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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Magnasoft SRS

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Street Address: 92 -94 Parramatta Rd CAMPERDOWN NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA
Telephone: (61) (02) 9577 9514 FAX (61) (02) 9577 9465

Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Magnasoft SRS

1. APPLICANT

Crompton Specialties Pty Ltd of 462 Burwood Road HAWTHORN VIC 3122 (ACN 057 525 970) has submitted a limited notification statement in support of their application for an assessment certificate for Magnasoft SRS.

2. IDENTITY OF THE CHEMICAL

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

Marketing Name: Magnasoft SRS Textile Softener

Method of Detection and Determination: GPC

Spectral Data: Two GPC traces were provided

3. PHYSICAL AND CHEMICAL PROPERTIES

No reports on physico-chemical properties accompanied the dossier, and the data tabulated below are taken from the MSDS for the product containing 25% of the notified polymer provided by the company.

Appearance at 20°C & 101.3 kPa: Pale yellow liquid

Melting Point: -40°C (estimated)

Boiling Point: 230°C (estimated)

Specific Gravity: 1.02 (estimated)

Vapour Pressure: < 0.13 kPa at 20°C

Water Solubility: Dispersable in water - see notes below

Partition Co-efficient (n-octanol/water):	No data - see notes below
Hydrolysis as a Function of pH:	No readily hydrolysable groups – see notes below.
Adsorption/Desorption:	No data - see notes below
Dissociation Constant:	No data - see notes below
Flash Point:	93°C (Pensky-Martens closed cup method)
Flammability Limits:	No data
Autoignition Temperature:	No data
Explosive Properties:	No data
Reactivity/Stability:	Burning can produce oxides of carbon, nitrogen and silicon

Comments on Physico-Chemical Properties

The notifier indicates that the new polymer is dispersable in water. The dispersion is presumably stabilised through electrostatic interactions between the cationic amino centres within the polymer (see further below) and solvated water molecules. The dispersion of the polymer in water may also be assisted by the presence of the dipropylene glycol, which may act as a "co-solvent". The true water solubility of the polymer was not provided by the notifier. However, it was noted that during the ecotoxicity tests against fish and Daphnia, that additions of Magnasoft SRS to water at nominal concentrations above 150 mg/L resulted in cloudy dispersions. Since the Magnasoft SRS formulation contains around 25% of the new polymer, it may be inferred that the water solubility of the polymer is < 37 mg/L.

Neither the O-Si-C linkages of the siloxane groups, nor the C-N bonds of the amino groups are likely to hydrolyse in the environment where the pH usually remains between 4 and 9.

No partition coefficient data was provided with the notification dossier. However, the relatively high charge density on the polymer and absence of long chain alkyl groups indicate that the polymer would have little affinity for the oil/fat phase.

No adsorption/desorption data was provided, but the presence of the positively charged amino groups in the polymer indicate that if released into the environmental water or soil compartment, it would probably become associated (through electrostatic interactions) with negatively charged colloidal and particulate material. Most organic colloidal material present in soils and suspended in natural waters carries negative charges as a consequence of the presence of carboxylate or phenolic groups. Once associated with colloidal material in this manner, the polymer would become assimilated into the soils or aquatic sediments. Also, if

released to soil, the polymer could become adsorbed to the negatively charged surface of clay minerals.

No dissociation constant data was provided with the notification dossier. However, the primary and secondary amino groups in the polymer would be appreciably basic (typical pKa 9.5-10.5 for such amino groups), and would be expected to remain protonated (and positively charged) under the environmental pH range 4-9.

