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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Merquat 2001

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Director
Chemicals Notification and Assessment

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Merquat 2001

1. APPLICANT

Nalco Australia Pty Ltd of 2 Anderson St Botany NSW 2019 (ABN 41 000 424 788) has submitted a limited notification statement in support of their application for an assessment certificate for Merquat 2001.

2. IDENTITY OF THE CHEMICAL

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

3. PHYSICAL AND CHEMICAL PROPERTIES

The physico-chemical properties discussed below were mainly determined for the aqueous solution, Merquat 2001.

Appearance at 20°C & 101.3 kPa:	clear to hazy, colourless to slightly yellow liquid (aqueous solution)
Boiling Point:	not determined
Specific Gravity:	1.06 (aqueous solution)
Vapour Pressure:	not determined
Water Solubility:	completely soluble
Particle Size:	not applicable
Viscosity:	16000 – 38000 CPS at 25°C and 20 rpm
Partition Co-efficient (n-octanol/water):	not determined
Hydrolysis as a Function of pH:	not determined
Adsorption/Desorption:	not determined

Dissociation Constant:	expected to be fully dissociated
Flash Point:	> 93°C
Flammability Limits:	not flammable
Autoignition Temperature:	not determined
Explosive Properties:	not expected to be explosive
Reactivity/Stability:	stable under normal environmental conditions

3.1 Comments on Physico-Chemical Properties

The water solubility is very high as expected for a polymer carrying a high density of cationic groups.

No data on the hydrolysis of the polymer were provided. The polymer backbone will not be susceptible to hydrolytic degradation. Amide side groups may be susceptible to hydrolysis under extreme pH conditions.

No data on the n-octanol/water partition coefficient were provided, but the ionic nature of the polymer together with the very high water solubility indicates no affinity for the oil phase.

No adsorption/desorption data were provided, but the high water solubility indicates that the polymer would have little affinity for organic matter. However, the high cationic charge density on the polymer will give it affinity through electrostatic interactions with colloidal organic matter (such as humic material) in water and sediments, since the colloidal matter usually carries negatively charged groups. Consequently the polymer would act as a flocculant with these materials and is expected to become associated with bottom sediments, and once deposited in this manner is not expected to be easily re-mobilised.

The polymer contains carboxylic acid groups with a pKa expected to be similar to that of acrylic acid which is around 4.25 at 25ºC (CRC Press, 1977), and so under usual environmental pH conditions these are expected to be un-dissociated –COOH groups. The polymer contains a high percentage of quaternary ammonium groups (FGEW = 491 g/mole) which will remain fully dissociated, and so the polymer will be cationic with a high density of positive charge.

4. PURITY OF THE CHEMICAL

Degree of Purity:	> 99.5 %
Hazardous Impurities:	none
Non-hazardous Impurities (> 1% by weight):	none

Maximum Content of Residual Monomers:	all residual monomers are present at below the relevant cutoff levels for the notified polymer to be classified as a hazardous substance

Additives/Adjuvants:

Chemical name:	sodium benzoate
CAS No.:	532-32-1
Weight percentage:	0.2 %

5. USE, VOLUME AND FORMULATION

The notified polymer is used in the formulation of cosmetic and personal care products, such as soaps and shampoos. The notified polymer is expected to comprise < 1 % of the final products.

The notified polymer will be imported as an aqueous solution (Merquat 2001) at a concentration of 10 - 30 % in 200 kg polyethylene drums or in bulk, and reformulated in Australia to produce the end use products.

The notifier estimates that the import volume for the notified polymer will initially be less than 16 tonnes per annum.

6. OCCUPATIONAL EXPOSURE

Transport and Storage
The notifier estimated that 2 waterside workers, 6 truck drivers, 6 receiving clerks, 8 warehouse workers and 2 forklift drivers will handle the notified polymer solution in sealed drums, for 2 to 3 hours per day on up to 15 occasions per annum. These workers are not expected to be exposed to the notified polymer except in the event of an accident involving damage to the drums. If the notified polymer solution is imported in bulk, there may be some exposure to drips and spills of the notified polymer solution when transfer hoses are connected or disconnected.

Laboratory Workers
The notified polymer solution will be sampled for quality control on receipt at the notifier's site. This will involve 4 chemists, for 2 hours per day, 8 times per year. Only small quantities are expected to be handled, and samples will be provided by the workers involved in repackaging. Laboratory staff will wear laboratory coats, gloves and safety glasses.

