File No: NA/765

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in Mackpro WWP

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Telephone: (61) (02) 9577 9514 FAX (61) (02) 9577 9465

Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

Polymer in Mackpro WWP

1. APPLICANT

Lever Rexona Pty Ltd of 219 North Rocks Road, NORTH ROCKS NSW has submitted a limited notification statement in support of their application for an assessment certificate for Polymer in Mackpro WWP.

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 use have been exempted from publication in the Full Public Report and the Summary Report.

3. PHYSICAL AND CHEMICAL PROPERTIES

All of the physicochemical properties were measured using the commercial product Mackpro WWP, which is an aqueous solution containing the notified chemical.

Appearance at 20°C and 101.3 kPa:	Clear amber semi-viscous liquid
Boiling Point:	Approximately 100°C - measured for the product
Specific Gravity:	1.03 g/cm^3 at 20°C
Vapour Pressure:	2.4 kPa at 20°C - measured for the product
Water Solubility:	Highly soluble at pH < 8.0 (see comments below)
Partition Co-efficient (n-octanol/water):	Not determined (see comments below)
Hydrolysis as a Function of pH:	Not determined (see comments below)
Adsorption/Desorption:	Not determined (see comments below)
Dissociation Constant:	pK_a of COO^- is 4.87; pK_a of NH_2 is 10.69

	These are based on propanamine and propanoic acid, respectively
Flash Point:	Not flammable (> 100ºC – PMCC Test, according to MSDS)
Flammability Limits:	Not applicable
Autoignition Temperature:	Not expected to undergo auto-ignition
Explosive Properties:	Not explosive
Reactivity/Stability:	Not reactive

Comments on Physico-Chemical Properties

It is stated that the water solubility is high at pH < 8, although no test data or explanation was provided. Under environmental pH (pH 4-9) the hydrolysed protein portion is likely to be very water soluble due to the high anionic charge (see discussion on dissociation constant below).

In respect of the above, the notifier supplied an estimate of the water solubility of the linoleic amido tertiary amine component derived from a Quantitative Structure Activity Relationship (QSAR) where water solubility is related to the (estimated) value for the n-octanol/water partition coefficient (see further below). The derived solubility for this molecule was 0.19 mg/L, and no comment was offered by the notifier as to why this very low solubility is different from the stated high water solubility of the notified material. The fatty acid amido amine components have large linear hydrocarbon moieties coupled to ionic protonated tertiary amine end groups. Compounds with these structural features are known to be surface active and capable of forming micellar aggregates of colloidal dimensions and fully dispersible in water.

The hydrolysed protein component containing peptide groups and the amide group in the fatty acid amido amine component will hydrolyse under extreme pH.

The high water solubility of the material indicates that the notified polymer would have little affinity for the oil phase, and that the partition coefficient would be small. While the hydrolysed protein portion is likely to have high affinity for water and little for the oil phase, the fatty acid amido amine components are likely to have some affinity for oil and grease due to the chemical compatibility of oil/grease with the hydrocarbon portions of these species. The notifier estimated the n-octanol/water partition coefficient of the fatty acid amido amine using a molecular fragmentation procedure (ACD software), and the resultant log P_{ow} was 5.87±0.39, supporting high affinity for the oil phase.

These species also contain protonated tertiary amine end groups and compounds with these structural features (ie. large, primarily linear hydrocarbon portion coupled to ionic end groups) are known to be surface active and capable of forming micellar aggregates dispersible in water. Consequently, while the molecular fragmentation procedure may provide reasonable estimates for the log P_{ow} of the hydrocarbon portion of the molecule, the presence of a terminal protonated tertiary amine group (ionic) has substantial effects on the

compound's physico-chemical interactions with water, and conclusions based on the estimated value for log P_{ow} for such molecules alone are likely to be erroneous. QSAR calculations are known to be of limited value for ionisable substances (as opposed to neutral molecules). This assertion is supported by the estimated low water solubility (0.19 mg/L), which conflicts with the notifier's statement of high water solubility for Mackpro WWP.