4. PURITY OF THE CHEMICAL

Degree of Purity: 90-95%

Hazardous Impurities:

Chemical name:	Jeffamine ED-2001
Synonyms:	Oxirane, methyl-, polymer with oxirane, bis(2-amino propyl) ether
CAS No.:	65605-36-9
Weight percentage:	<0.1

Non-hazardous Impurities (> 1% by weight):

Chemical name:	Isopropanol
Synonyms:	2-propanol
Weight percentage:	1
CAS No.:	67-63-0

Chemical name:	Water
Weight percentage:	4
CAS No.:	7732-18-5

Additives/Adjuvants:

Chemical name:	Dipropylene glycol
Synonyms:	Propanol, oxybis-
CAS No.:	25265-71-8
Weight percentage:	<75

Degradation Products: See notes on environmental fate below.

Loss of Monomers, Additives, Impurities: See notes on environmental fate below.

5. USE, VOLUME AND FORMULATION

The notified polymer will not be manufactured in Australia, but will be imported as a component of a formulated product MAGNASOFT SRS TEXTILE SOFTENER in which it is present (according to the Material Safety Data Sheet) at >25%. The other major ingredient is dipropylene glycol, which is present at <75%.

The formulated product will be imported by sea in 205 L steel drums, and the anticipated annual import volume of the notified polymer over the next five years would be between 1 and 10 tonnes, or 4 to 40 tonnes MAGNASOFT SRS TEXTILE SOFTENER.

No reformulation involving the notified polymer will take place in Australia. The notified polymer is intended for use as a textile softener at one textile plant in Australia. Textiles treated with the new polymer are to be used to produce articles of clothing (outer garments were specified).

6. OCCUPATIONAL EXPOSURE

Transport and storage
There will be one truck driver and two forklift driver/operators involved in transport and storage operations. These workers are unlikely to be contaminated with the notified polymer unless the steel drums were breached in an accident.

Textile Mill Operators
The textile plant runs on continuous shift basis with four operators on each shift. The notifier indicated that these operators are experienced and trained in the handing of textile chemicals. The overall potential exposure period for all workers is estimated to be approximately 30 minutes per day.

Mixing procedure
A quantity of finishing mix approximately 500 kg for each production run on the stenter will be prepared on a daily basis or more frequently. The mixing procedure is either completed in the chemical mixing room or near the stenter trough. The product containing Magnasoft SRS is manually weighed into buckets using gravity feed and poured into a mixing tank previously charged with water. The mixture is mixed by manual stirring and mechanically pumped to a header tank which feeds the stenter trough via gravity feed. The operator will wash the steel drum with water and discharge the residual notified polymer using gravity feed through a tap on the drum.

During mixing procedures, dermal contact to the notified polymer would be the main route of occupational exposure. Eye contamination is also possible. The notifier indicated that when mixing chemicals, the operators wear overalls, PVC gloves and safety glasses.

Stenter machine operation
The stenter machine operation is a continuous process. The notifier indicated that the concentration of Magnasoft SRS Textile Softener in the application solution (mixture) would typically be around 20 grams per litre (2%), ie 0.5% of the notified polymer. The fabric is introduced to the stenter by attaching it to a 'leader cloth' which is already threaded through the finishing trough. After leaving the bath, excess chemical solution is squeezed out of the fabric by rollers and returned to the bath, so the chemical application process is a closed loop system. The fabric is dried in special dryers where the applied chemicals become fixed to the fabric. The notifier has provided neither the fixation rate nor the methods of packing and transportation after the fabric treatment. However, the fixation rate for the notified polymer is estimated to be nearly 99% (see section 8).

Operators would rarely make any contact with the finish trough as the 'leader cloth' is used at the start and finish of a production run. The operator may become contaminated with treatment solution as fabric enters the stenter at the start of a run. The exposure for stenter machine operators is considered to be low. The notifier indicated that gloves, overalls, and safety glasses are worn during the operations.

There are no aerosols produced during the fabric finishing, though there may be some leakage of vapours at the stenter exit. The notifier indicated that stenter exhaust fans remove any volatiles and thermal decomposition products. In addition, room ventilation by mechanical fans exchanges air during the fabric finishing operation.

