File No: LTD/1011

March 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Optidose 1000

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Director
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FULL PUBLIC REPORT

Polymer in Optidose 1000

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Rohm and Haas Australia Pty Ltd.,
4th Floor, 969 Burke Rd, Camberwell, VIC 3124

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
All compositional information
Identity of residual monomers
Concentration of polymer in formulation
Molecular weight data
Customer identity and sites

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymer in Optidose 1000

CAS NUMBER (delete if confidential)
None allocated

3. COMPOSITION

All information on the composition of the polymer is exempt.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The polymer will be imported as a component (<10%) of Optidose 1000.

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

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

USE
Optidose 1000 will be reformulated into a water treatment solution (containing <5% notified polymer) which will be used in industrial water treatment applications as a corrosion and scale inhibitor in cooling tower and boiler water applications

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Geelong, Victoria

IDENTITY OF MANUFACTURER/RECIPIENTS
Optidose 1000 will initially be sold to one customer in Melbourne who will reformulate the product into a water treatment solution. The water treatment solution will then be sold to 2-5 end users at sites in Sydney and Brisbane. The product may be sold to one or two other end users in Australia at a later date, but these sites have not yet been identified.

TRANSPORTATION AND PACKAGING
Optidose 1000 polymer solution will be imported by sea in 200 litre steel drums. It will be transported by road without repackaging to Rohm and Haas for storage. Once received by Rohm and Haas, it will be stored in an undercover area protected by bunding, from where the drums will be periodically transported to the formulator's site. After reformulation, the water treatment solution will be transported by road to the end user in 1000 litre Intermediate Bulk Containers (IBCs).

5.2. Operation Description

Optidose 1000 will not be manufactured in Australia. At the customer site the drums are opened and hoses connected. Optidose 1000 will be pumped from the drums into closed stainless steel mixing vessels with a capacity between 500 and 10,000 L. The vessel is vented to the outside atmosphere to remove any vapours. Other chemicals and water are added to the mixing vessel. The final concentration of the polymer in the water treatment solution is <5%. Five to ten tonnes of the formulated water treatment are made per batch. One to two batches will be made during the first 12 months.

The water treatment solution will be sold by the formulator to 3-5 large industrial plants where end use will take place. The water treatment solution may be used straight from the IBCs or decanted to smaller containers. The water treatment solution will be automatically pumped and metered from these containers into the water to be treated. The water to be treated is in a closed system and continually re-used. The concentration of the water treatment solution in the water being treated will depend on the quality of the water being treated.

5.3. Release

RELEASE OF CHEMICAL AT SITE
Potential release during transport and storage to formulation sites would only be through accidental spills. The MSDS details adequate procedures to protect the environment in these cases. The notifier indicates there is potential for spillage of the notified polymer to occur during formulation at the formulator's site. The notifier estimates that a maximum of 0.5% of the notified polymer may be lost during formulation. A further 0.5% of notified polymer could be released through washing and residues in pipes and equipment. This would equate to about 20 kg in the first year rising to 50 kg by year five. All spills are contained in a bunded area and collected for disposal. After each batch of water treatment solution is produced, the first washings from pipes and mixing equipment are transferred to a holding tank for reuse in the next batch. Subsequent washings and spills are transferred to the on-site effluent treatment plant.

The notifier estimates that approximately 1% of the notified polymer will remain as residues in the importation drums. A further 0.5% of the notified polymer will remain as residues in the empty IBC containers. This equates to a maximum of about 75 kg of notified polymer remaining as residues in containers and requiring disposal when importation rates reach 5 tonnes. It is anticipated that the empty 200 L drums will be sent to licensed drum dealers or disposed of directly into landfill. The empty IBC containers are transported from end user sites back to the formulation site and rinsed with water. The washings containing the notified polymer are transferred to the formulator's effluent treatment plant.

RELEASE OF CHEMICAL FROM USE

The water treatment solution will be sold to large industrial plants where it will be used for the treatment of water contained in closed systems. During water treatment, the efficacy of the treatment chemical diminishes and new water treatment solution is continually added to the system. A continual bleeding and discharge of the treated water to end-user's effluent treatment plants also takes place and which compensates for replenishment of the chemical in the system.

