

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

POLYMER OF LOW CONCERN PUBLIC REPORT

5-Isobenzofurancarboxylic acid, 1,3-dihydro-1,3-dioxo-, polymer with 2,2-dimethyl-1,3-propanediol, 1,2-ethanediol and 1,3-isobenzofurandione (INCI Name: Phthalic Anhydride/Trimellitic Anhydride/Glycols Copolymer)

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.

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/1343	McPherson's Consumer Products Pty Ltd and Neon Cosmetics Pty Ltd	5- Isobenzofurancarboxylic acid, 1,3-dihydro-1,3- dioxo-, polymer with 2,2-dimethyl-1,3- propanediol, 1,2- ethanediol and 1,3- isobenzofurandione (INCI Name: Phthalic Anhydride/Trimellitic Anhydride/Glycols Copolymer)	No	< 10 tonnes per annum	Component of cosmetic nail 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

- 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.
 - further information becomes available on the sensitisation potential of the notified polymeror
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from component of cosmetic nail 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.

(Material) Safety Data Sheet

The (M)SDS of the notified polymer and a product containing the notified polymer were 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

McPherson's Consumer Products Pty Ltd (ABN: 36 000 020 495)
105 Vanessa Street
KINGSGROVE NSW 2208

Neon Cosmetics Pty Ltd (ABN: 32 005 437 865)
39 London Drive
BAYSWATER VIC 3153

Exempt Information (Section 75 of the Act)

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

2. IDENTITY OF POLYMER

Chemical Name

5-Isobenzofurancarboxylic acid, 1,3-dihydro-1,3-dioxo-, polymer with 2,2-dimethyl-1,3-propanediol, 1,2-ethanediol and 1,3-isobenzofurandione

CAS Number

186688-25-5

Molecular Formula

$(C_9H_4O_5.C_8H_4O_3.C_5H_{12}O_2.C_2H_6O_2)_x$

Other Name(s)

Phthalic Anhydride/Trimellitic Anhydride/Glycols Copolymer (INCI Name)

Molecular Weight

Number Average Molecular Weight (Mn) is > 1,000 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	Light yellow liquid*
Melting Point/Glass Transition Temp	Not determined
Density	1091 kg/m ³ *
Water Solubility	Insoluble
Dissociation Constant	Expected to be ionised under environmental conditions (pH

4-9)
 Reactivity Stable under normal environmental conditions
 Degradation Products None under normal conditions of use
 * Product containing 70% notified polymer and 30% butyl acetate.

5. INTRODUCTION AND USE INFORMATION

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

Total for both notifiers					
Year	1	2	3	4	5
Tonnes	< 10	< 10	< 10	< 10	< 10

Use

The notified polymer will be used in cosmetic nail polish and nail treatment products as a film forming and viscosity increasing agent. It will be imported in formulated finished products and premixes, and as a raw material.

6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer is part of a group of polymers (named Trimellitic Anhydride Copolymers) that are currently under evaluation by the Cosmetic Ingredient Review (CIR, 2016). The most recent Revised Tentative Report for Public Comment was released on 7/4/16. At this stage the conclusion of the CIR is that the data available to them at this stage is insufficient to determine that the polymers are safe under the intended conditions of use in cosmetic formulations. They requested further information in order to evaluate safety. For nail products the information requested was method of manufacture and composition data.

No toxicological data were submitted to NICNAS. The notified polymer meets the PLC criteria and is therefore expected to be of low hazard. The CIR Revised Tentative Report makes reference to two unpublished human repeated insult patch tests on formulations containing the notified polymer at 7% and 7.5%. In the latter study 1/103 subjects had minimal or definite erythema, often with itching, at all but 2 of the induction readings, and at challenge. No other irritation or sensitisation effects were seen. The CIR report also references several case reports where contact allergy to nail polish was identified and linked to the notified polymer (Nassif et al. (2007), Gach et al. (2005), Moffit & Sansom (2002).

One of the notifiers, who has previously imported and marketed nail polishes containing the notified polymer, reported that they had no consumer complaints related to irritation or sensitisation over the period 2013-2015.

NICNAS notes that there is an uncertainty regarding the potential sensitisation of the notified polymer. Based on the available information, the notified polymer cannot be classified for sensitisation, however the potential for sensitisation cannot be ruled out.

Although not considered in this risk assessment, NICNAS also notes that the notified polymer may contain 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. These are not present in the notified polymer as introduced above the cut off concentrations for classification.

Overall the risk of the notified polymer to occupational and public health is not considered to be unreasonable, noting that there is uncertainty regarding the polymer's potential to cause skin sensitisation.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. 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. The toxicity to algae is likely to be reduced due to the presence of calcium ions in environmental waters, which will bind to the functional groups.

The notified polymer will be imported as raw material into Australia for local reformulation into a variety of cosmetic nail care formulations, or as finished cosmetic nail care formulations. Release of the notified polymer during reformulation in Australia is expected to be limited to accidental spills or leaks and residue in import containers (estimated by the notifier to be 1% of the total import volume, or 100 kg). These releases are expected to be collected and disposed of to landfill in accordance with local government regulations.

Based on its use in cosmetic nail care formulations, it is expected that the majority of the notified polymer will be cured during use, with disposal to landfill as solid wastes or release to the aquatic compartment through sewers when washed off the body. Due to its high molecular weight, low solubility in water, and anionic properties, up to 50% of the notified polymer is expected to adsorb to sludge and sediment (Boethling and Nabholz, 1997). Therefore in landfill and in surface waters, the notified polymer is not expected to be mobile or bioavailable. Based on its high molecular weight and low water solubility, the notified polymer is not expected to cross biological membranes, and is therefore unlikely to bioaccumulate.

All wastes including container residues are expected to be disposed of to landfill. It is estimated by the notifier that 3% of the total import volume of the notified polymer (or 300 kg) may be disposed of to landfill as residues in empty end-use containers. Based on its high molecular weight and chemical structure, the notified polymer is not expected to be readily biodegradable. In both landfill and in surface waters, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon.

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.

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Boethling, RS, Nabholz, JV (1997). "Environmental Assessment of Polymers under the US Toxic Substances Control Act", in: Hamilton, JD, Sutcliffe, R (ed). Ecological Assessment of Polymers: Strategies for product stewardship and regulatory programs. Van Nostrand Reinhold, New York.

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Gach JE, Stone NM, and Finch TM. A series of four cases of allergic contact dermatitis to phthalic anhydride/trimellitic anhydride/glycols copolymer in nail varnish. Contact Dermatitis. 2005, 53(1):63-64.

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Nassif AS, Le Coz CJ, and Collet E. A rare nail polish allergen: phthalic anhydride, trimellitic anhydride and glycols copolymer. Contact Dermatitis. 2007, 56(3):172-173.