File No: EX/15 (NA/739)

2 April 2020

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in Lubritan SP

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

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Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polymer in Lubritan SP

1. ORIGINAL HOLDER OF ASSESSMENT CERTIFICATE (FIRST APPLICANT)

An Assessment Certificate for the notified polymer known by the name Polymer in Lubritan SP was granted to Rohm and Haas Australia Pty Ltd of 969 Burke Road CAMBERWELL VIC 3124.

The Assessment Report for Polymer in Lubritan SP is identified by the sequence number NA/739.

SECOND APPLICANT

Since granting of the abovementioned Assessment Certificate, Bayer Australia Pty Ltd of 633-647 Springvale Road MULGRAVE NORTH VIC 3170 has submitted a notification statement in support of their application for an extension of the Assessment Certificate for Polymer in Lubritan SP. Rohm and Haas Australia Pty Ltd has agreed to this extension.

There are no changes in information since the original notification statement submitted by Rohm and Haas Australia Pty Ltd, in matters affecting environmental, occupational or public exposure.

The original assessment report (NA/739) is republished here in full as EX/15 (NA/739) for the public record.

2. IDENTITY OF THE CHEMICAL

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

Marketing Name: Lubritan SP (30% solids polymer in water)

Comments on Chemical Identity

A GPC test report for the molecular weight determination and an infrared spectrum were supplied for the notified polymer. It was not possible to conduct a GPC on the original polymer, since it is an ester-acid co-polymer and not amenable to either aqueous or tetrahydrofuran (THF) GPC. After it was hydrolysed to convert the ester monomers to acids, it was possible to undertake an aqueous GPC. It should be noted that the low molecular weight values are only estimates since the test substance was contaminated by a low molecular weight component of the package. No polydispersity was given and it was not possible to calculate one from the test report.

3. PHYSICAL AND CHEMICAL PROPERTIES

The polymer exists only in aqueous solution and is not isolated. Unless otherwise stated, the physical and chemical data listed below are for the solution.

Appearance at 20°C

and 101.3 kPa: Milky white liquid, acrylic odour

Boiling Point: 100°C (water)

Specific Gravity: 1.0244 (water = 1.0)

Vapour Pressure: 2.261 kPa at 25°C (in water)

Water Solubility: < 40 mg/L

Partition Co-efficient

(n-octanol/water): Not determined

Hydrolysis as a Function

of pH:

Hydrolysis not expected between pH 4 and pH 12 at

room temperature

Adsorption/Desorption: Not determined

Dissociation Constant: pK_a 5 (approximately)

Flash Point: Not flammable, imported in aqueous solution

Flammability Limits: Not flammable, imported in aqueous solution

Autoignition Temperature: Not expected to auto ignite

Explosive Properties: Not expected to be explosive

Reactivity/Stability: Not reactive

Particle Size: Not applicable, imported in aqueous solution

Comments on Physico-Chemical Properties

Although requested, documented test reports for the physico-chemical parameters were not available, therefore this assessment has been unable to confirm the values provided.

The vapour pressure of the isolated polymer was not determined, but the vapour pressure for the polymer emulsion has been given. Due to the polymer's high molecular weight it is unlikely to have a high vapour pressure.

The notifier states that water solubility was determined via a benchtop serial dilution method. Generally, this is accepted as the preliminary investigation step prior to a detailed investigation. In the benchtop test at 30 ppm the solution was clear but at 40 ppm there was insoluble polymer present. Therefore, the solubility is between 30 ppm and 40 ppm (40 mg/L).

By analogy with similar polymers, the notified polymer is not expected to hydrolyse in the environmental pH range of 4-9 though it contains ester linkages. The notifier claims that a sample of Lubritan SP would need to be heated in ethanolic KOH at 180°C at elevated pressure in a Parr bomb for three days before it would hydrolyse. Subjecting the polymer to pH 12 in water would not be sufficient to cause hydrolysis.