The majority (>95%) of the notified polymer will be released to the environment during continuous discharge or when cooling systems undergo either short-term manual system blowdown or total shutdown and cleaning. The remaining (<5%) of the notified polymer contained in the cooling tower is expected to be released as drift and fall in the immediate vicinity of the towers. The notifier estimates that the concentration of notified polymer in plant effluent will be <3 ppm. This assumes 60% of the total volume of purge or blowdown is discharged, and the Optidose 1000 is being introduced at a rate of <5ppm.

5.4. Disposal

Residues in empty drums will be sent to licensed drum dealers. Solid and other wastes collected from effluent treatment facilities and generated from spills will be disposed of into landfill.

6. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa

Remarks Optidose 1000 is present as a solution in water

MELTING POINT/FREEZING POINT Not tested

BOILING POINT Not tested

SPECIFIC GRAVITY ≈1.2

Remarks For Optidose 1000 polymer solution

VAPOUR PRESSURE 0.13kPa @ 20ºC

Remarks For Optidose 1000 polymer solution. Optidose 1000 has a very high molecular weight and is expected to have low volatility and hence negligible vapour pressure.

WATER SOLUBILITY Not tested

Remarks As present in water as the sodium salt form, the polymer is readily soluble.

HYDROLYSIS AS A FUNCTION OF pH Not tested

Remarks The polymer in Optidose 1000 does not contain any functional groups that may undergo hydrolysis under normal environmental temperature and pH range 4-9.

PARTITION COEFFICIENT (n-octanol/water) Not tested

Remarks The partition coefficient log P_{OW} was not determined. However, the notified polymer, present as the sodium salt, is readily soluble in water and is not expected to partition in the n-octanol phase.

ADSORPTION/DESORPTION $\log_{10} K_{OC} \approx 9.48$

Method QSAR model PCKOCWIN version 1.66 (Meylan *et al*. 1992)

Remarks A quantitative structure activity relationship (QSAR) model was used to estimate the K_{OC} of the notified polymer. Because of the limitations inherent in the software package in dealing with large and complex molecules, an approach was taken whereby the smallest polymeric sub-unit was entered and the K_{OC} determined. Additional monomers were added sequentially and the K_{OC} determined for each structure until the maximum number of characters was entered. The results showed the estimated K_{OC} increases with each addition of monomeric sub-units and suggests the notified polymer will bind readily to organic matter in soils and sediments thereby rendering it immobile.

The estimated results should be treated with extreme caution. The K_{OC} value is extremely high, particularly for an ionised substance for which QSAR estimates are known to be difficult. Note that the carboxylic acid was assumed to be protonated in the calculations.

DISSOCIATION CONSTANT Not determined

Remarks The notified polymer contains carboxylic acid and other acid groups. The pK_a of the two main acid groups are expected to be <5. The notified polymer is expected to have typical acidity and to remain largely dissociated in water.

PARTICLE SIZE Not applicable

REMARKS

FLAMMABILITY LIMITS

Remarks Optidose 1000 is an aqueous solution and is not flammable. The dry polymer may support combustion.

EXPLOSIVE PROPERTIES

Remarks The polymer in Optidose 1000 is stable and not explosive

REACTIVITY

Remarks The polymer in Optidose 1000 has functional groups of low concern (carboxylic acid), but is considered to have low potential for reactivity under normal conditions of use and handling.

7. TOXICOLOGICAL INVESTIGATIONS

7.1. Acute toxicity – oral (gavage)

Test Substance	Polymer Solution (37.7% concentration)
Method	Toxic Substances Control Act (40CFR Part 793 Japanese Guidelines 59 NohSan No 3850 (10/8/84)
Species/Strain	Rat, 6 male
Vehicle	Administered undiluted
Remarks - Method	Summary only has been submitted
Results	No mortality
LD50	>500 mg/kg bw
Signs of Toxicity	No clinical signs of toxicity were observed.
Effects in Organs	Necropsy revealed no gross changes.
Conclusion	The notified polymer is of low toxicity via the oral route.
Test Facility	Rohm and Haas Company Toxicology Department (1995)

