File No PLC/1521

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Dimethicone/Vinyl Dimethicone Crosspolymer (INCI Name)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government 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 Australian Government Department of the Environment and Energy.

This Public Report is 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
NICNAS

May 2019

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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 SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1521	Dow Performance Materials (Australia) Pty Ltd Dow Chemical (Australia) Pty Ltd TULP Operations Australia Pty Ltd Ingredients Plus Pty Limited Connell Bros Australasia Pty Ltd L'Oreal Australia Pty Ltd	Dimethicone/Vinyl Dimethicone Crosspolymer (INCI Name)	No	≤ 100 tonnes per annum	Cosmetic ingredient

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

Environmental Risk Assessment
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Health and Safety Recommendations

- A person conducting a business or undertaking at a workplace should implement the following controls to minimise occupational exposure during reformulation of cosmetic products, where aerosols may be generated:
  - Ventilation system
  - Avoid inhalation of aerosols
  - Use respiratory protection if ventilation is inadequate

- Water insoluble high molecular weight polymers used in the respirable size range (< 10 μm) have the potential to cause lung overloading. Respiratory protection and local exhaust ventilation should be used to prevent inhalation exposure if mist/dust/aerosol formation is expected.

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

- In the interest of occupational health and safety, the following precautions should be observed for use of the notified polymer as introduced in powder form:
  - The level of atmospheric nuisance dust should be maintained as low as possible. The Safe Work Australia exposure standard for atmospheric dust is 10 mg/m^3.

- A copy of the 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 of 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.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency Procedures

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

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 polymer 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 polymer, 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 notified polymer is introduced in a chemical form that does not meet the PLC criteria;
- the notified polymer is proposed to be used in aerosol cosmetic spray products that are capable of generating respirable aerosols with $d_{ae} < 10$ µm during end use.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the notified polymer has changed from cosmetic ingredient, or is likely to change significantly;
- the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
- the notified polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the notified 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.

Safety Data Sheet
The SDS of the notified polymer and products containing the notified polymer were provided by the applicant. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants
Dow Performance Materials (Australia) Pty Ltd (ABN: 29 004 513 188)
Level 17, 8 Exhibition Street
MELBOURNE VIC 3000

Dow Chemical (Australia) Pty Ltd (ABN: 72 000 264 979)
Level 17, 8 Exhibition Street
MELBOURNE VIC 3000

TULP Operations Australia Pty Ltd (ABN: 67 615 093 822)
Level 5, 20 Rodborough Road
FRENCHS FOREST NSW 2086

Ingredients Plus Pty Limited (ABN: 25 112 469 619)
Unit 3, Parklands Estate, 13 South Street
RYDALMERE NSW 2116

Connell Bros Australasia Pty Ltd (ABN: 53 079 159 327)
3/32 Windorah Street
STAFFORD QLD 4053

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

Exempt Information (Section 75 of the Act)
Data items and details exempt from publication include: chemical name, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)
DOWSIL 9701 Cosmetic Powder
DOWSIL Trefil E-521
DOWSIL EP 9515 Cosmetic Powder

Molecular Weight
Number Average Molecular Weight (Mn) is > 10,000 g/mol

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa	Fine white powder
Melting Point/Glass Transition Temperature	Not determined
Density	978 kg/m^3 at 25 °C
Water Solubility	Insoluble due to high molecular weight and predominance of hydrophobic groups
Particle Size	1-10 µm
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-30	10-30	10-30	30-100	30-100

Use
The notified polymer will be used as a cosmetic ingredient at ≤ 10% concentration. The notified polymer will be introduced in finished cosmetic products. However the notified polymer may at some time in the future be imported as the raw material for reformulation of cosmetic products.

6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by tests submitted on the following toxicological endpoints.

Endpoint	*Result*	*Effects Observed*	*Test Guideline*
1. *In vitro* Eye Irritation Bovine Corneal Opacity & Permeability Assay	Non-irritating	no	Similar to OECD TG 437
2. *In vitro*,, predictive model, Reconstructed human epidermis model – Episkin -	Non-irritating	no	Similar to OECD TG 439
3. *In vitro* Eye Irritation HET-CAM	Non-irritating	no	-

All results were indicative of low hazard.

*In vitro: e*ye Irritation Bovine corneal opacity & permeability, predictive model, reconstructed human epidermis model – Episkin and eye irritation HET-CAM assays were all non-irritating.

