File No: NA/639

July 1999

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

TRC-289

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (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 National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, National Occupational Health and Safety Commission, 92-94 Parramatta Road, Camperdown NSW 2050, between the following hours:

Monday - Wednesday	8.30 am - 5.00 pm
Thursday	8.30 am - 8.00 pm
Friday	8.30 am - 5.00 pm

Copies of this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

For enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 9577-9514 FAX (61) (02) 9577-9465

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

TRC-289

1. APPLICANT

Hall Laboratories of Glenelg Highway, Pittong, LINTON, VIC 3360 has submitted a standard notification statement in support of their application for an assessment certificate for TRC-289.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and details of the polymer composition have been exempted from publication in the Full Public Report and the Summary Report.

Trade Name:	TRC-289 pHREEdom 200 (12 % notified polymer) pHREEdom 250 (12 % notified polymer) pHREEdom 410 (6 % notified polymer) pHREEdom 5200M (22 % notified polymer) pHREEdom T series (6 - 10 % notified polymer)

3. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer is manufactured and used as a component of an aqueous mixture and is never isolated as a pure substance. Hence the values below are for an aqueous 35 % polymer solution.

Appearance at 20°C and 101.3 kPa:	clear amber liquid
Boiling Point:	100°C (based on water)
Specific Gravity:	1.295 at 20°C
Vapour Pressure:	not determined - see comment below
Water Solubility:	not determined - see comment below
Partition Co-efficient	

(n-octanol/water):	not determined - see comment below
Hydrolysis as a Function of pH:	not determined - see comment below

Adsorption/Desorption:	not determined - see comment below
Dissociation Constant:	not determined - see comment below
Flash Point:	not expected to be flammable
Explosive Properties:	not expected to be explosive
Reactivity/Stability:	not expected to be reactive

Comments on Physico-Chemical Properties

The 35% polymer solution is a clear amber liquid, while the imported products range from a clear amber liquid to a clear dark brown liquid depending on the composition. The notified polymer is imported in an aqueous solution and therefore the boiling point should be equivalent to that of water. The polymer is expected to have a low vapour pressure due to the moderately high molecular weight.

The notifier states that the polymer is considered to be completely soluble in water and that conducting a water solubility test would produce no additional information. The presence of the four phosphonate moieties would be expected to effect a very high water solubility to the compound.

The polymer solution has a pH of 4.2 - 4.8 and is stable for a minimum of 12 months under normal conditions. It is not expected to hydrolyse in the pH ranges of 1 - 2 and 4 - 9 so hydrolysis is unlikely in the usual environmental pH range.

A value for partition coefficient was not determined. The notifier states that the polymer is insoluble in n-octanol and totally miscible with water. Under these conditions the P_{ow} is defined as zero.

The polymer is expected to be highly dissociated in aqueous systems. There are at least 8 protons that can potentially dissociate to yield several dissociation constants. Hence, it is expected that the pKa will vary from about 2 to 12. The polymer also contains two basic nitrogens. The products containing the notified polymer have pH commonly above 12, and will contain predominantly polysodium salts of the notified polymer.

4. PURITY OF THE CHEMICAL

Degree of Purity: 35 % in aqueous solution

Toxic or Hazardous Impurities:

Chemical name:	Formaldehyde
CAS No.:	50-00-0
Weight percentage:	< 0.06 %
Toxic properties:	On the *List of Designated Hazardous Substances* (National Occupational Health and Safety Commission, 1994b)
	R23/24/25 Toxic by inhalation, in contact with skin, and if swallowed R34 Causes burns R40(3) Possible risk of irreversible effects R43 May cause sensitisation by skin contact

Chemical name:	Phosphorous acid
CAS No.:	13598-36-2
Weight percentage:	< 2 %
Toxic properties:	Not on the *List of Designated Hazardous Substances* (National Occupational Health and Safety Commission, 1994b) As a strong acid, it is likely to be a skin irritant and to have corrosive properties at high concentrations

Maximum Content of Residual Monomers: The polymer is produced by adding functional groups to a pre-polymer. The residual reactants are detailed above.

Additives/Adjuvants:

Chemical name:	Water
CAS No.:	7732-18-5
Weight percentage:	64 %

5. USE, VOLUME AND FORMULATION

The notified polymer will be used to control corrosion and the precipitation of calcium carbonate and calcium sulphate in industrial water systems. All applications of the polymer will be for recirculating systems where process/cooling water is returned in a circuit either to the cooling tower or to a process water dam.

