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21 September 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in Mackpro WLW

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Director
Chemicals Notification and Assessment

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Polymer in Mackpro WLW

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 WLW, which is an aqueous solution containing the notified polymer.

Appearance at 20°C and 101.3 kPa:	Clear dark amber viscous liquid
Boiling Point:	Approximately 100°C – measured for the product
Specific Gravity:	1.057 g/cm^3 at 20°C
Vapour Pressure:	3.33 kPa at 20°C – measured for the product
Water Solubility:	Highly soluble (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:	Not determined (see comments below)
Flash Point:	> 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
Degradation Products:	Thermal decomposition- carbon monoxide, corrosive amines, hydrogen chloride, unidentified chlorinated/non-chlorinated organic compounds
Loss of Monomers, Additives, Impurities:	Polymer stable

Comments on Physico-Chemical Properties

The notifier stated that the water solubility is high. No test data were supplied. However, reasoning was provided for the high solubility. The new polymer is to be imported as a solution in water containing additives, which may act as co-solvents for the notified polymer.

Peptide groups in the hydrolysed protein component of the notified polymer and the amide group in the fatty acid amido amine component would hydrolyse under extreme pH.

The notifier indicated that the notified polymer is surface active so experimental determination of the oil/water partition coefficient is not possible. However, no other comments on the partition coefficient were offered. The high water solubility of the material indicates that overall it would have little affinity for the oil phase. While the hydrolysed protein portion of the new chemical is likely to have high affinity for water and little for the oil phase, the fatty acid amido amine portions are likely to have some affinity for oil and grease due to the compatibility of oil/grease with the hydrocarbon portions of these species.

Due to the surface-active nature of the material, no quantitative soil adsorption/desorption data could be obtained. The hydrocarbon portion of the molecule may have some affinity for these media. However, given the high water solubility, the polymer is expected to have little affinity and be mobile in soils and sediments.

The notified polymer has amino groups and carboxylate groups in the peptide component. Typical pKa for carboxylate groups is between 3.5 and 4.5 and for amine groups is between 9.5 and 10.5 (Pine et al., 1981). The ionisable groups on the peptide moiety are expected to remain substantially in their charged forms under environmental pH 4-9.

4. PURITY OF THE CHEMICAL

Degree of Purity:	> 99%
Hazardous Impurities:	None
Non-hazardous Impurities (> 1% by weight):	None

Maximum Content of Residual Monomers: Present in product, but difficult to quantify .

Additives/Adjuvants: A number of additives, all at < 10%, are present in the product. None were hazardous substances.

5. USE, VOLUME AND FORMULATION

The notified polymer will not be manufactured in Australia, but will be imported as an ingredient of Mackpro WLW (< 50%) in 250 L plastic drums and reformulated into skin 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 up to 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, 4 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, 175 days/year
Warehouse staff involved in transport and storage of the imported containers containing the neat commercial product, and of the final reformulated products (contain < 1% 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, 175 days/year
The skin care product is generally formulated in batch sizes of 3 000 kg with < 1% of the notified polymer.

Mackpro WLW 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 quality control (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 WLW 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 WLW. 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 WLW containing the notified polymer is a viscous liquid with 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 Staff: 4 hours/day, 175 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 and exposure 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, 175 days/year
The final product containers will be packed 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 (< 1%) of the notified polymer in the final product 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 hour/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 be applied directly to the skin. The most likely route of exposure will be dermal; ocular exposure is unlikely if directions for use are followed. 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

8.1 Release

The notifier indicated that around 1% of Mackpro WLW may be released from the formulation site 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, and to the metropolitan sewer system. While the DAF facility is capable of treating up to 4,000 L per hour of waste water, it is unlikely to remove substantial quantities of the new polymer due to its high water solubility. Consequently, most of the released polymer would enter sewage and be treated again at the metropolitan sewage treatment plant (see section on Fate below).