7. PUBLIC EXPOSURE

Widespread public contact is likely due to contact with clothing treated with the notified chemical. The percentage of notified chemical applied to the material is low, and it is indicated that the polymer is strongly bound to fabric, and is thus unlikely to be extensively leached during use of the clothes. The majority of leaching would be likely to occur during washing, which, if it occurs in a washing machine, is unlikely to result in extensive public contact.

8. ENVIRONMENTAL EXPOSURE

Release

No details of expected losses of Magnasoft SRS during transfer from the drums to the application vats was provided in the dossier. However, assuming that 1% of the formulation is lost as a result of spills and leaks in transfer equipment, this equates to an annual release of up to 100 kg of the new polymer. Empty drums are to be rinsed with water, which is to be

added to the application baths, so no release of the polymer resulting from drum cleaning/reconditioning is anticipated.

No fixation data for the binding of the polymer to the textiles was provided, but the notifier indicated that around 250 grams of polymer would be lost in waste water per day. Assuming that up to 10 tonnes of polymer are used each year, that the textile plant operates throughout the year, and around 27 kg of the polymer is used each day, this equates to a 99% utilisation rate. Thus, while direct fixation of the polymer to the textile may not be as high as 99%, operators attain near complete utilisation of the chemicals in the application bath due to the closed loop nature of the application process. Consequently release of excess chemical to the sewer system is minimised.

The notifier indicated that the textile plant releases around 1,000,000 L of effluent to the Melbourne sewer system each day. Assuming a daily release of 250 grams of polymer, the effluent concentration would be approximately 0.25 mg/L. However, it is probable that due to the positive charges carried by the protonated amino groups, the polymer would not remain in solution, but would become associated with negatively charged particulate and colloidal material. In this type of association, it would eventually be assimilated into sediments.

It is presumed that the polymer will be immobile when bound to the textile, and not likely to be released through everyday wear and washing of the clothing. However, any polymer washed off fabric during cleaning processes could be expected to be discharged to sewer and become associated with particulate matter and sediments.

Fate

The majority of the new polymer will be bonded to the fibres of fabric, and consequently its fate will be connected with that of the fabric. However, it is probable that degradation of the polymer to lower molecular weight oligomers will occur over time as a result of washing and other processes. The resultant molecules are likely to be discharged to sewer from laundry waste water. At the end of their useful lives, articles of clothing would be incinerated or be placed into landfill. Incineration would destroy the polymer with production of water vapour and oxides of carbon and nitrogen. The silicon within the polymer backbone would be oxidised to silicate, and associate with minerals in the furnace ash or slag material.

Silicone polymers are not readily biodegradable, but cellulose fabric in landfill is expected to slowly degrade through biological and abiotic processes operative in these facilities. Once the fabric has been sufficiently degraded, the silicone polymer could be released, but due to the positive charge protonated amine groups, is expected to become adsorbed onto the negatively charged surface of clay minerals. The relatively low water solubility (estimated as <37 mg/L) and hydrophobic nature of polydimethylsiloxanes indicates that when placed into landfill the material would be immobilised through association with soil and sediment particles (Hamelink, 1992; Varaprath et al., 1996). However, over time the polymer and degradation products could be expected to decompose to simpler species, with eventual production of silicate and landfill gases such as methane, carbon dioxide and ammonia. Polydimethylsiloxanes are unstable in landfill (Hamelink, 1992; Lehmann et al., 1994; Varaprath et al., 1996), and in dry conditions clay minerals catalyse their hydrolytic

decomposition to smaller molecules, some of which may be volatile and enter the atmosphere. When released to the atmosphere, low molecular weight organosilanes are rapidly degraded through photolysis (Varaprath et al., 1996).

Polymer and degradation products which enter sewer systems will be adsorbed onto the organic component of sediments, to be eventually associated with waste sludge from sewage plants and deposited into landfill or incinerated.

