumer containers via domestic garbage.

The notified polymer is not expected to dissipate into air from the surfaces to which the products containing it are applied. The estimated low P_{ow} indicates a poor affinity for the organic component of the soils and sediments and that the notified polymer will favour the aqueous phase. This is consistent with the high solubility of the polymer in water. However, the notified polymer has strong affinity to negatively charged material due to its cationic character. Therefore, when disposed of in landfill the polymer can be expected to eventually become associated with soil and sediment. Although not readily degradable the polymer will slowly degrade through biological and abiotic processes.

Based on maximum annual imports of 5000 kg per annum, and assuming a worst-case scenario that all of this is eventually released to sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 13.7 kg/day. Assuming a national population of 20 million and that each person contributes an average 200 L/day to overall sewage flows, the worst-case predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as 3.4 µg/L (Environment Australia, 2003). Based on the respective dilution factors of 0 and 10 for inland and ocean discharges of effluents, the PECs of the notified polymer in freshwater and marine water may approximate 3.4 µg/L and 0.3 µg/L, respectively.

The SIMPLETREAT model (European Commission, 2003b) was used to model the partitioning and losses in sewage treatment plants (STP) throughout Australia. A worst-case scenario was assumed with a very low Henry's Law Constant (log H $\leq$ -4) and the estimated log K_{ow}, (also a limit value of <-1.0). The SIMPLETREAT table for chemicals that are not biodegradable was used to approximate the partitioning behaviour of the notified polymer.

The results obtained indicate that when the polymer is released into the aqueous phase of a STP, approximately 0% is released to air through volatilisation, 100% (5000 kg) partitioned to water and 0% partitioned to biosolids. The resulting PECs for the aquatic environment from the nationwide release of the notified polymer into the sewage systems therefore, will also be the same as those derived for the above worst-case scenario. These PEC values are used in the following risk assessment. However, it should be noted that the adsorption of the notified polymer to sludge during sewage treatment as expected (due to its cationic nature) has not been accounted for in the use of the SIMPLETREAT model.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m^3). Using these assumptions, irrigation with a concentration of 3.4 µg/L may potentially result in a soil concentration of approximately 0.03 mg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 0.15 mg/kg and 0.3 mg/kg, respectively.

The potential for the notified polymer to bioaccumulate is low due to its high molecular weight and high water solubility and also will be limited due to the diffused release to the sewer Australia wide.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below.

Organism	Duration	End Point	mg/L dry matter
Fish	96 h	LC_{50}	>100
Daphnia	48 h	EC_{50}	>100
Algae	72 h	E_bC_{50} (Biomass)	>100
	72 h	E_rC_{50} (Growth)	>100

A predicted no effect concentration (PNEC - aquatic ecosystems) of >1000 µg/L has been derived by dividing the end point of >100 mg/L by a worst-case scenario uncertainty (safety) factor of 100 (as toxicity data are available for three trophic levels).

9.1.3. Environment – risk characterisation

The risk quotient (RQ) values (PEC/PNEC) for the aquatic environment were determined as follows.

Location	PEC µg/L	PNEC µg/L	RQ
Australia-wide STPs			
Ocean outfall	0.3	>1000	$<3 \times 10^{-4}$
Inland River	3.4	>1000	$<3.4 \times 10^{-3}$

PEC and the RQ values calculated assuming that the notified polymer is not removed during sewage treatment.

The resulting RQ values for the aquatic environment are significantly below 1 for both fresh and marine water, indicating no immediate concern to the aquatic compartment. Although the SIMPLETREAT model did not account for partitioning to sludge, a significant part of the notified polymer can also be expected to be removed due to adsorption to sludge during sewage treatment and to sediments in aquatic environment further reducing the PEC and the risk quotients.