7.2. Acute toxicity - dermal

Test Substance	Polymer Solution (37.7% concentration)
Method	Toxic Substances Control Act (40CFR Part 793) Japanese Guidelines 59 NohSan No 3850 (10/8/84).
Species/Strain	Rat
Vehicle	
Type of dressing	Occlusive
Remarks - Method	Summary only has been submitted
Results	
LD50	>1000 mg/kg bw
Signs of Toxicity - Local	Red-stained fur surrounding the eyes and muzzle were seen during the study; however these clinical signs were judged related to the occlusive test methodology and the use of collars.
Signs of Toxicity - Systemic	No clinical signs of systemic toxicity were observed.
Effects in Organs	Necropsy revealed no gross changes.
Remarks - Results	
Conclusion	The notified polymer is not more than slightly toxic via the dermal route.
Test Facility	Rohm and Haas Company Toxicology Department (1995)

7.3. Irritation – skin

Test Substance	Polymer solution (37.7% concentration)
Method	Toxic Substances Control Act (40CFR Part 793 *Japanese Guidelines 59 NohSan No 3850 (10/8/84)*
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Undiluted
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	Summary only has been submitted.

Results	No irritation (erythema or oedema) was observed.
Remarks - Results	All Draize scores were zero.
Conclusion	The polymer in Optidose 1000 is non-irritating to skin.
Test Facility	Rohm and Haas Company Toxicology Department (1995)

7.4. Irritation - eye

Test Substance	Polymer Solution (37.7% concentration)
Method	Toxic Substances Control Act (40CFR Part 793 *Japanese Guidelines 59 NohSan No 3850 (10/8/84)*
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	Summary only submitted
Results	No ocular effects were observed.
Remarks - Results	Moderate to severe conjunctivitis in 2/3 animals at one hour, resolved at 24 hours. All Draize scores zero at 24, 48 and 72 hours.
Conclusion	The polymer in Optidose 1000 is slightly irritating to the eye.
Test Facility	Rohm and Haas Company Toxicology Department (1995)

8. ENVIRONMENT

8.1. Environmental fate

No biodegradability or environmental fate data were provided.

8.2. Ecotoxicological investigations

8.2.1. ACUTE TOXICITY TO FISH

Test Substance	Polymer Solution (37.7% of notified polymer).
Method	In-house method of T.R. Wilbury Laboratories. The static test was performed following US EPA (TSCA) guidelines, and not conducted according to GLP.
Species	*Oncorhynchus mykiss*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	48 mg $CaCO_3$/L
Analytical Monitoring	
Remarks – Method	The test was performed under static conditions. Ten fish per test vessel were exposed to a control and 5 concentrations of test substance (0.10, 1.0, 10, 100 and 1000 mg/L) over the test period. A stock solution was not prepared and the test substance was added directly to each test vessel. No undissolved material was observed in the test vessel.
Results	
LC50	>1000 mg/L whole product at 96 hours (=377 mg/L of notified polymer)
NOEC (or LOEC)	≥1000 mg/L whole product at 96 hours.
Remarks – Results	No mortalities or behavioural abnormalities were observed in any of the fish exposed to the test substance at the concentrations tested.
Conclusion	The notified polymer is not toxic to fish.
Test Facility	T. R. Wilbury Laboratories Inc. Marblehead, Massachusetts (1995a).

8.2.2. ACUTE/CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

Test Substance	Polymer Solution (37.7% of notified polymer).
Method	In-house method of T.R. Wilbury Laboratories. The static test was performed following US EPA (TSCA) guidelines, and not conducted according to GLP.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	180 mg $CaCO_3$/L
Analytical Monitoring	Dissolved oxygen, pH, conductivity, temperature
Remarks - Method	One replicate containing 10 juvenile daphnids per test vessel were exposed to a control and 5 nominal test concentrations (0.10, 1.0, 10, 100 and 1000 mg/L) of the whole product. The stock solution was prepared by adding 0.5 g of whole product to 1000 mg/L of deionised water, then diluting to the required concentrations. The test concentrations in the test media were not determined analytically. The number of surviving organisms and sublethal effects were determined from visual observation and recorded at 24-hour intervals.
Results	No mortalities or sublethal effects were observed during the test

LC50	>1000 mg/L at 48 hours (whole product basis)
NOEC (or LOEC)	≥1000 mg/L at 48 hours
Remarks - Results	

Conclusion	The notified polymer is not toxic to *Daphnia magna* at the nominal test concentrations used in the study.
Test Facility	T. R. Wilbury Laboratories Inc. Marblehead, Massachusetts (1995b).