Due to its low water solubility and high molecular weight, the polymer will have little potential for bioaccumulation.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological studies were conducted using Magnasoft SRS according to corresponding OECD test guidelines at WIL Research Laboratories Inc. USA and MA BioServices Inc. USA. These facilities comply the OECD principles of good laboratory practice and full test reports were submitted.

9.1 Acute Toxicity

Summary of the acute toxicity of Magnasoft SRS

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 mg/kg	(Kern, 1997b)
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	(Kern, 1997a)
skin irritation	rabbit	Slight to moderate	(Kern, 1997c)
eye irritation	rabbit	Slight	(Kern, 1997d)
skin sensitisation	guinea pig	A skin sensitiser	(Kern, 1999)

9.1.1 Oral Toxicity (Kern, 1997b)

Species/strain: Rat/Crl:CD (SD)BR

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: A single dose of 5 000 mg/kg administrated orally by gastric intubation.

Test method: OECD TG 401

Mortality:	None
Clinical observations:	Hypoactivity and impaired muscle coordination were noted in all animals on the day of dosing. One male had dried red material around the mouth and one female had clear ocular discharge on day 0. Dried red material around the eye(s) was observed on a single male rat on days 4 and 5. All animals appeared normal by day 6 or earlier and throughout the remainder of the study.
Morphological findings:	None
Comment:	None
LD_{50}*:*	> 5 000 mg/kg
Result:	The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Kern, 1997a)

Species/strain:	Rat/Crl:CD(SD)BR
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	A single dose of 2 000 mg/kg applied to clipped, intact skin for 24 hours under semi-occlusive dressing.
Test method:	OECD TG 402
Mortality:	None
Clinical observations:	Wet and/or dried yellow material on the urogenital area in seven rats and dried material around the nose in two rats on the day of dosing. Hair loss on the hindlimb(s) and ventral trunk was noted for one female rat from days 11 to 14. All other animals appeared normal by day 1 or earlier and throughout the remainder of the study.
Draize scores:	Draize scores for erythema and edema in all animals were zero during days 1-14 except one male (erythema score 1 on day 1). Five rats had desquamation that completely subsided by day 13 or earlier.

Morphological findings:	None
Comment:	None
LD_{50}:	> 2 000 mg/kg
Result:	The notified chemical was of low dermal toxicity in rats.

9.1.3 Inhalation Toxicity

Not provided.

9.1.4 Skin Irritation (Kern, 1997c)

Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	6 females
Observation period:	13 days
Method of administration:	A single dose of 0.5 mL applied to clipped intact skin for 4 hours under semi-occlusive dressing.
Test method:	OECD TG 404

Draize scores:

Time after treatment (days)	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6***
Erythema						
1	0[a]	2	0	1	1	2
2	0	2	0	1	1	1
3	1	2	1	2	2	1
4	0	2	0	1	1	1
5	-	1	-	1	0	0
6	-	1	-	1	-	-
7	-	1	-	0	-	-
8	-	1	-	-	-	-
9	-	1	-	-	-	-

10	-	1	-	-	-	-
11	-	1	-	-	-	-
12	-	1	-	-	-	-
13	-	0	-	-	-	-

[a] see Attachment 1 for Draize scales

The Draize scores for oedema in all animals were zero.

Comment: The rating 2 of erythema is described as "slight erythema (pale red colour and edges definable)" by the author and "well-defined erythema" by NICNAS.

Result: The notified chemical was a slight to moderate irritant to the skin of rabbits.

9.1.5 Eye Irritation (Kern, 1997d)

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 3/sex

Observation period: 7 days

Method of administration: A single dose of 0.1 mL placed directly into the cupped lower conjunctival sac of right eye, while the left eye served as the control.