The notified polymer is manufactured overseas as an aqueous 35% polymer solution. The product is then formulated as an aqueous 6 - 22% polymer solution that will be imported at volumes of 5 - 50 tonnes annually in 1000 L export bins (EBs) made of high density

polyethylene, or in 200 L steel drums. No manufacture or reformulation will occur in Australia. The polymer will be added to water to control scaling at levels of between 1 ppm (for once-through industrial systems) to 20 ppm in mining operations. The notifier indicates that no once-through applications are currently planned. The notifier anticipates that the notified polymer will be imported in the form of pHREEdom 5200M (22 % notified polymer).

6. OCCUPATIONAL EXPOSURE

The notified polymer will be imported in 1000 L EBs. These will incorporate a valve delivery system for metering the solution into the industrial water systems.

The EBs containing the notified polymer are expected to be unloaded and transported to a warehouse, from whence they will be transported by road or rail to the end use sites. No exposure to the notified polymer would be expected to occur during transport or storage of the notified polymer except in the case of an accident involving rupture of the containers.

At the end use sites, the EBs will be connected through a closed system into the industrial water system. There is potential for dermal or ocular exposure to drips or spills of the product containing the notified chemical at 22 % during connection and disconnection of the EBs.

The notified polymer will be present in dilute solution (< 20 ppm) throughout the recirculated industrial water system, and there is the possibility of exposure to this solution by a number of routes. It is likely that dermal and ocular exposure will occur, particularly during maintenance of the water system, and there is also the possibility of mists being formed in cooling towers.

The container labels for the products indicate that safety glasses and chemical resistant gloves should be worn while the product is handled.

7. PUBLIC EXPOSURE

There will be negligible potential for exposure of the public to the notified polymer, as it is not available for retail sale and will be used only in industrial applications in areas with limited public access.

8. ENVIRONMENTAL EXPOSURE

Release

If the chemical is used in cooling tower systems, it will eventually be released through continuous cooling tower blowdown. Hence, in this use, all of the notified chemical will eventually be released into sewerage systems or drains. The notifier estimated the levels of release from blowdown, and drift and leakage to be in the range 0.05 - 0.1 % of recirculation rate in these applications. Given the usual concentration of the polymer in these applications (1 - 2 ppm), only a very low discharge of the polymer to the environment is expected.

In the case of polymer usage in the mining industry and power stations using ash systems, all of the polymer will be released as a component of controlled discharge of water from the recirculating system to tailings dams. These dams are enclosed systems and so no leakage or run-off is expected.

Fate

All of the notified polymer will eventually be released into the environment, and the majority could be expected to be discharged into sewerage systems. The polymer may either partition to sediment or stay in the aqueous compartment. Generally, extremely water soluble chemicals do not readily adsorb to sediments and soil, however, because of their good chelation properties phosphonates have a high affinity for soils and sediments (Gledhill & Feijtel) and any polymer released into waterways is expected to adsorb strongly to sediment.

The notifier did not submit any biodegradability information for the notified polymer, but did provide reports for similar tetraphosphonate compounds (Monsanto Industrial Chemicals Company, 1974). Previous studies have shown that little primary or ultimate biodegradation occurs for any phosphate products in biodegradation tests such as the OECD test, BOD20 test, Sapromat test and Closed Bottle test (Gledhill & Feijtel). Consequently the polymer is expected to be persistent in the environment and, though not readily biodegradable, is expected to slowly degrade through slow biological processes and other physical mechanisms.

In a tailings dam, any polymer in the system would bind to solids and remain associated with the sediment layer. Biodegradation would not be expected to occur due to the lack of biological activity. However, once rehabilitation of the dam is started, it would be expected that the polymer would eventually be degraded by slow biological processes.

The level of biodegradability would suggest that there is potential for bioaccumulation. Although the reported high solubility would suggest that the polymer is likely to be persistent in the water compartment, the low level exposure of the notified polymer and expected strong adsorption to sediment should limit the bioaccumulation potential.

9. EVALUATION OF TOXICOLOGICAL DATA

The toxicological tests were performed according to OECD test guidelines.