Product Repackaging
The notified polymer solution will be decanted into containers for shipment to customers at the notifier's site. Repackaging will be carried out using an automatic pump, either directly into the new containers or via a decanting vessel. Quality control samples will be collected before and after repackaging. The notifier estimated that 3 operators may handle the notified polymer solution, for up to 5 hours per day, 30 times per year. Dermal exposure may occur during opening drums and sampling for quality control, and while installing or removing the

drum pumps. The imported containers will then be cleaned by the repackaging operators. Details of the cleaning process were not provided.

Repackaging and cleaning operations will occur in well ventilated areas, and the operators will wear coveralls, chemical resistant gloves and goggles for splash protection.

Customer Service
These workers will set up feed equipment at the customer sites, and check the equipment for correct dosing. The notifier estimated that up to 70 workers will be involved in this process, for 1 to 4 hours per day, 60 times per year. The customer service workers are only expected to be exposed to the notified polymer while connecting the feed equipment and sampling the final product. Exposure will be predominantly dermal. While handling the notified polymer, these workers will wear coveralls, chemical resistant gloves and goggles for splash protection.

Reformulation
Up to 70 operators at customer sites through Australia may be exposed to the notified polymer solution during operation of the automated blending equipment. Exposure is estimated to be for up to 2 hours per day, on a daily basis. These workers may have dermal exposure to the notified polymer while switching drums and testing and calibration of the feed equipment. This exposure is expected to be for 5 to 10 minutes per time. They will also sample the final product, containing up to 1 % notified polymer, for quality control purposes.

End Products
The final products containing the notified polymer will be packaged into consumer size containers, typically of capacity around 200 mL, and transported to warehouses. The products will then be handled by retail workers including receiving staff, shelf packers and sales staff. No details of the number of workers or exposure duration for any of these workers was provided. Packaging workers may have dermal exposure to the final products during intervention in the packaging line. For other workers handling the final products, exposure is only likely in the event of an accident, and will be limited due to the small package size.

7. PUBLIC EXPOSURE

Members of the public will apply these products, as intended, directly to their hair and skin. Many will do so on a repetitive basis. The potential for exposure to the notified polymer among users will be high. The most likely form of contact will be dermal although contact with the eye will be common in hair formulations. The potential for the exposure of those members of the public who do not use formulations containing the notified polymer will be limited to unlikely situations such as accidental spillage and will be minimal.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Small quantities of the notified polymer will be released during repackaging and during manufacture of consumer products such as shampoos and soaps. The notifier stated that any leaks or spills of the polymer during repackaging activities would be adsorbed onto bentonite clay and that this would be disposed of to landfill. No quantitative estimation of likely losses through leaks and spills was provided, but if it is assumed that 1 % is lost during this activity, then a maximum of 160 kg per annum of the polymer could be disposed of into landfill. The notifier did not indicate the fate of the emptied 200 L drums or bulk containers or residual polymer solution left in these. It is probable that the emptied containers would be cleaned and recycled, and residual polymer washed out of the containers would be sent to the on site water treatment facilities where the polymer would associate with waste sludge. This would be either incinerated or placed into landfill. Assuming that a further 1 % of polymer is left in the emptied drums, a further 160 kg per annum could potentially be placed into landfill.

Similarly, spills occurring at customer sites during reformulation of the polymer solution into consumer products are also expected to be adsorbed and then incinerated or placed into landfill, and likewise for the residuals left in empty containers. Consequently, each year a further maximum 320 kg of polymer could go to landfill as a result of reformulation activity.

Small quantities of cosmetic formulations may be left in the consumer packages, and these would also be placed into landfill with domestic garbage. Assuming that as a worst case around 5 % of the cosmetic formulations are disposed of in this manner, then annually an additional 800 kg of the notified polymer may be placed into landfill.

Overall up to 1.6 tonnes of the polymer may be sent to landfill each year, although some may be incinerated with waste sludge from industrial water treatment facilities.

The use pattern of the consumer products indicates that most will be released into municipal sewage but, since the end use products will be used throughout Australia, the release into the sewer systems will be diffuse and at relatively low levels.

8.2 Fate

The majority of the notified polymer will be released to municipal sewers and, due to the high cationic charge density, is expected to become associated with negatively charged colloidal material and bacteria, and would eventually become assimilated into sludges in sewer pipes. The notifier indicated that 99 % of the polymer would become associated with sludge in this manner, although no corroborating data were provided. Colloidal organic material in sewers is typically anionic and cationic polymers are known to become associated with such material and act as flocculants. Flocculated material settles to the bottom of pipes and settling tanks and consequently becomes associated with sludges.

