File No: SAPLC/190

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in BURNOCK EQL-794

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 and Energy, has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

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

October 2016

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
SAPLC/190	DIC Australia Pty Ltd	Polymer in BURNOCK EQL-794	No	≤ 200 tonnes per annum	A component of printing inks

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 its assumed low hazard, low expected aquatic release and 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

- 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.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the notified polymer has changed from a component of printing inks, 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 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
DIC Australia Pty Ltd (ABN: 12 000 079 550)
323 Chisholm Road
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, and residual monomers/impurities.

2. IDENTITY OF POLYMER

Marketing Name(s)
BURNOCK EQL-794 (product containing 55 % of the notified polymer)

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	Colourless solid (solid residue remaining after evaporation of solvents).
Melting Point/Glass Transition Temp	Not determined as polymer is supplied as a dispersion in solvent
Density	1200~1400 kg/m^3 at 20°C
Water Solubility	Expected to be low based on the predominantly hydrophobic molecular structure
Dissociation Constant	Contains terminal functional groups that are expected to be ionised under environmental conditions (pH 4-9)
Particle Size	Not determined as polymer is supplied as a dispersion in solvent
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	10	100	150	175	200

Use
The notified polymer is a component of BURNOCK EQL-794 which will be used to manufacture solvent-based flexographic inks for use in the printing of flexible packaging. The imported BURNOCK EQL-794 will contain the notified polymer at a 55% concentration dispersed in ethanol, ethyl acetate & 2-propanol. The inks containing the notified polymer will be also used in Gravure press inks.

The BURNOCK EQL-794 will be imported initially in 200 litre metal drums and as the volume of importation increases 1,000 litre DG plastic tote tanks.

6. HUMAN HEALTH RISK ASSESSMENT

Occupational Health and Safety Risk Assessment

Transport and warehousing
Workers are not expected to be exposed to the imported notified polymer, as they will be handling closed containers. Exposure is possible in the event of an accident where the packaging is breached.

Ink Manufacturing Workers
The nature and demands of the printing ink manufacturing process and the application of the printed product determine the fundamental properties required of flexographic inks. Measuring the physical properties of inks and understanding how these are affected by the choice of ingredients is a large part of ink technology. Formulation of inks requires a detailed knowledge of the physical and chemical properties of the raw materials composing the inks, and how these ingredients affect or react with each other as well as with the environment. Flexographic printing inks are primarily formulated to remain compatible with the wide variety of substrates used in the process. Each formulation component individually full fills a special function and the proportion and composition will vary according to the substrate.

Flexographic printing press operators
A flexographic print is made by creating a positive mirrored master of the required image as a 3D relief in a rubber or polymer material. Flexographic plates can be created with analogy and digital platemaking processes. The image areas are raised above the none image areas on the rubber or polymer plate. The ink is transferred from the ink roll which is partially immersed in the ink tank. Then it transfers to the anilox or ceramic roll (or meter roll) whose texture holds a specific amount of ink since it is covered with thousands of small wells or cups that enable it to meter ink to the printing plate in a uniform thickness evenly and quickly (the number of cells per linear inch can vary according to the type of print job and the quality required). To avoid getting a final product with a smudgy or lumpy look, it must be ensured that the amount of ink on the printing plate is not excessive. This is achieved by using a scraper, called a doctor blade. The doctor blade removes excess ink from the anilox roller before inking the printing plate. The substrate is finally sandwiched between the plate and the impression cylinder to transfer the image. The sheet is then fed through a dryer, which allows the inks to dry before the surface is touched again.

The nature of the printing ink manufacturing process and procedures have been long standing in the industry and workers are supplied with the appropriate person protect equipment that is appropriate for their job function. Manufacture of the solvent based flexographic printing inks will be done in DIC Australia's purpose built factory that has been designed to take into account the flammable nature of the solvents used with the appropriate extraction, electrical equipment and trained workers.

The notified polymer will incorporate as the vehicle component of printing ink. Ink manufactured with the notified polymer will be filled in 18 litre metal or DG plastic pails. These containers are sealed and either stored in warehouse or transported by road to downstream users, i.e. commercial printing establishments.

Downstream users print characters and graphics images using printing machines on various kinds of film, such as polyester, polypropylene, nylon, and others. These printed materials are mainly used as flexible packaging. For example, food, snack, shopping bags, and so on. In the case of food packaging the printed image is on the outside of the packaging and does not come into direct contact with the food. In the case of food packaging the molecular weight of the notified polymer means that it is highly unlikely to cause an issue with migration into the food.

The inks with the notified polymer are run on printing machines like Flexographic and Gravure presses. During the printing process, inks are immediately dried on a substrate by using the heat drying process. Once the ink has been printed and dried, the polymer will be locked into the printed ink matrix.

The workers will wear protective equipment e.g. gloves and masks, therefore no direct exposure is expected to occur.

No toxicological data were available. The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

Although not considered in this risk assessment, the notified polymer contains residual monomers that are classified as hazardous according to the *Globally Harmonised System for the 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.

Public Health and Safety Risk Assessment

The notified polymer will not be sold to the general public. Once the notified polymer is used, it is irreversibly bound to the matrix of the substrate. As such, it is not bioavailable and cannot be released from the coated or printed media during any end uses.

As there will be no exposure of the public to the notified polymer (or products containing the notified polymer) the risk to the public from exposure to the notified polymer is considered to be negligible. Where exposure occurs, the low hazard of the polymer translates to low risk.

Public exposure to the notified chemical as a result of transportation within Australia is unlikely unless there is an accident. The material safety data sheets (SDS) supplied for the notified substance have adequate instructions for clean-up and disposal of any accidental spills and therefore public exposure as a result of a transport accident is likely to be negligible.

In the case of the notified polymer being used in flexographic printing inks that will be applied to flexible package for food the potential for migration of the notified polymer is minimal due to the high molecular weight of the polymer. However, given the assumed low hazard, the risk posed by exposure to the notified polymer is not considered unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

The notified polymer will be imported as a component of a product for reformulation into finished industrial flexographic printing inks. The finished printing inks containing the notified polymer will be applied to packaging films by a flexographic printing unit. Release of the notified polymer to the environment during import, reformulation, storage and transport is expected to be limited to accidental spills or leaks and residue in import containers. Spills or accidental release of the product containing the notified polymer are expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations. Residue in import containers is expected to be minimal. Empty import containers containing residues of the notified polymer will be disposed of through the standard recycling practices for metal and plastic containers of the printing industry.

ENVIRONMENTAL FATE

The majority of the notified polymer in flexographic printing inks will be bound within an inert ink matrix onto plastic packaging films. Once cured, the notified polymer is not expected to be mobile nor bioavailable, and is expected to share the fate of the plastic film substrates. These are expected to be disposed of to landfill at the end of their useful life. The notified polymer may also enter landfill as residues in empty import containers.

Based on the results of a biodegradability study, the notified polymer is not considered to be biodegradable. Uncured notified polymer is not expected to cross biological membranes based on its high molecular weight. Therefore, the notified polymer is unlikely to be bioaccumulative. In landfill, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted. The notified polymer contains a terminal functionality which has the potential to become cationic under environmental conditions (pH 4-9). However, the cationic charge density is > 5,000 Da. Based on its reported use pattern, significant aquatic release of the notified polymer is not expected. Therefore, the notified polymer is not expected to be toxic to aquatic organisms.

7.3. Environmental Risk Assessment

No significant release of the notified polymer to the aquatic environment is expected. Therefore, based on its assessed use pattern in flexographic printing inks for packaging films, the notified polymer is not expected to pose an unreasonable risk to the aquatic environment.