Based on the proposed use pattern the notified polymer is not expected to pose an unacceptable risk to the health of aquatic life. Bioaccumulation is not expected from the diffuse use pattern.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Use in dishwasher powder

In order to estimate worst-case exposure, the following exposure assessment assumes that the notified polymer is present at concentration of 20% in Mirapol Surf S410 and that Mirapol Surf S410 is present at a concentration of 1% in the dishwasher powder.

Formulation

Dermal and possibly ocular and inhalation exposure to the notified polymer may occur during transfer of Mirapol Surf S410 to the hopper. The estimated reasonable worst-case and typical case dermal exposure is 600 mg and 180 mg respectively using measured data for the exposure scenario 'dumping of powders in a formulation facility' (European Commission, 2003a) and assuming the notified polymer is present at a concentration of 20%. Therefore, for a 70 kg worker and a 10% dermal absorption factor (based on the high molecular weight and low log K_{ow}), reasonable worst-case and typical case dermal exposure is estimated to be 0.85 mg/kg bw/day and 0.26 mg/kg bw/day respectively.

Exposure would be further limited by the use of personal protective equipment (PPE).

The estimated atmospheric concentration of notified polymer due to dust is 1 - 10 mg/m^3, based on EASE model (EASE) using reasonable worst-case defaults (European Commission, 2003a) and assuming the notified polymer is present at concentration of 20%. Therefore for a 70 kg worker, assuming an inhalation rate of 1.3 m^3/hour, 30 minute exposure time and 100% bioavailability, inhalation exposure is estimated to be 0.009 – 0.09 mg/kg bw/day.

Following formulation of the dishwasher powder exposure to the notified polymer is expected to be very low due to the low concentration of the notified polymer and the use of PPE.

Other potential uses
In order to estimate worst-case exposure, the following exposure assessment assumes that the notified polymer is present at concentration of 20% in Mirapol Surf products and that the Mirapol product is present at a concentration of 4% in the formulated end-use products.

Formulation
Dermal and possibly ocular exposure could occur during the transfer of the polymer solution to the blending vessel. The level of exposure would vary from site to site depending on the level of automation of the formulation process. The estimated dermal exposure is 84 mg/day, based on EASE model (EASE) using reasonable worst case defaults for the exposure scenario 'manual addition of liquids' (European Commission, 2003a) and assuming the notified polymer is present at concentration of 20%. Therefore, for a 70 kg worker and a 10% dermal absorption factor (based on the high molecular weight and low log P_{ow}), systemic exposure is estimated to be 0.12 mg/kg bw/day.

Exposure would be further limited by the use of PPE.

Following formulation of the end use products, exposure to the notified polymer is expected to be very low due to the low concentration of the notified polymer and the expected use of PPE.

End use
Workers may be exposed to 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

Formulated products containing the notified polymer will be sold to the public and as such widespread public exposure is expected. 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.

Use in dishwasher powder
Incidental dermal exposure to the notified polymer could occur during the addition of the powder or tablet to the dishwasher. However, due to the short contact time, the expected very small skin contact area and the low concentration of the notified polymer, the dermal exposure from this use is considered negligible.

Other potential uses
Dermal exposure to the notified polymer due to the use of formulated products containing the notified polymer is estimated below. In order to estimate worst-case exposure, the following exposure assessments assume that the notified polymer is present at concentration of 20% in Mirapol Surf products and that the Mirapol product is present at a concentration of 4% in the formulated end-use products:

Product	*Concentration of notified polymer in product (mg/cm^3)*	*Contact Area (cm^2)**	*Thickness of Product Layer on Skin (cm)**	*Dermal Absorption (%)**	*Application Frequency (no of applications per day)*	*Exposure to notified polymer (mg/kg bw/day)***
Surface cleaner liquid	8	840	0.1	10	1*	1.12
Car wash	8	1980***	0.1	10	0.14****	0.37

* data from European Chemical Bureau Technical Guidance Document on Risk Assessment (European Commission, 2003a)
** assuming 60kg body weight
*** forearms have also been included for carwash applications
**** no frequency data was available for use of car wash products. An assumption of 1 wash per week has been used.