The high water solubility indicates little affinity for the organic component of soils and sediments. While the peptide portion of the polymer is likely to remain in the water column, it is likely that the fatty acid amido amine components may have some affinity for soils and be relatively immobile. An estimate for log $K_{oc} = 4.6 \pm 1$ was derived from the QSAR estimate for log P_{ow}, indicating high affinity and low mobility of the fatty acid derivative for the organic component of soils and sediments. However, the presence of the protonated tertiary amine group has not been considered (or commented on by the notifier) in the QSAR estimate for log K_{oc} and since the compound is likely to have strong surfactant properties with potential solubility through micelle formation, the derived value for log K_{oc} may not be valid.

The notified polymer has amino groups and carboxylate groups in the peptide component and tertiary amine moieties in the fatty acid amido amine components. Typical pKa for carboxylate groups is between 3.5 and 4.5 and for amine groups is typically between 9.5 and 10.5 (Pine, Hendrickson et al. 1981). Both components of the notified polymer are expected to remain in substantially ionised form under the usual environmental conditions of pH 4-9.

4. PURITY OF THE CHEMICAL

Degree of Purity:	> 99% (see comments above)
Hazardous Impurities:	None
Non-hazardous Impurities (> 1% by weight):	None
Polymer Constituents:	
Protein hydrozylate	Not specified (see comments above)
Fatty amido amine	Not specified (see comments above)
Maximum Content of Residual Monomers:	Present in product, but difficult to quantify (see comments above)
Additives and Adjuvants:	Details were supplied and are exempted from publication in Full Public Report.

5. USE, VOLUME AND FORMULATION

The notified polymer will not be manufactured in Australia, but will be imported in 250 L plastic drums as a raw ingredient of Mackpro WWP (< 50%) and reformulated in Australia

into personal care products. These preparations are manufactured in 3 000 kg batches, which typically involve blending Mackpro WWP with other components. Around 90 batches of the skin lotion would be produced each year.

The notifier indicated that less than 1 tonne/annum of the notified polymer will be imported over the next five years.

6. OCCUPATIONAL EXPOSURE

Transport and Delivery: 1-2 hours/day, 2 days/year
The commercial product containing the notified polymer is transported by road from the dockside to the notifier's warehouse, where it will be stored until required for reformulation. Waterside workers and transport drivers would only be exposed to the notified polymer in the event of a spill from a transport or handling incident. Approximately 4-6 workers will be involved in transportation and delivery.

Formulation

Warehouse Staff: 2 hours/day, 30 days/year
Warehouse staff involved in transport and storage of the imported containers containing the neat commercial product, and of the final reformulated products (containing < 1% of the notified polymer) would only be exposed to the notified polymer in the event of a spill from a transport or handling incident. Approximately 2-3 warehouse workers will be involved in transport, storage and delivery to retailers.

Formulation and Filling Staff: 8 hours/day, 90 days/year
The skin care product is formulated in batch sizes of 3 000 kg with < 1% of the notified polymer.

Mackpro WWP is decanted manually from the plastic drums and weighed before being transferred to the fully enclosed stainless steel mixing tank. Other ingredients are then added for compounding in a batch-wise process. Following QC assessment the formulation is transferred to the hopper of a multi-head filler machine and filled into 250 mL pump packs or 500 mL refill pump packs. Although the filling machine is not fully enclosed, local and exhaust ventilation systems exist and the operation is fully automated. The notifier stated that the same operator performs this process and cleans the equipment after each batch.

Worker exposure to the notified polymer is expected during weighing and transfer to the mixing vessel as they may receive dermal and eye contact with Mackpro WWP from drips and spills while handling the product. Exposure may also occur during filling operations in case of machine malfunction and/or removal of crushed containers, though these events are of rare occurrence. The notifier indicated that workers typically wear long sleeved overalls, a head covering, safety glasses, safety boots and impervious gloves. Between four and six operators will be involved in reformulation and filling operations.

