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

FULL PUBLIC REPORT

Tosylamide / Epoxy Resin

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 Ageing, 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, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full 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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FULL PUBLIC REPORT

Tosylamide / Epoxy Resin

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Coty Australia Pty Ltd (ABN 96 058 696 549)
Level 31, 1 Market Street
Sydney NSW 2000

NOTIFICATION CATEGORY

Limited-small volume: Synthetic polymer with Mn < 1000 Da (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS number, spectra, polymer details, concentration in final products.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Melting point, vapour pressure, water solubility, hydrolysis as a function of pH, dissociation constant, particle size, flash point, auto-ignition temperature, explosive properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Previously used in Australia under a low volume exemption.

NOTIFICATION IN OTHER COUNTRIES

None known

2. IDENTITY OF CHEMICAL

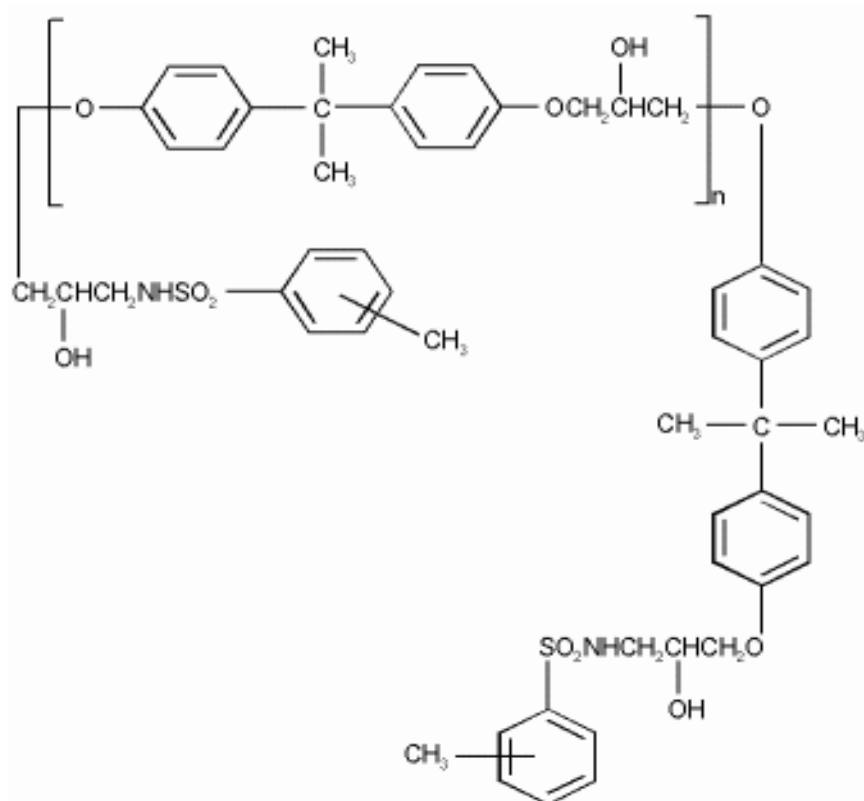
MARKETING NAME(S)

Polytex E-75, Polytex E-100

OTHER NAME(S)

Tosylamide / Epoxy Resin (INCI name)
Toluenesulfonamide / Epoxy Resin

STRUCTURAL FORMULA



where n may have a value ranging from 0 to about 5.

MOLECULAR WEIGHT

<1000 Da. The notified chemical is a low molecular weight polymer.

ANALYTICAL DATA

Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Expected to be low.

DEGRADATION PRODUCTS

Thermal degradation products are carbon dioxide, carbon monoxide, oxides of nitrogen, hydrocarbons and water.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE : White to pale yellow viscous liquid (solution containing notified polymer)

No data was provided on the physicochemical properties of the notified polymer

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Supplied in solvent solution
Density	Not determined	Supplied in solvent solution
Vapour Pressure	Not determined	Estimated to be low based on molecular weight
Water Solubility	Not determined	The structure of the notified chemical suggests low solubility.
Hydrolysis as a Function of pH	Not determined	There is one hydrolysable functionality present, but this 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 a high K_{ow} , based on the hydrophobic nature of the structure.
Adsorption/Desorption	Not determined	Not tested. Given its hydrophobic nature, the notified chemical is likely to partition to organic carbon and sludge.
Dissociation Constant	Not determined	The notified chemical contains dissociable functionality, with an expected pKa of ~6-9.
Particle Size	Not determined	Supplied in solvent solution
Flash Point	Not determined	Supplied in solvent solution which is flammable
Autoignition Temperature	Not determined	Supplied in solvent solution which is flammable
Explosive Properties	Not determined	Not expected to be explosive, based on its structure