Exposure would be further reduced if the formulated product is diluted prior to application.

Inhalation exposure of the notified polymer could occur from aerosols generated during spray applications. An estimate of exposure is as follows (assuming that the notified polymer is present at concentration of 20% in Mirapol Surf products and that the Mirapol product is present at a concentration of 4% in the formulated end-use products):

Product	*Product Concentration in Air (mg/m^3)**	*Inhalation Rate (m^3/d)***	*Duration of Application (fraction of day)***	*Application Frequency (no of applications per day)***	*Exposure to Notified Polymer (mg/kg bw/day)****
Surface cleaner spray	0.35	20	0.007	1	6.5 x 10^{-6}

* data from Human & Environmental Risk Assessment on ingredients of European household cleaning products (HERA)
** data from European Chemical Bureau Technical Guidance Document on Risk Assessment (European Commission, 2003a)
*** assuming 60kg body weight

9.2.3. Human health – effects assessment

Acute toxicity
No acute toxicity data were available for the notified polymer. Based on acute toxicity data on similar polymers, the notified polymer is expected to exhibit low acute oral toxicity with an estimated LD50 > 2000 mg/kg bw (Health Canada, 2004). This is supported by a 28-day repeat dose oral toxicity test (see below) during which no mortality was observed in animals treated up to 1000 mg/kg bw/day.

Irritation and sensitisation
An aqueous solution containing 18% notified polymer was negative in a skin sensitisation adjuvant test in guinea pigs, and therefore the notified polymer as introduced is unlikely to be a skin sensitiser.

Based on its structure, the notified polymer is likely to be slightly irritating to the skin and eyes. However, no signs of dermal irritation were noted following topical application of the notified polymer at a concentration of 18% in the skin sensitisation study and therefore the notified polymer as introduced is considered to be non-irritating to skin.

Repeated dose toxicity
In a 28-day oral repeat dose study in rats, a statistically significant ($P<0.05$) and biologically

significant (>10%) reduction in lymphocyte and white blood cell count was observed in animals (both sexes) dosed at 1000 mg/kg bw/day. There was evidence of lymphocyte and white blood count suppression indicative of suppression of the immune system by the notified polymer under the conditions of the test. The No Observed Adverse Effect Level (NOAEL) was established as 300 mg/kg bw/day in this study.

Mutagenicity
In an Ames bacterial reverse mutation test, 2.9 fold and 3.4 fold increases in the numbers of revertants were induced in the TA100 and TA98 strains, respectively, at 5000 µg/plate under preincubation conditions in the presence of metabolic activation. No evidence of genotoxicity was observed following an *in vivo* bone marrow micronucleus test in mice. Based on these studies, the notified polymer is considered to have a potential for mutagenicity. A negative result in the bone marrow micronucleus test accompanied by evidence of distribution to the bone marrow, is an indication of a lack of genotoxicity in animals.

Carcinogenicity
The notified polymer appears to be able to form nitrosamines under certain conditions. Nitrosamines are of concern for carcinogenicity (tumours following chronic exposure are confined mainly to the liver and kidney) (Health Canada, 2004).

The notifier reported on the basis of a HPLC study that all relevant nitrosamines in a 20% aqueous solution of the notified polymer were below the limit of detection (0.000001%).

Hazard classification for health effects
Based on the available data, the notified polymer 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

Use in dishwasher powder
Formulation
The notified polymer as introduced may be a slight eye irritant and has the potential to cause immunosuppression at high doses. Workers involved in the transfer of Mirapol Surf S410 should avoid contact with eyes and are recommended to wear eye protection as a precaution. Reasonable worst-case exposure to the notified polymer was estimated to be 0.94 mg/kg bw/day. Based on a NOAEL of 300 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 320. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data is acceptable for formulation workers.