Dermal exposure may also occur during clean up of weighing and mixing vessels and filling machinery. Exposure during clean up of the weighing vessels is of greatest concern, since the notified polymer constitutes < 50% of Mackpro WWP. Exposure during other clean up tasks involving the filling machinery is expected to be low given that the notified polymer constitutes < 1% of the formulation and the use of personal protective equipment and the

engineering control measures in place.

Exposure by inhalation is negligible since aerosol formation is unlikely to occur during weighing and transfer to the mixing vessel, as Mackpro WWP containing the notified polymer is a viscous liquid with relatively low vapour pressure, and the mixing vessel is a fully enclosed system.

Overall, the sampling, dispensing and compounding operations are carried out in an enclosed and automated system designed to not create aerosols or spillages, which further minimise worker exposure. The notifier stated that the manufacturing process is contained in a bunded area.

Quality Control (QC) Staff: 4 hours/day, 90 days/year
QC testing of each batch as it is manufactured and preparation of trial batches will be conducted. This involves the dispersion of the notified polymer and other components using laboratory mixers. QC involves sampling and testing the raw material and the final formulations containing the notified polymer. Sampling equipment and testing equipment for spectroscopy and for the determination of physicochemical properties such as pH and viscosity will be used. Exposure to the polymer at neat concentration and when mixed with other chemicals is expected to occur mainly through skin and/or eye contact. The notifier stated that laboratory staff would wear laboratory coats and safety glasses. Approximately 1-4 technicians will be involved in sampling and QC testing.

Packaging Operators: 4 hours/day, 90 days/year
The final product containers will be packaged in cardboard cartons and loaded onto pallets ready for distribution to retail outlets. Operator exposure to the notified polymer will only occur if the seal on product containers is compromised or in the event of a spillage from a handling incident. Skin or eye contact is the main route of exposure. The notifier stated that packaging operators will wear long sleeved overalls, a head covering, safety glasses, safety boots and impervious gloves while handling the packaged product. Given the low concentration of the notified polymer in the final product (< 1%) and the use of personal protective equipment, exposure to the polymer is expected to be negligible. Two to five workers are expected to be involved in the packaging of the final product.

Retail Workers: 1 hours/day, 100 days/year
The skin care product containers will be unloaded by retail workers from cartons and stacked on the shelves. Exposure to the notified polymer will only occur if the packaging on the containers is compromised. In such incidents, dermal exposure is expected to be low given the notified polymer is in diluted form (< 1%). The final product will be delivered to thousands of retailers. The notifier indicated that the skin products are not intended for professional use.

7. PUBLIC EXPOSURE

Public exposure to the notified polymer is expected to be widespread and repeated as the moisturising hand cleanser containing the notified polymer will be sold to the public and applied directly to the skin. The most likely route of exposure will be dermal; ocular exposure is unlikely. According to the notifier, consumers will be exposed to 2 mL of the

cleanser per application. If the cleanser is used as the only handwash substance, there may be up to 10 exposures per day. The handwash contains < 1% of the notified polymer, resulting in an exposure of < 100 mg per day.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier indicated that around 1% of the new formulation may be released from the production facility from spillage and cleaning filling lines and other equipment. This equates to an annual release of around 10 kg of the polymer, which would be sent with other factory waste to an on-site dissolved air flotation (DAF) water treatment plant, then to the metropolitan sewer system. While the DAF facility is capable of treating up to 4 000 L per hour of waste water, the notifier indicated it is unlikely to remove much of the new material due to its high water solubility. Consequently most of the released polymer would enter sewage and be treated at North Head sewage treatment plant.

Most imported material (around 1 tonne per annum) will eventually be released as a consequence of the intended use pattern of the consumer products. Most would be washed off skin and enter the sewer systems. End use is expected to be Australia wide, so release will be very diffuse and at low levels. The notifier indicated that around 2% of the skin lotions may remain unused in "empty" bottles of product and placed into landfill with domestic garbage. Assuming importation of 1 tonne of the new polymer each year, around 20 kg may be placed into landfill, but release would be throughout Australia and very diffuse.

