File No: LTD/1836

October 2015

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

# PUBLIC REPORT

## Alpha-Rez 9000 E

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the 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 Department of the Environment.

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**

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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 CHEMICAL | INTRODUCTION VOLUME | USE |
|---|---|---|---|---|---|
| LTD/1836 | Lawter (N.Z.) Limited | Alpha-Rez 9000 E | ND* | ≤ 800 tonnes per annum | Component of industrial inks |

*ND = not determined

# CONCLUSIONS AND REGULATORY OBLIGATIONS

**Hazard classification**
As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

**Human health risk assessment**
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

**Environmental risk assessment**
On the basis of the reported use pattern and assumed low hazard, the notified polymer is not considered to pose an unreasonable risk to the environment.

**Recommendations**

REGULATORY CONTROLS

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymers during ink formulation and printing:
  - Enclosed, automated processes during reformulation, where possible.
  - Adequate ventilation during reformulation and printing processes.

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymers during ink formulation:
  - Avoid inhalation of dust

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymers during ink formulation and printing:
  - Dust musk to prevent inhalation of any dust particles
  - Gloves, safety glasses, overalls, and safety boots

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

- In the interest of occupational health and safety, the following precautions should be observed for use of the notified polymer as introduced in powder form:
  - The level of atmospheric nuisance dust should be maintained as low as possible. The Safe Work Australia exposure standard for atmospheric dust is 10 mg/m$^3$.

- 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 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 or accidental release of the notified polymer should be handled by containment, physical collection and subsequent safe disposal.

**Regulatory Obligations**

*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 chemical 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 chemical, 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 polymer has a number-average molecular weight of less than 1000 Da;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from component of industrial inks, or is likely to change significantly;
  - the amount of polymer being introduced has increased, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the 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 the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

# ASSESSMENT DETAILS

## 1. APPLICANT AND NOTIFICATION DETAILS

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

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 Da.

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, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details and import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

## 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Alpha-Rez 9000 E

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

## 3. COMPOSITION

DEGREE OF PURITY
> 99%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
When the notified polymer is in a liquid form, any residual monomers and additives will be available for release.

DEGRADATION PRODUCTS
None

## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: brown flakes

| Property | Value | Data Source/Justification |
|---|---|---|
| Melting Point/Freezing Point | 215-225 °C | (M)SDS |
| Boiling Point | Not determined | Decomposition is expected to occur prior to the boiling point being reached. |
| Density | > 1,000 kg/m$^3$ | (M)SDS |
| Vapour Pressure | Not determined | Expected to be low based on its high molecular weight |

| | | |
|---|---|---|
| Water Solubility | 0.001 g/L at 20 °C | Measured |
| Hydrolysis as a Function of pH | Not determined | Contains hydrolysable functionalities; however, not expected to hydrolyse due to low water solubility. |
| Partition Coefficient (n-octanol/water) | Not determined | Expected to partition from water to n-octanol based on its low water solubility. |
| Adsorption/Desorption | Not determined | Expected to adsorb to soil and sediment based on its high molecular weight, low water solubility. |
| Dissociation Constant | Not determined | No dissociable functionalities. |
| Particle Size | Not determined | Mean particle size of fines is expected to be > 10 µm |
| Flammability | Not determined | Not expected to be flammable |
| Autoignition Temperature | Not determined | Not expected to be self-igniting |
| Explosive Properties | Not explosive | Contains no explosophores that would imply explosive properties. |
| Oxidising Properties | Not oxidising | Contains no functional groups that imply oxidative properties. |

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

*Reactivity*
The notified polymer is expected to be stable under normal conditions of use.

***Physical hazard classification***
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

## 5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported in neat form (> 99% concentration) or in finished ink products at 2-15%.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

| *Year* | *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Tonnes* | 300-400 | 300-600 | 300-800 | 300-800 | 300-800 |

PORT OF ENTRY
Sydney, Melbourne, Brisbane, Freemantle

TRANSPORTATION AND PACKAGING
The notified polymer will imported in 205 L steel drums or 1,000 L big bags and transported by road in Australia. The formulated inks containing the notified polymer at up to 15% in 200 kg steel drums will be transported by road.

USE
The notified polymer (at up to 15% concentration) will be used as a component of ink for web offset heatset printing of magazines, catalogues and flyers.

OPERATION DESCRIPTION
During reformulation the imported notified polymer will be transferred by vacuum into the sealed mixing tank to be combined with other ink components and solvents. After a sample is taken through a sampling port on the mixing tank for quality assurance purposes, the ink will be pumped *via* sealed pipework to a filling machine where it will be filled into 200 kg steel drums.