The polymer in skin lotions will eventually be released as a consequence of use, when washed from the skin into the sewer systems. Given that use is expected to be Australia wide, release will be very diffuse and at low levels. The notifier indicated that around 2% of the skin lotions (hence 2% of the notified polymer) may remain unused in empty lotion bottles, which would be 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 throughout Australia.

8.2 Fate

A report on the aerobic biodegradation of the new material conducted according to the protocols of OECD Test Guideline 301 E (Modified OECD Screening Test) was submitted for assessment. The polymer was incubated with sewage sludge for 28 days and the removal of the dissolved organic carbon monitored. After 28 days the degradation exceeded 80%, with 70% degradation achieved within approximately 8 days. According to OECD guidelines, the material can be described as readily biodegradable. This result is in accord with the biological origin of the new polymer where two different materials of biological origin have been reacted together, without major fundamental structural modifications.

Around 10 kg of the notified substance will be released to sewer system each year as a result of manufacture of skin lotions. After application in skin lotions, most of the remainder would enter sewage systems of cities and towns. While little may be removed during waste water treatment processes, the quaternarised fatty acid amido amine component will have some affinity for oil and grease and is likely to become associated with negatively charged colloidal material in sewage. Consequently, the new material may become associated with sewage sludge, but also be mobile in this medium because of the high water solubility.

In any event, the notified polymer 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. Once released from the containers, the polymer is likely to be mobile in the soil compartment. However, it is expected that the material will be quickly degraded through biological action.

The notified polymer is not expected to cross biological membranes and bioaccumulate due to its large size and high water solubility (Connell 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

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

9.1 Acute Toxicity

Summary of the acute toxicity of Mackpro WLW

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 mg/kg bw (2%)	(Fancsali 1993a)
skin irritation	rabbit	very slightly irritating (2%)	(Fancsali 1993c)
eye irritation	rabbit	slightly irritating (2%)	(Fancsali 1993b)

9.1.1 Oral Toxicity of Mackpro WLW (Fancsali 1993a)

Species/strain:	Rat/Sprague-Dawley
Number/sex of animals:	3 males; 2 females
Observation period:	14 days
Method of administration:	Test substance: 2% aqueous solution; 0.47 mL/100 g bw of 5 000 mg/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}:	> 5 000 mg/kg bw
Result:	the test substance was of very low acute oral toxicity in rats

9.1.4 Skin Irritation of Mackpro WLW (Fancsali 1993c)

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 3 (males and females)

Observation period: 72 hours

Method of administration: Test substance: 2% aqueous solution;
0.5 mL of the test substance applied to two areas of shorn intact skin and two areas of shorn abraded skin on the back of each rabbit and held under semi-occlusive dressing. After 24 hours, the patches were removed and the skin was examined for signs of irritation.

Test method: Similar to OECD TG 404

Draize scores:

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

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

Result: the test substance, 2% dilution of Mackpro WLW, was very slightly irritating to the skin of rabbits.

9.1.5 Eye Irritation of Mackpro WLW (Fancsali 1993b)

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 3 (males and females)
Observation period: 2 days

Method of administration: Test substance: 2% aqueous solution;
0.1 mL of test substance was instilled into the right eye of each rabbit; the left eye served as the untreated control.

Test method: Similar to OECD TG 405

Draize scores of unirrigated eyes:

Time after instillation

Animal	***1 hour***			***1 day***			***2 days***		
Cornea	***o***		***a***	***o***		***a***	***o***		***a***
1	0[1]		0	0		0	0		0
2	0		0	0		0	0		0
3	0		0	0		0	0		0
Iris									
1	0			0			0		
2	0			0			0		
3	0			0			0		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1	0	0	1	0	0	0	0	0
2	1	0	0	1	0	0	0	0	0
3	1	0	0	1	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 2% dilution (24, 48, 72 hours observation):

Animal	***Corneal opacity***	***Iridial inflammation***	***Conjunctival redness***	***Conjunctival chemosis***
1	0	0	0.3	0
2	0	0	0.3	0
3	0	0	0.3	0

Result: the test substance, 2% dilution of Mackpro WLW, was slightly irritating to the eyes of rabbits

9.1.6 Skin Sensitisation- Modified Buehler Test (Kukulinski 1995)

Species/strain: Guinea pigs/Hartley albino

Number of animals: Pilot study: 2 males
Main study: 10 males (test group), 10 males (positive control group); 2 males (negative control group)

Induction procedure:

Pre-test:

Topical induction 0.4 mL of 25, 50, 75 and 100% solution of the test substance in distilled water were applied to the skin of animals.