Fate

No biodegradation information was submitted with the notification, but since both components of the new material are of biological origin and have not undergone fundamental chemical transformation during the production of Mackpro WWP, the material is expected to be at least slowly degraded through aerobic biological processes.

Around 10 kg per year of the notified polymer will be released to the northern Sydney sewer system as a result of manufacture of skin lotions, while most of the remainder would enter the general sewage systems of cities and towns after application in skin lotions. The notifier indicated that due to the high polymer water solubility, little was expected to be removed during waste water treatment processes. However, while this is probable for the peptide component, the quaternarised fatty acid amido amine components will have some affinity for oil and grease. These components are also likely to associate with negatively charged colloidal material in sewage sludge via the positively charged amine end group. Regardless of whether the material remains in the water compartment or becomes associated with sludge, it is expected to degrade to water, carbonate and ammonia through biological processes.

Around 20 kg may be placed into landfill each year as empty container residue, and once released from these containers is likely to be mobile in the soil compartment. The polymer is expected to quickly degrade through biological action.

Due to the relatively large size and water solubility of the component species, the polymer is not expected to cross biological membranes and bioaccumulate (Connell 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

Tests were performed on Mackpro WWP, which contains < 50% of the notified polymer.

9.1 Acute Toxicity

Summary of the acute toxicity of Mackpro WWP

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 mg/kg bw	(Kukulinski 1992a)
skin irritation	rabbit	Slightly-moderately irritating (4%); Severely irritating (neat)	(Kukulinski 1992b); (Kukulinski 1990)
eye irritation	rabbit	Moderately irritating (4%); Severely irritating (neat)	(Kukulinski 1992b); (Kukulinski 1990)

9.1.1 Oral Toxicity (Kukulinski 1992a)

Species/strain:	Rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	5 mL/kg bw (at 5g/kg bw) was administered orally (gavage)
Test method:	OECD TG 401
Mortality:	None
Clinical observations:	No gross changes observed in any of the animals
Morphological findings:	None
LD_{50}:	> 5 mL/kg bw (> 5 g/kg bw)
Result:	the test substance was of very low acute oral toxicity in rats

9.1.2 Skin Irritation (Kukulinski 1992b) (Kukulinski 1990)

Species/strain:	Rabbit/New Zealand Albino
Number/sex of animals:	6 (males and females) for 4% dilution of test substance; 3 males for neat test substance
Observation period:	72 hours

Method of administration: 0.5 mL of:
diluted (4%) test substance;
neat test substance;
each applied to two areas (~ 6.45 cm^2) of shorn intact skin and two areas of shorn abraded skin on the abdomen of each rabbit and held under semi-occlusive dressing. After 24 hours, the patches are removed and the skin is examined for signs of irritation.

Test method: Similar to OECD TG 404

Draize scores:

4% dilution of test substance

Time after treatment (days)	***Animal #***											
	1		***2***		***3***		***4***		***5***		***6***	
	A*	***UA***	***A***	***UA***	***A***	***UA***	***A***	***UA***	***A***	***UA***	***A***	***UA***
Erythema												
1	1[a]	1	2	2	1	1	2	2	1	1	2	2
3	1	0	1	1	1	1	2	2	1	1	2	2
Oedema												
1	0	0	2	2	2	1	2	2	1	1	3	3
3	0	0	1	1	0	0	1	1	1	0	1	1

[a] see Attachment 1 for Draize scales
**A: Abraded Skin; UA: Un-abraded skin*

Comment: Erythema and oedema scores did not appear to differ significantly when test substance (4% solids) was applied to abraded or un-abraded skin at 24-hours and 72-hours observation. The primary irritation score was 2.46.