The notified polymer is a high molecular weight, water insoluble polymer with a particle size in the respirable range (1-10 µm). The exact molecular weight of the notified polymer could not be determined. However based on the molecular weight information for the monomers, the molecular weight of the polymer is estimated to be much greater than 10,000 g/mol. Inhalation of polymers with molecular weights > 70,000 g/mol has been linked with irreversible lung damage due to lung overloading and impaired clearance of particles from the lung, particularly following repeated exposure (US EPA). There is a data gap for polymers with MW between 10,000 and 70,000 g/mol, and uncertainty may exist.

Occupational Health and Safety Risk Assessment

Reformulation
In the future, the notified polymer may be imported in a solid form for local reformulation into cosmetic products. Inhalation exposure to workers may occur during reformulation if aerosols are formed. Control measures including respiratory protection and local ventilation should therefore be in place to prevent inhalation exposure and hence lower the risk of potential lung overloading.

End use
Professional workers (eg. cosmetic service providers) may use spray products containing the notified polymer at < 10% concentration. It has been proposed that the notified polymer may be used in spray products. Based on a CIR report (CIR, 2012), both pump sprays and propellant sprays (also called "aerosol sprays") produce aerosols, but the aerosols from pump sprays have much smaller fractions of respirable droplets/particles than aerosols from propellant sprays.

Droplets/particles with and aerodynamic equivalent diameter (d_{ae}) > 10 μm may enter the nasopharyngeal region through the nose/mouth or pass through the larynx to enter the trachea, bronchi and bronchioles. In these regions of the respiratory tract, mucus-secreting and ciliated cells form a protective mucociliary blanket that carries deposited droplets/particles to the throat to be sneezed or spit out, or swallowed. There is also scientific consensus that healthy people are able to clear particles with d_{ae} > 7 μm from the nasopharyngeal and bronchial regions within 24 hours through mucociliary action (CIR, 2012). However, droplets/particles with d_{ae} < 10 μm may reach the pulmonary region of the lung. In the pulmonary region, the clearance of water insoluble particles is mediated primarily by alveolar macrophages, and is slow and limited (CIR, 2012). Therefore, to avoid the potential for lung overloading effects, the notified polymer should not be used in spray products that are capable of generating respirable aerosols with d_{ae} < 10 μm during use.

Provided that respirable aerosols containing the notified polymer are avoided or controlled, the risk of the notified polymer to occupational health and safety is not considered to be unreasonable.

Public Health and Safety Risk Assessment
Cosmetic products containing the notified polymer at < 10% concentration will be sold to the public. The risk to the public is expected to be of a similar extent to that experienced by professional workers using the same products (see above). Therefore, provided that respirable aerosols containing the notified polymer are avoided, the risk to the public from use of the notified polymer at < 10% concentration in cosmetics via dermal and spray applications is not considered to be unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

No eco-toxicological data were submitted. Polymers without significant ionic functionality are generally of low concern to the environment.

The notified polymer will be formulated overseas and imported in end use cosmetic hair care and skin care products. Accidental spills of the products containing the notified polymer during import, transport or storage are expected to be adsorbed onto a suitable material and collected for disposal in accordance with local regulations. If the cosmetic product is formulated in Australia it will be packed on automatic filling lines into various retail cosmetic packs and aerosols. The equipment wash liquid/solvent waste will be collected by licensed disposal contractors for recycling. Solid waste will be disposed of to landfill.

The notifier estimates that approximately 3% of the notified chemical will remain as residues in empty end-use containers, which are expected to be disposed of to landfill, or washed to sewer when rinsing during recycling of containers.

Under a worst case scenario it will be assumed that 100 % of the notified polymer will be washed into sewers. Assuming none of the notified polymer will be removed via absorption to sludge in the sewage treatment plant, the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as 56.2 µg/L [PECriver = 274.0 kg notified polymer/day ÷ (200 L/person/day × 24.386 million people) × 1 (dilution factor)].

When applied to agricultural soils in bio-solids or disposed of to landfills, the notified polymer is expected to be associated with soil and organic matter and not expected to be mobile. Due to its high molecular weight and low water solubility, the notified polymer is not expected to cross biological membranes and therefore, is not expected to bio-accumulate. In surface waters, soils and landfills, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and silicon.

Therefore, based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

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