9.1 Acute Toxicity

There are no toxicity studies on the notified polymer, or on the 35 % (w/v) aqueous solution used for formulating the products. Acute oral toxicity and skin and eye irritation studies were provided on pHREEdom products containing lower proportions of the notified polymer, namely pHREEdom 200 (12 % notified polymer, also approximately 2 % each of monoethanolamine and sodium tolyltriazole) and pHREEdom 410 (6 % notified polymer, also 1 % sodium tolyltriazole). In addition, acute oral toxicity, skin and eye irritation and corrosivity and dermal toxicity studies of an analogue of the notified polymer, SP-237, were

provided on behalf of the notifier. The structure of SP-237 was not provided, but it was described as a similar phosphonate based product. The data from SP-237 is taken as representative of that of the notified polymer.

Summary of the acute toxicity of pHREEdom 200 (12 % notified polymer)

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5000 mg/kg	(Cervan, 1993b)
skin irritation	rabbit	non-irritant	(Keiffer, 1993a)
eye irritation	rabbit	slight irritant	(Cervan, 1993a)

Summary of the acute toxicity of pHREEdom 410 (6 % notified polymer)

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5000 mg/kg	(Cervan, 1993d)
skin irritation	rabbit	non-irritant	(Keiffer, 1993b)
eye irritation	rabbit	slight irritant	(Cervan, 1993c)

Summary of the acute toxicity of SP-237

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 16000 mg/kg	(Gabriel, 1980d)
acute dermal toxicity	rabbit	LD_{50} > 20000 mg/kg	(Gabriel, 1980b)
acute inhalation toxicity	rat	LC_{50} > 15.5 mg/L	(Gabriel, 1980c)
skin irritation	rabbit	non-irritant	(Gabriel, 1980g)
eye irritation	rabbit	non-irritant	(Gabriel, 1980e; Gabriel, 1980f)

9.1.1 Oral Toxicity

pHREEdom 200 (Cervan, 1993b), pHREEdom 410 (Cervan, 1993d)

Species/strain: rat/Wistar

Number/sex of animals: 5/sex

Observation period:	14 days
Method of administration:	gavage, as received
Test method:	Limit test, OECD TG 401
Clinical observations:	pHREEdom 200: no clinical signs of toxicity were observed; pHREEdom 410: instances of lethargy and ataxia in females on day of dosing; one female lost weight during the second week of the observation period
Mortality:	no deaths occurred during either study
Morphological findings:	no gross abnormalities were observed in either study
LD_{50}:	> 5000 mg/kg test material (> 600 mg/kg notified polymer for pHREEdom 200 > 300 mg/kg notified polymer for pHREEdom 410)
Result:	the notified polymer was of low acute oral toxicity in rats; the formulations tested were of very low acute oral toxicity in rats

SP-237 (Gabriel, 1980d)

Species/strain:	rat/Sherman-Wistar
Number/sex of animals:	5 groups, each 5/sex
Observation period:	14 days
Method of administration:	gavage, as received
Dose:	1000, 2000, 4000, 8000 and 16000 mg/kg
Test method:	OECD TG 401
Mortality:	1 male in the 16000 mg/kg group died on day 1
Clinical observations:	no unusual behavioural signs were noted
Morphological findings:	no gross abnormalities were observed
Comment:	no comments as to the circumstances of the death in the high dose group was made in the report
LD_{50}:	> 16000 mg/kg
Result:	SP-237 was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity

SP-237 (Gabriel, 1980b)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	2/sex
Observation period:	14 days
Method of administration:	test material was placed on a gauze patch and secured under an occlusive wrap for 24 hours
Dose:	4000, 8000, 16000 and 20000 mg/kg
Test method:	similar to OECD TG 402
Mortality:	no deaths occurred during the study
Clinical observations:	no unusual behavioural signs were noted
Morphological findings:	no gross abnormalities were observed
LD_{50}:	> 20000 mg/kg
Result:	SP-237 was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

SP-237 (Gabriel, 1980c)

Species/strain:	rat/not stated
Number/sex of animals:	5/sex
Observation period:	14 days
Dose Range:	aerosol, 15.5 mg/L (maximum attainable concentration)
Method of administration:	whole body, 1 hour exposure, dynamically operated chamber
Test method:	limit test, similar to OECD TG 403
Clinical observations:	no unusual behavioural signs were noted
Mortality:	no deaths were recorded during the observation period

Morphological findings:	no gross abnormalities were observed
LC_{50}:	> 15.5 mg/L for 1 hour exposure
Result:	SP-237 was of very low acute inhalation toxicity in rats