Following formulation of the dishwasher powder, exposure is expected to be very low and as such the risk to workers is also considered to be low.

Other potential uses
Formulation
Exposure to the notified polymer was estimated to be 0.12 mg/kg bw/day. Based on a NOAEL of 300 mg/kg bw/day, derived from a 28-day rat oral study the MOE is calculated as 2500. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data is acceptable for formulation workers. Due to the low concentration of the notified polymer as introduced the risk of irritant effects is considered to be low.

Following formulation of the end products exposure is expected to be very low and as such the risk to workers is also considered to be low.

Nitrosamines

The notified polymer appears to be able to form nitrosamines under certain conditions. The level of nitrosamines was determined to be below the limit of detection (0.000001%) in a 20% aqueous solution of the notified polymer. Products formulated with the notified polymer are currently packaged in nitrite free containers and do not contain chlorine based bleach. As such the formation of nitrosamines in the formulated products is considered unlikely and therefore the risk of exposure to nitrosamines for workers handling the notified polymer and products formulated with it is considered to be low.

9.2.5. Public health – risk characterisation

Although the notified polymer may be a slight skin and eye irritant, due to the low concentration of the notified polymer in formulated products the risk of an adverse irritant effect is considered unlikely. The notified polymer may cause an immunosuppressant effect at high doses.

Use in dishwasher powders
Public exposure to the notified polymer from its use in dishwasher powders is expected to be negligible and as such the risk to public health from this proposed use is also expected to be negligible.

Other potential uses
Assuming use of all end-use products, exposure to the notified polymer was estimated to be 1.5 mg/kg bw/day. Based on a NOAEL of 300 mg/kg bw/day, derived from a 28-day rat oral study the MOE is calculated as 200. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk to public health from these other proposed uses is considered to be low.

Accidental ingestion
Since products formulated with the notified polymer 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. However, as the notified polymer is considered to be of low acute toxicity the risk of lethal effects as a result of accidental ingestion is considered to be low.

Nitrosamines
The formation of nitrosamines in the formulated products is considered unlikely and therefore the risk of public exposure to nitrosamines from use of products containing the notified polymer is considered to be low.

Health Canada considered indirect exposure through drinking water to nitrosamines potentially formed during the reaction of the notified polymer with chemicals used in water treatment. It was concluded that the notified polymer would not represent a significant risk of carcinogenicity in the general population (Health Canada, 2004). The expected use and the consequent environmental releases in Australia (5 tonnes) are small compared to Canada (50 tonnes) and only about 25% of the sewage effluent in Australia is discharged into freshwater. In addition, nitrosamines do not appear to be formed when reactants are present at concentrations relevant to the notified use and release scenarios. Therefore, it is considered that the proposed use of the notified polymer would not pose an unreasonable risk to public health.

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

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

The notified polymer is not classifiable using the Globally Harmonised System for the

Classification and Labelling of Chemicals (GHS) (United Nations, 2003). 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 ratios, the notified polymer 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 for Mirapol Surf S410 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 S410 provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

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

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

  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.

Disposal

- The notified polymer and empty packaging should be disposed of either to landfill or by incineration in accordance with the relevant local regulations.

- Do not discharge into drains or rivers.

Emergency procedures

- Spills/release of the notified polymer should be recovered as much as possible by pumping up into a suitably labelled spare container. A large spill should be contained by bunding. Non-recoverable liquid should be absorbed with sand or inert absorbent.

- Wash contaminated area with large amounts of water. Dry polymerised residues may be cleaned up with a high pressure water jet.

Transport and Packaging

- The notified polymer and products formulated with the notified polymer should be packaged in nitrite free containers.

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 proposed to be formulated in products that contain a source of nitrite or chlorine.

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.

13. BIBLIOGRAPHY

Boethling RS and Nabholz JV (1997) Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act, Chapter 10. In: Ecological Assessment of Polymers: Strategies for Product Stewardship and Regulatory Programs. Hamilton JD and Sutcliffe R (Eds), Van Nostrand Reinhold NY.