The notifier has claimed that due to the low solubility of the polymer the partition coefficient and the adsorption/desorption could not be determined. This assessment acknowledges that measurement of log $P_{\rm ow}$ for polymers is difficult because of the variety of species in solution but that the moderate water solubility (NB: the polymer contains 20% free acid) should enable these parameters to be determined. Moderate log $P_{\rm ow}$ and sorption to soils and sediments may be expected.

The acrylic acid functional group may dissociate. The notifier has provided a dissociation constant (pK_a) of 5 for the polymer emulsion. This was estimated from the pK_a s for acrylic acid ($pK_a = 4.3$) and the acrylic acid homo-polymer ($pK_a = 5.3$).

4. PURITY OF THE CHEMICAL

Degree of Purity: >99%

Hazardous Impurities:

Chemical name: formaldehyde

CAS No.: 50-00-0 Weight percentage: 0.05%

Toxic properties: R40(3) carcinogen category 3;

R23/24/25 – toxic by inhalation, in contact with skin and

if swallowed R34 - corrosive

R43 – may cause sensitisation by skin contact

(NOHSC 1999)

Non-hazardous Impurities

(> 1% by weight): none

Maximum Content Total residual monomer content is less than 0.2%; the of Residual Monomers: concentration of each individual monomer residue is

concentration of each individual monomer residue is well below the concentration cut-off level for classification as a hazardous substance (NOHSC 1999)

Additives/Adjuvants:

Chemical name: Water

CAS No.: 7732-18-5

Weight percentage: 64-66%

5. USE, VOLUME AND REFORMULATION

Use

The notified polymer in Lubritan SP will be used as a waterproofing, retanning and liquoring agent for leather. Lubritan SP will be used at one customer site.

The notified polymer was in use in Australia during 1996 under a NICNAS commercial evaluation permit granted under section 21G of the Act.

Volume

Import volumes for the notified polymer are expected to be 15 tonnes of polymer in the first year (50 tonnes of Lubritan SP) increasing to 30 tonnes of polymer (100 tonnes of Lubritan SP) in the fifth year.

Reformulation

Lubritan SP, containing 30% notified polymer emulsion, will be imported in 200 L open head steel drums and transported by road to the Rohm and Haas warehouse, then again by road to the one customer. It is not reformulated prior to end use. The final end use concentration is 1.5% to 3% notified polymer.

At the customer site Lubritan SP will be mixed with water and other ingredients in a stainless steel mixing vessel and then pumped to large wooden processing drums containing raw hides. The drum is sealed and rotated for 4 to 5 hours. Uptake of the notified polymer by the leather is almost complete (>98%). The treatment mixture containing the notified polymer at 1.5 to 3.0% is made in batch mode; up to 2 batches per day of batch size two to five tonnes. Two tonnes of emulsion is used to treat 1 tonne of raw hide. Following treatment, the drums are automatically drained and spent liquid is pumped to an on-site waste treatment plant. The hides remain in the drum to undergo further processing. Once the treatment process is complete, the hides are removed from the drum, allowed to drain on racks then hung to dry in an enclosed, fan forced heated drying room. Drying takes approximately one hour per day.

6. OCCUPATIONAL EXPOSURE

Transport and Storage, 1.0 to 2.0 hours/day; 20 days/year

Lubritan SP is transported by road from the dock to the notifiers warehouse for storage. At the customer facility, storage is expected to be in an undercover area on a pallet rack system until required for leather processing.

Waterside, transport and storage workers would only be exposed to the material in the event of a spill.

Leather Treatment Site – Treatment Mixture Formulation, 30 minutes/day; 200 days/year At the customer site Lubritan SP drums are opened and hoses connected to pump the product to stainless steel mixing vessels. This operation is performed under local exhaust ventilation and mixing vessels are within bunded areas. One plant operator per shift will be involved in the mixing process and may receive dermal and eye contact to the notified polymer from drips and spills as hoses are connected/disconnected. The notifier indicates standard personal protective equipment will be worn at all times, which includes neoprene gloves, safety glasses and coveralls. The Material Safety Data Sheet (MSDS) recommends half-mask air purifying respirator where vapours or mists may occur.

