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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Siloxanes and silicones, di-Me, 3-hydroxypropyl Me, ethoxylated propoxylated, polymers with tert-Bu acrylate and methacrylic acid (Luviflex Silk)

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 and Heritage.

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Henkel Australia Pty Ltd
20 Rodborough Rd
Frenchs Forest NSW 286

BASF Australia Ltd
500 Princes Highway
Noble Park VIC 3174

NOTIFICATION CATEGORY
Synthetic Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Siloxanes and silicones, di-Me, 3-hydroxypropyl Me, ethoxylated propoxylated, polymers with tert-Bu acrylate and methacrylic acid

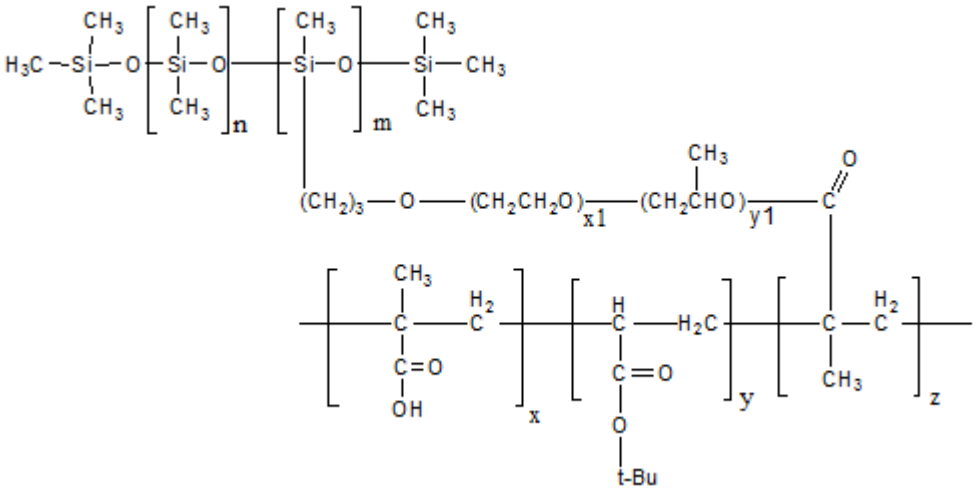
OTHER NAME(S)
PEG/PPG-25/25 Dimethicone / Acrylates copolymer

MARKETING NAME(S)
Luviflex Silk
Osis Elastic Flexible Hold Hair Spray

CAS NUMBER
248935-80-0

MOLECULAR FORMULA
$[(C_2H_6OSi)n\ (C_4H_9O_2Si)m\ (C_2H_4O)x_1\ (C_3H_6O)y_1\ (C_4H_6O_2)]y\ (C_7H_{12}O_2)x$

STRUCTURAL FORMULA



MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)	8480
Weight Average Molecular Weight (Mw)	222 000
Polydispersity Index (Mw/Mn)	26.1
% of Low MW Species < 1000	2.66 %
% of Low MW Species < 500	1.58 %

3. COMPOSITION

POLYMER CONSTITUENTS

Chemical Name	*CAS No.*	*Weight % starting*	*Weight % residual*
Tertiary butyl acrylate	1663-39-4	67	≤ 0.008
Methacrylic acid	79-41-4	22.3	≤ 0.002
Siloxanes and silicones, di-Me, 3-hydroxypropyl Me, ethoxylated propoxylated	71965-38-3	10.7	0.000

PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met (yes/no/not applicable)*
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
No Substantial Degradability	Yes
Not Water Absorbing	Yes
Low Concentrations of Residual Monomers	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0.4	0.4	0.4	0.4	0.4

USE
The notified polymer will be a component of a hair spray.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The notified polymer is not manufactured or reformulated in Australia. It will be imported as a component of a formulated hair spray, Osis Elastic Flexible Hold Hair Spray, containing 25 % notified polymer. It will be imported by sea in 225g aerosol hairspray cans ready for retail and consumer use. The aerosol cans will be packed into fibreboard cartons, with about 12 cans in each carton.

The hair products containing the notified polymer will be used in professional hair salons and in the home, by aerosol application.