8.2.3. ALGAL GROWTH INHIBITION TEST

Test Substance	Polymer Solution (37.7% of notified polymer).
Method	In-house method of T.R. Wilbury Laboratories. The test was performed following US EPA (TSCA) guidelines, and not conducted according to GLP.
Species	*Selenastrum capricornutum*
Exposure Period	96 hours
Concentration Range Nominal	0.10, 1.0, 10, 100, and 1000 mg/L
Concentration Range Actual	Not measured
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Cell counts
Remarks - Method	Algal cells were exposed to 2 replicates of each test concentration of test substance contained in dilution water comprising sterile enriched media with an initial pH of 6.9 and a temperature of 24°C. Test concentrations were not measured analytically. No insoluble material was observed during the test. The test substance decreased pH from about 6.9–7.0 in the controls and test vessels containing the lowest concentrations of test substance to 5.2 in test vessels with the highest test concentrations of test substance.

Results

Remarks - Results	Exposure of freshwater algal cells to the test substance resulted in a decrease in cell growth after 96 hours exposure. At nominal concentrations of 100 and 1000 mg/L, cell growth was reduced to <1% of the control, while at 10 mg/L, cell growth was reduced to 81% of control. The 96-hour EC50 was determined to be 20 mg/L and the NOEC was 10 mg/L on a whole product basis.
Conclusion	The notified polymer is moderately toxic to algae (Mensink *et al*. 1995). It was concluded the effects of the test substance were algistatic rather than algicidal because cell growth recovered when cells were transferred from the test media to a fresh vessel containing no test substance.
Test Facility	T. R. Wilbury Laboratories Inc. Marblehead, Massachusetts (1995c).

8.2.4. Inhibition of microbial activity

Not tested

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Usage patterns indicate that over 95% of the notified polymer will pass through the end user's water treatment systems through blow down, cleaning and continuous bleed from where it will enter on-site effluent treatment facilities prior to being released into the sewer.

A worst case scenario Predicted Environmental Concentration (PEC) for the aquatic environment was determined assuming direct discharge of the notified polymer from water treatment systems into the sewer of a large city and a medium sized town. The results are shown in the table below (modified from the method of Klaine *et al.* 1996).

	City	Town
A: Import volume (year 5)	5000 kg	500 kg
B: Daily release	13.7	1.37
C: Application concentration	5 mg/L	5 mg/L
D: Daily flow of cooling towers (B/C)	2.74 ML	0.27 ML
E: Sewer rate per day	250 ML	7.5 ML
F: Dilution factor in sewer (E/D)	91	27
G: Concentration in sewer (C/F)	0.05 mg/L	0.18 mg/L
H: Dilution factor in receiving waters	10	3
I: Concentration in Receiving Waters (G/H)	5×10^{-3} mg/L	0.06 mg/L

In determining the PEC values, the following assumptions were made:

Daily feed rates of the notified polymer are 5 mg/L of notified polymer.
All of the polymer imported in one year is released into the sewer over a 365 days period, with no dilution or adsorption in on-site effluent treatment facilities prior to release.
Release occurs from one site in one city (1.7 million people), or in one country town (50,000 people), with a sewer output based on an average water usage of 150 L per day person.

The K_{OC} indicates the notified polymer will bind readily to organic matter in sludge, soils and sediments. Consequently, in on-site effluent treatment facilities, it is expected that over 90% of the notified polymer will be removed through adsorption and treatment prior to release of the treated effluent to municipal sewage treatment systems. It is expected that sludge removed from treatment facilities will be disposed of in landfill.

