File No: LTD/1225

February 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Urea, N,N'-bis[3-(dimethylamino)propyl]-, polymer with 1,1'-oxybis[2-chloroethane]

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

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

Library
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

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

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

Director
NICNAS

TABLE OF CONTENTS

Urea, N,N'-bis[3-(dimethylamino)propyl]-, polymer with 1,1'-oxybis[2-chloroethane]

1. APPLICANT AND NOTIFICATION DETAILS

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

NOTIFICATION CATEGORY
Limited: Polymer with NAMW ≥ 1000.

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

- Polymer constituents
- Molecular weight
- Spectral data
- Purity and Identity of impurities
- Formulation details
- Import Volume
- Purity

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

Physicochemical Properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA & Canada

2. IDENTITY OF CHEMICAL

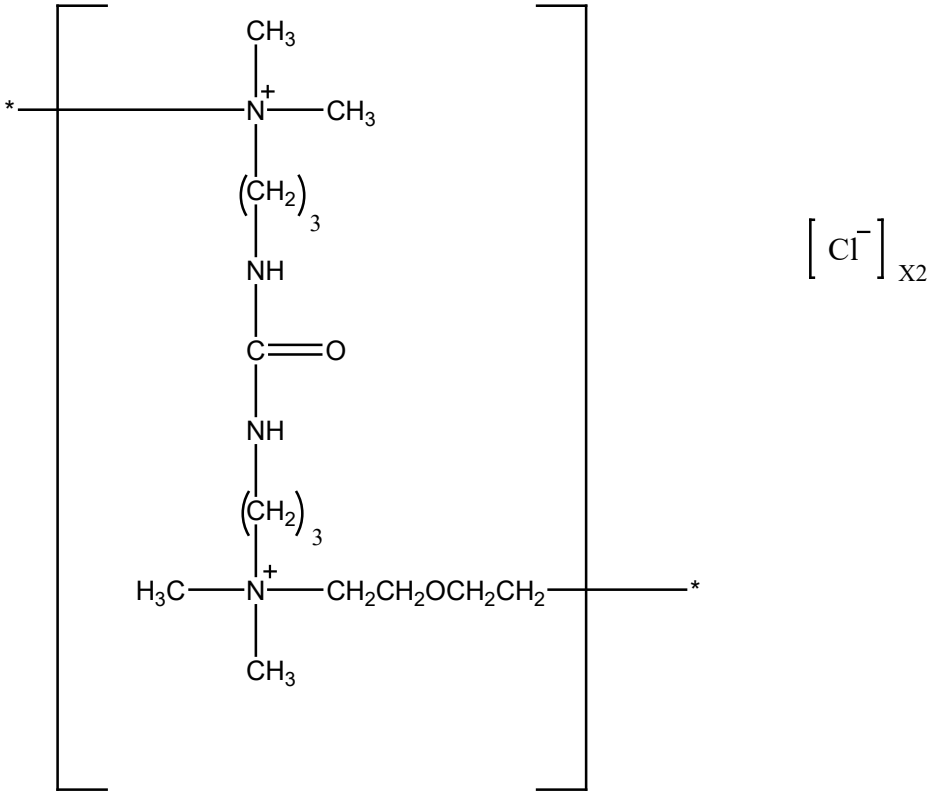
CHEMICAL NAME
Urea, N,N'-bis[3-(dimethylamino)propyl]-, polymer with 1,1'-oxybis[2-chloroethane]

MARKETING NAME(S)
The notified polymer is imported as a component (<70%) of MIRAPOL WT.

CAS NUMBER
68555-36-2

MOLECULAR FORMULA
$(C_{11}\ H_{26}\ N_4\ O.\ C_4\ H_8\ C_{l2}\ O)x$

STRUCTURAL FORMULA



METHODS OF DETECTION AND DETERMINATION

METHOD Gel Permeation Chromatography and Infrared Spectroscopy
Remarks Spectra provided.

3. COMPOSITION

DEGREE OF PURITY
> 85%

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 notified polymer is expected to be stable under normal conditions of use. On combustion or on thermal decomposition (pyrolysis), degradation products will include carbon oxides, nitrogen oxides and chlorinated compounds.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The notified polymer only contains low levels of residual monomers, additives and impurities. Following application to the metal surface, it is expected that any residual monomers, additives and impurities will be trapped in the solid matrix.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured or reformulated in Australia. It will be imported as a component of MIRAPOL WT, an aqueous solution containing < 70% notified polymer.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 90	< 90	< 90	< 90	< 90

USE
MIRAPOL WT will be used for metal electroplating.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
The notified polymer will be imported through Melbourne by wharf.