9.1.4 Skin Irritation

pHREEdom 200 (Keiffer, 1993a), pHREEdom 410 (Keiffer, 1993b)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	pHREEdom 200: 2 male 4 female pHREEdom 410: 1 male 5 female
Observation period:	3 days
Method of administration:	0.5 mL test material was applied to a clipped intact region of the dorsal skin and secured under a gauze patch with a semi-occlusive dressing for 4 hours; at the end of this time residual material was removed with distilled water; animals were examined for skin reaction 1, 24, 48 and 72 hours following application of the test substance
Test method:	OECD TG 404
Comment:	all Draize scores (Draize, 1959) after 24, 48 and 72 hours were zero; slight erythema (Draize score of 1) was observed for 2 animals with pHREEdom 200 and 1 animal with pHREEdom 410 after 1 hour
Result:	the formulations containing the notified polymer were not irritating to the skin of rabbits

SP-237 (Gabriel, 1980g)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	6, sex not specified
Observation period:	3 days
Method of administration:	0.5 mL test material was placed on gauze patches on clipped intact and abraded skin areas and secured under an occlusive wrap for 24 hours
Test method:	16 CFR

Comment: SP-237 was not irritating to intact skin; all Draize scores (Draize, 1959) were zero; it was a slight irritant to abraded skin; erythema persisting to day 3 and oedema which had cleared by day 3 were observed

a skin corrosivity study on intact rabbit skin (Gabriel, 1980a) using similar conditions according to 49 CFR Section 173.240 also showed SP-237 to be non-irritant and non-corrosive

Result: SP-237 was not irritating to the intact skin of rabbits

9.1.5 Eye Irritation

pHREEdom 200 (Cervan, 1993a), pHREEdom 410 (Cervan, 1993c)

Species/strain: rabbit/New Zealand White

Number/sex of animals: pHREEdom 200: 6 female
pHREEdom 410: 2 male, 4 female

Observation period: pHREEdom 200: 7 days
pHREEdom 410: 3 days

Method of administration: 0.1 mL of test material applied as supplied into conjunctival sac of one eye of each animal; the contralateral eye served as the control; animals were examined for eye lesions 1, 24, 48 and 72 hours after test substance application

Test method: OECD TG 405

Draize scores (Draize, 1959) of unirrigated eyes:

pHREEdom 200

			Time after instillation					
Animal	***1 day***		***2 days***		***3 days***		***7 days***	
Cornea	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0
Iris								

1		0			0			0			0	
2		0			0			0			0	
3		0			0			0			0	
4		0			0			0			0	
5		0			0			0			0	
6		0			0			0			0	
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	0	2	1	0	0	0	0	0	0	0	0	0
2	1	1	0	0	0	0	0	0	0	0	0	0
3	1	2	1	1	0	0	0	0	0	0	0	0
4	2	2	1	1	0	0	1	0	0	0	0	0
5	1	2	1	1	0	0	1	0	0	0	0	0
6	1	1	0	0	0	0	0	0	0	0	0	0

pHREEdom 410

Time after instillation

Animal	***1 day***		***2 days***		***3 days***	
Cornea	***o***	***a***	***o***	***a***	***o***	***a***
1	0[1]	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	0	0	0	0	0	0
5	0	0	0	0	0	0
6	0	0	0	0	0	0
Iris						
1	0		0		0	
2	0		0		0	
3	0		0		0	
4	0		0		0	
5	0		0		0	
6	0		0		0	

Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	0	1	0	0	0	0	0	0	0
2	1	1	0	0	0	0	0	0	0
3	1	1	1	1	0	0	0	0	0
4	1	2	0	1	0	0	0	0	0
5	1	1	0	0	0	0	0	0	0

6	0	1	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge

Comment: no abnormal results were observed in an ultraviolet fluorescein scan

Result: the formulations containing the notified polymer were slightly irritating to the eyes of rabbits

SP-237 (Gabriel, 1980e; Gabriel, 1980f)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 6 per study, sex not specified

Observation period: 7 days

Method of administration: 0.1 mL of test material applied as supplied into conjunctival sac of the right eye of each animal; the left eye served as the control; for the washout group, test material was washed out of the eye with 300 mL water after 5 seconds (3 animals) and after 30 seconds (3 animals); animals were examined for eye lesions 1, 2, 3, 5 and 7 days after test substance application