Results of pretest	Application of the test substance at 100% and 75% solution resulted in grade 2 erythema (moderate erythema) in the animals. A 50% solution resulted in grade 1 erythema (faint erythema) in the animals, whereas a 25% solution resulted in very faint erythema (graded 0.5) in one animal and no reaction (graded 0) in the other. Accordingly, a 50% solution was used for induction and a 25% solution for the challenge phase.
Main study:	
test group:	
day 1	Topical induction: 0.4 mL of 50% solution of the test substance in distilled water was placed directly into a Hilltop Chamber, which was placed over the shaved left trunk and over-wrapped around the trunk for 6 hours under occlusive dressing. The chamber was removed and the test site wiped with moistened paper towel to remove any remaining test substance. Animals were treated once weekly for a total of three treatments. Signs of skin irritation were scored at 24 and 48 hours following each induction.
day 36	Animals were topically challenged with a 25% solution of the test substance in water using a similar method, except that the test substance was applied to a naïve contact site (shaved right trunk). Animals were scored for skin irritation at 24 and 48 hours following challenge.
Positive control group:	treated similarly to test animals except that a 0.1% w/w solution of 1-chloro-2,4-dinitrobenzene in 80% aqueous ethanol was used for topical induction, and a 0.03% w/w in acetone was used for challenge.
Negative control group:	Two untreated animals (no induction phase) received only the challenge dose of the test substance.
Skin reactions following, Topical Induction:	Very faint to moderate erythema (grades 0.5-2) was observed in all test group animals at 24 hours following each induction. At 48 hours following each induction, erythema scores varied between 0-1 (no reaction to faint) in all animals. Similar erythema grades were observed in all positive control animals at 24 and 48 hours post each induction.
Test method:	Similar to OECD TG 406

Challenge outcome, test substance:

	Test animals		Control animals	
Challenge concentration	**24 hours***	**48 hours***	**24 hours***	**48 hours***
25%	2**/20	0/20	0/2	0/2

* time after patch removal
** number of animals exhibiting positive response

Challenge outcome, positive control:

	Test animals	
Challenge concentration	**24 hours***	**48 hours***
0.03%	10**/10	10/10

* time after patch removal
** number of animals exhibiting positive response

Comment: Very faint erythema was observed in 2 test group animals at 24 hours following challenge with the test substance. No erythema was observed in any test group animals at 48 hours following challenge.

No erythema was observed in control group animals following challenge with the test substance.

All positive control animals had erythema (graded 0.5-3) at 24 and 48 hours following challenge.

Result: the test substance was not sensitising to the skin of guinea pigs.

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: positive controls demonstrated the sensitivity of the various strains and negative controls were within historical limits; cytotoxicity was observed at 0.5 µg/plate in the absence of metabolic activation (- S9) and at 500 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 WLW was of very low acute oral toxicity in rats (LD_{50} > 5 000 mg/kg bw). At 2% dilution, it was a very slight skin irritant and a slight eye irritant in rabbits. The notified polymer was not a skin sensitiser in guinea pigs in a non-adjuvant test system (modified Bühler test). However, based on positive results observed in two animals (10%) its potential for sensitisation could not be excluded.

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 imported product Mackpro WLW, 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.

Additional health effects information can be derived from data available for the chemically similar product Mackpro WWP, assessed as NA/765. Mackpro WWP was a severe skin and eye irritant in rabbits.

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 findings of the skin effects in a skin irritation study and conjunctival effects in an eye irritation study supplied for Mackpro WWP. The overall classification is Irritant (Xi), and the risk phrases R38- Irritating to Skin and R36- Irritating to Eyes, are assigned.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data was supplied with the notification.