At the printing facility, the ink containing the notified polymer at a concentration of up to 15% will be pumped through hoses to a central reservoir (one for each colour). The printing units will be fed with ink from this central

ink reservoir. Once printed onto the paper, the ink will be dried in a 15 m long oven at a temperature of 100 to 180°C. The printed paper will be coated with a silicone overcoat to protect the dried ink matrix.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1. Exposure Assessment

#### 6.1.1. Occupational Exposure

CATEGORY OF WORKERS

| *Category of Worker* | *Exposure Duration (hours/day)* | *Exposure Frequency (days/year)* |
|---|---|---|
| Transport and storage | 4-8 | 50 |
| Ink formulation | 8 | 50-100 |
| QA | 1 | 50-100 |
| Printing press operators | 8-12 | 260 |
| Service technicians | 2 | 25 |

EXPOSURE DETAILS

*Transport and storage*

Transport and storage workers are unlikely to be exposed to the notified polymer except in the event of an accidental breach of the packaging.

*Reformulation*

Workers may be exposed to the notified polymer at > 99% concentration during several stages of reformulation including opening containers and transferring the imported material to the mixing tank by vacuum. Exposure will be predominantly dermal but inhalation exposure to dusts is also possible. Local ventilation, automated and enclosed systems and use of PPE (overalls, gloves, safety glasses and safety boots) are expected to minimise the potential for exposure to the notified polymer during the reformulation process.

*End-use*

Workers are not expected to be exposed to the notified polymer in finished ink products, as the process will be mainly automated. However, dermal and ocular exposure to the notified polymer at up to 15% may occur during the connection of the pumping equipment to the drums and during maintenance and servicing of the machines. The use of PPE (overalls, gloves, safety glasses and safety boots) by workers is expected to minimise the potential for exposure to the notified polymer during the printing process. Inhalation exposure to aerosols of the notified polymer may also occur during the operation of the printers. However, this is expected to be minimised by the use of exhaust ventilation installed within the printing machines.

After the application of the ink the printed paper will be coated with a silicone overcoat, and hence the notified polymer will no longer be available for exposure.

#### 6.1.2. Public Exposure

The notified polymer and the end-products containing the notified polymer would be used only in industrial settings. The public may come in contact with the printed substrates (magazines, catalogues and flyers) containing the notified polymer. However, after the application of the ink the printed paper will be coated with a silicone overcoat, and hence the notified polymer will no longer be available for exposure.

### 6.2. Human Health Effects Assessment

No toxicity data were submitted.

Given the high molecular weight (> 1,000 Da.) and low water solubility of the notified polymer, absorption across biological membranes is not expected to be significant. However, the polymer contains a relatively high percentage of low molecular weight species (< 1,000 Da) that may be absorbed.

***Health hazard classification***
As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

### 6.3. Human Health Risk Characterisation

#### 6.3.1. Occupational Health and Safety
There was no information provided on the toxicity of the notified polymer. However, systemic effects are expected to be limited by the predicted low absorption across biological membranes.

Exposure of reformulation workers when using the notified polymer at > 99% and printer operators using the notified polymer at up to 15% is expected to be limited by the use of local ventilation, automated and enclosed systems and the use of PPE (overalls, gloves, safety glasses and safety boots).

Therefore, provided that the stated PPE is used and engineering controls are in place to limit exposure, the risk posed to occupational health and safety of workers is not considered to be unreasonable.

#### 6.3.2. Public Health
The notified polymer and the end-products containing the notified polymer would be used only in industrial settings. The public may come in contact with the printed substrates containing the notified polymer. However, after the application of the ink the printed paper will be coated with a silicone overcoat, and hence the notified polymer will no longer be available for exposure. Therefore, when used in the proposed manner, the risk to public health is not considered to be unreasonable.

## 7. ENVIRONMENTAL IMPLICATIONS

### 7.1. Environmental Exposure & Fate Assessment

#### 7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will be imported neat into Australia for reformulation into printing inks for web offset heatset printing onto paper substrates, or as a component of finished printing inks. During reformulation, the notified polymer will be weighed out and vacuum transferred into the blending vessel in a closed, automated system to produce finished printing inks. Finished printing inks will be automatically pumped into drums for transport to printing facilities.

Environmental release of the notified polymer during reformulation and repackaging is expected to be limited to residues in import containers (estimated by the notifier to be 0.25% of the import volume, or 2,000 kg), dust generated during transfer of printing ink ingredients (0.25%, or 2,000 kg), and accidental spills and leaks (0.25%, or 2,000 kg). Spilled material is expected to be contained and collected for disposal to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE
The notified polymer will be used as a component of web offset heatset printing inks for printing onto paper substrates. Printing will be largely enclosed and automated. Following printing, the ink containing the notified polymer will be heat-cured and sealed with a silicone overcoat; the notified polymer is expected to be stable within an inert ink matrix on printed substrates once cured and sealed.