DISCUSSION OF PROPERTIES

Reactivity

The polymer is not expected to react or crosslink further in end-use, during drying of the nail polish film.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as part (< 5%) of a nail polish formulation, packed ready for consumer sale.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	1	1	1	1	1

PORT OF ENTRY

Sydney (wharf).

IDENTITY OF MANUFACTURER/RECIPIENTS

The nail polish products containing the notified polymer at concentration <5% will be transported in a container from the wharf, to the Coty Australia Pty Ltd's central warehouse at UTI (Aust) Pty Ltd, 33, McCauley Street, Alexandria NSW 2015. From there they will be sent by road to retail distribution centres and to major department stores.

TRANSPORTATION AND PACKAGING

The Nail Polish containing the notified polymer will be imported in 12 mL bottles suitable for retail sale. These bottles will be parked in blister cards and these blister cards will be packed 12 cards to a cardboard shipper.

Transport within Australia will be by road. From the notifier's warehouse the consumer products will be distributed to retail outlets, usually through distribution centres.

USE

The notified polymer is a film former and plasticiser in nail polish cosmetics.

OPERATION DESCRIPTION

The notified chemical will be imported in finished products and distributed for retail sale.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and Storage	10	4	12

Retail workers	> 1000	0.1	300
Nail beauticians	> 1000	2	300

EXPOSURE DETAILS

Approximately 10 dockside and warehouse workers will be involved in transporting the finished product Nail Polish from the wharf to the Coty central distribution centre and placing the pallets of product into the warehouse. Dockside and warehouse workers may handle monthly shipments for 4 hours per day.

A further two workers in the notifier's warehouse will be involved in transferring pallets from the Coty central warehouse at the retailer's central distribution depots. Dockside and warehouse workers routinely wear uniforms and safety shoes. They are not expected to have any contact with the notified polymer, except in the case of accidental breakage or spillage.

Similarly retail workers would not be expected to have any exposure to the product containing the notified polymer, except in the case of accidental breakage or spillage of the consumer packages.

Workers in Nail Salons may have accidental dermal exposure to the nail polish containing the notified polymer while applying the products containing the notified chemical to consumers.

6.1.2. Public exposure

Public exposure to the notified polymer during transport and storage is unlikely unless there is an accident during transportation of the products containing it. The material safety data sheets (MSDS) supplied for the product or the raw material have adequate instructions for clean-up and disposal of any accidental spills and therefore public exposure as a result of a transport accident is likely to be negligible.

Since the finished nail polish products containing the notified polymer will be sold to the general public, widespread public exposure is expected through their use. As a result of use of the products, consumers are likely to make dermal and possibly ocular contact with the notified polymer at concentrations of up to 5%.

Although the nail polish containing the notified polymer would be applied only to the nail, and accidentally to the skin near the nail, there is also a possibility for dermal exposure to the notified polymer at remote parts of the body such as the lower parts of the face, eye lids, sides of neck and the upper chest that are frequently in contact with the nails. In fact, exposure to areas of the body accessible to contact with moist nail lacquer has been considered to be linked to the cases of ectopic nail polish dermatitis (CIR, 1986).

Exposure is not expected to be significant once the nail products have dried. However it cannot be excluded, as it has been shown that low molecular weight species of the polymer can 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 chemical are summarised in the table below. Details of these studies can be found in Appendix A.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	oral LD50 > 5000 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, although >50% is less than 1000 Da. The notified polymer also contains low molecular weight species (<500 Da) that are estimated to have high log Kow which is favourable to absorption. However the level of these low molecular weight species in the notified polymer is relatively low (less than 10%)

Acute toxicity

The acute toxicity of the notified polymer was tested and is demonstrated to be low.