9.1.2. Environment – effects assessment

The notifier supplied ecotoxicity studies for fish, *Daphnia*, and algae using the test substance designated as TFM 2876B of which the notified polymer is 37.7%. The ecotoxicity data indicate the notified polymer is not harmful to fish or *Daphnia*, but is able to inhibit the growth of algae and is considered moderately toxic to these organisms (Mensink *et al* 1995). This is consistent with the literature (eg. Nabholz *et al*. 1993) which indicates that polymers of this kind are toxic due to their ability to chelate metals, with the highest toxicity occurring when there is a carboxylic acid on every alternate carbon atom of the polymer back bone, as is the case here.

A predicted no effects concentration (PNEC) can be determined when at least one acute LC_{50} for each of the three trophic levels is available (i.e. fish, *Daphnia*, algae). The PNEC is calculated by taking the LC_{50} value of the most sensitive species, and dividing this value by an assessment safety factor. The most sensitive species was freshwater algae with a 96 hour LC_{50} of 20 mg/L (or 7.54 mg/L of notified polymer) and the NOEC was 10 mg/L. Using a worst case scenario safety factor of 100 (OECD), the $PNEC_{aquatic}$ is 0.075 mg/L.

9.1.3. Environment – risk characterisation

Usage patterns indicate that over 95% of the notified polymer will be released into the aquatic environment via sewage treatment systems predominantly through discharge of water during boiler blow downs and from water cooling towers. The worst case scenario daily PECs of the notified polymer, discharged from a water treatment system into the domestic sewer of a large

city and a small town, are expected to be in the order of 5 μg/L and 0.06 mg/L respectively. These values assume all of the imported volume of chemical is released from one site over a 365-day period, with no on-site treatment, no losses or adsorption, and no further dilution once released into the natural environment.

The ecotoxicity data indicate the notified polymer is not harmful to fish or *Daphnia*, but is able to inhibit the growth of algae and is considered moderately toxic to these organisms (Mensink *et al* 1995). The PEC/PNEC ratios calculated for the aquatic environment of a city and a small town respectively, are 0.06 and 0.8, indicating no immediate concern toward aquatic organisms. It should also be emphasised that in reality, rather than being restricted to one city or town, release of the imported volume of polymer will be much more diffuse than is assumed in calculating the PEC values.

Given the nature of scale inhibitors, the calculated EC_{50} for algae and the PEC values are probably significantly overestimated. Scale inhibitors are able to prevent scale formation by adsorbing onto the crystal nuclei of chemical compounds such as calcium carbonate, calcium phosphate, and compounds of magnesium and silica thereby preventing crystal growth on the surfaces of equipment (Environmental Protection Group, 1997). Therefore, it is likely that the inhibition of algal cell growth results from the notified polymer sequestering critical micronutrient metals in the growth medium, and hence starving the algae. This phenomenon has been documented for other scale inhibitor substances as well (eg. Schowanek *et al*. 1996). Schowanek *et al*. (1996) suggest that both NOEC and EC_{50} values given by algal growth inhibition tests may be overestimated by at least one order of magnitude for strongly chelating chemicals.

The polyanionic nature of the notified polymer indicates that it will bind strongly to soils and sediments (Boethling and Nabholz, 1997). Consequently, while there is doubt about the K_{OC} estimated by QSAR, a large portion of the polymer is likely to be removed in sewage treatment facilities by adsorption and settling, leaving only a small amount associated with the water compartment. Any dissolved polymer released into natural surface water is expected to have much of its scavenging capabilities reduced. This is because many of the active sites will already be loaded with Ca^{2+}, Mg^{2+} and other ions scavenged from water treatment systems and the nutrient-rich sewage effluent, and as such, it should not limit available nutrient in the natural environment.

Any notified polymer released into the sewer and partitioning into sludge, will ultimately be disposed of in landfill as solid wastes. In landfill, the notified polymer is expected adsorb to soil and sediment due to its polyanionic nature and as such should not leach in aquatic compartments even though the chemical is water-soluble. In soil environments, the notified polymer is expected to undergo slow abiotic and microbial degradation.