Potential environmental release of the notified polymer during use is expected to be limited to residues in empty containers, accidental spills and leaks, and cleaning of printing equipment (estimated by the notifier to be up to 2% of the annual import volume of the notified polymer, or ≤ 16, 000 kg). Spills or leaks will be contained and collected with absorbents, and is expected to be disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL
The notified polymer will be used in printer ink for printing onto paper substrates. The majority of the notified polymer is expected to share the fate of the printed articles to which it is bound. It is assumed that 50% of the

printed paper will be disposed of to landfill, and the rest will undergo paper recycling processes. Empty containers containing residues of the notified polymer are expected to be disposed of to landfill. Hence, the majority of the notified polymer is expected to be disposed of to landfill, with a potential for some release to sewer through paper recycling processes. During paper recycling processes, waste paper is pulped using a variety of chemical treatments which, amongst other things, will enhance ink detachment from the fibres. Waste water containing the notified polymer will be released to sewer.

### 7.1.2. Environmental Fate

No environmental fate data was submitted for the notified polymer. The notified polymer in printing ink applied to paper substrates will be heat-cured and silicone sealed into an inert ink matrix, and is expected to remain adhered to the printed paper throughout its useful life and not be mobile, bioavailable or bioaccumulative in this form. The notified polymer will share the fate of the printed paper, which will involve eventual disposal to landfill. The notified polymer in solid wastes disposed of to landfill is not likely to be mobile or bioavailable due to its limited water solubility and high molecular weight.

Approximately 50% of the paper substrates to which the ink containing the notified polymer is applied are expected to be recycled. During the de-inking process, the cured ink containing the notified polymer is unlikely to be released into the supernatant waters. Based on its molecular weight and anionic properties, up to 50% of the cured ink containing the notified polymer is expected to adsorb to sludge and sediment (Boethling and Nabholz, 1997), with the sludge eventually disposed of to landfill or re-used for soil remediation.

Based on its molecular structure, the notified polymer is not expected to be biodegradable. Bioaccumulation of the notified polymer is not likely, as it is not expected to cross biological membranes due to its high molecular weight and low water solubility. The notified polymer in landfill is expected to eventually degrade by biotic and abiotic processes to form water and oxides of carbon.

### 7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with 50% of the paper products containing the notified polymer undergoing recycling, and the notified polymer to be released into sewers with 50% removal during recycling or STP processes. As the notified polymer bound to paper substrates is to be processed at paper recycling facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume.

| Predicted Environmental Concentration (PEC) for the Aquatic Compartment | | |
|---|---|---|
| Total Annual Import/Manufactured Volume | 800,000 | kg/year |
| Proportion expected to be released to sewer | 50% | |
| Annual quantity of chemical released to sewer | 400,000 | kg/year |
| Days per year where release occurs | 260 | days/year |
| Daily chemical release: | 1,538.46 | kg/day |
| Water use | 200.0 | L/person/day |
| Population of Australia (Millions) | 22.613 | million |
| Removal within STP | 50% | Mitigation |
| Daily effluent production: | 4,523 | ML |
| Dilution Factor - River | 1.0 | |
| Dilution Factor - Ocean | 10.0 | |
| PEC - River: | 170.088 | µg/L |
| PEC - Ocean: | 17.009 | µg/L |

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/$m^2$/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/$m^3$). Using these assumptions, irrigation with a concentration of 170.088 µg/L may potentially result in a soil concentration of approximately 1.134 mg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymer in the applied soil in 5 and 10 years may be approximately 5.67 mg/kg and 11.34 mg/kg, respectively.

### 7.2. Environmental Effects Assessment

No ecotoxicological data were submitted for the notified polymer. Based on its chemical structure, the notified polymer has functionality that has the potential to be anionic. Therefore, the notified polymer has potential to be toxic to aquatic life. However, no significant exposure of the notified polymer to aquatic organisms is expected based on the reported use pattern.

#### 7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) was not calculated as no ecotoxicological data were submitted.

### 7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) was not calculated as a PNEC was not available. Based on its reported use pattern, the majority of the notified polymer used in printing ink will eventually be disposed of to landfill as printed waste paper, or as sludge from STP. In landfill, the notified polymer is not expected to be mobile or bioaccumulative, based on its high molecular weight and low water solubility. Therefore, on the basis of the assessed use pattern in printing ink and assumed low hazard, the notified polymer is not expected to pose an unreasonable risk to the environment.

## APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

**Water Solubility** 0.001 g/L at 20 °C

| | |
|---|---|
| Method | OECD TG 120 Water Extractability of Polymers. |
| Remarks | Full study report not provided (read-across data only). |
| Test Facility | NedLab (2015) |

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