Test method: CFR 16

Comment: no Draize scores (Draize, 1959) above zero were recorded at any time either in the unwashed or washed group

Result: SP-237 was not irritating to the eyes of rabbits

9.1.6 Skin Sensitisation

No skin sensitisation studies were provided in the notification package. Variation of the data requirement was sought as no data were available. The Material Safety Data Sheet (MSDS) for the product pHREEdom T1000, which contains the related chemical trisodium hydroxyphosphonoacetate at 4 – 6 %, reports that hydroxyphosphonoacetic acid has been reported to be a skin sensitiser in guinea pigs. It is not clear whether this is related to the phosphonate group, which is common to this chemical and the notified polymer. The notifier did not propose this chemical as an analogue of the notified polymer. Secondary notification of the notified chemical will be required if future studies on the notified polymer or close analogues show evidence of skin sensitising potential.

9.2 Repeated Dose Toxicity

No repeated dose toxicity studies were provided in the notification package. Variation of the data requirement was sought as no data were available.

There is a statement on an Internet page from Solutia (Solutia Inc), concerning the hazards of the related Dequest® series of phosphonate water treatment chemicals, that "long term feeding studies have been conducted on most classes of these products. These studies indicate that DEQUEST phosphonates do not have toxic effects other than those resulting from calcium sequestration (and the subsequent effects on bone) and their high affinity for bone itself."

Secondary notification of the notified polymer will be required if future studies on the notified polymer or close analogues show significant systemic toxicity.

9.2 Genotoxicity

No genotoxicity studies were provided in the notification package. Variation of the data requirement was sought as no data were available.

A summary of reproductive effects and genotoxicity assays for the related compound diethylenetriaminepenta(methylenephosphonic acid) was given in the Monsanto MSDS for the related compound Dequest® 2060 (Monsanto Industrial Chemicals Inc, 1985). It was tested in acid form in a *salmonella* reverse mutation assay and in an *in vitro* L5178Y TK mouse lymphoma assay. It was tested in neutralised form in an *in vitro* L5178Y TK mouse lymphoma assay, an *in vitro* study of transformation of Chinese hamster ovary cells and an *in vivo* study of rat bone marrow cell clastogenesis. Apart from the mouse lymphoma assay, the tests gave negative results.

A positive result was seen in the initial mouse lymphoma assay for the acid form in the presence and absence of metabolic activation, and for the neutralised form in the presence of metabolic activation. This was considered contradictory to the lack of genotoxicity observed in the other studies, and several additional studies were performed under conditions of controlled pH and osmolality. It was concluded that the results for the acid form were a false positive, as has been observed for other compounds at acidic pH, and that the high concentrations of neutralised form gave false positive results due to the effect of osmolality on spontaneous mutation survival and growth. These two factors were shown to influence false positive results by Scott et al. (1991). On the basis of this evidence, the analogue compound is not considered mutagenic.

Secondary notification of the notified polymer will be required if future studies on the notified polymer or close analogues show evidence of mutagenic potential.

9.4 Overall Assessment of Toxicological Data

The formulations containing the notified polymer (6 % and 12 %) and the analogue chemical, SP-237, were all found to have very low acute oral toxicity in rats. The LD_{50} values for the notified chemical derived from the limit tests using the formulations show at most low oral toxicity.

The analogue chemical, SP-237, was found to be of low acute dermal toxicity in rabbits and

very low acute inhalation toxicity in rats. SP-237 was stated to be a similar phosphonate based product to the notified polymer, so this toxicity is taken to reflect that of the notified polymer.

The formulations containing the notified polymer and SP-237 were found to be non-irritant to intact rabbit skin, although SP-237 was found to be a slight irritant to abraded rabbit skin. SP-237 was found to be non-irritant to rabbit eyes, with or without washing, but the two formulations tested were found to be slight irritants. The MSDS for these formulations indicate that the pH of the formulations is around 12, so irritant properties would be expected. It is probable that the irritant properties of formulations containing the notified chemical will be primarily dependent on the pH of the solutions, as there is no indication that the irritation caused by the notified chemical is greater than would be expected on the basis of the pH.

No skin sensitisation, repeated dose toxicity or genotoxicity studies were provided by the notifier. The MSDS for the product pHREEdom T1000, which contains the related chemical trisodium hydroxyphosphonoacetate, reports that hydroxyphosphonoacetic acid is a skin sensitiser in guinea pigs. This suggests that the notified polymer may be a skin sensitiser, although hydroxyphosphonoacetic acid is a poor analogue because it contains several types of functional group. Further studies to determine the sensitising potential of the notified polymer should be performed.

