NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in HA-400B, HA-450B, HA-460B

This Self Assessment has been compiled by the applicant and adopted by NICNAS in accordance with the provisions of the Industrial Chemicals (Notification and Assessment) Act 1989 (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), administered by the Department of Health and the Department of the Environment, has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

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

January 2015

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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
SAPLC/169	DIC Australia Pty Ltd	Polymer in HA- 400B, HA-450B, HA-460B	No	≤ 150 tonnes per annum	Component of adhesive for flexible packaging

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 for the 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

• The notified polymer should be disposed of by landfill or incineration.

Storage

- The following precautions should be taken by workers regarding storage of the notified polymer:
 - Store in a segregated and approved area.

Emergency Procedures

• Spills/release of the notified polymer should be handled by absorbing with sand or other appropriate absorbent material and sealed into metal containers. The adhesive containing the notified polymer should not be allowed to enter drains or waterways.

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 an adhesive for flexible packaging, 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 SDS of products containing 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

DIC Australia Pty Ltd 323 Chisholm Rd AUBURN NSW 2144

Exempt Information (Section 75 of the Act)

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

2. IDENTITY OF POLYMER

Marketing Name(s)

HA-400B, HA-450B, HA-460B (notified polymer present at 60-100% concentration)

Other Name(s)

Polyester resin

Molecular Weight

Number Average Molecular Weight (Mn) is > 1,000 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 Transparent liquid
Density 1160 kg/m³ at 25 °C

Water Solubility Not determined. The notified polymer is expected to have

limited solubility in water due to its high molecular weight

and predominately hydrophobic structure.

Reactivity Stable under normal environmental conditions

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	< 100	< 100	< 100	< 150	< 150

Use

The notified polymer will be imported into Australia in metal cans or drums. No reformulation of the notified polymer will occur in Australia. The adhesive containing the notified polymer will not be reformulated or repacked in Australia; it will be supplied to flexible packaging printers where it will be applied via adhesive application equipment and inline curing units. The notified polymer is a component of a solvent free lamination adhesive which has end use in the production of flexible general and food packaging. The cured adhesive will not have direct food contact. A high molecular weight urethane film is generated when the terminal group of the notified polymer reacts with another polymer.

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.

The notified polymer will be used as a component of an adhesive for flexible general and food packaging. Once the adhesive is cured and dried, the notified polymer will be bound in the adhesive matrix and is not expected to migrate into the package contents. Furthermore, the notified polymer meets the USA 21CFR 175–105 indirect food contact packaging adhesive requirements (21CFR175.105).

Overall, given the assumed low hazard of the notified polymer and provided the adhesive is cured within the manufacturer's specification, the notified polymer is not considered to pose an unreasonable risk to workers or the public.

7. ENVIRONMENTAL RISK ASSESSMENT

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Release to the environment during shipping, transport and warehousing will only occur through accidental spills or leaks to the metal packaging containers. Empty adhesive containers will disposed of through the standard recycling practices for metal containers of the printing industry.

ENVIRONMENTAL FATE

Once the notified polymer as a component of the adhesive has been cured it is expected to be hydrolytically stable and not to be readily biodegradable. The dried adhesive containing the notified polymer will be part of the flexible plastic waste stream.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted. PLCs without significant ionic functionality are of low concern to the aquatic environment.

7.3. Environmental Risk Assessment

No studies of the environmental fate of the notified polymer were provided. The majority of the notified polymer will be converted to form a new polymer, although some waste from manufacture may be disposed of to landfill. The notified polymer contains potentially hydrolysable functionalities. However, significant hydrolysis is not expected under standard environmental conditions based on its expected low water solubility. The notified polymer is not expected to be readily biodegradable but due to its high molecular weight, it is not expected to bioaccumulate. In landfill, the notified polymer is expected to degrade via abiotic or biotic pathways into water and oxides of carbon.

No aquatic exposure is anticipated during end use of the notified polymer. It is expected that practically all of the waste generated from manufacture or handling release will be disposed of to landfill.

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

BIBLIOGAPHY

21CFR175.105 - Code of Federal Regulation Title 21, Volume 3 (Revised as of April 1, 2013), http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=175.105