File No PLC/1269

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Cellulose, carboxymethyl ether, sodium salt, polymer with bis(isocyanatomethyl)benzene, 2,2-dimethoxyacetaldehyde, ethanedial, 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, 2-oxoacetic acid, 1,3,5-triazine-2,4,6-triamine and 1H-1,2,4-triazole-3,5-diamine (INCI name: Polyurethane crosspolymer-2)

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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also 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

June 2015

Table of Contents

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/1269	Firmenich Pty Limited	Cellulose, carboxymethyl ether, sodium salt, polymer with bis(isocyanatomethyl)benzene, 2,2-dimethoxyacetaldehyde, ethanedial, 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, 2-oxoacetic acid, 1,3,5-triazine-2,4,6-triamine and 1H-1,2,4-triazole-3,5-diamine (INCI name: Polyurethane crosspolymer-2)	No	< 1 tonne per annum	Component of fragrances

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.

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 introduced in powdered form;
- the notified polymer is proposed to be used in aerosol cosmetic spray products;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the notified polymer has changed from a component of fragrances, 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 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
Firmenich Pty Limited (ABN: 86 002 964 794)
73 Kenneth Road
BALGOWLAH NSW 2093

Exempt Information (Section 75 of the Act)
Data items and details claimed exempt from publication: other names, molecular formula, structural formula, molecular weight, spectral data, use details, polymer constituents, residual monomers/impurities and import volume.

2. IDENTITY OF POLYMER

Marketing Name
Polyurethane crosspolymer-2 (INCI name)

Chemical Name
Cellulose, carboxymethyl ether, sodium salt, polymer with bis(isocyanatomethyl)benzene, 2,2-dimethoxyacetaldehyde, ethanedial, 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, 2-oxoacetic acid, 1,3,5-triazine-2,4,6-triamine and 1H-1,2,4-triazole-3,5-diamine

CAS Number
1422377-33-0

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

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	Solid off-white powder
Melting Point/Glass Transition Temp	Not determined
Density	Not determined
Water Solubility	Not Determined. Based on its high molecular weight and predominantly hydrophobic structure, the notified polymer is expected to have low water solubility.
Dissociation Constant	Not Determined. The notified polymer contains ionisable functionalities which are expected to be ionised in the environmental pH range (4 - 9).
Particle Size	5-50 µm

Reactivity	Stable under normal conditions of use
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	< 0.5	< 1	< 1	< 1	< 1

Use
The notified polymer will be imported into Australia either: (1) as a component of a formulation for reformulation into cosmetic products for consumer use; or (2) as a component of finished 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*
Rabbit, skin irritation	non-irritating	no	OECD TG 404
Rabbit, eye irritation	slightly irritating	yes	OECD TG 405
Phototoxicity – in vitro	low toxicity	no	OECD TG 432

All results were indicative of low hazard.

The notified polymer is a high molecular weight (> 70,000 Da) polymer with low water solubility. Inhalation of polymers with molecular weights > 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. If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs.

Occupational Health and Safety Risk Assessment
Powdered notified polymer will not be handled by reformulation workers in Australia. The notified polymer will be introduced in liquid formulation for reformulation into cosmetic products; hence inhalation exposure is not expected. Furthermore, transfer, blending and packaging processes are expected to be highly automated and fully enclosed.

Therefore, given the assumed low hazard and the assessed use pattern, the risk of the notified polymer to occupational health and safety is not considered to be unreasonable.

Public Health and Safety Risk Assessment
The finished products containing the notified polymer for consumer use will be in liquid form and will not be applied as an aerosol spray; hence inhalation exposure is not expected.

Therefore, under the proposed use scenario, the risk of the notified polymer to public health is not considered to be unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. The notified polymer is a potentially anionic polymer where anionic polymers are generally of low toxicity to fish and daphnia. However, they 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. However, this does not apply to the notified polymer and it is therefore not considered to be

an over-chelation hazard to algae. The notified polymer also contains potentially cationic functionality, however the cationic charge density is low and the notified polymer is therefore not expected to be of concern to the aquatic environment.

The majority of the notified polymer will be released to sewer as a result of its use as a component of cosmetic products that will be washed off the skin. Release is assumed to occur daily, and to be diffuse in nature. Under a worst case scenario it will be assumed that 100% of the notified polymer will be washed into sewers. Assuming 0% 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 0.61 µg/L [PECriver = 2.74 kg notified polymer/day ÷ (200 L/person/day × 22.613 million people) × 1 (dilution factor)]. The PEC is well below the EC_{50} for algae of the most toxic anionic polymers (EC_{50} > 1 mg/L). In sewage treatment plants, most of the notified polymer is expected to partition to sludge and sediments as it is a potentially cationic polymer and has high molecular weight.

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

Accidental spills and empty containers will be disposed of to landfill. Following use of consumer products containing the notified polymer, empty containers are disposed of through domestic garbage and hence will enter landfill or recycling.

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