9.2. Human health

9.2.1. Occupational health and safety

9.2.1.1 OCCUPATIONAL EXPOSURE ASSESSMENT

Optidose 1000 will be imported by ship in 200 litre open head steel drums, then transported by road to the notifier's Geelong warehouse where it will be stored in a bunded area. Transport to customer and end use sites will be by road. Waterside workers, transport drivers and warehouse workers would only be exposed to the material in the event of and accident. The potential for exposure is 1-2 hours per day, 10-20 days per year.

At the customer site the drums are open and hoses connected. Optidose 1000 will be pumped from the drums into a closed stainless steel mixing vessel (capacity range 500 to 10,000 L) vented to the outside to remove any vapours. The final concentration of the polymer in the formulated water treatment solution is <5%. The solution will be pumped and transferred through the hard pipe system to 1000 L IBCs. Two operators per shift will be involved in the mixing and packaging process (3-4 hours/day and 20-60 days/year). All areas of the reformulation area are bunded, and local and general ventilation is located in all areas of the

plant. Skin and/or eye contact may occur during this process. Standard personal protective equipment, which will be worn at all times, includes neoprene gloves, safety glasses and coveralls.

The water treatment solution will be sold by the reformulators to 3-5 large industrial plants where end use will take place. Plant operators at the end use sites will handle the water treatment solution in the process of connecting pipes to the IBCs (0.5 hours/day, 50-100 days/year). The water treatment solution will be automatically pumped and metered from these containers into the water to be treated. In some cases, the solution will be decanted into smaller containers for use. The water is in a closed system and continuously re-used. The concentration of the polymer in the treated water is <5 ppm. Skin and/or eye contact may occur during this process. Standard personal protective equipment, which will be worn at all times, includes neoprene gloves, safety glasses and coveralls.

9.2.2. Public health

Exposure of the general public as a result of reformulation, transport and disposal of the product containing the notified chemical is assessed as being negligible. Products containing the notified chemical will only be used in industrial situations. They will not be used by the general public in domestic situations. Therefore public exposure is unlikely as a result of the industrial uses of products containing the notified polymer.

9.2.3. Human health - effects assessment

A summary of toxicological studies (acute oral, acute dermal, skin irritation and eye irritation) was provided with this submission. The information submitted indicates that the polymer is of low acute toxicity, is not irritating to the skin and only slightly irritating to the eye. Information provided by the notifier indicates that the results of toxicity testing of the notified polymer are consistent with toxicity data for the monomer poly(acrylic acid) and other acid functional groups. A 91-day inhalation study of rats exposed to poly(acrylic acid)s resulted in a NOAEL of 1.0 mg/m^3. Mild pulmonary irritation was found after exposure, but not after a 91-day recovery period. Another acid group present was reported to be slightly toxic following acute oral exposure of rats (1000-2500 mg/kg) and practically non-toxic following acute dermal exposure in rabbits (LD_{50} >4000 mg/kg). A 20% solution was moderately irritating to the intact skin of guinea pigs and corrosive to abraded skin. A 5% solution applied to the abraded skin of guinea pigs was only slightly irritating. A 100% concentration was corrosive to the eyes of rabbits, while a 10 or 15% solution was characterised as substantially irritating.

While assessment of the results is difficult without the full reports of the studies, there is no data available that would indicate a potential toxicity for this polymer. The physical and chemical properties of the polymer preclude the potential for inhalation exposure. The polymer solution has low oral and dermal toxicity and is non-irritating to the skin and slightly irritating to the eyes. Final use concentrations of the polymer will further diminish the toxicity to insignificant levels.

9.2.4. Human health – risk characterisation

9.2.4.1 *OCCUPATIONAL HEALTH AND SAFETY

The polymer has low toxicity, volatility and reactivity. Engineering controls are in place in the workplaces where the polymer will be used. Therefore, the probability of exposure to the polymer is low and the risk to workers is minimal.

9.2.4.2 *PUBLIC HEALTH

The risk to public health is considered to be minimal since public exposure is unlikely as a result of the industrial uses of products containing the notified polymer.

10. CONCLUSIONS

10.1 Hazard classification

Based on the available data the polymer in Optidose 1000 is not classified as hazardous under

the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999).