Periodically sewer pipes are scoured to remove build up of sludge, and this is either placed into landfill or incinerated. Any polymer which reaches the sewage treatment plants is unlikely to be degraded through biological action, but would become associated with either primary sediments or activated sludge, and these waste products are usually also placed into landfill after stabilisation with lime.

As a result of the expected high affinity of the notified polymer for sludge and negatively charged colloidal material, very little will be released to receiving waters with sewage plant

effluent but, due to the recognised high toxicity of cationic polymers to aquatic organisms, it is necessary to comment on the fate of any polymer which may be released to the wider aquatic compartment. The notifier provided a copy of a paper (Cary et al, 1987) which demonstrated that the presence of suspended solids and colloidal organic material has a dramatic mitigating effect on the toxicity of cationic polymers to fish (fathead minnow) and daphnia. This paper is briefly discussed below (see section on Environmental Effects), but the reason for the reduced toxicity is presumably due to the association of the polymer with the colloidal material (particularly the organic matter), which reduces the exposure of the polymer to susceptible organisms.

No data on biodegradation of the notified polymer were provided, but the structure indicates that it is not expected to be readily biodegradable. However, in a landfill situation the polymer will be slowly degraded through biological and abiotic processes and would eventually be mineralised to water, ammonia, methane and oxides of carbon.

Incineration of sludges or domestic garbage containing the new polymer would lead to its destruction with release of water vapour and oxides of carbon and nitrogen.

The polymer will have no potential for bioaccumulation due to its very high water solubility and high molecular weight (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicity testing was carried out using Merquat 2001, an aqueous solution containing < 30 % notified polymer.

Summary of the toxicity of Merquat 2001

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5000 mg/kg	(MB Research Laboratories, 1997a)
skin irritation	rabbit	slight irritant	(MB Research Laboratories, 1997b)
eye irritation	rabbit	slight irritant	(MB Research Laboratories, 1997c)
skin sensitisation	human	non-sensitiser at 5 % solids	(Product Investigations, 1997)
induction of point mutations	*S. typhimurium, E. coli*	non-mutagenic	(MA Bioservices, 1997)

9.1 Acute Toxicity

9.1.1 Acute Toxicity – Oral

TEST SUBSTANCE Merquat 2001 (< 30 % aqueous solution of notified polymer)

METHOD	40 CFR Part 798.1175
Species/Strain	Rat/Wistar
Vehicle	Test material used as received
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number & Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	5000	0/10

LD50	> 5000 mg/kg bw
Signs of Toxicity	There were no deaths or test substance-related clinical signs or remarkable body weight changes during the study period.
Effects in Organs	There were no remarkable necropsy findings.
CONCLUSION	The test material is of low toxicity via the oral route.
TEST FACILITY	MB Research Laboratories, Inc. (1997a)

9.1.2 Irritation – Skin

TEST SUBSTANCE	Merquat 2001 (< 30 % aqueous solution of notified polymer)
METHOD	40 CFR Part 798.4470
Species/Strain	Rabbit/New Zealand White
Number of Animals	2 male 4 female
Observation Period	3 days
Vehicle	Test material used as received
Type of Dressing	Semi-occlusive.
Remarks - Method	The method involved 24 hour exposure, and two separate patch sites per animal were tested using 0.5 mL test substance per site.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.17	2	48 hours	0
Oedema	0	0		0

*Calculated on the basis of the scores at 24, 48, & 72 hours for ALL animals.

Remarks - Results	No oedema was observed at any time. Moderate erythema was observed in one animal 30 – 60 minutes after patch

removal; all other animals showed slight erythema at at least one patch site at this observation time. After 24 hours, 4 animals showed slight erythema at at least one patch site; all responses resolved by the 72 hour observation time.
One animal showed mucoid diarrhoea at most of the observation times; no other clinical signs of systemic toxicity were observed.

CONCLUSION The test material is slightly irritating to skin.