Irritation

Skin irritation potential of the notified polymer was tested in rabbits and was demonstrated to be very low. Only one animal showed very slight erythema 4 hours after treatment, which was entirely reversible by 24 hours, post treatment.

Skin sensitisation

The notifier submitted a Cosmetic Ingredient Review (CIR) report on an analogous polymer Tosylamide Formaldehyde resin (CIR, 1986) used in nail lacquers, that shares similar overall structure and one monomer in common with the notified polymer.

In addition the notifier has tested products containing the notified polymer at concentrations of up to 4% by providing it to consumers for test use during 1-4 weeks and noting any adverse effects in a designated data base. The worldwide complaints history during a three year period indicate 0, 0.03 and 0.15 complaints per million units tested in 2005, 2006 and 2007, respectively. The complaints have not been linked to any specific components of the products tested.

Information on sensitisation potential of analogous polymer

The CIR report concluded that the analogue polymer was safe for use in nail products up to 10%. It summarises five studies employing between 50 and 200 subjects in which nail care products containing various concentrations of the analogous polymer (up to 15%) were tested in different 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 polymers 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 analogous 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 analogous polymer to be classified as a hazardous substance with respect to Sensitisation by Skin Contact (NICNAS, 2005). The assessment of the human data was considered to most likely represent isolated incidents of skin sensitisation considering the widespread use of products containing the analogous polymer. This was supported by a survey of skin sensitising potential tests for 134 chemicals that included the analogous polymer TSFR (Basketter et al., 1999). The survey reports that in one standard local lymph node assay (LLNA) and one standard guinea pig maximisation test (GPMT) the analogous polymer (unspecified concentrations) did not induce positive skin sensitising reactions (Basketter et al., 1999).

Overall 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 polymer both 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 2% 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 (< 0.02%), and the epoxy content of the polymer to be low (epoxy equivalent weight > 4000).

Additional data

Additional data available to NICNAS using a skin sensitisation (LLNA) study concluded that the notified 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.

Taken together, this information is not sufficient to classify the notified polymer as a skin sensitiser, however skin sensitising potential of the notified chemical cannot be entirely excluded for certain individuals.

Other toxicological endpoints

No other data with regard to the repeat dose toxicity or mutagenicity was available for the notified polymer. The repeat dose toxicity of the analogous polymer is assessed to be low (CIR, 1986). The analogous polymer was considered to be non mutagenic in several bacterial tests (CIR, 1986).

Based on the available data, the notified polymer is not classified as a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) for skin sensitisation, acute oral and skin irritation.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The notified polymer will not be manufactured, processed or reformulated in Australia. It will only be imported into Australia as part of a fully formulated, finished, packaged product (consumer-ready bottles).

Workers are not expected to have any contact with the notified polymer, except in the case of an accident. The nature of the packaging used for transport minimises the likelihood of release or loss of the chemical in incidents. However, during cleanup of an accidental spill workers should wear protective eyewear, and impermeable gloves.

Overall, the risk to transport, storage and retail workers from handling the products containing the notified polymer is expected to be negligible.

There is a low risk for skin sensitisation for workers in Nail Salons, who may have accidental dermal exposure to the notified polymer that would be minimised by the use of protective gloves.

6.3.2. Public health

The public is likely to be exposed to the notified polymer through the use of nail polish products containing the notified polymer at <5%. The main route of exposure will be dermal and it is likely to be initially limited to small areas around the nails. 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 only slightly irritating to the skin, the risk of skin irritation around the fingernails is expected to be low.

Acute oral toxicity of the notified chemical is low and no significant systemic exposure is expected due to the relatively high molecular weight of the notified polymer and because the products containing it would be applied to the keratin of the nail plate where absorption is considered to be nil or minimal. Thus, the risk of acute toxicity for the use of the products containing the notified polymer is low. Accidental oral exposure is possible for children, however due to the low acute toxicity of the notified polymer this risk is considered to be low.

The available data indicate that the notified polymer was not sensitising at up to 50%. However, there are a number of case reports on contact dermatitis in the human population related to use of nail care products containing the analogous polymer. The risk for the general population would be minimized by limited area of exposure due to the application to the nail plate. However it is noted that some dermal exposure to other parts of the body may also occur.