Test method: OECD TG 405

Draize scores:

	Time after instillation																	
Animal	***1 hour***			***1 day***			***2 days***			***3 days***			***4 days***			***7 days***		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1	1	2	1	1	1	1	1	0	1	0	0	0	0	0	-	-	-
2	1	1	1	1	1	0	1	1	0	1	0	0	1	0	0	0	0	0
3	1	1	0	1	0	0	1	0	0	0	0	0	-	-	-	-	-	-
4	1	1	1	2	2	2	1	1	0	1	0	0	1	0	0	0	0	0
5	2	1	1	1	1	0	1	1	0	1	0	0	1	0	0	0	0	0
6	2	1	2	1	1	0	1	0	0	1	1	0	1	0	0	0	0	0

see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge

Draize scores for cornea (both opacity and area) in all animals were zero from 1 hour post dosing to day 7. Draize scores for iris lesions in all animals were zero from 1 hour to day 7 except for 3 rabbits that scored 1 at 1 hour post dosing only. At 1 hour post dosing, some positive conjunctival reactions were noticed.

Comment: Sodium fluorescein examination was negative in all animals at day 3 and/or day 7.

Result: The notified chemical was a slight irritant to the eyes of rabbits.

9.1.6 Skin Sensitisation (Kern, 1999)

Species/strain: Albino guinea pig/Hartley (Crl: (HA)BR)

Number of animals: Test group: 10/sex,
Negative control: 5/sex, and
Positive control: 5/sex.

Induction procedure:

test group: day 0

Intradermal induction: 3 pairs of intradermal injections (0.1 mL) were made for each animal:

- Freund's Complete Adjuvant (FCA) without notified chemical emulsified with 0.9% physiological saline (1:1 w/v)
- 5% (w/v) of the notified chemical in propylene glycol
- 3% (w/v) of the notified chemical in 1:1 FCA:saline

day 7

Topical induction: dermal application of 100% test substance under occlusive dressing for 48 hours.

control group: day 0

Negative control group was treated similarly to the test group but without the notified chemical.

Positive control group received 3 pairs intradermal injections of a 1:1 solution of FCA and saline, a 5% mixture of HCA (α-hexylcinnamaldehyde) in 0.5% methylcellulose/ 0.1% Tween 80, and a 5% solution of HCA in 1:1 FCA:saline.

day 7

Negative control animals were treated similarly with deionized water.

Positive control group was treated with a 50% HCA in

acetone.

Challenge procedure:

day 21 — One occluded application of 100% the notified chemical to the left flank for 24 hours for the test and negative groups.

The positive group received an occluded topical challenge of 1% HCA solution in acetone on the left flank, and the vehicle, acetone, on the right flank for 24 hours.

Test method: OECD TG 406

Challenge outcome:

	Test animals		***Negative control animals***		***Positive control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***	***24 hours***	***48 hours***
100%	**6/20	1/20	0/10	0/10	5/10	4/10

* time after patch removal

** number of animals exhibiting positive response (Draize score ≥1)

Comment: Slight to severe dermal irritation was observed at 24 and 48 hours post the intradermal induction in test group.

Slight to moderate dermal irritation was noted in the test group 24 hours after topical induction, but recovered by 48 hours.

Positive and negative controls responded appropriately.

Result: As 30% animals in the test group showed positive responses, the notified chemical was a sensitiser to the skin of guinea pigs at a challenge concentration of 100%.

9.2 Repeated Dose Toxicity

Not provided.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium/Escherichia coli* Reverse Mutation Assay (Wagner & Burnett, 1997)

Strains: S. *typhimurium* TA98, TA100, TA1535 and TA1537;