Result: the 4% dilution of the test substance was slightly-moderately irritating to the skin of rabbits.

neat test substance

Time after treatment (days)	***Animal#***					
	1		***2***		***3***	
	A*	***UA***	***A***	***UA***	***A***	***UA***
Erythema						
1	3[a]	3	4	3	3	3

3	4	4	4	4	4	4
Oedema						
1	4	4	4	4	4	4
3	3	3	4	4	3	3

[a] see Attachment 1 for Draize scales
***** *A: Abraded Skin; UA: Un-abraded skin*

Comment: Only two observation time-points were conducted, at 24 hours and 72 hours following administration of the test substance.

When the test substance was applied undiluted (neat), eschar, blanching and severe oedema were observed in the animals at 24 hours. The animals showed severe eschar and fissuring when examined at 72 hours. The primary irritation score was 7.25.

Result: the neat concentration of the test substance was severely irritating to the skin of rabbits.

9.1.3 Eye Irritation (Kukulinski 1992b) (Kukulinski 1990)

Species/strain: Rabbit/New Zealand Albino

Number/sex of animals: 6 (males and females) for 4 % dilution of the test substance;
3 males for the neat substance

Observation period: 14 days for 4% dilution;
7 days for neat concentration

Method of administration: 0.1 mL of test substance:
at 4% dilution;
neat concentration;
instilled into the right eye of each rabbit; the left eye served as the untreated control

Test method: Similar to OECD TG 405

<u>4% dilution of test substance</u>

Draize scores of unirrigated eyes at 4% dilution:

	Time after instillation									
Animal	***1 day***		***2 days***		***3 days***		***7 days***		***14 days***	
Cornea	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***
1	1[1]	4	1	3	1	2	1	1	0	0
2	1	3	1	2	1	1	0	0	0	0

3	1	1	0	0	0	0	0	0	0	0
4	1	3	1	3	1	2	0	0	0	0
5	1	2	0	0	0	0	0	0	0	0
6	1	2	0	0	0	0	0	0	0	0

Iris						
1	1	1	0	0	0	
2	1	0	0	0	0	
3	0	0	0	0	0	
4	1	1	0	0	0	
5	0	0	0	0	0	
6	0	0	0	0	0	

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

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

Mean scores at 4% dilution (24, 48, 72 hours observation):

Animal	***Corneal opacity***	***Iridial inflammation***	***Conjunctival redness***	***Conjunctival chemosis***
1	1	0.7	3	3
2	1	0.3	3	1.3
3	0.3	0	1.7	1
4	1	0.7	3	1.7
5	0.3	0	1.3	1
6	0.3	0	1.7	1

Comment: By day 7, all scores were zero except in one animal that

displayed corneal opacity score of 1 and conjunctival chemosis and redness scores of 1 and discharge score of 2.

Result: the 4% dilution of the test substance was moderately irritating to the eyes of rabbits

Neat test substance

Draize scores of un-irrigated eyes at neat concentration:

	Time after instillation														
Animal	***1 day***			***2 days***			***3 days***			***7 days***			***14 days***		
Cornea	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***
1	1[1]		4	1		4	1		4	2		4	-		-
2	1		4	1		4	2		4	2		4	-		-
3	1		4	1		4	2		4	2		4	-		-
Iris															
1	1			1			1			1			-		
2	1			1			1			1			-		
3	1			1			1			1			-		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	3	3	3	2	3	3	2	2	3	2	2	2	-	-	-
2	2	3	3	2	3	3	2	3	3	2	2	3	-	-	-
3	2	3	3	2	3	3	2	3	3	2	2	3	-	-	-

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

Mean scores at neat concentration (24, 48, 72 hours observation):

Animal	***Corneal opacity***	***Iridial inflammation***	***Conjunctival redness***	***Conjunctival chemosis***
1	1	1	2.3	2.7
2	1.3	1	2	3
3	1.3	1	2	3

Comment: Signs of corneal and conjunctival irritation persisted during the seven days observation period.