IDENTITY OF MANUFACTURER/RECIPIENTS
MIRAPOL WT containing < 70% notified polymer will be stored at Rhodia Australia Pty Limited site in Victoria before distribution to metal treatment industry customers.

TRANSPORTATION AND PACKAGING
MIRAPOL WT will be imported in 200 Kg metal drums by ship. It will be transported by road from wharf to the notifier's site and stored. No repackaging operations will be carried out at the notifier's site. MIRAPOL WT will then be transported by road to the metal treatment industry Australia-wide.

5.2. Operation description

Electroplating facility
MIRAPOL WT containing < 70% notified polymer will be transferred to a tank from the 200 L drums via a sealed pipe through the use of pumping equipment where it is mixed with other ingredients. The final solution contains approximately < 1% of the notified polymer. During the process, samples are taken to the laboratory for batch adjustment and quality control testing. The finished coating is then filtered and pumped into the coating bath ready for coating of metal parts. If repairs to vessels or machinery are required, the affected areas are isolated and cleaned before and after maintenance.

Metal parts are suspended in baskets (16 items per basket) on an overhead conveyor, and are then immersed in a sequence of baths. After each bath the metal parts are rinsed with water followed by air blow-off of excess solution into the bath. The final bath in this sequence contains the notified polymer. The coated parts are then passed through a dry oven to effect curing. The entire coating process is a closed system with recovery of rinse effluents. Water from the rinsing baths is recycled into the metal solution baths.

The metal parts are individually sealed in plastic packaging and placed into cardboard box for distribution to end-users such as hardware retailers (taps and bathroom fittings, tools) and car manufacturers.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Waterside, transport and warehouse	4	1	210
Formulation and application of coating			
Tank operators	10	2	210
Application/drying operators	10	1-2	210
Maintenance operators	2	1-2	210
Laboratory technicians	5	2	210

Exposure Details

Transport and storage

Workers are not expected to be exposed to the notified polymer, as they will be handling closed containers. Exposure is possible only in the event of an accidental spill where the packaging is breached.

Electroplating Facility

Incidental skin contact and possibly ocular exposure to the notified polymer (< 70%) from drips, spills and splashes may occur during the opening of the drums, connection of the transfer pipes and during the dilution stage with other ingredients. Incidental dermal and possibly ocular exposure with the notified polymer (< 1%) may also occur during QC sampling and testing. Tank operators will wear overalls or PVC apron, gloves and safety glasses with side shields. Laboratory technicians will wear laboratory coats, gloves and eye protection during sampling and testing.

The coating process is a closed and automated system under local exhaust ventilation and therefore negligible exposure to workers is expected.

Drying of the coated metal part is carried out by oven baking under exhaust ventilation. Exposure to notified polymer at this stage is expected to be minimal. After coating the notified polymer is bound within the coating matrix and is unavailable for exposure.

Maintenance workers responsible for repairs and maintenance of transfer lines and pumps may be exposed to the notified polymer (< 70%) in the event of repairs being required while a batch is in process. To minimise exposure workers will wear overalls or PVC apron, gloves and eye protection.

It is anticipated that a range of workers Australia-wide involved in metal working and fabrication industries will handle and use the coated metal parts.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured in Australia. Local operations will include transport and storage, formulation and application by metal treatment industry.

MIRAPOL WT containing the notified polymer at (< 70%) will be imported and stored in 200 kg metal drums. It will be transported from dockside by road to Rhodia Australia Pty Limited for storage. It will then be sold to the metal treatment industry for coating of metal parts.

Release at Rhodia's site to the environment may result only in the event of an accidental spill. It is estimated that a maximum of 1% of the MIRAPOL WT (< 900 kg) would be lost during spillage. Spills are contained and soaked up with absorbent materials (e.g. sand, earth, vermiculite) and placed in a sealable, labelled container and disposed of to landfill. The spilled area is flushed with water. The waste material from flushing will go to a drain in the floor where it is collected in a pit. The pit is cleaned out periodically and the waste is sent off site for disposal to landfill by a licensed waste contractor. There will be no release to on-site treatment plant or to sewer.