TEST FACILITY MB Research Laboratories, Inc. (1997b)

9.1.3 Irritation – Eye

TEST SUBSTANCE Merquat 2001 (< 30 % aqueous solution of notified polymer)

METHOD OECD 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3 male
Observation Period 3 days
Remarks - Method No significant protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	*2*	*3*			
Conjunctiva: redness	0.67	0	0	1	48 hours	0
Conjunctiva: chemosis	0	0	0	2	< 24 hours	0
Conjunctiva: discharge	0	0	0	2	< 24 hours	0
Corneal opacity	0	0	0	0		0
Iridial inflammation	0	0	0	0		0

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

Remarks - Results Signs of conjunctival irritation were observed 1 hour after instillation. All animals showed moderate chemosis and one showed moderate discharge; slight conjunctival redness was seen in all animals. At the 24 hour observation, slight conjunctival redness persisted in one animal. No signs of corneal or iris irritation were observed.
Animal 2 showed diarrhoea on days 1 and 2, and few faeces and alopecia on the face on day 3.

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY	MB Research Laboratories, Inc. (1997c)

9.1.4 Skin Sensitisation – Human Volunteers

TEST SUBSTANCE	Merquat 2001, 20 % solids (induction); 5 % solids (challenge)
METHOD	Human repeat insult patch test – In house modification of Shelanski and Shelanski (1953) procedure
Study Design	The study was conducted in a single phase, as part of a study of multiple chemicals.
Study Group	116 volunteers (84 female, 42 male)
Vehicle	water
Induction Procedure	An occlusive patch with 0.2 mL test material (20 % solids) was applied to the back on successive days for 24 hours, on 4 days per week for 3 weeks.
Rest Period	1 week
Challenge Procedure	An occlusive patch with 0.2 mL test material (5 % solids) was applied to the arm on 3 successive days for 15 minutes, followed by two applications for 24 hours on successive days. A final examination occurred 72 hours after the end of the last exposure.
RESULTS	
Remarks - Results	During the induction phase 16 subjects exhibited faint erythema , one subject exhibited moderate erythema and and 13 subjects exhibited severe erythema including papules; during the challenge phase 6 subjects exhibited slight erythema on the treated arm and 3 subjects exhibited slight erythema on the back.
CONCLUSION	A human repeat insult patch test was conducted using the notified polymer at 20 % in water (for induction) and 5 % in water (for challenge) under occlusive dressing. The response patterns during induction provided evidence of possible sensitisation to the 20 % solids solution in at least one subject; cumulative irritation was a possible cause of high intensity responses for other panellists; the responses seen at challenge were concluded to indicate that the 5 % solution does not have sensitising potential. The study authors concluded that the induction phase data contraindicate dermal contact with a solution containing 20 % notified polymer.
TEST FACILITY	Product Investigations, Inc. (1997)

9.2 Genotoxicity

9.2.1 Genotoxicity – Bacteria

TEST SUBSTANCE	Merquat 2001 (< 30 % aqueous solution of notified polymer)
METHOD	OECD 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2 uvrA (pKM101)
Metabolic Activation System	rat liver S9 fraction from animals pretreated with Arochlor 1254, 10 % (v/v) in standard cofactors
Concentration Range in Main Test	a) With metabolic activation: 100 – 5000 µg/plate. b) Without metabolic activation: 100 – 5000 µg/plate.
Vehicle	water
Remarks - Method	A single test was performed in triplicate.
RESULTS	
Remarks - Results	No toxicity or precipitation was observed. The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of microsomal enzymes prepared from Aroclor 1254 induced rat liver (S9). Negative controls were within historical limits. 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	MA Bioservices, Inc. (1997)

9.3 Overall Assessment of Toxicological Data

A < 30 % aqueous solution of the notified polymer was of very low acute oral toxicity in rats (LD_{50} > 5000 mg/kg). It was a slight irritant to rabbit skin and eyes, with respectively slight to moderate erythema and slight to moderate conjunctival redness, chemosis and discharge being observed a short time after exposure. Skin and eye irritant effects of low severity were observed 24 hours after exposure, and all irritant effects cleared by 72 hours after exposure. No symptoms indicative of significant dermal toxicity were observed after 24 hour exposure in the skin irritation study.

In a human repeat insult test study, the notified polymer at 20 % in aqueous solution produced results indicative of sensitisation and/or cumulative irritation during the induction phase in a small number of subjects. The results of the challenge phase using a 5 % aqueous solution of the notified polymer indicated that sensitisation in humans at this concentration was unlikely.

The notified polymer was found to be non-mutagenic under the conditions of the test in a bacterial point mutation assay.