Result: the neat concentration of the test substance was severely irritating to the eyes of rabbits

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (Marquardt 1995)

Strains:	TA 97, TA 98, TA 100, TA 102, TA 1535, TA 1537 and TA 1538
Concentration range:	0.05, 0.1, 0.5, 1, 10, 50, 100 μg/plate
Metabolic activation:	liver fraction (S9 mix) from rats pretreated with Aroclor.
Test method:	OECD TG 471, pre-incubation method
Comment:	No significant increase in the frequency of revertant colonies/plate was observed in any of the bacterial strains, at any concentration, with or without S9 metabolic activation. positive controls demonstrated the sensitivity of the various strains and negative controls were within historical limits; cytotoxicity was observed at 5 μg/plate in the absence of metabolic activation (- S9) and at 100 μg/plate in the presence of metabolic activation (+ S9) with strain TA 98.
Result:	the test substance was not mutagenic in *Salmonella* in either the absence or the presence of metabolic activation provided by rat liver S9 fraction

9.3 Overall Assessment of Toxicological Data

Mackpro WWP was of very low acute oral toxicity in rats (LD_{50} > 2 000 mg/kg bw). At 4% dilution, it was a slight to moderate skin irritant and a moderate eye irritant in rabbits, whereas at neat concentration it was a severe skin and eye irritant in rabbits.

It was not genotoxic as judged by a lack of mutagenicity in bacteria.

Although the notified polymer was not tested independently, its toxicological profile is not expected to differ significantly from that of the product Mackpro WWP, which is an aqueous solution of the notified polymer.

The notified polymer has been in use in the USA for a number of years. The submission indicates no adverse health effects have been noted from its use in the USA.

The notified polymer is classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission 1999b) based on the information supplied and the findings of the skin effects in a skin irritation study and conjunctival effects in an eye irritation study. The overall classification for the neat product is Irritant (Xi), and the risk phrases R38- Irritating to Skin and R36- Irritating to Eyes, are assigned. Although the product is a skin and eye irritant at 4% dilution, the degree of irritation is not sufficient to warrant classification.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided QSAR generated data for a tertiary fatty amido amine derivative, which may be representative of these species present in the new material.

The ECOSAR program was used to estimate the toxicity of the neutral amido amine derived from linoleic acid, with the results tabulated below.

Test	*Species*	*Results*
acute toxicity	Fish (species not identified)	96 h LC50 = 0.33 mg/L
acute toxicity	Green algae (species not identified)	96 h EC50 = 0.29 mg/L
acute toxicity	*Daphnia magna*	48 h LC50 = 0.041 mg/L

Although the data sets on which the structure activity relationships are based were not indicated, nor the fish and algal species for which the QSAR data were generated, these results suggest that the fatty acid amido amine components of the new material are very toxic to aquatic species at all trophic levels. It should be noted that compounds containing amino groups (particularly when they become positively charged through protonation or are quaternarised) are well known to exhibit high toxicity to aquatic organisms (Boethling and Nabholz 1997).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Almost all the notified polymer will be released to the environment in sewage as a result of its use in skin care products. However, this release will be nationwide (ie. diffuse) and at low levels. Assuming an annual import of 1 tonne, and that each person produces 150 L of sewage per day, that the national population is 19 000 000 and that no biodegradation occurs in the sewer or at sewage treatment plants, the estimated Predicted Environmental Concentration (PEC) for the new material in sewage is 1 μg/L. If it is assumed to be diluted by a factor of 10 on release of the sewage plant effluent to receiving waters, the final PEC in the wider environment is around 0.1 μg/L. Biodegradation of both the peptide and fatty acid component is likely in both sludge and water so the material is not expected to persist in the environment, and actual environmental concentrations may be significantly less than estimated.

No ecotoxicity data were provided for the notified polymer, although QSAR estimates for a

typical fatty amide amine component indicate that these constituents may be very highly toxic to aquatic species with the indicated 48 hour LC50 to daphnia (the most sensitive species) being 41 μg/L. Using the PEC of 0.1 μg/L gives a safety margin of over two orders of magnitude. However, QSAR estimates of toxicity should be treated with caution and the apparent safety margin could be substantially lower than estimated. Toxicity of the fatty amido amine would be very likely mitigated through its association with sludge.

