

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

POLYMER OF LOW CONCERN PUBLIC REPORT

**PLC/1554: SP-HL-04
PLC/1555: SP-HL-07**

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**

September 2019

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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/1554 PLC/1555	Kao Australia Pty Ltd	SP-HL-04 SP-HL-07	No	< 2 tonnes per annum	Component of printing ink

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment

Based on the assumed low hazard and the assessed use pattern, the notified polymers are 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 polymers are 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 polymers themselves. 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 SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymers 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 polymers 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 polymers 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 polymers 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 polymers, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymers are 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 polymers are 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 polymers has changed from component of printing ink, or is likely to change significantly;
 - the amount of notified polymers being introduced has increased, or is likely to increase, significantly;
 - the notified polymers have begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the notified polymers 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 polymers were 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

Kao Australia Pty Ltd
Level 1
19 – 23 Prospect Street
BOX HILL VIC 3128

Exempt Information (Section 75 of the Act)

Data items and details exempt from publication include: chemical name, CAS number, molecular and structural formulae, molecular weight, polymer constituents, use details and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

PLC/1554: SP-HL-04
PLC/1555: SP-HL-07

Other Name(s)

PLC/1554: None provided
PLC/1555: None provided

Molecular Weight

PLC/1554: Number Average Molecular Weight (Mn) is > 10,000 g/mol.
PLC/1555: Number Average Molecular Weight (Mn) is > 10,000 g/mol.

Hazardous Impurities/Residual Monomers

PLC/1554 and PLC/1555

<i>Chemical Name</i>	Sodium hydroxide
<i>CAS No.</i>	1310-73-2 <i>Weight %</i> < 0.1
<i>Hazardous Properties</i>	H335 (May cause respiratory irritation) H314 (Causes severe skin burns and eye damage)

3. PLC CRITERIA JUSTIFICATION

PLC/1554:

<i>Criterion</i>	<i>Criterion met</i>
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Not applicable
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

PLC/1555:

<i>Criterion</i>	<i>Criterion met</i>
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Not applicable
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 polymers meet the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

PLC/1554:

Appearance at 20 °C and 101.3 kPa	White solid
Melting Point/Glass Transition Temperature	Not determined; expected to decompose before reaching melting point
Density	1.18 kg/m ³ at 20 °C
Water Solubility	Insoluble
Dissociation Constant	Contains anionic functionalities but significant dissociation in the environmental pH range (4-9) is not expected due to its insolubility in water
Particle Size	D50 = 7.3 µm*
Reactivity	Stable under normal environmental conditions.
Degradation Products	None under normal conditions of use

* The notified polymer is imported in a liquid.

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Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

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5. INTRODUCTION AND USE INFORMATION

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

PLC/1554:

Year	1	2	3	4	5
Tonnes	< 2	< 2	< 2	< 2	< 2

PLC/1555:

Year	1	2	3	4	5
Tonnes	< 2	< 2	< 2	< 2	< 2

Use

The notified polymers will not be manufactured in Australia and will be imported in end-use printing inks (containing each notified polymer at $\leq 5\%$ concentration). Packaging containing the end-use inks will be connected to commercial printers manually, and the ink will be printed to paper-based substrates under closed, automated processes. The end-use inks containing the notified polymers will be available for industrial users only and will not be used in food contact applications.

6. HUMAN HEALTH RISK ASSESSMENT

No toxicological data were submitted. The notified polymers meet 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 polymers contain a residual monomer that is classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. This monomer is present at levels below the concentration required hazard classification.

The notified polymers are mainly water-insoluble with molecular weight $> 10,000$ g/mol. Inhalation of polymers with molecular weights $> 70,000$ g/mol 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, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new>, accessed on 20 May 2019). There is a data gap for polymers with MW between 10,000 and 70,000 g/mol, and uncertainty may exist. However, based on the proposed use patterns, inhalation exposure to inks containing the notified polymers is not expected due to the presence of local fume extraction supplied with printing equipment.

Given the low hazard, the risk of the notified polymers to occupational and public health is not considered to be unreasonable.

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 leading to chelation of essential nutrients. This applies to the notified polymers but the polymers also contain functionality that dilutes the chelating effect, which results in significantly reduced toxicity to algae (Boethling & Nahbolz, 1997).

The notified polymers will be imported in end-use printing ink solutions. No manufacture, reformulation or repackaging of the ink products will occur in Australia. The inks containing the notified polymers will be used for printing on paper through automatic processes in industrial settings. Accidental spills of the ink containing the notified polymers during import, transport, storage and use only occur if the packaging is breached. These spills, estimated by the notifier to account for up to 1% of the import volume of the notified polymers, are expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations. The notifier estimates that empty containers may contain residues of the notified polymers up to 2% of the import volume. These empty containers may be recycled into low grade plastic products, but eventually will be sent to landfill for disposal.

Most of the notified polymers are expected to share the fate of the paper to which they have been applied, either subjected to paper recycling processes or being disposed of to landfill at the end of their useful lives. According to the recent Australian National Waste Report (Blue Environment Ltd., 2016), 60% of the waste paper treated with the notified polymers is expected to be recycled domestically. During recycling processes, waste paper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks and coatings from the fibres. Based on their high molecular weight and insolubility in water, the notified polymers discharged to wastewater from paper recycling processes

are expected to be effectively removed through adsorption to sludge or by flocculation at wastewater treatment plants (US EPA, 2013; Boethling and Nabholz, 1997), and only a small proportion of the notified polymers may be released to surface waters after treatment processes.

With 60% release of the notified polymers into the sewer systems through paper recycling processes and no removal within wastewater treatment plants as the worst case scenario, the conservative predicted environmental concentration (PEC) of each notified polymer in sewage effluent on a nationwide basis over 260 working days per year is calculated to be 0.95 µg/L [$0.6 \times 2,000 \text{ kg/year} \div 260 \text{ days/year} \div (24.386 \text{ million persons} \times 200 \text{ L/person/day})$]. As the notified polymers are expected to be of low toxicity to aquatic organisms, their release during the recycling and deinking processes is not expected to lead to ecotoxicologically significant concentrations in the aquatic environment.

Sludge containing the notified polymers may be sent to landfill for disposal or agricultural land for remediation. Based on their high molecular weight and insolubility in water, the notified polymers are expected to have low mobility in landfill and soil. The notified polymers are not expected to be bioaccumulative given their insolubility in water, high molecular weight and an absence of a significant percentage of low molecular weight constituents. In landfill, soil and water, the notified polymers are expected to undergo degradation by biotic and abiotic processes, eventually forming water, oxides of carbon and sodium salts.

Therefore, based on their assumed low hazard and assessed use pattern in printing ink, the notified polymers are not considered to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

Blue Environment Pty Ltd (2016) Australian National Waste Report 2016. Canberra, Australia.

Boethling, RS & Nabholz VJ (1997) Chapter 10 Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton, JD Sutcliffe R ed. Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, 1st ed. New York, Van Nostrand Reinhold, pp 187-234.

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