	E. coli WP2 *uvr*A
Metabolic activation:	Aroclor-induced rat liver (S9)
Concentration range:	100 to 5 000 μg/plate with and without S9 activation vehicle: water. Positive controls: All *Salmonella* Strains (+S9) and WP2*uvr*A (+S9): 2-aminoanthracene (1.0 μg/plate); TA98 (-S9): 2-nitrofluorene (1.0 μg/plate); TA100 (-S9) and TA 1535 (-S9): sodium azide (1.0 μg/plate); TA1537 (-S9): 9-aminoacridine (75 μg/plate); WP2*uvr*A (-S9): methyl methanesulfonate (1 000 μg/plate). Negative control: Water. The test substance was soluble but cloudy in water at 100 mg/mL, the maximum concentration tested.
Test method:	OECD TG 471
Comment:	The test substance induced revertants in the strains tested in the presence and absence of metabolic activation. However, the numbers of revertants per plate with the test substance were not significantly different than with the vehicle. The positive and negative controls responded appropriately. All criteria for a valid study were met.
Result:	The notified chemical was non mutagenic under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

The notified chemical is of very low acute oral toxicity (LD_{50}> 5 000 mg/kg) and low acute dermal toxicity (LD_{50}> 2 000 mg/kg) in rats. It is a slight to moderate skin irritant and a slight eye irritant in rabbits. The notified chemical is a skin sensitiser in guinea pigs with 30% positive responses in an adjuvant type test.

The notified chemical was non mutagenic in the *Salmonella typhimurium* and *Escherichia coli* reverse mutation studies.

According to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999), Magnasoft SRS is classified as a

hazardous substance based on its skin sensitising effect. The risk phrase for Magnasoft SRS is R43 (May cause sensitisation by skin contact).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Not normally required by the Act for polymers assessed as Limited Notifications. The notifier provided the following ecotoxicity data, because cationic polymer are known to be toxic to aquatic species (Nabholz et al., 1993).

ECOTOXICITY FOR MAGNASOFT SRS

Test	Species	Results (nominal)
Acute Toxicity	Fathead minnow	LC_{50}(96 h) >1 000 mg/L
	Pimephales promelas	NOEC (96 h) =1 000 mg/L
Acute Immobilisation	Fresh water invertebrates	EC_{50} (48 h) > 1 000 mg/L
	Daphnia magna	NOEC (48 h) = 1 000 mg/L
Growth Inhibition	Algae	E_bC_{50} (72 h) = 0.83 mg/L
	Selenastrum apricornutum	E_rC_{50} (72 h) = 2.5 mg/L
		NOEC (biomass) < 0.4 mg/L
		NOEC (growth rate) = 0.4 mg/L

The tests on Fathead minnow were performed using static test methodology. Test media containing the new polymer were prepared by adding Magnasoft SRS containing (nominally) 25% of the polymer to the test water stirred to produce homogeneous mixtures. The test was conducted over 96 hours, with test media containing (nominally) 150, 250, 400, 600 and 1 000 mg/L of the test material, together with one control containing no test substance. It was noted that while no insoluble material was observed during the tests, the mixtures containing more than 150 mg/L (nominally) of the Magnasoft SRS were cloudy. The test was performed at 22±1°C in water with hardness approximately 175 mg/L as $CaCO_3$. The pH and dissolved oxygen levels were between 7.7 and 8.3, and between 4.9 and 8.8 mg/L, respectively. Ten fish were used at each test concentration, and no mortalities or aberrant behaviour was observed with any of the test media throughout the 96 hour test. Since the Magnasoft SRS contains (nominally) 25% of the new polymer (ie nominally 250 mg/L of polymer in the test media with the highest loading), it may be inferred that the new polymer is practically non toxic to fathead minnow up to the limit of its water solubility.

The tests on *Daphnia magna* were performed using static test methodology. Test media containing the new polymer were prepared by adding Magnasoft SRS containing (nominally) 25% of the polymer to the test water stirred to produce homogeneous mixtures. The test was conducted over 48 hours, with test media containing (nominally) 150, 250, 400, 600 and 1 000 mg/L of the test material, together with one control containing no test substance. It was noted that while no insoluble material was observed during the tests, the mixtures containing more than 150 mg/L were cloudy. The test was performed at 20±1°C in water with hardness approximately 172 mg/L as $CaCO_3$. The pH and dissolved oxygen levels were between 7.3 and 7.5, and between 8.3 and 9.1 mg/L respectively. Ten daphnia were used at each test

concentration, and only one replicate test was performed at each nominal concentration. No immobilisation or aberrant behaviour was observed with any of the test media throughout the 48 hour test. Since the Magnasoft SRS contains (nominally) 25% of the new polymer (ie nominally 250 mg/L of polymer in the test media with the highest loading), it may be inferred that the new polymer is practically non toxic to daphnia up to the limit of its water solubility.