Conclusions
Despite the indications that the polymer may exhibit very high toxicity to aquatic organisms, the environmental hazard from use of the notified polymer is considered to be low due to the diffuse nature and low level of release and the expected rapid biodegradation. Accordingly, the notified polymer is not likely to present a hazard to the environment when it is stored, transported and used in the proposed manner.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Mackpro WWP was of very low acute oral toxicity in rats. At 4% dilution, it was a slight to moderate skin irritant and a moderate eye irritant in rabbits, whereas at neat concentration it was a severe skin and eye irritant in rabbits. It was not mutagenic in the bacterial study. No repeat dose toxicity studies or sensitisation studies were provided for assessment.

Although the notified polymer was not tested independently, its toxicological profile is not expected to be of greater severity than that of the product Mackpro WWP containing additives and adjuvants some of which are known skin and eye irritants.

The submission indicates no adverse health effects have been noted from the polymer's use in the USA.

The notified polymer is classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission 1999b) based on the information supplied and the findings of the skin effects in a skin irritation study and conjunctival effects in an eye irritation study. The overall classification is Irritant (Xi), and the risk phrases R38- Irritating to Skin and R36- Irritating to Eyes, are assigned.

Occupational Health and Safety

Transport and Storage
Exposure to the notified polymer is not expected during transport or storage as long as the packaging remains intact. Exposure after a spill would be controlled by use of the recommended practices for spillage clean up given in the MSDS supplied by the notifier. The risk of adverse health effects for transport and storage workers is considered low.

Formulation
Occupational exposure is expected to occur during formulation operations involving dispensing and weighing of the notified polymer and transfer to the mixing tank, and during quality control sampling and testing. Inhalation exposure is expected to be insignificant since aerosol formation is unlikely to occur because Mackpro WWP, containing the notified

polymer, is a viscous liquid with low vapour pressure. Also, general and local ventilation is employed throughout the manufacturing process to minimise aerosols/vapours in the work area.

Skin and eye contact will be the main routes of exposure. Exposure to neat Mackpro WWP, which contains < 50% active ingredients, may occur during decanting, weighing and sampling for QC testing. Exposure to the notified polymer during the mixing process is expected to be minimal because it is an enclosed process. The filling operation, though a fully automated system is not an entirely enclosed system, presents another source of exposure to the notified polymer as workers handle crushed containers or attend to malfunction in the machine. Exposure may also occur during the cleaning and maintenance of mixing vessels and filling machinery. Of greatest concern is clean up of containers/utilities used in weighing the neat product containing < 50% of the notified polymer, at which concentration it is a hazardous substance. The notified polymer has a high molecular weight (WAMW > 1 000) and significant dermal absorption through intact skin is not expected. However, given the hazardous nature of the notified polymer, the risk of adverse skin and/or eye irritation exists. Workers will need to wear long sleeved overalls, a head covering, respiratory protection, safety glasses, safety boots and impervious gloves.

Dermal and ocular contact with the notified polymer may also occur during laboratory testing, however, given the smaller quantities handled, the potential for skin and eye irritancy is reduced. The notifier states that sampling, dispensing and compounding operations are carried out in an enclosed and automated system under local and general ventilation designed to minimise worker exposure and laboratory personnel are also required to wear appropriate personal protective equipment.

Overall, the controls employed in the workplace minimise dermal and ocular exposure and therefore reduce the risk of and protect against dermal and eye irritation that may arise.

Workers involved in packaging of the end product and retail workers will have negligible exposure to the notified polymer since it is present at < 1% within sealed containers. Therefore, the health risk to these workers is also negligible.

Public health

Public exposure to the notified polymer is expected to be widespread and repeated as the moisturising hand cleanser containing the notified polymer will be sold to the public and be applied directly to the skin. The slight to moderate skin irritation and moderate eye irritation of a 4% solution of the notified polymer are of concern. However, it is noted that the proposed labels bear warnings regarding avoiding contact with eyes and the need to discontinue use if skin rash or irritation develops. It is difficult to make conclusions on the potential eye irritancy of the notified polymer at < 1%, given that irritation of the 4% solution was not markedly less than that of the 100% solution.