RELEASE OF CHEMICAL FROM USE

During coating of metal parts via dipping in large application tanks, environmental controls such as fully contained facilities, fully automated processes, bunding and safety procedures will limit releases. The final dipping stage involves the coating containing the notified polymer, where after dipping, excess coating is air blown-off from metal parts and collected back into the coating tank for reuse. Oven baking results in the polymer being locked within a tightly cross-linked network. Volatile products generated during baking are extracted to an afterburner and incinerated (forming oxides of nitrogen). This application system provides for reuse of the notified polymer by air blow-off into tank and therefore resulting in minimal waste.

On an annual basis, the contents of the coating application tank (10,000 L, containing up to 100 kg of the notified polymer) are pumped to a road tanker for disposal to liquid waste treatment facility by local contractor, to allow cleaning of the application tanks. Wastes from leaks and spills, up to 1800 kg per year of the notified polymer (2% of the import volume), are also collected using absorbent material and placed in labelled containers and sent off site for treatment and disposal by licensed waste contractor.

5.5. Disposal

The expected quantity of waste generated from coating application is less than 4500 kg of the notified polymer per annum. Up to 1% residue will remain in the empty 200 kg drums used in the metal finishing industry, which is up to 900 kg per annum. The drums will be cleaned with water and the wash water resulting from cleaning of the drums will be reused in the coating process. Clean drums will be collected by a licensed waste contractor and sent off-site for disposal.

5.6. Public exposure

The notified polymer in MIRAPOL WT is not available to the public and will be used in industrial scenarios only. The public is likely, however, to make contact with the cured polymer as coating on finished metal components (taps, bathroom fittings, tools and car parts).

6. PHYSICAL AND CHEMICAL PROPERTIES

Limited physicochemical data has been provided for MIRAPOL WT, an aqueous solution containing < 70% notified polymer.

Appearance at 20ºC and 101.3 kPa Yellow liquid (MIRAPOL WT)

Melting Point/Freezing Point 0ºC (MIRAPOL WT)

Remarks Initial solidification is stated to occur at 0 ºC (From the MSDS, test report not seen by NICNAS.)

Boiling Point 105ºC (MIRAPOL WT)

Remarks From the MSDS, test report not seen by NICNAS.

Density 1130 kg/m^3 at 25ºC (MIRAPOL WT)

Remarks From the MSDS, test report not seen by NICNAS.

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 that of water (3.17 kPa at 25 ºC).

Water Solubility >500 g/L at 20ºC

Remarks The water solubility of the notified polymer has not been determined. The notified

polymer is introduced in a clear aqueous solution containing 50-70% notified polymer indicating that the water solubility of the notified polymer is high (at least 500 g/L).

Hydrolysis as a Function of pH Not Determined

Remarks The notified polymer contains functional groups that may undergo hydrolysis only under extreme conditions. Hence, hydrolysis of the notified polymer under the environmental pH range (4-9) is not expected.

Partition Coefficient (n-octanol/water) Not Determined

Remarks The notified polymer is polycationic and highly soluble in water and is expected to have a low water/octanol partition coefficient.

Adsorption/Desorption Not Determined

Remarks Based on the high water solubility and expected low log Pow, the notified polymer is not expected to bind strongly to organic matter in soil. However, due to its cationic nature it may bind strongly to negatively charged particles in soil such as silicates.

Dissociation Constant Not determined

Remarks The notified polymer is in a salt form and is expected to remain fully dissociated in water under environmental conditions (pH 4-9). The pH of the MIRAPOL-WT is 7.5.