Based on the results of the toxicity studies submitted by the notifier, the notified polymer would not be classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (NOHSC, 1999). However the results of the human repeat insult patch test indicate that prolonged or repeated dermal contact with concentrated solutions of the notified polymer should be avoided.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided test reports on the toxicity of the polymer to two fresh water species, *Daphnia magna* and the green algae *Selenastrum capricornutum*. The teats were conducted according to OECD test guidelines with a material identified by the testing facility as EH&S 01-112. Although no further information was provided in the reports, the notifier indicated that the test material EH&S 01-112 is the notified polymer.

Test	*Species*	*Results (nominal)*
Acute toxicity OECD TG 202	*Daphnia magna*	48 h LC_{50} > 1000 mg/L 48 h NOEC = 250 mg/L
Algal reproduction OECD TG 201	*Selenastrum capricornutum*	96 h E_bC_{50} = 0.73 mg/L 96 h NOEC < 0.25 mg/L 96 h E_rC_{50} = 3.2 mg/L

* NOEC - no observable effect concentration

Daphnia

The daphnia test (Wilbury, 2001a) was conducted under static conditions over a 48 hour test period at 20±2ºC using nominal concentrations of the test substance of 0 (control), 150, 250, 400, 600 and 1000 mg/L. The pH of the test solutions was always between 6.8 and 7.5, the dissolved oxygen level between 8.4 and 8.9 mg/L and the water hardness 170 mg/L as $CaCO_3$. Each test was performed in duplicate using 10 daphnia in each test chamber with the number of dead (immobilised) animals and their general condition monitored every 24 hours. After 24 hours two daphnids in one of the nominally 400 mg/L replicate solutions was immobile and after 48 hours three animals were dead in the same replicate vessel, and one in the other replicate. With increasing concentration no significant increase in immobilisation (death) was noted. No significant aberrant behaviour or other sub-lethal effects were noted over the duration of the test.

The data was analysed to provide a (nominal) LC_{50} of > 1000 mg/L and a (nominal) No Observed Effect Concentration (NOEC) of 250 mg/L. These results indicate that the polymer is not toxic to this species of cladoceran (Mensink et al, 1995).

Green Algae

The definitive test against the green algae *Selenastrum capricornutum* (Wilbury, 2001b) was conducted over a 96 hour test period at 24±2ºC using nominal concentrations of the test substance of 0 (control), 0.25, 0.50, 1.0, 2.0, 5 and 4.0 mg/L. Each test was performed in triplicate and the growth in biomass determined through cell counts in each test vessel after 24, 48, 72 and 96 hours. The cell count data was analysed using standard statistical techniques to provide a (nominal) 96 hour E_bC_{50} of 0.73 mg/L and a (nominal) No Observed Effect Concentration (NOEC) of < 0.25 mg/L, and consequently the polymer is regarded as highly toxic to this species of algae (Mensink et al, 1995).

The rate of algal biomass growth was also determined and the 96 hour E_rC_{50} determined as 3.2 mg/L, which appears to indicate a lower toxicity. However, from the graphs of cell numbers against time for each of the nominal dose regimes, the slopes between successive points varied erratically, so higher confidence should be placed in the E_bC_{50} value.

At the conclusion of the test a small aliquot of the nominally 4.0 mg/L solution was transferred to fresh media (containing no test polymer), and the flask incubated for a further 72 hours. The cell count increased from 1750 cells/mL to 544000 cells/mL over the 72 hour period, which indicated that the polymer was algistatic rather than algicidal.

Discussion
The polymer exhibited highly toxic properties against algae, yet was virtually non toxic to daphnia. This is unusual, since it is accepted that cationic polymers are generally toxic to aquatic life at all aquatic trophic levels (Boethling and Nabholz, 1997). The report on toxicity of the polymer against daphnia did not mention the level of organic matter or inorganic suspended solids present in the water, and it is well known that the interaction of cationic polymers with such colloidal material has a significant mitigating effect on the toxicity of the polymers (Boethling and Nabholz, 1997, Cary et al, 1987). It is possible that the water used in the tests contained colloidal material, and this may have mitigated the observed toxicity.

No data on the toxicity of the polymer to fish were provided, and such a report would have been useful in clarifying the overall toxicity.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

A maximum of 1.6 tonnes of the polymer is expected to be placed into landfill each year with manufacturing waste and domestic garbage containing incompletely consumed packages of the consumer products. Although not readily biodegradable, the polymer is expected to be slowly mineralised to water and landfill gases as a result of slow biological and abiotic processes. Some of the polymer may also be incinerated, in which case it would be destroyed liberating water vapour and oxides of carbon and nitrogen.