The statement about repeat dose toxicity concerning the Dequest products indicates that it is unlikely that the notified chemical will have major systemic toxic effects except those associated with calcium sequestration. The analogue genotoxicity data indicates that the notified chemical is not likely to be genotoxic, but further investigation of the genotoxic potential of the notified chemical should be performed.

The product labels for pHREEdom 200 and pHREEdom 250 indicate that the products are authorised by the US Department of Agriculture for use in federally inspected meat and poultry plants.

On the basis of the toxicological data provided, the notified chemical can not be determined to be a hazardous substance according to the National Occupational Health and Safety Commission *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a). However there are data gaps concerning skin sensitisation, repeat dose toxicity and genotoxicity.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided the following ecotoxicity data in support of their application. The tests were performed in compliance with U.S. EPA methods for compound testing (Toxic Substance Control Act).

Species	Test	Result[a]
Fathead Minnow (*Pimephales promelas*)	Acute Toxicity (static) (OECD TG 203)	96 h LC_{50} > 1000 mg/L
Water Flea (*Daphnia pulex*)	Acute Toxicity - Immobilisation Test (Static Test) (OECD TG 202)	48 h EC_{50} > 1000 mg/L

[a]1000 mg/L of the product HI-SAT-2X is equivalent to 120 mg/L of the notified polymer.

Nominal concentrations up to 1 g/L were tried in the test method for two solutions of 6 % and 12 % polymer formulation in the product HI-SAT-2X. The standard synthetic dilution water was prepared by adding reagent grade chemicals to deionised water to produce moderately hard water. At the time of testing, the mean hardness of the diluent was 112 mg/L $CaCO_3$ and the mean alkalinity was 55 mg/L $CaCO_3$. The methods used in the tests conformed to the recommended guidelines specified by the US EPA for static acute tests.

Results from the tests showed that the 96 h LC_{50} for fathead minnows and the 48 h LC_{50} for daphnia for HI-SAT-2X were greater than 1 g/L. Both organisms tested achieved 100 % survival at 1000 mg/L of HI-SAT-2X containing up to 120 mg/L of the notified polymer.

Hence, test data indicate little or no toxicity of the notified polymer to *Pimephales promelas* juveniles and *Daphnia pulex* at these concentrations.

The notifier did not submit any test reports of the toxicity of the polymer to algae, but did submit a study of the toxicity effects of similar tetraphosphonate compounds (that did not contain the same type of repeat unit) on a variety of species of algae (Monsanto Industrial Chemicals Company, 1974). In these tests the algal inoculum was exposed to various concentrations of the products and was allowed to grow for periods up to 21 days. It was found that for some products, algal growth was inhibited in the presence of the chemicals, but after removal into a fresh growth medium with no chemical, normal growth resumed. Low concentrations (1-10 mg/L) demonstrated a slight growth stimulating effect on some species of algae. The report concluded that industrial water effluents containing low levels of the compounds should not have adverse effects on the surrounding aquatic life.

The notified polymer is amphoteric since it contains both cationic (tertiary amine) and anionic (phosphonate) moieties. Boethling and Nabholz (1997) note that the aquatic toxicity of amphoteric substances is primarily determined by the cation to anion ratio (CAR) and the cationic charge density. Toxicity to aquatic organisms increases with cationic charge density. Hence, the CAR for the notified polymer and adsorption of the polymer to sediment suggests little toxicity due to cationic behaviour as the ratio is 2:1. The authors also note that anionic polyaliphatics such as the notified tetraphosphonate-containing polymer are of moderate toxicity to algae in laboratory testing. This appears to be associated with the polymer chelation of nutrient elements that are needed by the algae for growth. However, there is some mitigation of toxicity in the presence of divalent salts. Hence, the use of the notified polymer as a scaling inhibitor will see the polymer already chelated with Ca^{2+} when it is released and so appreciable mitigation of toxicity may be expected.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Release of the notified polymer to the environment is most likely the consequence of blowdown from the cooling towers and non-evaporative water loss through leaks and drift. Given the low concentrations of polymer used in these applications and dilution upon entering receiving waters, a high level of environmental hazard is not expected. However, large industrial cooling towers in rural areas may discharge directly to natural waterways – *i.e.*, rivers and creeks. Since the chemical is water soluble but is not readily biodegradable, it would be expected to be persistent in the water compartment. However, the expected binding affinity of the polymer to sediment suggests that it should become associated with soil and sediment and its concentration in the water compartment should be low.