Leather Treatment Site – Hide Treatment, 1.0 hour/day; 200 days/year

At the end of the treatment process, one to two workers will manually remove the treated hides from the wooden drums and hang them on draining racks. Workers may make skin or indirect eye contact with any residual treatment mixture trapped within creases or folds of the hide. However, exposure to the notified polymer is expected to be negligible as the notifier indicates that trace amounts (> 99% fixation) of uncrossed polymer remain on the leather. As above, local or general ventilation is in place and personal protective equipment is worn.

Leather Furniture Manufacture, 8.0 hours/day; 200 days/year

Craftsman will handle the treated leather whilst upholstering furniture frames. Exposure to the notified polymer is expected to be negligible as only trace amounts of non-crosslinked polymer remain on the treated hides. No details were given on any personal protective equipment worn by these workers. However, safety instructions (details not provided) are provided by the leather treatment company.

7. PUBLIC EXPOSURE

Lubritan SP containing the notified polymer at 30% will not be sold to the public.

Lubritan SP will be transported by road to the notifiers warehouse for subsequent dispatch to a customer site. No public exposure to the notified polymer emulsion is expected except in the event of a spill during transportation.

Spillages during transport are to be contained by use of inert material (earth or sand) before being transferred to suitable containers for recovery or disposal in accordance with local, state and federal regulations. Prompt attention to spillages is needed to prevent spill and clean up material from entering waterways.

At the customer site, the leather treatment process occurs under local exhaust ventilation. Spillages are be contained by bunding. Spills and spent mixture will be collected in the plant waste treatment facility, where the polymer is precipitated and the solid residue taken to a licensed waste landfill.

The public may be exposed to the crosslinked polymer in furniture coverings.

8. ENVIRONMENTAL EXPOSURE

Release

The following table indicates the possible sources and quantities of polymer loss/waste.

Source	Percentage	Quantity (kg)	
		Year 1	Year 5
Spills	0.5	75	150
Drum residues	1.0	150	300
Spent processing liquid	2.0	300^{a}	600 ^b
& wash water			
TOTAL		525	1050

^a Value estimated during this assessment; no value provided by the notifier.

Values for the waste polymer in the spent liquid were estimated during this assessment, using the following parameters: losses due to spills/drum residue are 1.5% with 98.5% of the imported volume available to produce the tanning mixture. Of this 98.5%, 98% (that is, 96.5% of the imported polymer volume) becomes crosslinked to the hides, according to data provided. This leaves 2.0% of the imported volume in the spent mixture.

Spilt material and spent processing liquid enters the on-site waste treatment facility. Thus the mass amount of polymer entering the treatment plant for year 1 is approximately 75 kg from

^b Value estimated during this assessment; the notifier quoted this value as <10kg.

spills and 300 kg from spent liquid, a total of approximately 375 kg. The approximate amounts for year 5 are 150 kg from spills and 600 kg from spent liquid, a total of 750 kg. The submission claims that the spent liquid containing the polymer forms 10% of the total effluent stream entering the treatment plant. Thus, the notifier has indicated that the concentration of the polymer in the treatment plant will be 30-60 ppm. In the treatment plant the effluent is treated with ferric chloride and lime to flocculate the polymer. At least 50% of the polymer (annually up to 187.5 kg in year 1 and up to 375 kg in year 5) precipitates into the sludge and is taken to landfill. At most the same quantities of polymer will remain in the supernatant, which will undergo BOD and pH treatment before being released to sewer. In year 5, up to 375 kg of polymer will enter the sewer. The polymer is used in the tannery for 200 days of the year, equating to a daily release of polymer to sewer of 1.88 kg.

A licensed drum reconditioner will collect the drums. The residual polymer in the drum will either be scraped out (solid) and go to landfill or washed out (liquid) and go to a licensed liquid waste processor.

Fate

The majority of the notified polymer (estimated 96.5% of imported quantity) will become firmly fixed to the leather protein. Consequently, the fate of the majority of the polymer will be the same as that of the final leather articles. At the end of their serviceable life these articles would be disposed of to landfill, or possibly be incinerated.

