File No.: PLC/1422 PLC/1423

PLC/1424

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

PLC/1422: MP-BK-185-CN PLC/1423: MP-C-102-CN PLC/1424: MP-YM-104-CN

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:

Street Address: Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.

Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.

TEL: + 61 2 8577 8800 FAX: + 61 2 8577 8888 Website: www.nicnas.gov.au

Director NICNAS

June 2017

Table of Contents

SUM	[MARY	. 2
CON	ICLUSIONS AND REGULATORY OBLIGATIONS	. 2
ASS]	ESSMENT DETAILS	. 4
	APPLICANT AND NOTIFICATION DETAILS	
2.	IDENTITY OF POLYMER	. 4
	PLC CRITERIA JUSTIFICATION	
	PHYSICAL AND CHEMICAL PROPERTIES	
5.	INTRODUCTION AND USE INFORMATION	. 4
6.	HUMAN HEALTH RISK ASSESSMENT	. 5
	ENVIRONMENTAL RISK ASSESSMENT	

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/1422	Kao Australia	MP-BK-185-CN	No	≤ 1 tonne per	Components of printing
PLC/1423	Pty Ltd	MP-C-102-CN		annum for each	ink
PLC/1424		MP-YM-104-CN		polymer	

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

• Water insoluble high molecular weight polymers have the potential to cause lung overloading if inhaled. Respiratory protection and local exhaust ventilation should be used to prevent inhalation exposure if the notified polymers are expected to become airborne.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Service personnel should wear disposable gloves and ensure adequate ventilation is present when removing spent ink bags or printer cartridges containing the notified polymers and during routine maintenance and repairs.
- 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 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 polymers are introduced in chemical forms that do not meet the PLC criteria.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymers have changed from components 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 product containing the notified polymers 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

Kao Australia Pty Ltd (ABN: 059 054 708 299)

Level 1, 19-23 Prospect Street

BOX HILL VIC 3128

Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication: chemical names, other names, CAS numbers, molecular and structural formulae, molecular weight, spectra data, polymer constituents, residual monomers/impurities, use details and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

PLC/1422: MP-BK-185-CN PLC/1423: MP-C-102-CN PLC/1424: MP-YM-104-CN

Molecular weight

Number Average Molecular Weight (Mn) > 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 White solid
Melting Point/Glass Transition Temp
Density Not determined
1,180 kg/m³ at 20 °C

Water Solubility Not determined. Expected to be low based on the high

molecular weight and predominantly hydrophobic structures

Particle Size 4.9 µm*

Reactivity Stable under normal environmental conditions

Degradation Products None under normal conditions of use

* Powder form of the polymers will not be imported.

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 polymers will be used (at $\leq 2\%$ concentration) as components of printing ink for commercial printers and duplicators.

6. HUMAN HEALTH RISK ASSESSMENT

No toxicological data were submitted. The notified polymers meet the PLC criteria and are therefore assumed to be of low hazard. The risk of the notified polymers to occupational and public health is not considered to be unreasonable given the assumed low hazard and the assessed use pattern.

Although not considered in this risk assessment, NICNAS notes that the notified polymers 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 polymers as introduced above the cut off concentrations for classification.

It is also noted that the notified polymers are water-insoluble polymers with molecule weight > 10,000 Da. 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 (US EPA, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new, accessed on 15 June 2017). There is a data gap for polymers with MW between 10,000 and 70,000 Da, and uncertainty may exist. If the notified polymers are inhaled at low levels and/or infrequently, it is assumed that they will be cleared from the lungs. However, based on the proposed use scenarios, inhalation exposure to the notified polymers is not expected to be significant during normal use unless the polymers become airborne.

The risk of the notified polymers to occupational and public health is not considered to be unreasonable given the assumed low hazard and the assessed use patterns.

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 overchelation 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 polymers and is therefore not considered to be an over-chelation hazard to algae.

The notified polymers will be imported into Australia as components of finished ink products. Spills or accidental leaks of the products containing the notified polymers are expected to be vacuum-collected and disposed of to landfill.

Ink products containing the notified polymers will be printed onto paper substrates. It is assumed that 50% of the printed paper will end up in landfill, and the rest will undergo paper recycling processes. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of inks from the fibres. The majority of the notified polymers in waste water produced from paper recycling process are expected to partition to sludge or sediment. Very little of the notified polymers are expected to partition to the supernatant water, due to

its low solubility in water. All wastes, including container residues, accidental spill waste, and sludge waste from paper recycling, are expected to be disposed of to landfill.

The notified polymers are not expected to be readily biodegradable based on their structures and low solubility in water. Based on their high molecular weight and low water solubility, the notified polymers are not expected to cross biological membranes, and are therefore unlikely to bioaccumulate. In landfill, the notified polymers are expected to eventually degrade by biotic and abiotic processes to form water and oxides of carbon and inorganic salts.

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