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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

LUBRITAN GX COPOLYMER

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

LUBRITAN GX COPOLYMER

1. APPLICANT

Rohm and Haas Australia Pty Ltd, Hays Rd, Point Henry, Geelong, Victoria, 3221.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, Lubritan GX is considered to be non-hazardous. Therefore, the chemical identity, exact use and import volume have been exempted from publication in the Full Public Report and the Summary Report.

Chemical name: Lubritan GX Copolymer

Chemical Abstracts Service (CAS) Registry No.: Not available

Trade names: Emulsion E-2984 PMN

Number-average molecular weight: > 1000

Maximum percentage of low molecular weight species (molecular weight < 1000): < 1%

Method of detection and determination:

Infrared Spectroscopy

Spectral data:{type of spectrum and major identification peaks}

The IR spectrum exhibited major characteristic peaks at 1160, 1235 and 1735 cm^{-1}.

3. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer will be imported as a 35% aqueous emulsion. This emulsion is referred to as Experimental Emulsion E-2984 PMN for testing purposes. All properties listed below refer to the emulsion unless otherwise specified.

Appearance at 20°C and 101.3 kPa:	Milky white liquid
Odour:	Acrylic
Glass-transition Temperature:	-42°C (notified polymer)
Density:	1114 kg/m^3 (notified polymer)
Water Solubility:	110 g/L at 20°C (notified polymer)
Hydrolysis as a function of pH:	< 1.1% hydrolysis at 25°C for 7 days at pH 2.5 and pH 8.8 (notified polymer)
Dissociation Constant pKa:	6.95
Decomposition Products:	10% decomposition at 291°C; decomposition may yield acrylic monomers
Autoignition Temperature:	> 291°C
Explosive Properties:	None

4. PURITY OF THE CHEMICAL

Degree of purity (of the notified chemical alone): 95.6%

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

. **Chemical name:** Anionic surfactant
Weight percentage: <5%

Maximum content of residual monomers: <1%

Additives/Adjuvants: None

5. INDUSTRIAL USE

The notified chemical will be imported as a 35% aqueous emulsion called Lubritan GX and will be used for the treatment of certain non-woven fibres in aqueous media.

6. OCCUPATIONAL EXPOSURE

Lubritan GX will be imported in 200 kg steel drums at up to 10 sites.

At each site one weigh-up operator and one process worker work an 8 hour shift, 250 days per year. After addition of the notified chemical to the weighing vessel by pumping or gravity feed, it is diluted with water to the required concentration. The diluted chemical is then fed into an enclosed rotating mill containing the material to be treated. Exposure is estimated at 10 minutes per batch for each of the operators and 2 batches are processed per shift. This includes examination of the contents of the mill during processing.

Almost all of the notified chemical is quantitatively bound to the treated material. As a result, exposure to the notified chemical after processing is expected to be minimal from both the aqueous waste and from the treated material.

7. PUBLIC EXPOSURE

There is low potential for public exposure to the notified chemical during shipment and distribution.

The public should not be exposed to the chemical during processing. As the chemical is quantitatively bound to the treated material, exposure after processing should be minimal.

8. ENVIRONMENTAL EXPOSURE

. Release

Lubritan GX is shipped and used as an aqueous emulsion (64-65% water) and as such should not be considered as a potential atmospheric pollutant.

During transportation, risk of environmental exposure is limited to incidents involving an accident or leaking drum.

The Lubritan GX reacts with the chromium (Cr^{3+}) present in the non-woven fibre after primary treatment. Under normal operating conditions, using the recommended dose rates (8-15% by wt), uptake of the chemical is expected to approach 100%. This is supported by brief details of a test which measured uptake at 98.8% after 2.5 hours treatment at a dose of 20%. Applying linear correction factors for reaction time and applied dose to this result, a worst case residue figure of 2.25% at the highest dose rate of 15% by wt is expected.

Leakages or spills of the notified chemical during processing are to be treated with other wastes.

Typically, liquid wastes generated during processing are treated with a coagulating agent. The residue particles are then agglomerated and removed by aeration and flotation or by settling. The resultant sludge is dewatered by filtration and then disposed of in a secure landfill.

