

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

POLYMER OF LOW CONCERN PUBLIC REPORT

**Polymer in BELSIL® P 1101 (INCI Name: Crotonic Acid/
Vinyl C8-12 Isoalkyl Esters/VA/Bis-Vinyldimethicone Crosspolymer)**

This Self Assessment has been compiled by the applicant and adopted by NICNAS in accordance with the provisions of the Industrial Chemicals (Notification and Assessment) Act 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), administered by the Department of Health and the Department of the Environment and Energy, has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

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
SAPLC/195	Wacker Chemie AG	Polymer in BELSIL® P 1101 (INCI Name: Crotonic Acid/Vinyl C8-12 Isoalkyl Esters/VA/Bis-Vinyldimethicone Crosspolymer)	No	≤ 5 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

- 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 (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 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.

Storage

- The following precautions should be taken by workers regarding storage of the notified polymer:
 - Keep container tightly closed and store in a cool, well ventilated place.

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.

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.

(Material) Safety Data Sheet

The (M)SDS of the a product containing the notified polymer was provided by the applicant. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants

Wacker Chemie AG (ABN: 11 607 113 062)
1/35 Dunlop Road
MULGRAVE VIC 3170

Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, polymer constituents and residual monomers/impurities.

2. IDENTITY OF POLYMER

Marketing Name

BELSIL® P 1101 (Product containing the notified polymer)

Other Name

Crotonic Acid/Vinyl C8-12 Isoalkyl Esters/VA/Bis-Vinyldimethicone Crosspolymer (INCI name)

Molecular Weight

Number Average Molecular Weight (Mn) is > 1,000 Da

3. PLC CRITERIA JUSTIFICATION

Criterion

Molecular Weight Requirements
Functional Group Equivalent Weight (FGEW) Requirements
Low Charge Density
Approved Elements Only
Stable Under Normal Conditions of Use
Not Water Absorbing
Not a Hazard Substance or Dangerous Good
The notified polymer meets the PLC criteria.

Criterion met

Yes
Not applicable
Yes
Yes
Yes
Yes
Yes

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa	Liquid
Melting Point/Glass Transition Temp	36-40 °C
Density	1,122 kg/m ³ at 20°C
Water Solubility	1.5 g/L at 20 °C ; The notified polymer will not be isolated from solution in normal use and distribution conditions.
Dissociation Constant	pKa = 7.39
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

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

Use

The notified polymer will be introduced as a 50 % solution in ethanol denatured with methyl ethyl ketone (MEK), or in ready formulated products by our customers.

Disposal via waste-water in the process of hair washing (personal hygiene).

The notified polymer will be produced in Germany and reformulated by our customers either in or outside of Australia and imported as ready to use products.

It is a hair styling polymer for cosmetic use such as aerosol sprays, pump sprays, hair balms, dry shampoo, hair mousse. Typical use levels are 1 – 6 % of the notified polymer in the final cosmetic formulation.

6. HUMAN HEALTH RISK ASSESSMENT

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

The notified polymer will be delivered as solution in ethanol denatured with MEK. The occupational exposure assessment must be based on the hazards posed by a 50% solution of Ethanol denatured with 0.5 - 1% of MEK, present in the Belsil P 1101. The final products containing the notified polymer will be used in an occupational context by hairdressers, cosmeticians, and beauticians. Use will be intermittent, wide-dispersive with direct handling.

PUBLIC EXPOSURE

The notified polymer will be used for hair styling cosmetics in the end-user market, so the general public will be exposed to the notified polymer in concentrations up to 6% of the final cosmetic formulation. Exposure to the notified polymer will vary depending on individual use patterns. Typical exposure will be by skin contact and inhalation of aerosol (over-)spray. However, the exposure times will be in the range of a few (up to 5) minutes per day.

6.2. Toxicological Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the notified polymer or on analogue chemicals:

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Rat, acute oral (tested on similar polymer)*	LD50 > 2000 mg/kg bw	no	-
Rat, acute dermal (tested on similar polymer)*	LD50 > 2000 mg/kg bw	no	-
Rat, acute inhalation (tested at 10% concentration)**	LC50 > 5.29 mg/L/4 hour	no	OECD TG 403
Genotoxicity - bacterial reverse mutation (tested on similar polymer)***	non mutagenic	no	OECD TG 471 – 472

* Test result with similar polymers (polydimethylsiloxanes & various Vinyl acetate copolymers)

** A 10% solution of the polymer in ethanol/water was tested; no mortality was observed at this concentration.

*** Test result with a similar polymer (Siloxanes and Silicones, di-Me, vinyl group-terminated, polymers with vinyl acetate)

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

The notified polymer meets the PLC criteria and is therefore expected to be of low hazard. Eye irritation cannot be excluded for the formulation containing ethanol. In case of mist/aerosol formation, relevant Occupational Exposure Limits must be observed for 50% Ethanol and <1% MEK when Belsil P 1101 is being used to formulate cosmetic products. The risk of the notified polymer to occupational health is not considered unreasonable, given the assumed low hazard and the assessed use pattern.

PUBLIC HEALTH

The public will be exposed to the notified polymer during use of hair spray and hair styling products. The risk to public health is not considered to be unreasonable due to the predicted low hazard of the notified polymer and the assessed use pattern.

7. ENVIRONMENTAL RISK ASSESSMENT

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

The notified polymer is intended for cosmetic application to be used on the human skin. Most of it will end up in the waste-water system, going to the waste water treatment plant.

ENVIRONMENTAL FATE

The notified polymer is expected to be stable under normal environmental conditions. Due to its low water solubility and low vapour pressure, the notified polymer in solid wastes is expected to remain bound within the soils and sediments of landfills and eventually degrade through biotic and abiotic processes. When used in cosmetic applications, the final fate of the product is the waste-water system. The notified polymer is expected to be removed from the waste water in treatment plants by adsorption to the sewage sludge, which is expected to be land filled. The notified polymer is not expected to be readily biodegradable but due to its high molecular weight, it is not expected to bioaccumulate. In landfill the notified polymer is expected to eventually degrade to form water and oxides of carbon and silicon.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted. Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. This does not apply to the notified polymer and it is therefore unlikely to be an over-chelation hazard to algae.

7.3. Environmental Risk Assessment

The notified polymer will mainly end up in the waste water system and be carried out of the water compartment via the sewage sludge. Based on its assumed low hazard and assessed use pattern, and its properties (non-hazardous, low vapour pressure, high molecular weight), the notified polymer is not considered to pose an unreasonable risk to the environment.