The above information indicates there are three waste streams that will take the polymer off-site:

- drum reconditioning, where the majority of drum residue will go to landfill;
- sludge from the on-site treatment plant which goes to landfill; and
- supernatant from the on-site treatment plant that goes to sewer then a municipal sewage treatment plant (STP).

Because of the polymers moderate solubility, and inert state following treatment in the on-site treatment plant, polymer disposed of to landfill is unlikely to leach out.

If it is assumed that 50% of the polymer in the supernatant is removed in the STP, on the basis of the 50% removal in the on-site treatment plant, then in year 5 approximately 187.5 kg will be released into the environment over 200 days. The following table contains the PECs for various scenarios.

Estimated Daily PEC Values (ppb)

YEAR 1 YEAR 5
187.5 kg to sewer for the year, over 200 days over 200 days

	No Removal	50% Removal	No Removal	50% Removal
In Werribee plant	1.88	0.94	3.67	1.88
(500 ML/day)				
In receiving water	0.19	0.09	0.37	0.19
(1:10 dilution)				
In typical STP	3.67	1.88	7.52	3.76
(250 ML/day)				
In receiving water	0.75	0.38	1.50	0.75
(1:5 dilution)				

9. EVALUATION OF TOXICOLOGICAL DATA

In support of the application for an Assessment Certificate the notifier has provided acute toxicity studies on a polymer of similar composition to the notified polymer. The analogue substance, E-2984 PMN, is a polymer of acrylic monomers containing a chain transfer agent at 5%. In the following studies, E-2984 PMN was tested as supplied (34.6% acrylic copolymer) and no adjustment was made for percent acrylic copolymer.

9.1 Acute Toxicity

Summary of the acute toxicity of E-2984 PMN

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	$LD_{50} > 5~000~mg/kg$	(Gingrich 1991)
Acute dermal toxicity	Rat	$LD_{50} > 2\ 000\ mg/kg$	(Gingrich 1991)
Skin irritation	Rabbit	Non irritating	(Gingrich 1991)
Eye irritation	Rabbit	Non irritating	(Gingrich 1991)

9.1.1 Oral Toxicity (Gingrich 1991)

Species/strain: Rats/ Crl:CD BR

Number/sex of animals: 6/sex

Observation period: 14 days

Method of administration: 5 000 mg/kg body weight administered as supplied

Test method: OECD TG 401

Clinical observations: No adverse clinical findings

Mortality: nil

Morphological findings: No abnormalities detected

 LD_{50} : > 5 000 mg/kg

Result: E-2984 PMN was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Gingrich 1991)

Species/strain: Rat/Crl: CD BR

Number/sex of animals: 6/sex

Observation period: 14 days

Method of administration: 2 000 mg/kg applied as supplied to an area of shaved, intact

skin and held under occlusive dressing for 24 hours

Clinical observations: No adverse clinical findings; red stained fur surrounding eyes

and muzzle was noted

Mortality: nil

Morphological findings: No abnormalities detected

Dermal effects: Dessication was noted between days 6 to 9;

linear areas of erythema on the back; alopecia was noted

around eyes and head

Comment: The observed erythema and alopecia was not considered

related to test substance administration

Test method: OECD TG 402

 LD_{50} : > 2~000~mg/kg

Result: E-2984 PMN was of low dermal toxicity in rats

9.1.3 Skin Irritation (Gingrich 1991)

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 6/sex not stated

Observation period: 7 days

Method of administration: 0.5 ml of test substance applied to gauze patch and then

applied to shorn intact skin and held in place with a body cuff; after 4 hours the application site was wiped with water

saturated paper towels and then blotted dry

Test method: OECD TG 404

Draize scores:

Time after	Animal #					
treatment	1	2	3	4	5	6
Erythema		all	individual so	cores were z	ero	
Oedema						
1 hour	$^{\mathrm{a}}\mathrm{O}$	0	0	0	0	0
24 hours	0	1	0	0	0	0
48 hours	0	0	0	0	0	0
72 hours	0	0	0	0	0	0
7 days	0	0	0	0	0	0

^a see Attachment 1 for Draize scales

Skin irritation score Erythema: 0.0 (24, 48 and 72 Hours): Oedema: 0.1

Comment: No erythema was observed (all individual scores were zero).

