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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

LODYNE 87'87

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989, as amended* and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health, Housing, Local Government and Community Services.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

LODYNE 87'87

1. APPLICANT

CIBA-GEIGY Australia Ltd., 140 Bungaree Road, Pendle Hill, NSW 2145.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and data provided, Lodyne 87'87 is not considered to be hazardous. Therefore, the chemical name, CAS registry number, names of component monomers, molecular and structural formulae, spectral information, import volume, number of sites at which the product will be used and the release to the environment at each site have been exempt from publication in the Full Public Report and the Summary Report.

Trade name(s): Lodyne 87'87; Oleophobol C; C334880 (The notified chemical, Lodyne 87'87 forms 15.1% of the commercial product, Oleophobol C.)

Number-average molecular weight: 14500

Lowest molecular weight polymer synthesised: 1500

Maximum percentage of low molecular weight species [molecular weight (MW) < 1000]: 16.2% comprising of 3.8% MW 990, 10.2% MW 690 and 2.2% MW 300.

Method of detection and determination:

Gel Permeation Chromatography was used to determine the number average molecular weight of the polymer.

Spectral data:

Infrared absorption spectrum was provided.

Comments on chemical identity:

It should be noted that the maximum amount of low molecular weight species < 1000 is high - 16.2%. The structure of the lower molecular weight species have not been provided. The GPC trace shows a number of discrete but unidentified low molecular weight species. Should import levels rises above 1 tonne per annum the structure of the lower molecular weight species should be provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

Detailed physical-chemical data on Lodyne 87'87 is not available, however, the notifier has indicated that its solubility and hydrolysis in water are negligible and its high molecular weight suggests negligible vapour pressure. Lodyne 87'87 in its pure form is a white powder which is flammable.

The following data are those of the commercial product, Oleophobol C, an aqueous emulsion which contains 15.1% of Lodyne 87'87.

Appearance at 20°C and 101.3 kPa:	cream coloured emulsion
Odour:	none
Boiling Point:	approximately 100°C
Specific Gravity:	1030-1070 kg/m^3 @ 20°C
Vapour Pressure:	not determined
Water Solubility:	negligible, as the polymer is required to impart durable oil and water repellent properties
Fat Solubility:	not determined

Partition Co-efficient (n-octanol/water) log $P_{O/W}$:	not determined
Hydrolysis as a function of pH:	not determined, not expected to hydrolyse
Adsorption/Desorption:	not determined but entry into soil is unlikely
Dissociation Constant:	not determined pH = 3.5-5.0
Flash Point:	not applicable
Flammability Limits:	not flammable
Combustion Products:	vapours of HF, NO_X
Decomposition Temperature:	not available
Decomposition Products:	none known
Autoignition Temperature:	not applicable
Explosive Properties:	not explosive
Reactivity/Stability:	stable for one year at 20°C in closed containers. Oleophobol C is affected at temperatures below -10°C and above 40°C.

Comments on physico-chemical properties:

The notified chemical is a complex perfluronated polyurethane which may be expected to have low water solubility. However, although the polymer contains at least two basic nitrogen atoms which could be protonated at low pH, the hydrophobic groups on the polymer prevent a significant change in its very low solubility. The chemical also contains a number of urethane functionalities that may be susceptible to hydrolysis.

The lack of test results are acceptable for the proposed level of importation (< 1 tonne per annum), but noting a significant amount is released to water, results, literature support or more

detailed argument for water solubility and hydrolytic stability should be provided if this rises above 1 tonne per annum.

Data for the partition coefficient are not provided. This is acceptable due to the complex composition of the notified chemical.

Data for adsorption-desorption are not provided. The notified chemical is likely to become associated with sludge/sediment as a result of its low water solubility and large molecular weight and size.

4. PURITY OF THE CHEMICAL

Degree of purity of Lodyne 87'87: >93%.

Lodyne 87'87 consists of a range of polymers of which the lowest molecular weight polymer synthesised is 1500.

Impurities:

.	Residual intermediate	4.0%
.	By-products	<2.7%
.	Residual thiols	0.3%
.	Residual diisocyanates	<0.05%

Additive(s)/Adjuvant(s):

Chemical name: Dibutyltindilaurate (as catalyst)
CAS No: 77- 58-7
Residual : 0.04%

5. INDUSTRIAL USE

Lodyne 87'87 will be imported into Australia as a component (15.1%) of the commercial product, Oleophobol C, which is a cream coloured emulsion to be used solely for the finishing treatment of cotton and synthetic/cellulose blends of cloth or fabric to

render them rainproof and oil, water, stain and soil repellant. The estimated quantity of Lodyne 87'87, to be imported is less than 1 tonne per year for the first five years.

6. OCCUPATIONAL EXPOSURE

The major route of worker exposure to the notified chemical, Lodyne 87'87, in Oleophobol C, will be through skin contact.

Significant risk of worker exposure to the notified chemical during transport and storage is unlikely except in the event of an accident as the chemical will be contained in robust secure containers.

At CIBA-GEIGY, some Oleophobol C will be repacked by two workers for use in trials for new customer introductions. The estimated total quantity to be repacked is estimated by the notifier to be 60 kg per year. The exposure of these workers to the notified chemical is anticipated to be low due to the small amount to be repacked and the level of Lodyne 87'87 in Oleophobol C. Direct contact with the notified chemical is possible if personal protection measures are not implemented.

The emulsion will be applied to cloth/fabric by the cold-pad batch and pad thermal fixation method. The cloth/fabric to be treated will be first run through a padder which contains the correct dilution of the emulsion in water, then it will be passed through a set of mangle rollers to remove excess liquor from the cloth/fabric. From the mangle rollers, the cloth/fabric will then pass through the stenter for the thermofixation of the emulsion onto the finished goods. Two workers at each site may be exposed to the notified chemical during the weighing and mixing operations. If personal protection measures and good work practices to avoid splashings and spillages are not implemented, direct contact with the notified chemical is possible. Contact with the notified chemical is also possible during the passage of the cloth/fabric from the padder to the stenter, and during equipment maintenance. The low level of Lodyne 87'87 in the emulsion after dilution in the padder suggests that worker exposure will be very low. It is stated by the notifier that once the emulsion has been thermofixed to the finished good, exposure will be negligible.

Exposure of handlers and users of the treated finished goods to the notified chemical is expected to be negligible due to its fastness characteristics. The emulsion has a fixation degree of 90%.

7. PUBLIC EXPOSURE

The public is unlikely to be exposed to Lodyne 87'87 during importation and distribution to manufacturers as it will be transported in robust containers.

The public is unlikely to be exposed to Lodyne 87'87 during textile manufacturing. Residual liquor from this process is estimated to be under 5 kg per year. The notified chemical is of low volatility with negligible release to the atmosphere. Disposal of unused emulsion is by trade waste effluent removal, incineration or removal to secure landfill.

The notified chemical will be strongly bound to textiles by the thermofixation process and would not undergo hydrolysis, thereby minimising public exposure to the chemical through the handling of the treated finished goods or in clothing.

8. ENVIRONMENTAL EXPOSURE

. Release

The product will be applied in the textile industry in New South Wales, Victoria and South Australia. The processing mills are located in the city and country areas. The emulsion has a fixation degree of 90%. The notifier has not provided any evidence for the rate of fixation and data supporting this statement should be provided if imports rise to above 1 tonne per annum. The release at each site will be relatively low. Discharge at all sites will be to municipal sewage works.

. Fate

Once released, the notified chemical is expected to be associated with sludge at the sewerage treatment plants. Any of the notified chemical that enters receiving waters is likely to

become associated with the sediment compartment. Bioaccumulation of the notified polymer is unlikely since it is unlikely to cross biological membranes due to its large molecular weight and size. While the polymer contains urethane groups, these are unlikely to hydrolyse under environmental conditions. The polymer will also be unlikely to readily biodegrade under aerobic conditions as a result of its structure and low water solubility.

Disposal of textile products treated with Oleophobol C is likely to be via landfill or incineration. When landfilled, the notifed polymer is likely to remain at the site of deposition. Incineration of the polymer is unlikely to produce toxic compounds.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicity data are not required for polymers with NAMW > 1000. However, the following studies were provided and were evaluated.

9.1 Acute Toxicity

Summary of the acute toxicity of Lodyne 87'87

Test	Species	Outcome	Reference
Oral	Rat	LD_{50}: >5000 mg/kg	1
Skin irritation	Rabbit	slight irritant	2
Eye irritation	Rabbit	moderate irritant	3

9.1.1 Oral Toxicity (1)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 401 (4).

A single 5000 mg/kg dose of Lodyne 87'87 in 2% methyl cellulose was administered by gavage to five males and five females Wistar Albino rats. The animals were observed 1, 2 and 4 hours after dosing and once daily thereafter for 14 days. All animals survived the study. Gain in bodyweight was unaffected. Ptosis was seen in one female on Day 12 and one male exhibited soiling of the anogenital area on Day 14. Necropsy revealed small white nodules in the lungs of another male but results were normal for the other animals.

The results of this study indicate an acute oral LD_{50} of >5000 mg/kg for Lodyne 87'87 in rats of both sexes.

9.1.2 Skin Irritation (2)

A single dose of 0.5 g/site of Lodyne 87'87 in 2% methyl cellulose was applied by occlusive application to one intact and one abraded site of each of six New Zealand Albino rabbits which have been previously clipped free of hair. Twenty-four hours post exposure, the dressings were removed and skin reactions were assessed according to Draize (5) at 24 and 72 hours and 7 days after dosing. At the intact site, one animal exhibited very slight erythema at 24 and 72 hours post-exposure and another showed very slight oedema at 24 hours post-exposure. Similar effects were observed in these animals at the abraded site but moderate erythema was noted at 72 hours in one animal. Slight oedema was also observed in another two animals. These effects were transient and had disappeared by Day 7.

The results of this study suggest that Lodyne 87'87 is a slight skin irritant in rabbits at the concentration tested.

9.1.3 Eye Irritation (3)

This study was carried out in accordance with OECD Guidelines for Testing of Chemicals No: 405 (6).

A single dose of 0.1 g of Lodyne 87'87 was instilled into the conjunctival sac of one eye of each of six New Zealand Albino rabbits. The other untreated eye served as the control. The eyes were examined 1, 24, 48 and 72 hours post-exposure. Irritation was graded according to Draize (7). Fluorescein dye was used to evaluate corneal response after the 24 hour reading

and at 72 hours post-exposure. Corneal opacity was noted in 2/6 eyes but had cleared by Day 3. Iritis which cleared by 48 hours was also noted in 2/6 eyes. Conjunctival irritation was noted in all treated eyes but had disappeared by 72 hours. The effects ranged from slight to moderate in intensity. No abnormal physical signs were noted during the study.

The results of this study suggest that at the concentration tested, Lodyne 87'87 is a moderate eye irritant.

9.2 Overall Assessment of Toxicological Data

Animal studies show that Lodyne 87'87 has very low acute oral toxicity (oral LD_{50} in rats: >5000 mg/kg), and that it is a slight skin irritant and a moderate eye irritant.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicity data were provided. Ecotoxicity data are not required under the Industrial Chemicals (Notification and Assessment) Act, 1989 for polymers of NAMW > 1000. The notified polymer contains at least two basic nitrogen atoms, which may be protonated under environmental conditions. Some polycationic polymers have been reported to cause toxicity in fish (8). However, the expected low water solubility of the notified polymer indicates that the it would not be hazardous to fish.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

While it is expected that up to 10% of the notified substance will not be fixed to cloth, the quantity of Lodyne 87'87 that will be discharged to sewage treatment works per year is relatively low. The notified polymer is expected to be associated with sludge or sediment in receiving waters.

The concentration of the notified chemical at the treatment works would be approximately 130 ppb. Further dilution will result in a receiving water concentration of up to an order of magnitude lower. Dyeworks located in metropolitan areas will have their discharges diluted by up to two orders of magnitude higher (eg. Melbourne's Werribee treatment plant has a flow rate of 500 ML per day), resulting in a receiving water concentration in the low to sub-ppb range.

The likely fate of the notified polymer, its expected low concentration in receiving waters and its high molecular weight, indicate that it is unlikely to present a hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

No adverse health effects have been reported with the handling and use of Lodyne 87'87. High molecular weight polymers such as the notified chemical are expected to exhibit low toxicological concerns as they are unlikely to cross biological membranes to cause systemic toxicity. However, based on the results of animal studies, direct contact with the notified chemical should be avoided because of its skin and eye irritant properties. The levels of residual intermediate, Lodyne 941 B/C, and diisocyanates totalling <4.05%) and impurities present (<2.78%) are low. Although the level of low molecular weight (MW < 1000) polymer species is significant at 16.2%, the majority of these low molecular weight polymers are of molecular weight >650 and would not be expected to readily cross biological membranes.

Lodyne 87'87 in its pure form is a powder which is flammable and has the potential of causing a dust explosion. However, as the notifier will only be importing Lodyne 87'87 as part of a water based emulsion, such safety hazards do not apply.

Under normal use conditions, Lodyne 87'87 is unlikely to pose any significant acute health or safety hazard to workers and the public.

13. RECOMMENDATIONS

To minimise occupational exposure (and public/environmental if recommendations have been made by these agencies) to Lodyne 87'87, the following guidelines and precautions should be observed:

. as the chemical is a slight skin and moderate eye irritant, the following personal protection equipment should be worn when contact with the notified chemical is anticipated:

  . safety glasses (AS 1336 and AS 1337) (9,10);

- impervious gloves (AS 2161) (11);

- protective clothing (AS 3765.1, AS 3765.2) (12,13);

. good work practices should be implemented to avoid spillages or splashings and in the case of handling Lodyne 87'87 in the pure form, the formation of a dust cloud;

. good housekeeping and maintenance should be practised. Dust accumulation should be avoided and spillages should be promptly cleaned up using a vacuum cleaner for the powder and inert absorbents for Oleophobol C, for disposal according to local or State regulations;

. good personal hygiene should be observed; and

. a copy of the Material Safety Data sheet for Lodyne 87'87 or Oleophobol C as appropriate, should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

A Material Safety Data Sheet (MSDS) was not provided for the notified chemical, Lodyne 87'87. The MSDS submitted for the emulsion, Oleophobol C (Attachment 1), was provided in Worksafe Australia format (14). This MSDS was provided by Ciba-Geigy Australia 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 Ciba-Geigy Australia Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Lodyne 87'87 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. The Director of Chemicals Notification and Assessment should be informed if there are significant changes to worker or public exposure.

The notifier should note that any submission for secondary notification would need to include the following information:

- structure of low molecular weight (<1000) species,

- results, literature support or argument for water solubility and hydrolytic stability; and

- results or literature support to confirm the emulsion (Olephobol C) has a fixation degree of 90%.

16. REFERENCES

1. Single Dose Oral Toxicity in Rats/ Acute Oral LD_{50} in Rats. Data on file, CIBA-GEIGY, Switzerland. Protocol# 31-02 (1988).

2. Primary Dermal Irritation in Albino Rabbits. Data on file, CIBA-GEIGY, Switzerland. Protocol# 125-02 (1988).

3. Eye Irritation in Albino Rabbits. Data on file, CIBA-GEIGY, Switzerland. Protocol# 212-03 (1988).

4. *OECD Guidelines for Testing of Chemicals*, "Acute Oral Toxicity" No: 401, 1981.

5. Draize, J.H., et. al., *The Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics - Dermal Toxicity,* Association of Food and Drug Officials of the United States, Topeka, Kansas, 1965.

6. *OECD Guidelines for Testing of Chemicals*, "Acute Eye Irritation/Corrosion" No: 405, 1987.

7. Draize, J.H., et. al., *The Appraisal of Chemicals in Foods, Drugs, and Cosmetics - Eye Toxicity*, Association of Food and Drug Officials of the United States, Austin, Texas, 1965.

8. "EPA Proposed Revision of Expanded Criteria for Exempting Polymers from Premanufacture Notification", Chemical Regulation Reporter, 12 Feb. 1993, p2226-2247.

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

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

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

12. 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.

13. 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.

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