6. EXPOSURE INFORMATION

6.1. Summary of Environmental Exposure

The end product containing the notified polymer will be widely distributed and used throughout Australia. It is assumed that 1-2% residue will occur in emptied containers, which will be disposed of via domestic waste to land fill and recycling processes.

The majority of the notified polymer contained in the hair spray will be deposited on hair, clothing or immediate surroundings. It will end up in the water compartment as a result of washing, laundering and cleaning. Wastewater will enter the domestic sewage system and ultimately the aquatic environment.

In the unionised form the notified polymer is not soluble in water and as such is unlikely to be mobile in the aquatic and terrestrial compartments of the environment. However, for most of the environmental pH range it will be in the much more soluble ionic form and where a significant portion may remain in the aqueous phase. Nevertheless there will be some sorption to soils and sediment due to the anionic charge. The notified polymer contains ester functionality, however, it is not expected to hydrolyse at environmental pH, but will degrade slowly through abiotic and biotic processes.

6.2. Summary of Occupational Exposure

Exposure to the notified polymer is not expected during import and storage of the hair product. Imported pressure-pack containers are not opened, and exposure could only be envisaged if the packaging is accidentally broken. Likewise, the containers will not be opened at warehouses and distribution centres. The highest level of worker exposure is expected to occur at hair salons. Hairdressers will be subject to dermal and inhalational exposure to the hair products containing the polymer during normal use. Retail workers will handle the products in their retail packaging, and exposure can only be expected if the containers are accidentally breached.

6.3. Summary of Public Exposure

The hair product containing the notified polymer is for sale to the general public. Members of the public will make dermal, inhalational and possibly accidental ocular contact with products containing the notified polymer, when applied to hair at home. However, exposure will be low because the notified polymer is present at low concentrations (3.25%). The only other possibility of public exposure is in the unlikely event of a road accident during transportation.

7. PHYSICAL AND CHEMICAL PROPERTIES

The physical and chemical properties reported below are for the notified polymer in a 50% ethanol solution, unless otherwise stated.

Appearance at 20ºC and 101.3 kPa	Colourless to faint yellow, clear to slightly opalescent.
Glass Transition Temp	55ºC (notified polymer)

Density	960 kg/m^3 at 20^{o}C
Water Solubility	< 0.1% solubility in water as the unneutralised form based on a simple visual test. However, this is only present at low pH and as used the notified polymer will be in the ionic form where, it will be much more soluble due to the presence of the carboxylate anion and polyoxyethylene glycol chains.
Reactivity	Stable under normal conditions.
Degradation Products	None if stored and handled correctly. Oxides of carbon may form upon incineration.

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

Summary information on a number of toxicity studies conducted on the notified polymer in 50% ethanol was submitted. The toxicological end-points from these studies are provided below:

Endpoint	*Result*	*Classified?*	*Effects Observed?*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity	no	no
Rabbit, skin irritation	slightly irritating	no	yes
Rabbit, eye irritation	Slightly irritating	no	yes
Guinea pig, skin sensitisation - non-adjuvant test.	no evidence of sensitisation	no	no
Rat, inhalation repeat dose toxicity - 5 days.	No Observed Adverse Effect Concentration (NOAEC) 3-10 mg/m^3	no	no
Genotoxicity - bacterial reverse mutation	non mutagenic	no	no

8.1.1. Discussion of observed effects

The notified polymer has low oral toxicity. It is slightly irritating to the eyes as shown by transient conjunctival effects. In a skin irritation study, the notified chemical showed irritant effects as evidenced by well-defined erythema, which persisted up to 5 days in all animals and up to 11 days in one animal. The irritation effects observed would trigger a skin irritant classification for the notified polymer. However, the observed irritation effects were reported to be likely due to the adhesive effects of the notified polymer in ethanol causing mechanical injury to the skin. This phenomenon is apparently seen in polymers with adhesive properties where the superficial layer of the epidermis can be pulled out on removal of the dressing. This claim was also supported by a study which was conducted on a similar polymer (refer to NA/557), and was previously assessed by NICNAS, where no skin irritation was seen when an alternative vehicle was used which did not lead to any adhesive effects.