CIT (2002a) 4 Week Toxicity Study by Oral Route (Gavage) in Rats (Study No. 23206 TSR, 24 September 2002). Evreux, France, CIT. Sponsor: Rhodia HPCII (unpublished report submitted by notifier).

CIT (2002b) Bacterial Reverse Mutation Test (Study No. 23645 MMO, 13 September 2002). Evreux, France, CIT. Sponsor: Rhodia HPCII (unpublished report submitted by notifier).

CIT (2003) Bone Marrow Micronucleus Test by Oral Route in Mice (Study No. 34891 MAS, 13 June 2003). Evreux, France, CIT. Sponsor: Rhodia HPCII (unpublished report submitted by notifier).

Estimation and Assessment of Substance Exposure (EASE). The EASE system was developed by the UK Health and Safety Executive in conjunction with the Artificial Intelligence Applications Institute. For a further description see: Marquart et al., Evaluation of Methods of Exposure Assessment for Premarket Notifications, TNO Report V 94.229 TNO Nutrition and Food Research (Zeist), 1994.

Environment Australia (2003) Model and Guidance for Estimating Predicted Environmental Concentrations to Surface Water and Soil from Chemicals Released to the Environment Through a Sewage Treatment Plant. Chemical Assessment Section, Environment Australia, Canberra Australia.

Environment Canada (2004) New Substance Evaluation Report. NSN No. 12881, Schedule VII, Environment Canada.

European Commission (2003a) Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and of the Council Concerning the Placing of Biocidal Products on the Market – Part I. Institute for Health and Consumer protection, European Chemicals Bureau, European Communities.

European Commission (2003b) Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and of the Council Concerning the Placing of Biocidal Products on the Market – Part II. Institute for Health and Consumer protection, European Chemicals Bureau, European Communities.

Health Canada (2004) NSN Health Assessment Summary. NSN No. 12881 Health Canada.

HERA Human and Environmental Risk Assessment on ingredients of household cleaning products Home Page http://www.heraproject.com/RiskAssessment.cfm. Accessed January 2005.

INERIS (2001) Inhibition of the Mobility of *Daphnia magna* (Study No. BA904a, 21 November 2001). Verneuil-en-Halatte, France, INERIS Site d'Essai Ecotoxicologie (unpublished report submitted by notifier).

INERIS (2002a) Fish Acute Toxicity Test to Zebra Fish. (Study No. BA904b, 10 January 2002). Verneuil-en-Halatte, France, INERIS Site d'Essai Ecotoxicologie (unpublished report submitted by notifier).

INERIS (2002b) Amendment No. 1 to the Final Report: Alga, Growth Inhibition Test (Study No. BA948, 23 September 2002). Verneuil-en-Halatte, France, INERIS Site d'Essai Ecotoxicologie (unpublished report submitted by notifier).

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.

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.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

Rhodia (2001) GPC of an aqueous solution of the notified polymer (Request No. 010411, 25 July 2001). Cranbury, USA, Rhodia Inc. Cranbury Analytical Laboratories (unpublished report submitted by notifier).

Rhodia (2004) Determination of pKa for an aqueous solution of the notified polymer (31 August 2004). Aubervilliers, France, Rhodia Research (unpublished report submitted by notifier).

RTC (2002) Delayed Dermal Sensitisation Study in the Guinea Pig (Magnusson and Kligman Test) (Study No. 9107, 19 April 2002). Roma, Italy, Research Toxicology Centre. Sponsor: Rhodia HPCII (unpublished report submitted by notifier).

Stantec (2003) Ready Biodegradability Evaluation of an aqueous solution of the notified polymer. (Study ID: 62773883, 10, September 2003). Guelph, Canada, Stantec Consulting Ltd. Sponsor: Globaltox International Consultants Ltd (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.