PEC Calculation

The notifier did not provide any Predicted Environmental Concentration (PEC) values. A PEC value for the product in a dispersive release across the continent has therefore been calculated. The following assumptions have been made:

1. all release is to sewer, where no degradation/hydrolysis occurs.
2. sewer output per day is 2,700 ML, based on an Australian population of 18 million, and a daily per capita water usage volume of 150 L.
3. the total import volume (50 tonnes) is released over 365 days of the year, giving a daily release of the notified polymer of 137 kg.

Using these assumptions, a continental PEC due to end use, prior to release to receiving waters, is 0.05 mg/L. This value is well below the calculated LC_{50} values of the polymer for fathead minnow and water flea that are reported to be greater than 120 mg/L and below the expected toxicity values for algae (see *Environmental Effects* section). Even so, this is a global assessment calculation whereas the polymer will be used at a limited number of sites possibly leading to a more intense release of the polymer and therefore a much higher localised PEC. The polymer may also potentially be released to stormwater drains or creeks where dilution levels would be significantly lower than indicated in the calculation. However, the maximum use level is 20 ppm which only requires a 2-3 fold dilution to be below expected toxic levels, keeping in mind mitigation of algal toxicity by chelation and sorption to suspended solids. When used in power stations or mining operations, no polymer is expected to be released into the environment, since the systems are completely enclosed. Further, the notifier states that the polymer is expected to completely adsorb to sediment, so even if some water run-off from the tailings dams should occur, the actual release of the polymer into the environment would be expected to be close to zero.

Data on the algal toxicity of the polymer would help clarify the hazard if higher concentrations are proposed to be released to the environment.

There may be some build up of the polymer in sediments but this should not be bioavailable due to the expected strong binding.

Given the above, environmental exposure and the overall environmental hazard of the notified chemical is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer is to be used in a number of specialised industrial water treatment applications at low concentrations (< 20 ppm). There is a possibility of dermal or ocular exposure to the notified chemical when it is present at high concentrations (up to 22 %) for the workers who connect and disconnect the imported containers containing the imported product.

The major hazards associated with the formulations are likely to be skin and eye irritation due to the pH of the products. There are a number of products which contain the notified chemical. The product to be initially imported is pHREEdom 5200M, containing 22 % notified chemical. The MSDS for this product indicates that the pH is 4.2 – 5.2, unlike a number of the other products which are strongly basic solutions. The water to which the product is added is likely to have the pH independently adjusted to a desired range, and pH dependent irritant properties of the product containing the notified chemical will not be relevant.

The acute oral toxicity and acute dermal toxicity of the notified chemical are low, and therefore no acute effects due to the notified chemical would be expected from contact with water treated with this chemical. There is insufficient data to determine the hazards associated with chronic exposure to low levels of the notified chemical in the absence of sensitisation, repeat dose toxicity and genotoxicity studies. There is, however, a long history of occupational exposure to this and other similar chemicals overseas, with no adverse health effects being attributed to this class of chemicals.

It is probable on the basis of the data on the notified chemical and analogue chemicals which has been submitted that the notified chemical will not present a major occupational health and safety risk.

The notified polymer is not expected to present any significant public health risk as the potential for public exposure for the uses detailed in the notification statement is negligible.

13. RECOMMENDATIONS

To minimise occupational exposure to pHREEdom 200, pHREEdom 250, pHREEdom 410, pHREEdom 5200M and pHREEdom T Series the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);

- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.2 (Standards Australia, 1990);

- Impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994c).

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.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Secondary notification under Section 64(1) of the Act will be required if any sensitisation, repeat dose toxicity or genotoxicity studies on the notified polymer become available to the notifier. Secondary notification of the notified chemical will be also required if future studies on close analogues of the notified polymer show evidence of skin sensitising potential, significant systemic toxicity or mutagenic potential.

Secondary notification of the notified polymer shall also be required if any of the circumstances stipulated under Section 64(2) of the Act arise. Should secondary notification under subsection 64(2)(a) of the Act be required on the grounds of increased environmental exposure, data on the algal toxicity of the polymer will be required.