The notifier indicates that the following operational parameters are typical of those of a prospective user of the notified chemical:

- 500 kg of Lubritan GX used daily;
- 4000 kg of treated non-woven fibres produced; and
- 0.25 ML to 1.0 ML of waste water generated daily.

Based on the usage patterns of a typical factory it is possible to estimate the amount of notified chemical released to sewer after in-house treatment (flocculation). Prior to flocculation, 3.94 kg of notified chemical will be released to the waste stream (based on 500 kg/day Lubritan GX at 35% solids, 2.25% unfixed polymer). Dilution by the factory liquid wastes (typically 0.25 ML/day) yields a maximum of 15.8 ppm of the chemical. Assuming that 11% of the chemical is not removed by the flocculation process (that is, the soluble fraction of the chemical in aqueous solution), then approximately 1.8 ppm of the notified chemical will be released with the factory effluent into the sewage.

The notifier indicates that 1% of the Lubritan GX treated fibres will be designated as waste and dumped as landfill.

. Fate

No data were presented on the bioaccumulation and biodegradation of Lubritan GX and this information is not required for a limited notification. In any case the high molecular weight (NAMW > 1000) and water solubility of the notified chemical suggest it would not be expected to cross biological membranes. Traces entering the environment in sewage effluent would be expected to disperse and partition to sediment. The polymer is not expected to undergo biodegradation at significant rates.

9. EVALUATION OF TOXICOLOGICAL DATA

In all of the studies described below, Lubritan GX (also called Experimental Emulsion E-2984 PMN) containing 34.6% of the notified polymer was used.

Toxicological data are not required under the *Industrial Chemicals (Notification and Assessment) Act, 1989, as amended* for polymers with a NAMW > 1000. However, for Lubritan GX, data on acute oral toxicity, acute dermal toxicity, skin irritation and eye irritation were included in the submission.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Lubritan GX Copolymer

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD_{50} > 1.7 g/kg	(1)
Acute dermal toxicity	Rat	LD_{50} > 0.7 g/kg	(2)
Skin irritation	Rabbit	Non-irritant	(3)
Eye irritation	Rabbit	Non-irritant	(4)

9.1.1 Oral Toxicity (Ref No:1)

Experimental Emulsion E-2984 PMN was administered to 6 male and 6 female rats (Crl:CD BR) by gavage at 5.0 g/kg. No mortalities were observed and all rats were necropsied on day 14 after administration of the test substance.

No changes in body weight were noted during the 14 day observation period and the only clinical signs noted were alopecia and scabs below the ears in one male rat.

The acute oral LD_{50} for the notified substance was greater than 1.7 g/kg.

9.1.2 Dermal Toxicity (Ref No:2)

Experimental Emulsion E-2984 PMN was applied topically to the intact shaven skin of the flank of 6 male and 6 female rats (Crl:CD BR) at 2.0 g/kg. The entire trunk was wrapped in polyethylene sheet secured by adhesive and elastic bandages and adhesive tape. After a 24 hour exposure period, each cuff was removed and the application site wiped with paper towels saturated with tap water and blotted dry.

No deaths or body weight changes were observed during the 14 day observation period. Clinical symptoms were alopecia in 2 females, linear areas of erythema on the back of 1 female, red stained fur surrounding the eyes in 3 males and 3 females, red stained fur surrounding the muzzle in 6 males and 5 females and dessication of the skin at the site of application in 4 males and 1 female.

Following necropsy at day 14, the pelvic regions of the right kidneys of 2 males were dilated.

The acute dermal toxicity of the notified substance was greater than 0.7 g/kg.

9.1.3 Skin Irritation (Ref No:3)

Experimental Emulsion E-2984 PMN (0.5 ml) was applied to the intact, shaven skin of the flanks of 6 adult, male New Zealand White rabbits prior to application of a gauze-lined adhesive bandage held in place by a polyethylene sheet and fabric cuff affixed with adhesive tape. After 4 hours the cuff and patch were removed and the application site wiped with paper towels saturated with tap water and blotted dry.

No deaths or clinical signs were observed during the study.

Skin irritation was evaluated at 1, 24, 48 and 72 hours and 7 days after patch removal. Very slight oedema was observed in 1 rabbit at 24 hours.