Based on the above information, it is considered that Mackpro WWP will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to Mackpro WWP the following guidelines and precautions should be observed:

- Protective eyewear, chemical resistant industrial clothing and footwear and impermeable gloves should be used during occupational use of the products containing the notified polymer; where engineering controls and work practices do not reduce vapour and particulate exposure to safe levels, an air fed respirator should also be used;

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then 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.

The notified chemical may be recommended to the National Occupational Health and Safety Commission (NOHSC) for consideration for inclusion in the NOHSC List of Designated Hazardous Substances with the risk phrases Irritant (Xi) R38- Irritating to Skin and R36- Irritating to Eyes.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b), workplace practices and control procedures consistent with State and territory hazardous substances regulations must be in operation.

Guidance in selection of protective eyewear may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 3765.1 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/ Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994a); for respirators, in AS/NZS 1715 (Standards Australia/ Standards New Zealand, 1994b) and AS/NZS 1716 (Standards Australia/ Standards New Zealand, 1994c).

14. MATERIAL SAFETY DATA SHEET

The MSDS for Mackpro WWP 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 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 subsection 64(1) of the Act, secondary notification of the notified polymer shall be required:

- if the conditions of use are varied, either by increasing the concentration of the notified polymer in the product, or by adding a greater range of products, in particular facial cleansers, further information will be required to assess the hazards to public health. In particular, data addressing the irritation of the notified polymer at concentrations close to those found in the proposed product will be required; or

- if the method of use changes in such a way as to greatly increase the environmental exposure of the notified chemical, particularly to natural waters, or if additional information becomes available on adverse environmental effects of the chemical; or

- if import quantities exceed 1 tonne per annum, the notifier should provide ecotoxicity test reports conducted against representative species of fish, daphnia and green algae. Biodegradation data and data clarifying likely soil and sediment adsorption/desorption properties should also be provided.

- Under subsection 64(2) of the Act, secondary notification shall be required if any of the circumstances stipulated arise.

No other specific conditions are prescribed.

16. REFERENCES

Merck Index.(1989).

Boethling, R. and J. Nabholz (1997). Environmental Assessment of Polymers under the US Toxic Substances Control Act. Ecological Assessment of Polymers. J. Hamilton and R. Sutcliffe, Van Nostrand Reinhold**:** 187-234.

Connell, D. (1990). Bioaccumulation of Xenobiotic Compounds, CRC Press.

Kukulinski, M. (1990). Mackpro WWP, Primary eye irritation study and primary skin irritation study in the Albino rabbit, Tox Monitor Laboratories, Inc.

Kukulinski, M. (1992a). Mackpro WWP, Acute oral toxicity study in the Sprague-Dawley rat,
Tox Monitor Laboratories, Inc.

Kukulinski, M. (1992b). Mackpro WWP (4%), Primar eye irritation study and primary dermal
irritation study in the Albino rabbit, Tox Monitor Laboratories, Inc.

Marquardt, H. (1995). Mackpro WWp, Toxicity and mutagenicity in the Salmonella/ Microsome assay (Ames).

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

National Occupational Health and Safety Commission (1999b). Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Canberra, Australian Government

Publishing Service.

Pine, S., J. Hendrickson, Cram, D and Hammond, G. (1981). Organic Chemistry, Mcgraw Hill.

Sparrow, L. (1999). CSIRO Biomolecular Engineering, Australia.

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

Standards Australia (1990). Australian Standard 3765.1-1990, Clothing for Protection against Hazardous Chemicals Part 1 Protection against General or Specific Chemicals. Sydney, Standards Association of Australia.

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

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

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

Standards Australia/Standards New Zealand (1994b) Australian/New Zealand Standard 1715-1994, Use and Maintenance of Respiratory Protective Devices. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994c) Australian/New Zealand Standard 1716-1994, Respiratory Protective Devices. Standards Association of Australia/Standards Association of New Zealand.

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

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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	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

MSDS