Particle Size Not determined

Remarks The notified polymer is imported in an aqueous 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 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 Expected to be stable under normal conditions of use. The MSDS for MIRAPOL WT advises to avoid contact with strong oxidising agents, strong acids, strong bases and strong reducing agents

7. TOXICOLOGICAL INVESTIGATIONS

The following toxicological studies were conducted using MIRAPOL-WT, an aqueous solution containing 50-70% notified polymer or dilute solutions of MIRAPOL-WT

Endpoint and Result	*Test Substance*	*Assessment Conclusion*
Rat, acute oral	MIRAPOL-WT	low toxicity, LD50 >5650 mg/kg bw
Rabbit, skin irritation	diluted MIRAPOL-WT (3% notified polymer)	slightly irritating
Rabbit, eye irritation	aqueous solution of MIRAPOL-WT (2% notified polymer)	non-irritating
Guinea pig, skin sensitisation – adjuvant test.	MIRAPOL-WT	no evidence of sensitisation
Genotoxicity – bacterial reverse mutation	MIRAPOL-WT	non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE: MIRAPOL WT

METHOD
- Species/Strain: Mice/Carworth
- Vehicle: Test substance administered as supplied.
- Remarks - Method: Only a summary of the test report was provided. Statement of Good Laboratory Practice (GLP) compliance not included.

Significant deviations from OECD guidelines for acute toxicity (401, 420, 423):

- Observation period 7 days

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	10	5650*	1/10

* based on a density of 1130 kg/m^3

- LD50: > 5650 mg/kg bw (MIRAPOL WT)
- Signs of Toxicity: Not reported. One death occurred during the observation period (unspecified day).
- Effects in Organs: Not reported
- Remarks - Results: No detailed results were provided in the test report provided. The LD50 for the notified polymer can be estimated to be > 2825 – 3955 (based on a concentration of 50-70% notified polymer).

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

TEST FACILITY: Lerbeco (1976a)

7.2. Irritation – skin

TEST SUBSTANCE: Diluted Mirapol-WT (3% notified polymer)

METHOD
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3

Vehicle	Test substance (pH 7.0) administered as supplied
Observation Period	48 hours (after patch removal)
Type of Dressing	Occlusive
Remarks - Method	Significant deviations from OECD TG 404 Acute Dermal Irritation/Corrosion:

- Increased Exposure period: 24 hours
- Test substance applied to abraded and non-abraded skin
- Occlusive dressing used
- It is not clear from the studies whether the test sites examined for signs of irritation 24 and 48 hours after test substance application or patch removal.

It is considered that these deviations would not lead to an under classification of the irritation potential of the test substance.

Statement of GLP compliance not included.

RESULTS

Non-abraded skin

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1	0.5	1	2	< 48 hours	0
Oedema	0	0	0	0	n/a	0

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

Abraded skin

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1	1	1	2	< 48 hours	0
Oedema	0	0	0	0	n/a	0

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

Remarks - Results	Although classification for skin irritation using the NOHSC approved criteria (NOHSC, 2004) requires skin irritation scores for 24, 48 and 72 hours after patch removal, as the maximum score for erythema/eschar was 2 and all effects had reversed by 72 hours after test substance application or patch removal, it is considered that the test substance as applied would not be classified as irritating to skin.
CONCLUSION	The notified polymer at a concentration of 3% is slightly irritating to the skin.
TEST FACILITY	American Standards Biosciences (1986)

7.3. Irritation – eye

TEST SUBSTANCE	Aqueous solution of MIRAPOL WT (pH 7.0) (2% notified polymer)
METHOD	In house
Species/Strain	Rabbit/Albino
Number of Animals	3
Observation Period	7 days
Remarks - Method	Only a summary of the test report was provided. Statement of GLP

compliance not included.

Significant Deviations from OECD TG 405 Acute Eye Irritation/Corrosion:

- No examination of the eyes occurred 1 hour after application.

This deviation is not expected to significantly alter the conclusions of the test.

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 at a concentration of 2% is non-irritating to the eye.

TEST FACILITY Lerbeco (1976b)

7.4. Skin sensitisation

TEST SUBSTANCE MIRAPOL WT

METHOD OECD TG 406 Skin Sensitisation – Magnusson and Kligman Maximisation Method
EC Directive 96/54/EC B.6 Skin Sensitisation - Magnusson and Kligman Maximisation Method

Species/Strain Guinea pig/ Dunkin-Hartley

PRELIMINARY STUDY No preliminary study conducted.

MAIN STUDY

Number of Animals Test Group: 10 per sex Control Group: 5 per sex

INDUCTION PHASE Induction Concentration:
intradermal: Test substance at 0.5 % (w/w) in isotonic saline solution
topical: Test substance administered as supplied

Signs of Irritation 0.5 ml of 10 % sodium lauryl sulphate in vaseline was applied to provoke local irritation before the topical induction phase. After the topical induction phase, signs of irritation (non-specified) in control and treated groups were observed at the intradermal injection sites.