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

The chemical is not considered to pose a risk to the environment based on its reported use pattern.
or
The chemical may pose a risk to the environment based on the notified use pattern. Further work or actions (such as additional testing in the area of concern, detailed exposure analysis, in-depth risk assessment or further risk management actions) should be considered.

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 manner described in the notification.

11. RECOMMENDATIONS

Control Measures
Occupational Health and Safety

Employers should implement the following engineering controls to minimise occupational exposure to the polymer in Optidose 1000:
local exhaust ventilation

Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the polymer in Optidose 1000:
Gloves, glasses, coveralls

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 polymer in Optidose 1000 are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

The notified polymer should be disposed of in landfill or incinerated in accordance with local, state, and federal regulations.

Emergency procedures

Spills/release of the notified polymer should be contained immediately with inert material and placed in suitable containers for disposal in accordance with the MSDS. Spills and cleaning runoff should not be allowed to enter municipal sewers or open water bodies.

11.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

Under Sub section 64(2) of the Act:
if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

12. MATERIAL SAFETY DATA SHEET

The MSDS for the polymer in Optidose 1000 was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1999).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

13. BIBLIOGRAPHY

Boethling, S.B. and Nabholz, J.V. (1997). Environmental assessment of polymers under the US Toxic Substances Control Act. In: Hamilton, J.D. and Sutcliffe, R. (eds.), *Ecological Assessment of Polymers*, p 211. Van Nostrand Reinhold, USA.

Environment Protection Group, Environment Australia (1997). Water Treatment Industry Chemical Use and Resulting Environmental Exposure Levels. Sinclair Knight Merz, Malvern Victoria.

Klaine SJ, Cobb, GP, Dickerson RL Dixon, KR, Kendell RJ, Smith EE and Solomon KR (1996). An ecological risk assessment for the use of the biocide, dibromonitrilopropionamide (DBNPA), in industrial cooling systems. *Environmental Toxicology and Chemistry*, 15 (1): 21-30.

Mensink BJWG, Montforts M, Wijkhuizen-Maslankiewicz L, Tibosch H and Linders JBHJ (1995). Report no. 679101022: Manual for Summarising and Evaluating the Environmental Aspects of Pesticides. National Institute of Public Health and Environmental Protection, Bilthoven, The Netherlands.

Meylan, W., Howard, P.H. and Boethling R.S. (1992). Molecular Topology/Fragment Contribution Method for Predicting Soil Sorption Coefficients. *Environmental Science and Technology*, 26:1560-7.

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 (1999) *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008]* National Occupational Health and Safety Commission

NOHSC (1994) *National Code of Practice for the Preparation of Material Safety Data Sheets. [NOHSC:2011]* National Occupational Health and Safety Commission.

Rohm and Haas (1995) Human Health Risk Assessment of QRXP-1488 PMN, QRXP-1489 PMN, and QRXP-1519 PMN. Laboratory Report No 97R-1067. Rohm and Haas, Spring House, PA (unpublished report provided by the notifier)

Schowanek D, McAvoy D, Versteeg D and Hanstveit A (1996). Effects of nutrient trace metal speciation on algal growth in the presence of the chelator [S,S]-EDDS. *Aquatic Toxicology* 36:253-275.

T. R. Wilbury (1995a). Acute Toxicity of Polymer Solution TFM 2876B to the Rainbow Trout, *Oncorhynchus mykiss*. T. R. Wilbury Study Number 715-RH. T. R. Wilbury Laboratories Inc., Marblehead, Massachusetts (Unpublished report provided by the notifier).

T. R. Wilbury (1995b). Acute Toxicity of Polymer Solution TFM 2876B to Daphnid, *Daphnia Magna*. T. R. Wilbury Study Number 714-RH. T. R. Wilbury Laboratories Inc., Marblehead, Massachusetts (Unpublished report provided by the notifier).

T. R. Wilbury (1995c). Acute Toxicity of Polymer Solution TFM 2876B to the Freshwater Alga, *Selenastrum capricornutum*. T. R. Wilbury Study Number 713-RH. T. R. Wilbury Laboratories Inc., Marblehead, Massachusetts (Unpublished report provided by the notifier).