Almost all the notified polymer will be released to the aquatic compartment and it is emphasised that it contains a significant amount of quaternarised amino group in the moiety derived from the fatty acid. Compounds containing this structural feature are well known to exhibit high toxicity to aquatic organisms (Nabholz et al. 1993; Boethling Nabholz, 1997). The polymer also contains an excess of a quaternarised amine epoxide surfactant or its derivatives, plus components with molecular weight below 1,000 g/mol. Consequently, this assessment considers significant toxicity of the notified substance to aquatic organisms a real possibility.

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, 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 polymer in sewage is 1.8 μg/L. If it is assumed that sewage plant effluent released to receiving waters is diluted by a factor of 10, then the final PEC in the wider environment is around 0.18 μg/L. However, as biodegradation of the polymer is likely in both sludge and water and it is not expected to persist in the environment, and actual environmental concentrations may be significantly less than suggested by the above rough estimates.

No ecotoxicity data were provided for the polymer, although the presence of significant content of quaternarised amine components indicates the potential for high toxicity to aquatic organisms. Further, although no information on the mechanisms for biodegradation is available, more of the potentially toxic quaternary amine species will be released if cleavage of the secondary amino link between the peptide and quaternarised fatty amide occurs. However, it should be noted that any toxicity of the quaternary amines would be very likely mitigated through its association with sludge.

Despite the possibility of very high toxicity of the polymer to aquatic organisms, the environmental hazard from its use is considered to be low due to the diffuse nature, low release concentrations and the expected rapid biodegradation. However, without quantitative ecotoxicity data, it is not possible to be more conclusive in respect of the environmental hazard.

Conclusions
The absence of quantitative ecotoxicity data and significant uncertainty on the molecular weight of the new material raise difficulties in reaching definitive conclusions on the environmental hazard of the notified polymer. This assessment emphasises the near total release to the aquatic environment and indications of very high toxicity to aquatic organisms.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Mackpro WLW was of very low acute oral toxicity in rats. At 2% dilution, it was transiently a very slight skin irritant and a very slight eye irritant in rabbits. It was not a skin sensisitiser in a non-adjuvant type test, but potential for sensitisation could not be conclusively excluded. It was not mutagenic in the bacterial strains investigated.
Although the notified polymer was not tested independently, its toxicological profile is not expected to differ significantly from that of the imported product Mackpro WLW, which is an aqueous solution of the notified polymer.

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

Additional health effects information can be derived from data available for the chemically similar product Mackpro WWP, assessed as NA/765. Mackpro WWP was a severe skin and eye irritant in rabbits.

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 findings of the skin effects in a skin irritation study and conjunctival effects in an eye irritation study supplied for Mackpro WWP. 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 are 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 WLW, which contains < 50% notified polymer, 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 and significant dermal absorption through intact skin is not expected. However, given the hazardous nature of the notified polymer, based on data supplied for its analogue polymer in Mackpro WWP, the risk of adverse skin and/or eye irritation exists. Workers will need to wear long sleeved overalls, a head covering, 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.

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 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. Given the end use concentration of < 1%, the notified polymer is unlikely to result in skin or eye irritation.

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

13. RECOMMENDATIONS

To minimise occupational exposure to Mackpro WLW 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* (National Occupational Health and Safety Commission 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); or other internationally acceptable standards.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified polymer in Mackpro WLW 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, the notifier must notify the Director if any of the following circumstances arise, whereby secondary notification of the notified polymer may 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:

  a) ecotoxicity test reports conducted against representative species of fish, daphnia and green algae;

  b) biodegradation data and data clarifying likely soil and sediment adsorption/desorption properties;

  c) definitive molecular weight percent content data, particularly low molecular weight species.

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

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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.
		Swelling with lids half-closed	3 mod.		
Diffuse beefy red	3 severe	Swelling with lids half-closed to completely closed	4 severe	Discharge with moistening of lids and hairs and considerable area around eye	3 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