CHALLENGE PHASE

1st challenge topical: 50% test substance in isotonic saline solution

Remarks - Method No significant protocol deviations. The study was performed in compliance with the OECD principles of GLP.

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 %	0/20	0/20	-	-

Control Group	50 %	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. Dryness of the skin was noted at the 24-hour reading in one control and one treated animal. It persisted at the 48-hour reading in the control animal only. 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 at a concentration of 50-70% under the conditions of the test.

TEST FACILITY: CIT (1995a)

7.5. Genotoxicity – bacteria

TEST SUBSTANCE: MIRAPOL WT

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-Mix from Aroclor 1254 induced rat liver

Concentration Range in Main Test:
Test 1
a) With metabolic activation: 30-3000 µg/plate
b) Without metabolic activation: 30-3000 µg/plate

Test 1
a) With metabolic activation: 125-2000 µg/plate
b) Without metabolic activation: 125-2000 µg/plate

Vehicle: Distilled water

Remarks - Method: No significant protocol deviations. The study was performed in compliance with the OECD principles of GLP.

The preliminary toxicity test was conducted on strains TA98, TA100 and TA102 up to a dose of ~5000 µg/plate.

Test 1 and Test 2 in the absence of activation was performed according to the direct plate incorporation method. Test 2 in the presence of activation was performed according to the preincubation method.

The concentration of the notified polymer in the test substance was taken into account for the calculation of the concentrations.

RESULTS

Metabolic Activation	*Test Substance Concentration* (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	2511 (all strains)			
Test 1		1000 (all strains)	> 3000	negative
Test 2		500 (TA1535, TA102), 1000 (TA100, TA98), 2000 (TA1537)	> 2000	negative

Present	1004 (TA98), 2511 (TA100, TA102)			
Test 1		3000 (all strains)	> 3000	negative
Test 2		500 (TA98), 1000 (Ta1535, TA1537, TA100), 2000 (TA102)	> 2000	negative

* concentration of notified polymer.

Remarks - Results	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 activation. A 2.25 fold increase in the number of revertants observed in strain TA1537 in the absence of activation in test 1 was not considered to be significant as the response was not dose-related, a similar effect was not observed in test 2 and number of revertants were within historical controls. 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 (1995b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: MIRAPOL WT

METHOD: OECD TG 301 D Ready Biodegradability: Closed Bottle Test.

Inoculum	Domestic waste water treatment plant secondary effluent
Exposure Period	28 days
Auxiliary Solvent	Not specified
Analytical Monitoring	Dissolved oxygen
Remarks - Method	Reference substance – sodium benzoate Treatments - nutrient medium and inoculum - test substance (7.5 mg/L) - reference substance (3 mg/L) All treatments were done in quadruplicate.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	62
14	0	14	64
28	0	28	67

Remarks - Results: The degradation of the reference substance validates the test procedure and activity of the inoculum used.

The threshold of ≥ 60% degradability of the test substance was not obtained within the study. The report suggests that a possible reason for this may be a certain bacterial toxicity of the test substance as the oxygen depletion in the bottles with the test substance was lower than in the bottles of the blank control without test substance.

CONCLUSION: The test substance is not considered to be readily biodegradable.

TEST FACILITY: Institut Fresenius (1993)

8.1.2. Inherent biodegradability

TEST SUBSTANCE: MIRAPOL WT

METHOD: OECD TG 302 B Zahn-Wellens/EMPA Test.

Inoculum	Aerobic activated sludge from a domestic sewage treatment plant
Exposure Period	36 days
Auxiliary Solvent	None
Analytical Monitoring	Chemical Oxygen Demand (COD)
Remarks - Method	The test and/or reference item was dissolved in test water. No emulsifier or solvent was used. Mineral nutrients and test substance (4.0 g) were added to 1 L activated sludge and made up to a total volume of 4 L with test water. The test was conducted in duplicate with a single control. The test flasks were incubated under diffuse illumination. The reference Glucose/Glutamic acid was employed as control. The inoculated flasks were incubated in temperature-controlled room at 22 ± 3 °C. Sampling was done on Day 0, 1, 3, 5, 7, 10, 14, 18, 22, 28 and 36 of the incubation period for COD.