Almost all of the notified polymer will be released to the sewer as a consequence of its use in consumer products such as soaps and shampoos. If it is assumed that annually 16 tonnes of the polymer are used in these products, and that daily each person in Australia contributes 150 L to the volume of sewage, that the population of Australia is 19 million and that the cosmetic products would be used 365 days each year, the Predicted Environmental Concentration (PEC) of the polymer in sewage is estimated as 15.4 µg/L. The polymer is expected to remain substantially associated with sewage sludge and very little is expected to be released with sewer plant effluent to receiving waters. However, assuming no degradation or assimilation of the polymer into sludge and that a dilution factor of 1:10 is appropriate, then the PEC in receiving waters would be reduced to 1.54 µg/L.

The E_bC_{50} for green algae (the most sensitive species for which toxicity data are available) is 0.73 mg/L, and taking this as the Predicted No Observed Effect Concentration (PNEC), the safety margin (Q), which is the ratio PNEC/PEC, is estimated as around 500 using the assumptions above. Reducing this by a factor of 1000 to account for the fact that only two ecotoxicity end points are available (ie daphnia and green algae), the Q value becomes 0.5

indicating a possible environmental hazard. However, receiving waters usually contain suspended colloidal matter of both mineral and organic origin (eg. humic material), and the interaction of cationic polymers with this material has been demonstrated to dramatically reduce the toxicity of the polymers. In addition, most of the polymer will become associated with sewage sludge during passage through the sewer mains and the sewage treatment plants and will not be released to receiving waters.

It is not expected that the notified polymer will constitute a hazard to the environment when used in cosmetics in the manner indicated by the notifier. However, if released in quantity to natural waters (for example as a result of transport accident) the available toxicity data indicate that such a spill may cause severe ecological damage. The MSDS supplied by the notifier indicates that it is characterised as a moderate hazard to the environment, and also indicates that the polymer should not be allowed to enter waterways due to its toxicity to aquatic species.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment
The notified polymer has low acute oral toxicity in rats but is a slight irritant to rabbit skin and eyes. In a human repeat insult test study, the notified polymer at 20 % in aqueous solution produced results indicative of sensitisation and/or cumulative irritation during the induction phase in a small number of subjects, although results indicative of sensitisation were not seen in a challenge phase using a 5 % aqueous solution of the notified polymer. The notified polymer was found to be non-mutagenic under the conditions of the test in a bacterial point mutation assay.

Based on the results of the toxicity studies submitted by the notifier, the notified polymer would not be classified as a hazardous substance in accordance with the Approved Criteria. However the results of the human repeat insult patch test indicate that prolonged or repeated dermal contact with concentrated solutions of the notified polymer should be avoided.

Occupational Health and Safety
The results of the hazard assessment indicate that skin sensitisation in sensitive individuals and skin and eye irritation on dermal contact with concentrated solutions of the notified polymer are the main occupational risks in handling the notified polymer. Little risk is expected in handling reformulated consumer products containing the notified polymer at low concentrations.

Workers who may handle the concentrated solutions, apart from in sealed containers only, include laboratory staff, repackaging operators, and customer service and reformulation workers. Contact with residues of the notified polymer on equipment may occur when transfer hoses are connected or disconnected at the drums. All workers handling the notified polymer in concentrated solutions will wear chemical resistant gloves and safety glasses or goggles.

Public Health
The use of these products is likely to be widespread among consumers. However the low

toxicity of the Merquat 2001 and the low concentration of it in the proposed consumer formulations suggests that it will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

Regulatory controls

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified polymer:
  - S24: Avoid contact with skin
  - S37: Wear suitable gloves

Control Measures

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - impermeable gloves, safety goggles and industrial clothing

  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.

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 Subsection 64(1) of the Act; if
  - the import volume increases above 30 tonnes notified polymer per annum, in which case a test report on the toxicity of the notified polymer against fish should be provided;

or

(2) Under Subsection 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.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified polymer was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

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. REFERENCES

Boethling, R. S. and Nabholz, J. V. (1997) Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act, Chapter 10 (pp 187-234) of Ecological Assessment of Polymers, Hamilton, J. D. and Sutcliffe, R. (ed), Van Nostrand Reinhold.

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Attachment 1

The Draize Scale (Draize, 1959) 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 (Draize *et al*., 1944) 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

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