Overall, the use of the notified polymer is not considered to pose any unreasonable risk to the public, however the risk of skin sensitisation cannot be excluded for some especially sensitive subgroups including children.

Quality control measures to monitor the level of low molecular weight species in the polymer and the level of 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 or reformulated in Australia, but will be imported as a 5% component of a finished cosmetic nail polish in 12 mL retail bottles. Therefore, there is no risk associated with these processes.

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, the warehouse is bunded 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 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.

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

Non-ionic synthetic polymers of NAMW>1000 are considered to be of low concern to the aquatic compartment.

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 notified polymer is insoluble in water, as inferred from its structure, and the fact that it is a component in a solvent based mixture. Polymers are generally expected to be persistent in the environment; therefore the notified polymer would not be expected to be readily biodegradable.

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, the majority would be expected to partition to sludge.

Although a high K_{OW} value is expected, the high molecular weight indicates low bioaccumulation potential for the notified polymer entering the aquatic environment. Overall, the notified polymer does not appear to be a risk to the environment at the levels of use proposed.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data, the notified polymer is not classified as a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) for skin sensitisation, acute oral and skin irritation.

Human health risk assessment

Under the conditions of the occupational settings described and based on the available data the notified chemical is not expected to pose unreasonable risk.

When used in the proposed manner the notified polymer is not expected to pose an unreasonable risk to the public. However the risk of skin sensitisation cannot be excluded for some especially sensitive subgroups and children.

The current ACCC (Australian Competition and Consumer Commission) requirement for ingredient labelling on consumer cosmetic products would assist in identifying any allergies resulting from use of the notified polymer. A copy this full public report will be made available to the dermatologists with interest in contact dermatitis for their information.

Environmental risk assessment

The notified chemical is not considered to pose a risk to the environment based on its reported use pattern.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A copy of the MSDS should be easily accessible to employees

Public Health

- The following measures should be taken by suppliers:
 - Levels of low molecular weight species in the notified polymer should be monitored and minimised.
 - Levels of potentially hazardous impurities / residual monomers in the polymer should be monitored and minimised.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment with sand or other absorbent material.

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 chemical 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 chemical; or
 - formulation of products is carried out in Australia; or
 - if the supplier and/or a person becomes aware of user health complaints related to the products containing the notified chemicalor
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from **component of nail polish products at <5%**, or is likely to change significantly;
 - **if the chemical has begun to be manufactured in Australia;**
 - additional information has become available to the person in relation to the health effects of the notified polymer;
 - additional information has become available to the person as to an adverse effect of the chemical 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 MSDS of the notified chemical [and products containing the notified chemical](#) provided by the notifier [were](#) reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	EPA guidelines
Species/Strain	Rat/Crl : CD®BR
Vehicle	Corn Oil
Remarks - Method	Ten young adult animals, 5/sex were used and treated with one dose of the test material. They were dosed after 7 days of acclimatization period. Clinical symptoms were observed 1, 2.5 and 5 hours following administration and twice daily for the following 14days. Body weight was recorded at the time of dosing, and on day 7 and 14 of the study. All animals were sacrificed on day 14 and the organs were examined macroscopically.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5 male	5000	0
2	5 female	5000	0

LD50	> 5000 mg/kg bw
Signs of Toxicity	No significant signs of toxicity. Two animals had soft stool 4 hours after dosing.
Effects in Organs	No visible lesions were observed at necropsy.

CONCLUSION The notified chemical is of low toxicity via the oral route.

TEST FACILITY Hazelton (1993a)

B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	EPA guidelines. Based on the Draize method.
Species/Strain	Rabbit/Hre: (NZW) SPF
Number of Animals	3/sex
Vehicle	Saline
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	0.5 g of the test material was moistened with 0.9% saline solution and applied to area of approximately 6.25 cm ² . Area was occluded with gauze for 4 hours. After removal of the occlusion the treatment site was washed with warm water. The degree of erythema and oedema using Draize scale were evaluated after 30 min after gauze removal (4 hour test time) and 24, 48h, 72h and seven days post treatment.

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>
<i>Erythema/Eschar</i>	0	1	4h	0
<i>Oedema</i>	0	0	n/a	0

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

CONCLUSION

The notified chemical is slightly irritating to the skin.

TEST FACILITY

Hazelton (1993b)

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