RESULTS

Test Substance		*Glucose/Glutamic acid*	
Day	*% Degradation*	*Day*	*% Degradation*
1	2.5	1	99.1
3	26.0	3	100.0
5	25.4	5	<100.0
7	35.6	7	<100.0
10	14.1	10	<100.0
14	13.4		
18	23.2		
22	45.2		
28	14.0		
36	55.4		

Remarks - Results

The report indicates that the result at 36 days indicates that the test material is inherently biodegradable as defined by the OECD Guideline (i.e. > 20% and < 70% degradation). However, it should be noted that according to the guideline the duration of the test is up to 28 days at which point the degradation reported is below 20 hence, the test substance would not meet criteria.

The reference item was ultimately and completely degraded by 100% within the first three days of exposure, thus confirming suitability of the activated sludge.

CONCLUSION

The test report concludes, the test item can be classed as inherently biodegradable under the test conditions, but note the comments above.

TEST FACILITY

ECM (1990)

8.1.2. Bioaccumulation

The relatively high molecular weight and charged nature of the notified polymer indicates that unlikely to bioaccumulate (Connell 1989).

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: MIRAPOL WT

METHOD: EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - Semi-static.

Species	Rainbow trout (*Onchorhynchus mykiss*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	146-192 mg $CaCO_3$/L
Analytical Monitoring	None, all results are expressed in terms of nominal concentrations.
Remarks – Method	The test was conducted according to good laboratory practices of the OECD. The test vessels, each with 5 fish, were covered, maintained between 14-17±1°C, exposed to a photoperiod of 16 dark/8 hours light and were aerated throughout the study. Temperature, pH and dissolved oxygen were recorded daily. Test solution was renewed daily. Observations were made at 3, 24, 48, 72 and 96 hours. Preliminary, final and supplementary tests were performed.

RESULTS

Final Test

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control		10	0	0	0	0	0
0.18		10	0	0	9	10	-
0.32		10	0	0	5	5	6
0.55		10	0	0	1	9	10
1.0		10	0	0	10	-	-
1.8		10	0	0	10	-	-

Supplementary Test

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control		10	0	0	0	0	0
0.055		10	0	0	0	0	0
0.1		10	0	0	0	0	0
0.18		10	0	1	9	10	-
0.32		10	0	1	1	2	6

LC50	0.1-0.18 mg/L at 96 hours.
LOEC	0.1 mg/L at 96 hours.
Remarks – Results	In the final test, sublethal effects were observed including; unbalanced swimming (1 fish at 1.0 mg/L after 48 h and 1 fish at 0.32 mg/L after 96 h), swimming on the side at the bottom of the tank (1 fish at 0.55 mg/L after 72 h) and swimming in an excited state (1 fish at 0.55 mg/L after 48 h and 3 fish at 0.32 mg/L after 96 h). Sublethal effects were also observed in the supplementary test including; unbalanced swimming (1 fish at 0.32 mg/L after 72 h), swimming slowly (5 fish at 0.1 mg/L after 96 h and 2 fish at 0.32 mg/L after 96 h) and swimming in an excited state (2 fish at 0.32 mg/L after 48 h).

	While the report indicates an LC50 of 0.13 mg/L, given the lack of partial responses in the supplementary test it is not possible to calculate the LC50 using probit analysis, and the value is estimated to lie between the nominal concentrations of 0.1-0.18 mg/L.
CONCLUSION	Under the study conditions the test substance is highly toxic to fish (United Nations, 2003).
TEST FACILITY	Rhône-Poulenc (1994)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The environmental safety controls and use pattern for the notified polymer would indicate a limited potential for its release into the environment. The only potential release is from inappropriate emptying of the baths for cleaning.

The notified polymer is readily soluble in water; however, aquatic release during use is considered unlikely and after oven baking the polymer is locked within a tightly cross-linked network. Hence, majority of the notified polymer will share the fate of the metal substrates to which it is bound which will include disposal to landfill or recycling. It is anticipated that prolonged residence in an active landfill environment would eventually degrade the compound. The metal recycling process is expected to result in the incineration of the notified polymer. Recycling will destroy the compound with the generation of water vapour and oxides of carbon, nitrogen, HCl and salts.

Waste generated during the use of the notified polymer will be disposed of through licensed waste contractors. Treatment of the liquid wastes will result in the flocculation of the notified polymer and the resulting flocculent will be disposed of as solid waste to landfill.

As a worst case assuming the inappropriate disposal of a single dipping bath to the sewer containing 100 kg of the notified polymer into a metropolitan sewer with a flow rate of 250 ML/day typical of a city such as Perth. The predicted environmental concentration (PEC) of the notified polymer would be:

Amount in effluent entering sewer	100 kg	
Number of days discharge occurs	1	
Sewer Volume	250 ML/day	
Receiving waters	Ocean	River
Dilution factor	1:10	1:1
PEC	40 µg/L	400 µg/L

9.1.2. Environment – effects assessment

The notified polymer is highly toxic to fish (LC50 0.1-0.18 mg/L). As only one toxicity endpoint is available a worst case PNEC of 0.1 µg/L has been determined from the endpoint and applying an assessment factor of 1000. It should also be noted that that algal toxicity may be expected to be 6 × higher (Nabholz *et al.* 1993).

9.1.3. Environment – risk characterisation

The notified polymer is not likely to present a risk to the environment when it is stored, transported, used, recycled and disposed of in the proposed manner as little release to the aquatic environment is anticipated. However, the inappropriate disposal of the notified polymer to the sewer during the annual bath cleaning of a single electroplating bath would result in unacceptable risk quotients for both ocean outfall and inland rivers as the receiving waters.

Receiving Waters	*PEC*	*PNEC*	*Risk Quotient (RQ)*
Ocean	40 µg/L	0.1 µg/L	400
River	400 µg/L	0.1 µg/L	4,000

This emphasises the importance of the need for the notified polymer to be disposed of appropriately and not to be released to the aquatic compartment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Due to the largely automated nature of the coating formulation, minimal exposure to the notified polymer is expected, however, tank operators and maintenance workers have the potential to be exposed to the notified polymer at a concentration of up to 70%, due to drips, spills and splashes and contact with equipment. Dermal and possibly ocular exposure are considered to be the main routes of exposure. Exposure will be limited by the use of PPE.

Although laboratory technicians have the potential to be exposed to the notified polymer during QC sampling and testing, exposure is expected to be low due to the low concentration of the notified polymer (< 1%), the small quantities involved and the use of PPE.

The coating is automatically applied to car bodies in a process isolated from workers and exposure to the notified polymer is not expected during this process. Once the coating surface has dried, the notified polymer is bound within an inert matrix and as such exposure is expected to be negligible.

9.2.2. Public health – exposure assessment

Public exposure to the notified polymer is expected to be negligible as the notified polymer will not be directly available to the public and although the public will come into contact with the exterior of car bodies coated with notified polymer, the notified polymer will be bound within an inert matrix and hence unavailable for exposure.

9.2.3. Human health – effects assessment

Acute toxicity.
The notified polymer is of low acute toxicity via the oral route.

Irritation and Sensitisation.
Based on the studies available, the notified polymer at a concentration of 3% is slightly irritating to skin whereas the notified polymer at a concentration of 2% was non-irritating to the eye. The irritation potential of the notified polymer itself or as introduced cannot be ascertained from the studies available. The notified polymer as introduced is not likely to induce skin sensitisation.

Mutagenicity.
The notified polymer was negative in an Ames test and therefore is not considered to be mutagenic.

Hazard classification for health effects.
Based on the available data, the notified polymer is not classified for acute toxicity as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004). Classification of other endpoints in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* was not possible from the data provided.

9.2.4. Occupational health and safety – risk characterisation

The notified polymer as introduced may be irritating to skin and eyes. Due to the largely automated nature of the coating formulation minimal exposure to the notified polymer is expected and hence the risk to workers is expected to be low. Where contact with the notified polymer as introduced could occur (tank and maintenance operators), the use of PPE (impermeable gloves, eye protection and coats) would limit exposure and thus the risk of adverse irritant effects.

At the concentrations present in the coating formulation, the notified polymer is non-irritating to eyes but still maybe slightly irritating to skin, therefore laboratory technicians should still avoid contact with skin by the use of appropriate PPE.

Exposure and hence the risk is expected to be negligible for application operators.

9.2.5. Public health – risk characterisation

Public exposure to the notified polymer is expected to be negligible and therefore the risk to public health is also expected to be negligible.

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 for acute toxicity as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004). Classification of other endpoints in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* was not possible from the data provided.

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***
Chronic hazards to the aquatic environment	1	Very toxic to aquatic life with long lasting effects

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of MIRAPOL WT 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 WT 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 skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced and/or in the final coating product:
  - Coveralls (as introduced/final coating product)
  - Impervious gloves (as introduced/final coating product)
  - Eye protection (as introduced)

  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 end users to minimise environmental exposure during use of the notified polymer:
  - Do not allow material or contaminated packaging resulting from spills to enter drains, sewers or water courses.
  - Use in controlled environment with no drains in the immediate area.
  - Spent dipping baths must not be released to the sewer.

Disposal

- The notified polymer should be disposed of by incineration or to landfill in accordance with State/Territory waste disposal regulations.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by containment to prevent run-off sorbed onto an absorbent material (soil, sand or other inert material). Collect and seal in properly labelled containers for disposal. Do not allow material to contaminate ground, groundwater or waterways. Prevent product from entering drains or stormwater system.

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 use pattern of the notified polymer changes in such a way as to result in release of the polymer to the aquatic compartment.

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. Given the high toxicity of the notified polymer to fish, if there will be release of the notified polymer to the aquatic environment from a change in use pattern, then daphnia and algae tests with measured concentrations and a chronic daphnia study will be required to be submitted.

13. BIBLIOGRAPHY

American Standards Biosciences (1986) Primary Dermal Irritation on Abraded and Nonabraded Skin of New Zealand Albino Rabbits (Project Number 86-233, 28 March 1986). Reading, PA, USA, American Standards Biosciences Corp. Sponsor: Miranol Chemical Co. Inc. (Unpublished report provided by notifier).

CIT (1995a) Skin Sensitisation Test in Guinea-Pigs (Maximisation method of Magnusson, B. and Kligman, A.M.) (Study Number 12982 TSG, 11 August 1995). Evreux, France, Centre International de Toxicologie (CIT). Sponsor: Rhone-Poulene, France. (Unpublished report provided by notifier).

CIT (1995b) Reverse Mutation Test in Bacteria *Salmonella Typhimurium* (Study Number 12117 MMO, 28 March 1995). Evreux, France, Centre International de Toxicologie (CIT). Sponsor: Rhone-Poulene, France. (Unpublished report provided by notifier).

Connell DW (1989) General characteristics of organic compounds which exhibit bioaccumulation. In: Connell DW ed, Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA.

ECM (1990) Inherent biodegradability – Modified Zahn-Wellens Test - OECD Guideline 302 B, ECM Study No. EF-0149, Environmental Compliance Monitoring Inc.

Institut Fresenius (1993) Study on the ready biodegradability of Mirapol A-15 according to Closed Bottle Test (OECD Guideline 301 D version 0f 17.7.92) (IF Study No. IF-93/15450-01, December 20, 1993) Taunusstein-Neuhof, Germany, Institut Fresenius Chemische und Biologische. (Unpublished report provided by notifier).

Lerberco (1976a) Toxicity in mice of the test material as submitted (Assay Number 67679, 3 August 1976). Roselle Park, NJ, USA, Lerberco Laboratories. Sponsor: Miranol Chemical Co. Inc. (Unpublished summary report provided by notifier.)

Lerberco (1976b) To Determine if the test material produces any irritation when instilled into rabbits' eyes (Assay Number 67618, 3 August 1976). Roselle Park, NJ, USA, Lerberco Laboratories. Sponsor: Miranol Chemical Co. Inc. (Unpublished summary report provided by notifier.)

Nabholz JV, Miller P & Zeeman M (1993) Environmental Risk Assessment of New Chemicals Under the Toxic Substances Control Act (TSCA) Section Five. In: Landis WG, Hughes JS & Lewis MA eds, Environmental Toxicology and Risk Assessment. ASTM STP 1179. American Society for Testing and Materials, Philadelphia, p 49.

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 (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. 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.

Rhône-Poulenc (1994) Determination of acute ecotoxicology in Onchorhynchus mykiss after 96 hours of exposure to Mirapol A 15 – according to the method of published in the official Journal of the European Community of 29 December 1992 (semi-static test) (Report of Study P 118, 7 November, 1994). Cedex, France, Rhône-Poulenc Industrialisation. (Unpublished summary report provided 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.