

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

POLYMER OF LOW CONCERN PUBLIC REPORT

SETALIN™ V441 E

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**

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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/1420	Lawter (N.Z.) Ltd and DIC Australia Pty Ltd	SETALIN™ V441 E	No	≤ 300 tonnes per annum	Component of lithographic printing ink

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.

- Water insoluble high molecular weight polymers used in the respirable size range ($< 10 \mu\text{m}$) have the potential to cause lung overloading. Respiratory protection and local exhaust ventilation should be used to prevent inhalation exposure if the polymer is expected to become airborne.
- A copy of the 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;
 - the notified polymer is intended to be used on food contact materials;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component of lithographic printing ink, 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.

Safety Data Sheet

The SDS of the notified polymer and products containing the notified polymer 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

Lawter (N.Z.) Ltd (ABN: 67 149 000 733)
211 Totara Street
MOUNT MAUNGANUI 3030
New Zealand

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, other names, CAS number, molecular and structural formulae, molecular weight, spectral data, polymer constituents, residual monomers/impurities, and import volume.

2. IDENTITY OF POLYMER

Marketing Name

SETALIN™ V441 E

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	Pale yellow liquid
Melting Point/Glass Transition Temp	Not determined
Density	< 1,000 kg/m ³ at 20 °C
Water Solubility	Insoluble
Dissociation Constant	pKa = 3.5–4.5 (monomer)
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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
Tonnes	200	200	200	200	300

Use

The notified polymer will be imported as a component of heat-set lithographic printing ink containing < 10% concentration of the notified polymer. The ink product will be imported to Australia in 200 kg steel drums and 1,000 kg bulk bags, and then repackaged using dedicated ink pumps into various container sizes, including bulk transport tanks. The ink product will not be reformulated in Australia.

The ink containing the notified chemical will be transferred to the printing machine with a pump and through a filter. For heat-set inks, the printed material will be placed in a heat-set oven at 120 °C to reduce its viscosity. The ink product will be used for printing magazines, newspapers, catalogues and other point of sale materials, but will not be used on food packaging. Residual ink on the printing machine and filters will be removed with organic solvents.

6. HUMAN HEALTH RISK ASSESSMENT

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

It is noted that the notified polymer is a water-insoluble polymer with certain fractions of the molecules > 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 31 May 2017). There is a data gap for polymers with MW between 10,000 and 70,000 Da, and uncertainty may exist. If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs. However, based on the proposed use scenarios, inhalation exposure to the notified polymer is not expected to be significant during normal use unless the polymer becomes airborne.

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. However, the toxicity to algae is likely to be reduced due to the presence of calcium ions in the aquatic environment, which will bind to the functional groups.

The notified polymer will be imported into Australia as a component (< 10% concentration) of heat-set lithographic printing ink in steel drums and bulk bags, which will be repackaged using dedicated ink pumps into various container sizes and distributed to commercial facilities for printing onto paper substrates. All the printing presses have automatic solvent wash-up systems for cleaning the rollers, printing blankets and plates. The solvent will then be collected for recycling. Spills or accidental leaks of the ink containing the notified polymer are expected to be collected using a suitable adsorbent and will be disposed of to landfill.

Most of the notified polymer is expected to share the fate of the paper on which it applied to, to be either disposed of to landfill or subject for paper recycling. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of inks

from the fibres. Very little of the notified polymer is expected to partition to the supernatant water, due to its low solubility in water and high molecular weight. Based on its low water solubility and high molecular weight, the notified polymer is not expected to cross biological membranes, and is therefore unlikely to bioaccumulate. In landfill, the notified polymer is expected to eventually degrade by 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.