The tests on green algae (*Selenastrum capricornutum*) were performed using static test methodology with solutions of the test substance Magnasoft SRS containing (nominally) 25% of the polymer. The test was conducted over 72 hours, with solutions containing (nominally) 0.40, 0.80,1.5, 3.0 and 6.0 mg/L of the test material, together with one control containing no test substance. No insoluble material or cloudiness of test medium were observed. Three replicate tests were conducted at each concentration (6 replicates for the control), and temperature was controlled at 24±1°C.

The results based on the biomass (algal cells per mL) and the rate of biomass growth indicated significant inhibition of the growth of this algal species – see results tabulated above. Based on the cell concentration (biomass), the E_bC_{50} of 0.83 mg/L indicates that the Magnasoft SRS formulation is highly toxic to this species of algae. Magnasoft SRS contains a nominal 25% of the new polymer, so it is inferred that the E_bC_{50} for the new polymer is around 0.21 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The new polymer is highly toxic to algae with an inferred E_bC_{50} around 0.21 mg/L, consequently it is appropriate to estimate the environmental concentration resulting from release from typical usage patterns.

The notifier indicated that all the new material would be used at one textile mill and that this plant would discharge around 250 grams per day of the new polymer to the sewer at a concentration of approximately 0.25 mg/L. Once diluted with other sewage (assuming dilution factor 1:10) the PEC (predicted environmental concentration) in the sewer system is 25 μg/L. This is an order of magnitude below toxic levels to algae, and further dilution would occur following release of the sewage effluent to the receiving waters. However, it should be appreciated that this PEC estimate is predicated on an (inferred) 99% fixation rate of the polymer to textile, and lower fixation rates would lead to correspondingly larger PECs. For example, if the fixation rate were 90%, the PEC after dilution in the sewer becomes 0.25 mg/L, which is close to the measured toxicity to algae.

The PEC calculation above is based on the effluent of a metropolitan treatment plant and assumes no assimilation of polymer into sediments or sludge. In view of the ecotoxicity data described above for algae, this PEC appears to indicate a potential environmental hazard from the predicted release of residuals. However, the cationic nature of the polymer indicates that most would adsorb onto particles of sediment and sludge (Hamelink, 1992; Varaprath et al., 1996), and would not remain in the water compartment for assimilation by biota. Furthermore, Nabholz et al. (1993) have pointed out that the interaction between this class of

compound and the dissolved and suspended organic matter in natural waters can significantly mitigate toxicity of the compounds.

Discarded garments fabricated from the textiles would be incinerated or be placed into landfill. Incineration would destroy the polymer with evolution of water vapour and oxides of carbon and nitrogen, while the silicon content would become associated with ash or slag. In a landfill, it is expected that slow degradation of the cellulose in the fabric would lead to release of the polymer. However, once released it is expected to adsorb to and become associated with the clay minerals in soils and sediments. In this situation, it is expected that the polymer would be slowly degraded through various biological and abiotic processes operative in these facilities.

The environmental hazard from the notified polymer is expected to be low when the material is used in the described manner.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

On the basis of the submitted data, Magnasoft SRS is classified as hazardous in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999) based on its skin sensitising effect. Accordingly, the risk phrase R43 May cause sensitisation by skin contact is assigned for the notified polymer. The imported product Magnasoft SRS Textile Softener will be hazardous substance (sensitiser) on the basis of the polymer concentration.