16. REFERENCES

Boethling RS & Nabholz JV (1997) Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton, J. D. and Sutcliffe, R. eds. Ecological Assessment of Polymers: Strategies for Product Stewardship and Regulatory Programs. Van Nostrand Reinhold, New York.

Cervan DR (1993a) pHREEdom 200 #3468-8A Primary Eye Irritation and/or Corrosion in Rabbits, Project No. 930002, MB Research Laboratories Inc, Spinnerstown Pa USA.

Cervan DR (1993b) pHREEdom 200 #3468-8A Single Dose Oral Toxicity in Rats/LD50 in Rats, Project No. 930001, MB Research Laboratories Inc, Spinnerstown Pa USA.

Cervan DR (1993c) pHREEdom 410 #3468-9B Primary Eye Irritation and/or Corrosion in Rabbits, Project No. 930005, MB Research Laboratories Inc, Spinnerstown Pa USA.

Cervan DR (1993d) pHREEdom 410 #3468-9B Single Dose Oral Toxicity in Rats/LD_{50} in Rats, Project No. 930004, MB Research Laboratories Inc, Spinnerstown Pa USA.

Draize JH (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49 : 2-56.

Gabriel KL (1980a) D.O.T. Skin Corrosivity - Rabbits, Project No. 79-1786A, Biosearch Inc, Philadelphia Pa USA.

Gabriel KL (1980b) SP-237 - Acute Dermal Toxicity LD50 - Rabbits, Project No. 79-1786A, Biosearch Inc, Philadelphia Pa USA.

Gabriel KL (1980c) SP-237 - Acute Inhalation Toxicity - Rats, Project No. 79-1786A, Biosearch Inc, Philadelphia Pa USA.

Gabriel KL (1980d) SP-237 - Acute Oral Toxicity LD50 - Rats, Project No. 79-1786A, Biosearch Inc, Philadelphia Pa USA.

Gabriel KL (1980e) SP-237 - Primary Eye Irritation - Rabbits, Project No. 79-1786A, Biosearch Inc, Philadelphia Pa USA.

Gabriel KL (1980f) SP-237 - Primary Eye Irritation - Rabbits (Washout), Project No. 79-1786A, Biosearch Inc, Philadelphia Pa USA.

Gabriel KL (1980g) SP-237 - Primary Skin Irritation - Rabbits, Project No. 79-1786A, Biosearch Inc, Philadelphia Pa USA.

Gledhill WE & Feijtel T Environmental properties and safety assessment of organic phosphonates used for detergents and water treatment applications, provided by Calgon Corporation.

Keiffer LA (1993a) pHREEdom 200 #3468-8A Primary Dermal Irritation in Albino Rabbits, Project No. 930003, MB Research Laboratories Inc, Spinnerstown Pa USA.

Keiffer LA (1993b) pHREEdom 410 #3468-9B Primary Dermal Irritation in Albino Rabbits, Project No. 930006, MB Research Laboratories Inc, Spinnerstown Pa USA.

Monsanto Industrial Chemicals Company (1974) The Environmental Acceptability of the DEQUEST Products - A Research Update, Special Report No. 8042, St Louis, Mo, USA.

Monsanto Industrial Chemicals Inc (1985) MSDS Dequest® 2060 Deflocculant and Sequestrant, Project No. St Louis, Mo, USA.

National Occupational Health and Safety Commission (1994a) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1994b) List of Designated Hazardous Substances [NOHSC:10005(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1994c) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

Scott D., Galloway S. M., Marshall R. R., et al. (1991) Genotoxicity Under Extreme Culture Conditions. Mutation Research, 257 : 147-204.

Solutia Inc Dequest® Safety and Handling. (1999) http://www.dequest.com/Safety/General.htm.

Standards Australia (1987) Australian Standard 2919-1987, Industrial Clothing. Standards Association of Australia, Sydney.

Standards Australia (1990) Australian Standard 3765.2-1990, Clothing for Protection against Hazardous Chemicals Part 2 Limited protection against specific chemicals. Standards Association of Australia, Sydney.

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Standards Association of Australia, Sydney.

Standards Australia/Standards New Zealand (1992) Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

Standards Australia/Standards New Zealand (1994) Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

Standards Australia/Standards New Zealand (1998) Australian/New Zealand Standard 2161.2-1998, Occupational protective gloves, Part 2: General requirements. Standards Association of Australia, Sydney.

Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0 Very slight erythema (barely
perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe