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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

PUBLIC REPORT

Polymer in Polytex NX-55

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director
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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1669	L'Oreal Australia Pty Ltd	Polymer in Polytex NX-55	ND*	≤ 1 tonne per annum	Component of cosmetic nail and manicure products

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

Environmental risk assessment

On the basis of its limited aquatic exposure and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced in the product Polytex NX-55:
 - Formulation should be carried out in closed systems where possible
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced in the product Polytex NX-55:
 - Avoid skin/eye contact with the product
 - Rinse off any skin/eye contamination immediately
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced in the product Polytex NX-55:
 - Protective clothing
 - Impervious gloves
 - Safety glasses
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced in finished products containing the polymer:
 - Protective clothing

- Impervious gloves

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Public Health

- The following measures should be taken by the notifier to minimise public exposure to the notified polymer:
 - Low molecular weight species in the notified polymer should be monitored and minimised.
 - Potentially hazardous impurities / residual monomers in the polymer should be monitored and minimised.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the importation volume exceeds one tonne per annum notified polymer;
 - additional information on the sensitisation potential of the polymer has become available;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of cosmetic nail and manicure products, or is likely to change significantly;
 - the amount of polymer being introduced has increased, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

(Material) Safety Data Sheet

The (M)SDS of the notified polymer and products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT

L'Oreal Australia Pty Ltd (ABN: 40 004 191 673)
564 St Kilda Road
MELBOURNE VIC 3004

NOTIFICATION CATEGORY

Limited-small volume (Reduced fee notification): Synthetic polymer with Mn < 1000 Da (1 tonne or less per year), similar to a chemical previously assessed by NICNAS.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, import volume, site of reformulation and identity of manufacturer / recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME

Polytex NX-55 (product containing the notified polymer)

OTHER NAME

Tosylamide/Epoxy Resin (INCI name)

Note: The trade name (Polytex NX-55) of the notified polymer is associated with INCI name of Tosylamide/Epoxy Resin in the Personal Care Products Council (PCPC) database. However the description and structural formula of Tosylamide/Epoxy Resin in the PCPC monograph does not match the notified polymer.

MOLECULAR WEIGHT

> 500 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 85%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Light yellow liquid (product containing the notified polymer)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	The notified polymer is imported in solution.
Boiling Point	124 - 129°C*	MSDS of the product containing > 60% notified polymer
Density	Not determined	The notified polymer is imported in solutions.
Vapour Pressure	Not determined	Expected to be relatively low, based on Mn > 500

Water Solubility	Not determined	The structure of the notified polymer suggests low solubility.
Hydrolysis as a Function of pH	Not determined	There is hydrolysable functionality present, but hydrolysis is not expected to occur in the environmental range of pH 4 - 9 due to low solubility.
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to have partition to n-octanol based on the hydrophobic nature of the structure.
Adsorption/Desorption	Not determined	Given its hydrophobic nature, the notified chemical is likely to partition to organic carbon and sludge.
Dissociation Constant	Not determined	The notified polymer contains dissociable functionality, with an expected pKa of ~ 6 - 10.
Particle Size	Not determined	The notified polymer is imported in solution.
Flash Point	26°C*	MSDS of the product containing > 60% notified polymer
Flammability	Not determined	The notified polymer is imported in a flammable solution.
Autoignition Temperature	Not determined	-
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

* Properties of the product containing > 60% notified polymer in solvent

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification

Based on the limited physico-chemical data depicted in the above table, the notified polymer cannot be recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	1	2	3	4	5
Tonnes	≤ 1	≤ 1	≤ 1	≤ 1	≤ 1

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING Finished products

Consumer products containing the notified polymer (≤ 7.5% concentration) will be shipped to Australia by sea in containers. The products will be packed in dozens inside a shipper, with multiple shippers per pallet and multiple pallets per container. Upon arrival, the containers will be transported to distribution centres. Large packs will be divided into individual orders and then delivered to major retailer warehouses. The packages of the consumer products will have sizes up to 500 mL in bottles or tubes made mainly from glass or plastic (HDPE). The consumer products will then be sold to the public.

Polytex NX-55

The notified polymer will also potentially be imported in solution at 75% concentration as a component of Polytex NX-55 packed in 226.8 kg (500 lb) steel drums (standard packaging) or 18.1 kg (40 lb) steel pails (made to order packaging).

The notified polymer will then be reformulated into consumer products in Australia for cosmetic uses (at ≤ 7.5% concentration).

USE

The notified polymer will be used as a component in the cosmetic nail and manicure products at concentrations up to 7.5%.

OPERATION DESCRIPTION**Finished products**

Consumer products containing the notified polymer ($\leq 7.5\%$ concentration) will be distributed in bottles and tubes through retail supply chains to the general public for cosmetic end use, or to beauty salons. Repackaging of the finished products is not expected.

End use of the products containing the notified polymer will occur either at home (DIY) or in beauty salons. The applicable body areas are expected to be nails. The use patterns and frequencies will be widely spread and largely depend on consumer habits.

Polytex NX-55

The product containing the notified polymer at 75% will be handled by workers during transport and storage using routine warehouse facilities and practises.

When first delivered, store persons will receive Polytex NX-55 and store it in the raw material store. As required, quantities of the notified polymer will be issued to compounders for reformulation once cleared by QA.

Chemists will take samples and test the notified polymer for QA purposes. Later samples of the finished products at bulk or packaged stages will also be taken and tested. Samples will be retained for reference purposes.

Professional compounders will measure out an appropriate amount of the notified polymer from the original containers and add the polymer directly into mixing tank. Mixing and dispensing will be carried out in a closed system designed to prevent aerosol or dust hazards.

6. HUMAN HEALTH IMPLICATIONS**6.1. Exposure Assessment****6.1.1. Occupational Exposure****CATEGORY OF WORKERS**

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and Storage Workers	4	12
Professional Compounders	8	12
Chemists	3	12
Packers (Dispensing & Capping)	8	12
Store Persons	4	12
Beauty salon workers	8	300

EXPOSURE DETAILS**Finished products**

Dockside, warehouse and retail workers will be involved in transporting, storing and transferring the finished products containing the notified polymer at up to 7.5% for distribution throughout of the retail supply chains. Dockside and warehouse workers routinely wear protective clothing and safety shoes, and are not expected to have potential for exposure to the notified polymer, except in the case of accidental breakage or spillage. Similarly, retail workers are also not expected to have potential for exposure to the notified polymer unless an accident happens.

Beauty salon workers may have potential for dermal and accidental ocular exposure to the finished products containing the notified polymer at up to 7.5% while applying the products to consumers. Use of gloves and protective clothing would reduce the exposure.

Polytex NX-55

Dockside and warehouse workers will be involved in transporting, storing and transferring Polytex NX-55 containing the notified polymer at 75%. However, dockside and warehouse workers routinely wear protective clothing and safety shoes, and are not expected to have potential for exposure to the notified polymer, except in the case of accidental breakage or spillage.

Professional compounders, chemists, packers and store persons are expected to have potential for accidental dermal and ocular exposure to the notified polymer at concentrations up to 75%. Handling of hot mixtures containing the notified polymer by the workers is possible. However, as the reformulation of Polytex NX-55 will be an isolated process in flame proof closed systems with adequate engineering controls, the exposure potential for the workers is expected to be low. Safe work practices and application of personal protective equipment (PPE) will also reduce the exposure potential. Under normal operation procedures the level of exposure to the notified polymer by the workers is not considered to be unreasonable.

6.1.2. Public Exposure

Public potential for exposure to the notified polymer during transport and storage is unlikely unless there is an accident where the packaging is breached.

Since the finished products containing the notified polymer will be distributed to nail salons as well as to the general public, widespread public exposure is expected through the end use either at home or in the specialised nail salons. Consumers are likely to come into dermal and possibly ocular contact with the notified polymer at concentrations up to 7.5%.

The finished products containing the notified polymer are expected to be applied to the nails; however, skin areas near the nails are also susceptible to exposure. There are also possibilities for direct dermal contact with the notified polymer on other parts of the body which polished nails can frequently reach, such as the lower parts of the face, eye lids, sides of neck and the upper chest. Exposure to areas of the body accessible to contact with moist nail lacquer has been considered to be linked to cases of ectopic nail polish dermatitis (CIR 1986).

The absorption of the notified polymer through the nail bed is unknown; however, is expected to be low. Under normal use patterns, the average dermal exposure to the notified polymer for each end user is estimated at 0.027 mg/kg bw/day. This is based on the assumption that all applied polymer is absorbed through the skin adjacent to the nail bed (RIVM 2006):

Dermal exposure to the finished product	50 mg/application
Maximum concentration of the notified polymer	7.5%
Frequency of use	156 times/year (3 times/week)
Dermal exposure to the notified polymer	585 mg/year ($50 \times 156 \times 0.075 = 585$)
Equivalent to	0.027 mg/kg bw/day ($585 \div 60 \div 365 = 0.027$)

Exposure is not expected to be significant once the nail products have dried; however, it cannot be ruled out, as it was shown that low molecular weight species of the polymer may be readily extracted from various dried nail polish matrices (Hausen 1995).

Since the nail polish will be stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	Slightly irritating

Toxicokinetics, metabolism and distribution

No information on the toxicokinetic characteristics of the notified polymer was provided. The notified polymer has a molecular weight of > 500 Da, which is expected to limit dermal absorption. However the level of low

molecular weight species (< 500 Da) is significant at up to 15% and overall > 50% of the polymer is less than 1,000 Da.

Acute toxicity

The acute oral toxicity of the notified polymer in rats was low. Acute toxicity data via other routes are not available.

Irritation

Skin irritation potential of the notified polymer in rabbits was moderate, but not sufficient for classification. Skin sites treated with the notified polymer showed slight erythema (3/3 animals) and oedema (1/3 animals) lasting over 72 hours. The erythema resolved in 7 days and the oedema resolved in 10 days. Desquamation was present in 1 rabbit by Day 10.

Information on the eye irritation potential of the notified polymer was not provided.

Sensitisation

No data was available on the sensitisation potential of the notified polymer.

Analogue polymer

A Cosmetic Ingredient Review (CIR) report is available on an analogous polymer Tosylamide Formaldehyde resin (CIR 1986) used in nail lacquers, which shares similar overall structure and one monomer with the notified polymer. In Human Repeat Insult Patch Tests, the majority of subjects did not show any positive skin reactions. However, a few subjects developed faint, barely perceivable to mild erythema. Overall, the sensitising potential of the analogous polymer was assessed not to be significant. However, the CIR report cites a number of case reports in which patients with contact dermatitis at body parts distant but accessible to the nails were also shown to be positive when tested for hypersensitivity to the analogous polymer and/or its components, such as formaldehyde.

In addition to the case reports cited in the CIR report, there are a number of case reports of contact dermatitis at body parts accessible to the nails, for subjects that have used nail products containing the analogous polymer. In a number of the studies it has also been reported that the subjects with contact dermatitis in these studies were also hypersensitive to the analogous polymer resin (de Wit et al. 1988, Giorgini et al. 1994, Liden et al. 1993). Some of the subjects were also tested for hypersensitivity to formaldehyde and was shown to be negative (Giorgini et al. 1994, Liden et al. 1993).

Thus, it is not clear which component of the analogous polymer may be linked to these dermatitis reactions.

A study examining sensitising potential of components extracted from commonly used nail polishes containing the analogous polymer in 10 patients with known nail polish allergies, found that they were all sensitive to the Toluenesulfonamide containing low molecular weight species, while only 1/10 was sensitive to formaldehyde and only one was sensitive to o-toluenesulfonamide (Hausen 1995).

In 2005 NICNAS assessed the sensitising potential of the analogue polymer and concluded that the available data do not meet the Approved Criteria for Classifying Hazardous Substances in the workplace [NOHSC:1008(2004)] for the analogue polymer to be classified as a hazardous substance with respect to Sensitisation by Skin Contact (NICNAS 2005). In summary, there are studies indicating that the analogue polymer may have sensitisation potential in certain individuals, but not sufficient for classification as a hazardous substance. It is noted that nail polish allergies often manifest in other parts of the body, thus making their cause more difficult to establish.

Comparison of analogue and notified polymer

The notified and the analogue polymers contain toluenesulfonamide moieties linked through epoxy generated ether groups (in the case of the notified polymer) or through formaldehyde generated alkyl groups (in the analogous polymer). Therefore, the two classes of polymers are considered to have some structural similarity. However, they have some structural differences, and the residual monomers differ as formaldehyde is used as a crosslinking/polymerising agent in the analogue polymer, while in the notified polymer the formaldehyde is substituted with epoxy moieties.

The tosylamide moiety is present in both the analogue and notified polymer. Free toluene sulphonamide at up to 15% is also present in the notified polymer and is expected to be present in the analogue polymer. It is not

classified as a skin sensitiser but is considered to be a potential sensitiser. The Danish Technological Institute (DTI 2004) has recommended that companies apply a self-classification of R43. Hausen et al. (1995) suggested that free toluene sulphonamide was a sensitiser but was less potent than toluene sulphonamide containing low molecular weight oligomers eluted from the polymer.

The formaldehyde moiety is present in the analogue polymer but not the notified polymer. Free formaldehyde, known to be a sensitiser, may also be present in the analogue polymer. However in several studies it was found that patients sensitised to the analogue polymer were not sensitised by formaldehyde (NICNAS 2005).

The epoxy moiety is present in the notified polymer but not the analogue. The epoxy group itself is a structural alert for sensitisation, however the level of free epoxy group in the residual monomer is stated to be very low.

Previously assessed polymer

Additional data available to NICNAS using a skin sensitisation (LLNA) study concluded that the previously assessed polymer was not considered a dermal sensitiser at up to 50% (maximum concentration tested). The study reported a stimulation index of 1.8, 2.4 and 2.9 at 10%, 25% and 50% respectively. It is not known as to whether testing at higher concentrations may report a stimulation index above 3 (indicating a positive response). It was stated that the test was not run at concentrations higher than 50% because the notified polymer was not sufficiently soluble in the carrier solvent above that level.

Overall the information available on the analogue polymer and previously assessed polymer is not sufficient to classify the notified polymer as a skin sensitiser; however, the sensitisation potential cannot be determined. The result of the LLNA study on the previously assessed polymer suggests that the notified polymer would not be a skin sensitiser; however, skin sensitising potential cannot be ruled out for certain sensitive individuals.

Repeated dose toxicity

CIR (1986) reported that there were no significant treatment-related effects of the analogue polymer up to 10,000 ppm in a subchronic oral study in dogs.

Other toxicological properties

No other data was available for the notified polymer. The above analogue polymer was considered to be non-mutagenic in several bacterial tests (CIR 1986).

Impurities

The notified polymer contains a significant percentage (up to 10%) of related impurities which are expected to be skin and eye irritants and may be sensitising, and show adverse effects in rats after repeated oral exposure. In one study a lowest observed adverse effect level (LOAEL) of 20 mg/kg bw/day for systemic toxicity and a no observed adverse effect level (NOAEL) of 100 mg/kg bw/day for reproductive toxicity were reported. Acute oral toxicity is low (US EPA 2012).

Health hazard classification

Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Limited information is available on the hazard of the notified polymer. It has some potential for skin irritation, but is not classified for this endpoint. The risk of skin sensitisation cannot be ruled out. The polymer also contains related impurities (up to 10% concentration) which may be sensitising, and may cause adverse effects after repeated exposure.

Transport, storage and retail workers are not expected to have any contact with the notified polymer in finished products or in Polytex NX-55, except in the case of an accident. During clean-up of an accidental spill, use of PPE by workers would minimise exposure.

Workers may have contact with Polytex NX-55 during formulation of end-use products. However exposure is expected to be minimised by use of closed systems and PPE. Controls in place to minimise exposure to other volatile ingredients of Polytex NX-55 would also reduce exposure to the notified polymer.

There is a potential for skin sensitisation for workers in nail salons, who may have accidental dermal exposure to the notified polymer at < 7.5%. Exposure and risk would be minimised by the use of protective gloves.

When used in the proposed manner, the risk of the notified polymer to the health of the workers is not expected to be unreasonable.

6.3.2. Public Health

The notified polymer has some potential for skin irritation, but is not classified for this endpoint. The risk of skin sensitisation cannot be ruled out. The polymer also contains related impurities which may be sensitising and cause adverse effects after repeated exposure.

The public is likely to be exposed to the notified polymer and its impurities through the use of nail polish products containing the notified polymer at up to 7.5% and impurities at up to 0.75%. The main route of exposure will be dermal and it is likely to be initially limited to the nails and small areas surrounding them. However, subsequent contact of the nails with other skin sites may lead to wider skin contact with the notified polymer from the undried and/or low molecular weight components leached from the dried nail polish matrix. Considering that the notified polymer is applied in low concentrations (< 7.5%), the risk of skin irritation around the fingernails is not expected to be unreasonable.

Accidental oral exposure is possible for children, however due to the low acute toxicity of the notified polymer and impurities this risk is not considered to be unreasonable.

Based on the very low estimated dermal exposure (0.027 mg/kg bw/day) during consumer use of nail products, the risk of repeated dose toxicity caused by the notified polymer or its impurities is not considered unreasonable.

Overall, the use of the notified polymer is not considered to pose unreasonable risk to the public; however, the risk of skin sensitisation cannot be ruled out, particularly for sensitive individuals.

Quality control measures to monitor and minimise the level of low molecular weight species in the polymer and the level of impurities, residual monomers and free epoxy groups would also assist to reduce risk.

In addition, the risk of sensitisation from residual epoxy components of the notified polymer would be minimised by measures that remove any free epoxy groups that could be present at the polymer ends and/or within residual monomer. Formulation of the polymer with solvents that will react with epoxy groups (e.g. ethanol, isopropanol) would eliminate any residual reactive epoxy groups.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured in Australia. The notified polymer will be imported as a 7.5% component of a finished cosmetic nail polish and manicure products in < 15 mL retail bottles. However, there is a potential for the notified polymer to be imported (at a concentration of 75%) for reformulation in Australia.

In the unlikely event of spillage occurring during transport or storage in the warehouse, the product will be adsorbed with sand or other absorbent material and disposed of in accordance with Federal, State and local regulations. In the case of a large spillage during the reformulation process, the manufacturing site is expected to be bounded so the spilled material can be directed to waste water pits on site.

RELEASE OF CHEMICAL FROM USE

The notified polymer, after application of the nail polish to finger nails, will be contained within an inert matrix once the solvent has evaporated. The majority of the nail polish containing the notified polymer will be removed

with nail polish remover and absorbed to tissues or cotton buds, which will eventually be released via household garbage to landfill.

Based on the maximum import volume of 1000 kg of the notified polymer, an average daily release of 2.7 kg is expected, and this is expected to be relatively diffuse. A small amount of this release may enter the sewer as it flakes away from the nail during washing. Any notified polymer released to the sewer is expected to partition to sludge.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer is expected to be disposed to landfill after normal use. Spillages will be absorbed with sand or other absorbent materials, which will then be disposed to landfill. If the product is incinerated, oxides of carbon, sulphur and nitrogen are the expected combustion products.

7.1.2. Environmental Fate

No environmental fate data were submitted. Based on the high molecular weight and hydrophobic nature of the chemical structure, and its containment within an organic solvent, the notified polymer is expected to be stable and immobile and adsorb to organic carbon in a terrestrial environment, and partition to sludge in the aquatic environment. Polymers are generally expected to be persistent in the environment; therefore the notified polymer would not be expected to be readily biodegradable. Although a high K_{ow} value is expected, the high molecular weight indicates low bioaccumulation potential for the notified polymer entering the aquatic environment.

7.1.3. Predicted Environmental Concentration (PEC)

Since only limited amount of the notified polymer will reach water, a PEC cannot be calculated.

7.2. Environmental Effects Assessment

Polymers without significant ionic functionality are generally considered to be of low concern to the aquatic environment.

7.2.1. Predicted No-Effect Concentration

Given the absence of ecotoxicity data, it is not possible to determine a Predicted No-effect Concentration.

7.3. Environmental Risk Assessment

The majority of the notified polymer will be absorbed to tissues or cotton buds after removal from nails, and will enter landfill, where it is expected to adsorb to soil and persist in an immobile manner. Small amounts of the notified polymer may enter the sewer through flaking from nails during washing, however, it would be entrapped in inert matrix and is expected to partition to sludge in this form. The notified polymer is not expected to pose an unreasonable risk to the environment at the levels of use proposed.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	Similar to OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Sprague-Dawley derived, albino
Vehicle	Corn oil
Remarks - Method	Test substance was ground and mixed with corn oil as a 23% (w/w) suspension before administration.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose (mg/kg bw)</i>	<i>Mortality</i>
1	5 M/5 F	2,000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
Remarks - Results	Twenty-four hours following the administration, several test animals exhibited oily stains at the bases of the tails.

CONCLUSION	The notified polymer is of low toxicity via the oral route.
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TEST FACILITY	PSL (2002a)
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B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand albino
Number of Animals	3
Vehicle	Mineral oil
Observation Period	10 days
Type of Dressing	Semi-occlusive.
Remarks - Method	Test substance was ground and mixed with mineral oil as a 60% (w/w) dry paste before administration.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	2	2	2	2	< 10 d	0
<i>Oedema</i>	2	0	0	2	< 7 d	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	Calculated primary dermal irritation index for the test substance was 2.7. Skin sites treated with the notified polymer showed slight erythema (3/3 animals) and oedema (1/3 animals) lasting over 72 hours. The erythema resolved within 7 days and the oedema resolved within 10 days. Desquamation was present in 1 rabbit by Day 10.
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CONCLUSION	The notified polymer is slightly irritating to the skin.
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TEST FACILITY	PSL (2002b)
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