There was no evidence of skin sensitisation potential and the bacterial mutation study gave a negative result. The NOAEC is 3 to 10 mg/m^3 for 5 consecutive days. No adverse effects were reported during the study.

Overall, the observed effects from the above studies were indicative of low hazard.

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. The submitted toxicity data support the conclusion of low hazard.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No ecotoxicological data were submitted for the notified polymer. The following ecotoxicity end points were obtained from the MSDS:

The toxicity of the notified polymer towards zebra fish was measured according to OECD 203 with a reported LC50 (96 h) of > 100 mg/L. No test report was provided.

The toxicity of the notified polymer towards *Daphnia magna* was measured according to OECD 202 with a reported EC50 (48 h) of > 100 mg/L. No test report was provided.

The toxicity of the notified polymer towards algae was measured according to OECD 201 with a reported EC50 (72 h) of > 100 mg/L. No test report was provided.

The toxicity of the notified polymer towards bacteria (present as activated sludge) was measured according to OECD 209 with a reported EC20 (3 h) of > 1000 mg/L. No test report was provided.

9.2. Environmental Hazard Assessment

No test reports were provided for the notified polymer. Based on the above results, the notified polymer is practically non-toxic to fish, daphnia, algae and bacteria

10. RISK ASSESSMENT

10.1. Environment

The notified polymer will be used in hair care products and, as such, there will be eventual release of almost the entire import volume to the aquatic environment from use. Based on annual imported volume of 400 kg, and assuming the majority of this is eventually released to sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 1.1 kg/day. The predicted concentrations in sewage effluent on a nationwide basis are estimated to be:

Amount entering sewer annually (V)	400 kg
Population of Australia (P)	20 million
Amount of water used per person per day (W)	200 L
Number of days in a year (D)	365
Estimated $PEC_{aquatic}$ (Ocean)	0.027 μg/L
Estimated $PEC_{aquatic}$ (River) (V/[P x W x D])	0.27 μg/L

No test reports for aquatic toxicity were supplied. Using a safety factor of 1000 to account for the lack of toxicity data, the predicted no effect concentration (PNEC) for the notified polymer for the protection of aquatic ecosystems is (100 mg/L/1000) = 100 μg/L. The worst-case PEC/PNEC ratios for the aquatic environment if the notified polymer is used nation wide when released to ocean and inland rivers are 0.0003 and 0.003, respectively. These values are significantly less than 1, indicating small concern to the aquatic compartment. During wastewater treatment procedures, some attenuation of the notified polymer is expected.

The notified polymer is not likely to present a hazard to the environment when it is transported and used in the proposed manner.

10.2. Occupational Health and Safety

The OHS risk presented by the notified polymer is expected to be low. The notified polymer may be present in formulations containing hazardous ingredients. If these formulations are classified as hazardous to health in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

The level of atmospheric nuisance dust should be maintained as low as possible, particularly during use in hair salons. The NOHSC exposure standard for atmospheric dust is 10 mg/m^3.

10.3. Public Health

The end products containing 3.25% of the notified polymer will be used by the general public applying the products themselves, and also by hairdressers. The notified polymer has a MW > 1000, and thus is unlikely to cross biological membranes. Despite the potential of widespread use, the risk to public health is considered low due to the non-hazardous nature of the notified polymer. The notified chemical may cause slight skin irritation; therefore hands should be washed after use. Contact with the eyes and deliberate inhalation of the product should also be avoided.

11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

11.1. Environmental Risk Assessment

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

11.2. Human Health Risk Assessment

11.2.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

11.2.2. Public health

There is Low Concern to public health when used as a component of hair spray.

12. MATERIAL SAFETY DATA SHEET

12.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

13. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.

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

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

- If products and mixtures containing the notified polymer are classified as hazardous to

health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills/release of the notified polymer should be handled by suitable absorbent material and put into suitable container for disposal.

13.1. Secondary Notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under subsection 64(1) of the Act; if
  – the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

(2) Under subsection 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.