Magnasoft SRS is of very low acute oral toxicity (LD_{50} > 5 000 mg/kg) and low acute dermal toxicity (LD_{50} > 2 000 mg/kg). It is a slight to moderate skin irritant and a slight eye irritant, and a skin sensitiser. No data were provided on its acute inhalation toxicity. The notified polymer is non-mutagenic in bacterial systems in the presence and absence of metabolic activation.

The notified polymer does not contain impurities or low molecular species that present major toxicological hazards.

Occupational Health & Safety
The notified polymer will be imported in a product packaged in 205 L steel drums containing >25% the notified polymer and <75% dipropylene glycol. Occupational exposure to the notified polymer will only occur through contact with the product and its solution.

Waterside, warehouse and transport workers will only be exposed to the notified polymer in the event of an accident or damage to packaging. The occupational health risk to these workers is negligible.

Workers in the mixture preparation area will weigh and pour the product containing the notified polymer, stir the mixture and wash empty drums manually. Both dermal and eye exposure are possible during these operations. The notifier estimates that the overall

exposure period for all workers is approximately 30 minutes per worker per day. Given that the chemical is a skin sensitiser and may cause skin and eye irritation, it is important to ensure that topical exposure does not occur. Any dermal contact to the notified polymer is of occupational health concern, specially within the sensitised subpopulation. In addition, possible eye contamination due to splashing should be avoided. The exposure mitigation methods described by the notifier, namely room ventilation and local exhaust fans and the use of safety goggles, overalls and PVC gloves are adequate to minimise the risk of adverse health effects.

During stenter machine operation, the notified polymer is diluted in the mixture (5 g/L) and the process is enclosed. Operators will be exposed to the mixture when feeding fabric into the stenter at the start of a run. Personal protective equipment for stenter machine operators namely gloves, overalls, and safety glasses is necessary to minimise the health risk, as the notified polymer is a skin sensitiser. In addition, industrial control measures, such as room ventilation and local exhaust fans will be used in the workplace.

The notified polymer will be fixed to textile after treatment, however, the risk, if any to workers handling treated fabric, is not ascertained, as no information or fixation rate has been provided.

Public Health
Members of the public will make dermal contact with clothing made from textiles treated with the notified chemical. The chemical is used in solution at 0.5% for the treatment of fabric, with the polymer strongly bound to the fibres. The notifier specifies that treated textiles would be used to manufacture outer garments, which may decrease the potential for skin contact. Little leaching of the polymer from the fibres is expected during normal wear, with the majority of any possible leaching occurring during washing. While the notified chemical is a skin sensitiser, producing a reaction in 30% of the challenge rats, all reactions were of a low grade (Draize score 1), and the irritation had resolved by 48 hours after exposure.

Based on the toxicity profile and use pattern of the notified chemical, it is considered that the notified chemical will not pose a significant hazard to public health.

13. RECOMMENDATIONS

Occupational Health & Safety
To minimise occupational exposure to Magna SRS 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 3765.1 (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;

- A copy of the MSDS should be easily accessible to employees.

- Workers who become sensitised to the notified chemical should not continue to handle it in the workplace.

The notified polymer is nominated to the National Occupational Health and Safety Commission for consideration for inclusion in the NOHSC List of Designated Hazardous Substances.

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*, then workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public Health
To minimise public exposure to Magna SRS the following guidelines and precautions should be observed:

- If the conditions of use are varied, greater exposure of the public to the product may occur. In particular, should the chemical be used for the treatment of textiles used to manufacture underwear or towels, which may result in greater dermal exposure to the notified chemical, additional information on the binding of the chemical to the textile in a range of conditions would be required.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 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. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical may be required if any of the circumstances stipulated under section 64 of the Act arise. If greater exposure to the aquatic environment is expected from new or changing use patterns of the new polymer, the notifier

may be required to provide further ecotoxicology test reports (eg for chronic toxicity to Daphnia). No other specific conditions are prescribed.

16. REFERENCES

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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