9.1.4 Eye Irritation (Ref No:4)

Experimental Emulsion E-2984 PMN (0.1 ml) was instilled into the conjunctival sac of one eye of each of 6 adult, male New Zealand White rabbits. After instillation of the test material, the eyelids were held closed momentarily. The untreated eye served as control. Treated and control eyes were examined at 1, 24, 48 and 72 hours and 7 days after dosing. At 24 hours treated and control eyes were irrigated with physiological saline (0.9%) for 60 seconds.

No deaths or clinical signs were observed during the study.

No obvious effects on the conjunctiva, cornea or iris of the treated eye of any animal were observed at any time point although one rabbit exhibited a green corneal stain after treatment with 2.0% aqueous sodium fluoroscein at 24 hours.

9.4 Overall Assessment of Toxicological Data

The notified substance was of low acute toxicity in rats when administered by the oral route (LD_{50} > 1.7 g/kg) and may be of low acute toxicity in rats when administered by the dermal route

(LD_{50} > 0.7 g/kg - Lubritan GX was tested at 2.0 g/kg and exhibited low acute dermal toxicity). Some clinical signs were noted in both acute toxicity studies. It was stated that these effects were not substance-related. However, in the absence of control groups, it is not possible to judge the validity of the statements.

Only the formulation to be imported was tested for skin and eye irritation in rabbits and was shown not to be an eye irritant or a skin irritant following short term exposure.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Due to its high NAMW, the notified polymer is not expected to cross biological membranes. The literature suggests that polycarboxylic acid derivatives are moderately toxic to green algae, with polyacrylic acid being the most toxic (96 hour, EC_{50} of 37.4 mg/L) as a result of its ability to chelate nutrient elements required for algal growth (5).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The aquatic environment will be exposed to Lubritan GX residues which have not been bound to the fibres or subsequently removed during on-site treatment. These residues will be discharged with waste water. However, as indicated previously, the estimated concentration of the notified chemical in the waste water is of the order of 1.8 ppm and will be reduced further during subsequent sewage treatment. For example, the South Eastern Purification Plant (Vic.) has a sewage inflow in excess of 300 ML per day, if we assume no further Lubritan GX is removed during sewage treatment, mixing with the daily waste stream provides a dilution factor in excess of 1200 to yield 1.4 ppb (from 1.8 ppm). Even if no polymer were to be removed during waste treatment at the tannery or sewage plant, the concentration of notified polymer would not exceed 13 ppb in the sewage outfall.

To establish a worst case scenario, a smaller scale sewerage treatment plant is used to estimate the dilution factor. Given an annual water usage rate of 57.8 GL from industrial and commercial facilities (not including domestic use) from the combined S.A. Gulf region (6) and that there are 18 provincial town sewerage schemes in S.A. (7), the throughput for an average

sewage treatment facility in Adelaide may be estimated at 8.7 ML/day. Therefore for a factory based in Adelaide the minimum dilution factor for the polymer would be 35, which equates to a maximum of 51 ppb of the notified substance being released in the sewage effluent.

The concentration of the notified polymer will be reduced even further as the sewage water is released to the rivers, oceans and lakes which act as receiving waters to nearly all sewage treatment plants in Australia.

Using the most toxic of the polycarboxylic acid derivatives as a reference (that is, polyacrylic acid; EC_{50} of 37.4 mg/L towards green algae), a safety margin in excess of 2 orders of magnitude with respect to green algae is expected.

The low environmental exposure resulting from normal use of Lubritan GX and its apparent low toxicological profile indicate that the overall environmental hazard should be minimal.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is of low acute oral toxicity, possibly of low acute dermal toxicity, is not a skin irritant following short term exposure and is not an eye irritant. Consequently, contact with Lubritan GX is unlikely to result in adverse acute health effects. Also, since the residual monomer content in the notified substance is less than 0.1%, adverse health effects from this source are unlikely. However, the fact that the imported formulation is stated to have an acrylic odour suggests the possibility of vapour build-up in containers and this may represent a possible hazard associated with use of the notified substance.

The public is only likely to be exposed to the notified substance in the event of an accident during transport and the effects of this exposure are expected to be minimal. After treatment of the non-woven fibres, the aqueous waste contains little residual polymer so that public exposure from disposal of waste is expected to be minimal.

Exposure of each worker involved in the fibre treatment process to the notified substance is expected to be 20 minutes per day on 250 days per year. Given the toxicological profile of the notified substance, this exposure is unlikely to result in any adverse health effects.

13. RECOMMENDATIONS

To minimise occupational exposure (and public/environmental if recommendations have been made by these agencies) to Lubritan GX Copolymer the following guidelines and precautions should be observed:

. If engineering controls and work practices are insufficient to reduce exposure to Lubritan GX to a safe level, personal protection devices which conform to and are used in accordance with Australian Standards for eye protection (AS 1336; AS 1337) (8, 9), impermeable gloves (AS 2161) (10) and protective clothing (AS 3765.1, 3765.2) (11, 12) should be worn;

. good work practices should be implemented to avoid spillages and splashing;

. good housekeeping and maintenance should be practised. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal in accordance with local or State regulations;

. the workplace should be well ventilated and care should be taken when opening containers to avoid breathing escaping vapours; local exhaust ventilation should be used if heating of the polymer occurs;
. good personal hygiene should be observed; and

. a copy of the Material Safety Data Sheet should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Lubritan GX (Attachment 1) was provided in Worksafe Australia format (Ref No:13). This MSDS was provided by Rohm and Haas Pty Ltd as part of their notification statement. It is reproduced here as a matter of

public record. The accuracy of this information remains the responsibility of Rohm and Haas Pty Ltd

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Lubritan GX Copolymer 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

1. Gingrich, S. L. and Hamilton, J. D., Experimental Emulsion E-2984 PMN, Acute Oral Toxicity Study in Male and Female Rats Protocol No. 91P-152, Report No. 91R-152. Rohm and Haas Company Toxicology Department, Spring House, PA, USA, October 16, 1991.

2. Gingrich, S. L. and Hamilton, J. D., Experimental Emulsion E-2984 PMN, Acute Dermal Toxicity Study in Male and Female Rats Protocol No. 91P-153, Report No. 91R-153. Rohm and Haas Company Toxicology Department, Spring House, PA, USA, October 16, 1991.

3. Gingrich, S. L. and Hamilton, J. D., Experimental Emulsion E-2984 PMN, Skin Irritation Study in Rabbits Protocol No. 91P-154, Report No. 91R-154. Rohm and Haas Company Toxicology Department, Spring House, PA, USA, October 16, 1991.

4. Gingrich, S. L. and Hamilton, J. D., Experimental Emulsion E-2984 PMN, Eye Irritation Study in Rabbits Protocol No. 91P-155, Report No. 91R-155. Rohm and Haas Company Toxicology Department, Spring House, PA, USA, October 16, 1991.

5. USEPA draft document, Discussion of US Regulatory Strategies for Certain New Chemical Polymers, revised September 21, 1992.

6. Australian Bureau of Statistics, Australia's Environment - Issues and Facts, ABS Catalogue No.: 4140.0, 1992.

7. CEPA internal document, Australian Sewage Profile, amended August 17, 1988.

8. Australian Standard 1336-1982, "Recommended Practices for Eye Protection in the Industrial Environment", Standards Association of Australia Publ., Sydney, 1982.

9. Australian Standard 1337-1984, "Eye Protectors for Industrial Applications", Standards Association of Australia Publ., Sydney, 1984.

10. Australian Standard 2161-1978, "Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)", Standards Association of Australia Publ., Sydney, 1978.

11. Australian Standard 3765.1-1990, "Clothing for Protection Against Hazardous Chemicals, Part 1: Protection Against General or Specific Chemicals", Standards Association of Australia Publ., Sydney, 1990.

12. Australian Standard 3765.2-1990, "Clothing for Protection Against Hazardous Chemicals, Part 2: Limited Protection Against Specific Chemicals", Standards Association of Australia Publ., Sydney, 1990.

13. National Occupational Health and Safety Commission, *Guidance Note for the Completion of a Material Safety Data Sheet*, 2nd. edition, AGPS, Canberra, 1990.