Very slight oedema was observed in one rabbit at the 24 hour

observation

Result: E-2984 PMN was non irritating to the skin of rabbits

9.1.4 Eye Irritation (Gingrich 1991)

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 6/sex not stated

Observation period: 7 days

Method of administration: 0.1mL of the neat test substance was instilled into the

conjunctival sac of one eye; the left eye served as the control; after the 24 observation, each eye (treated and control) was

irrigated for 60 seconds with physiological saline

Test method: OECD TG 405

Comment: No corneal, iridial or conjunctival effects observed (all

individual scores were zero).

Result: E-2984 PMN was non irritating to the eyes of rabbits

9.2 Overall Assessment of Toxicological Data

E-2984 PMN is claimed by the notifier to be compositionally similar to the notified polymer.

E-2984 PMN was of very low acute oral toxicity (LD₅₀> 5 000 mg/kg) and low dermal toxicity (LD₅₀ > 2 000 mg/kg). It was non irritating to rabbit eye or skin.

On the basis of the limited data provided, E-2984 PMN would not be classified as acutely toxic under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999). No hazard determination can be made of acute inhalation toxicity, sensitising potential, repeat toxicity or genotoxicity.

During 1996, the notified polymer was in use in Australia under a commercial evaluation permit granted under Section 21G of the Act. The submission indicates no adverse health effects have been noted from its use.

The notified polymer is of large molecular weight (> 1 000) and not likely to readily cross cell membranes. Its constituent monomers are classifiable as hazardous according to the NOHSC List of Designated Hazardous Substances (NOHSC 1999), however, the residual content of each individual monomer is well below its respective hazard concentration cut off level. The residual monomer content is not given for the analogue, however, its constituent monomers have the same hazard classification as those of the notified polymer. No adverse effects related to treatment were observed with the analogue in the above toxicity studies. Being similar in size and monomer hazard classification to the analogue, the notified polymer is expected to share the same biological activity and the same low order of acute toxicity as the analogue. Therefore, it is considered the notified polymer would not be classified as acutely toxic under the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The assessment considers that the polymer will be a low hazard in the environment when the material is used in tannery operations as indicated.

The polymer is to be used at only one site and effluent from the site is likely to enter the Werribee Treatment Plant. This plant handles approximately 500 ML/day (182.5 GL/year) of effluent which would result in a worst case daily PEC for the polymer of 3.67 ppb in the outfall effluent in year 5. After a ten-fold dilution with receiving waters, the PEC would fall to 0.37 ppb. If the waste effluent enters a smaller city STP, the worst case daily PEC for the polymer would be 1.50 ppb in the receiving water, utilising a 1 in 5 dilution.

Since it is most likely that the effluent from the plant will enter the Werribee Treatment Plant, the expected PEC of <1 ppb is estimated to pose a low hazard to aquatic organisms. No aquatic toxicity data are available. However, polymers of this type are not known to be toxic unless there are only 1 or 1.5 carbons between acid functionalities. Under these conditions slight to moderate toxicity (greater than 3 mg/L) to algae is encountered (Boethling 1997).

Discarded leather products are also likely to be incinerated or placed into landfill. The notified polymer is considered to be stable in landfill.

The MSDS provided by the notifier includes adequate directions for spill clean-up and subsequent disposal of contaminated material.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

During 1996 the notified polymer (30%) in Lubritan SP was in use in Australia under a commercial evaluation permit granted under Section 21G of the Act. The notifier reports no adverse health effects have been noted from its use in Australia or elsewhere.

In animals, E-2984, a compositionally similar polymer to the notified polymer, had very low acute oral toxicity and low dermal acute toxicity. It was non irritating to rabbit skin and eyes.

According to the MSDS for Lubritan SP, the product may cause eye and skin irritation and inhalation of vapour or mist may cause headache, nausea and respiratory irritation. The notifier states the irritant warning effects are primarily based on the pH (4.6-5.0) of the product.

Each of the residual monomers of the polymer is below its hazardous concentration cut off level (NOHSC 1999).

