

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Formaldehyde, polymer with 1,3-benzenediol and 1,3,5-triazine-2,4,6-triamine

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/1459	Symrise Pty Ltd	Formaldehyde, polymer with 1,3-benzenediol and 1,3,5-triazine-2,4,6-triamine	No	1 tonne per annum	Component of cosmetic and household products

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

- Water insoluble high molecular weight polymers in the respirable size range ($< 10 \mu\text{m}$) have the potential to cause lung overloading. Respiratory protection and local exhaust ventilation should be used to prevent inhalation exposure if dust or 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 when dust formation is expected during handling:
 - 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,or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component of cosmetic and household products, 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 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

Symrise Pty Ltd (ABN: 67 000 880 946)
168 South Creek Road
DEE WHY NSW 2099

Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication: molecular and structural formulae, polymer constituents, residual monomers/impurities, use details and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

K4 Polymer Fuer MH2K

Chemical Name

Formaldehyde, polymer with 1,3-benzenediol and 1,3,5-triazine-2,4,6-triamine

CAS Number

37889-17-1

Molecular Weight

Number Average Molecular Weight (Mn)	>> 10,000 Da (estimated)
Weight Average Molecular Weight (Mw)	>> 10,000 Da (estimated)
Polydispersity Index (Mw/Mn)	Not determined
% of Low MW Species < 1000 Da	Estimated to be very low
% of Low MW Species < 500 Da	Estimated to be very low

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	White powder
Melting Point/Glass Transition Temperature	Not determined
Density	> 1000 kg/m ³ at 20 °C
Water Solubility	Insoluble
Particle Size	d10: 16-20.6 µm d50: 27.6 -34.2 µm d90: 41.9 – 50.9 µm < 10 µm: 7.2% (calculated)

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	1	1	1	1	1

Use

The notified polymer will not be manufactured in Australia. It will be imported either as a component of fragrance formulations at $\leq 3\%$ concentration for reformulation into end-use cosmetic and household products or as a component of finished cosmetic and household products at $\leq 0.05\%$ concentration.

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.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains 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.

Water insoluble high molecular weight polymers in the respirable size range ($< 10 \mu\text{m}$) have the potential to cause lung overloading. The notified polymer is water insoluble and the particle size of the notified polymer indicates that a small portion (calculated to be 7.2%) will be respirable ($< 10 \mu\text{m}$).

Occupational Health and Safety Risk Assessment

The notified polymer will be imported in fragrance formulations at $\leq 3\%$ concentration for reformulation into end-use cosmetic and household products. Reformulation and repackaging processes are expected to occur in automated and closed systems. Respiratory protection and local exhaust ventilation are also expected to be used to prevent inhalation exposure if dust or aerosol formation is possible. Given the low concentrations and expected use of engineering controls and personal protection equipment, the risk posed by exposure to the notified polymer is not considered to be unreasonable.

Exposure to the notified polymer in end-use products at $\leq 0.05\%$ concentration may occur in professions where the services provided involve the application of cosmetic and household products for clients (e.g. hair dressers, workers in beauty salons and cleaners). The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible. Such professionals may use some personal protective equipment (PPE) to minimise repeated exposure and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

Public Health and Safety Risk Assessment

The public may be exposed during use of cosmetic and household products containing the notified polymer at $\leq 0.05\%$. Given the assumed low hazard and the proposed low use concentrations, the risk posed by exposure to the notified polymer is not considered unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Polymers that are solid materials that are not soluble or dispersible in water and will only be used in the solid phase are generally of low concern to the environment.

The notified polymer will not be manufactured in Australia. Release to the environment may only occur in the unlikely event of an accident during transport or an accidental spill. Release of the notified polymer to the aquatic environment is not expected during reformulation as any accidental spills are expected to be collected by inert material and disposed of according to local regulations. Some of the notified polymer may remain as residue in empty import containers (approximately 1% of the total annual import volume) or empty end-use containers, which is expected to be disposed of to landfill along with the empty containers.

The majority of the notified polymer will be released to sewer as a result of its use in cosmetic and household products. Release is assumed to occur daily, and to be diffuse in nature. In sewage treatment plants, most of the notified polymer is expected to partition to sludge and sediments as it has high molecular weight. Therefore, the release of the notified polymer during the use will not lead to ecotoxicologically significant concentrations in the aquatic environment.

The notified polymer is not expected to cross biological membranes due to its high molecular weight and it is therefore not expected to bioaccumulate. The notified polymer is expected to eventually degrade by abiotic and biotic processes to form water and oxides of carbon and nitrogen.

Based on its assumed low hazard and reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.