

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in Dow Corning 9509 Silicone Elastomer Suspension and AF-3073 Antifoam Compound (INCI name Dimethicone/Vinyl Dimethicone Crosspolymer)

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**

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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/1413	Dow Corning Australia Pty. Ltd. Dow Chemical (Australia) Pty Ltd. Rohm and Haas Australia Pty Ltd.	Polymer in Dow Corning 9509 Silicone Elastomer Suspension and AF- 3073 Antifoam Compound (INCI name Dimethicone/Vinyl Dimethicone Crosspolymer)	No	≤ 50 tonnes per annum	Additive in cosmetics and paper pulp processing

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 where aerosols may be generated:
 - Ventilation system
 - Avoid inhalation of aerosols
 - Use respiratory protection if ventilation is inadequate

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

- 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 to be used in aerosols for cosmetic use.
- or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from an additive in cosmetics or in paper pulp processing, 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 formulation containing the notified polymer was 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 Corning Australia Pty Ltd. (ABN 36 008 444 166)
Level 20, 201 Sussex Street
Sydney NSW 2000

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

Rohm and Haas Australia Pty Ltd. (ABN 29 004 513 188)
Level 17, 8 Exhibition Street
Melbourne VIC 3000

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, polymer constituents, residual monomers/impurities, use details and import volume.

2. IDENTITY OF POLYMER

Marketing Names

Dow Corning 9509 Silicone Elastomer Suspension (product containing notified polymer)
Dow Corning AF3073 Antifoam Compound (product containing notified polymer)

Other Names

INCI Name: Dimethicone/Vinyl Dimethicone Crosspolymer

Molecular Weight

Number Average Molecular Weight (Mn) is > 10,000 Da.

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
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	Liquid (product)
Melting Point/Glass Transition Temp	Not determined
Density	997.0 kg/m ³ at 25 °C
Water Solubility	Not determined. Expected to be very low as the notified polymer is heavily cross-linked and has high molecular weight.

Reactivity
Degradation Products

Stable under normal environmental conditions
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	30-50	30-50	30-50	30-50	30-50

Use

The notified polymer will be used as an antifoam agent in paper industry and as an additive in leave-on and rinse off cosmetic products. It will be imported in end use products at <10% concentration. In future it may be imported at higher concentrations for reformulation into end-use products with in Australia. The notified polymer will not be used in spray products which generate aerosols.

6. HUMAN HEALTH RISK ASSESSMENT

No toxicological data were submitted. The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

The notified polymer is expected to have low water solubility and a high molecular weight >10,000 Da, and some particles may be > 70,000 Da. Inhalation of respirable particles of polymers with MW > 70,000 Da 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, 2013). It is also noted (SEHSC, 2001) that some silicone polymers and emulsions demonstrate acute toxicity to the lungs in experimental animals, when inhaled as an aerosol.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains impurities/residual monomers that are classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

Occupational Health and Safety Risk Assessment

Workers may be exposed to the notified polymer during reformulation of the notified polymer into end-use cosmetic products and during addition of the notified polymer containing antifoam agent in paper pulp processing. Provided that proper control measures are employed to reduce inhalation exposure, the risk to workers posed by exposure to the notified polymer is not considered unreasonable.

Public Health and Safety Risk Assessment

The public may be exposed during use of cosmetic products containing the notified polymer at up to 6.3%. As the notified polymer is not expected to be used in spray products, inhalation exposure and the risk of lung overloading is not expected to occur. Based on the proposed use profile, the risk to the public posed by exposure to the notified polymer is not considered unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological 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 products or as antifoaming agents for paper pulp production. Accidental spills of 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. Small amounts of the notified polymer may remain as residues in empty containers, which are expected to be disposed of in accordance with local regulations.

In future, the notified polymer may be imported for reformulation into end-use products in Australia. Solvent washings from the reformulation equipment cleaning will be treated as site industrial waste and will be collected by licensed disposal contractors for recycling. The wash-water generated during equipment cleaning will be collected for disposal.

Based on its use pattern, it is assumed that the total import volume of the notified polymer will be released to sewers from its use. In sewage treatment processes, very little of the notified polymer is expected to partition to the supernatant water as it is slightly soluble in water and has high molecular weight. Therefore, the notified polymer is not expected to be released to surface waters at ecotoxicologically significant concentrations.

Solid wastes including container residues are expected to be disposed of to landfill. When applied to agricultural soils in biosolids or disposed of to landfills, the notified polymer is expected to be associated with soil and organic matter. Due to its high molecular weight, the notified polymer is not expected to cross biological membranes and therefore, is not expected to bioaccumulate. 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 its assumed low hazard and assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

- SEHSC (2001) Guidance for Aerosol Applications of Silicone-Based Materials, Reston USA, Silicones Environmental, Health and Safety Council, North America
- US EPA (2013) High Molecular Weight Polymers in the New Chemicals Program. <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new> (Accessed 9 Jun. 17)