On the basis of the data provided, the notified polymer would not be considered acutely toxic under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999). There are insufficient data to effect a comprehensive health effects classification.

Occupational Health and Safety

During import and transport of the notified polymer, there is unlikely to be any worker exposure, except in the event of a spill. 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. No significant risk to health is expected for workers involved in transport and storage workers given the predicted low hazard of the notified polymer.

At the customer site, the leather treatment mixture which includes Lubritan SP (final concentration of polymer 1.5% to 3%), is prepared in stainless steel mixing vessels, and then pumped to large wooden processing drums containing raw hides. Treated hides are manually hung to dry in a drying room. All operations are performed under local exhaust ventilation. Uptake of the notified polymer by the leather is almost complete (greater than 99%) and negligible amounts of non-crosslinked polymer remain on the treated hide. The greatest opportunity for exposure to the notified polymer is during preparation of the leather treatment mixture. This operation occupies a short time per shift. The polymer in Lubritan SP is not volatile, therefore worker exposure will be limited to eye and skin contact from drips and spills. Minimal exposure during manual handling of the treated hides is expected as the notified polymer is highly crosslinked to the hide (>99%) and negligible amounts of non-crosslinked polymer remain on the hides when they are removed from the drums. Standard personal protective equipment, namely neoprene gloves, safety glasses and coveralls will be worn at all times. Half mask respirators are recommended where inhalation of vapour or mist may occur. As long as the described control and protective measures are in place, exposure is expected to be low and no significant risk to health is expected for leather treatment plant operators.

Exposure to the notified polymer for furniture craftsman will be low because the polymer is highly crosslinked to the leather. The leather treatment company issues safety instructions with the treated leather for furniture craftsman. No significant risk to health is expected for craftsman handling the treated hides.

Public Health

Lubritan SP containing the notified polymer at 30% will not be sold to the public. No public exposure to the notified polymer emulsion is expected except in the event of a spill during transportation. The public may be exposed to the crosslinked polymer in furniture coverings. However, given the low acute systemic and topical toxicity of the polymer, the low concentration in the leather treatment mixture and the negligible amount of non-crosslinked polymer in the treated leather, the potential for public exposure to the notified polymer is expected to be low.

Based on the above information, it is considered that Lubritan SP, containing 30% of the notified polymer, will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to Polymer in Lubritan SP 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 1998). The notifier recommends neoprene gloves;
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand 1994);
- Where vapours or mist may occur, respiratory protection should conform to AS 1715 (Standards Australia/Standards New Zealand 1994), and AS 1716 (Standards Australia/Standards New Zealand 1994);
- Spillage of Lubritan SP should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

If the conditions of use are varied from the notified use, greater exposure of the public may occur. In such circumstances, further information may be required to assess the hazards to public health.

14. MATERIAL SAFETY DATA SHEET

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

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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Gingrich, S. H. J. (1991). Experimental Emulsion E-2984 PMN Acute Dermal Toxicity Study in Male and Female Rats. Spring House, Rohm and Haas Company.

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NOHSC (1999). List of Designated Hazardous Substances [NOHSC:10005(1999)]. Canberra, Australian Government Publishing Service.

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

Standards Australia (1998). AS/NZS 2161.2:1998, Australian/New Zealand Standard Occupational Protective Gloves Part 2: General Requirements. Sydney/Wellington, Standards Australia and Standards New Zealand.

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

Standards Australia/Standards New Zealand (1994). AS/NZS 1715-1994, Australian/New Zealand Standard Selection, Use and Maintenance of Respiratory Protective Devices. Sydney/Wellington, Standards Australia and Standards New Zealand.

Standards Australia/Standards New Zealand (1994). AS/NZS 1716-1994, Australian/New Zealand Standard Respiratory Protective Devices. Sydney/Wellington, Standards Australia and Standards New Zealand.

Standards Australia/Standards New Zealand (1994). AS/NZS 2210-1994, Australian/New Zealand Standard Occupational Protective Footwear. Sydney/Wellington, Standards Australia and Standards New Zealand.

Attachment 1

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

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

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

CORNEA

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

CONJUNCTIVAE

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

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