File No: LTD/1974

June 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in FennoSize S C180

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 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 CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1974	Kemira Australia Pty Ltd	Polymer in FennoSize S C180	ND*	≤ 700 tonnes per annum	A component in cardboard manufacturing

*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.

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 PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- 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 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 physical containment, 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 chemical/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;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a component in cardboard manufacturing 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.

Safety Data Sheet
The SDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Kemira Australia Pty Ltd (ABN: 74 007 413 185)
15 Conquest Way
HALLAM VIC 3803

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, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, manufacture/import volume, and site of manufacture/reformulation.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
FennoSize S C180 (containing notified polymer at < 30%)

MOLECULAR WEIGHT
> 10,000 Da

ANALYTICAL DATA
A reference GPC spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
< 30% (Synthesised as a component of a mixture).

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
No loss of monomers is expected to occur under normal conditions of use.

DEGRADATION PRODUCTS
No degradation, decomposition or depolymerisation of the notified polymer is expected to occur under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: off-white liquid (aqueous dispersion)*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Notified polymer will be imported in an aqueous dispersion and will not be separated from the aqueous mixture
Boiling Point	Not determined	Notified polymer will be imported in an aqueous dispersion and will not be

		separated from the aqueous mixture
Density	1,020-1,050 kg/m^3 at 20 °C	SDS*
Vapour Pressure	Not determined	Notified polymer will be imported in an aqueous dispersion and will not be separated from the aqueous mixture
Water Solubility	Not Determined	The notified polymer is expected to be miscible in water
Hydrolysis as a Function of pH	Not Determined	The notified polymer is expected to hydrolyse very slowly over the environmental pH range (4–9) at ambient temperature
Partition Coefficient (n-octanol/water)	Not Determined	The notified polymer is expected to have low partition coefficient based on its water dispersability
Adsorption/Desorption	Not Determined	The notified polymer is expected to adsorb strongly to soil, sediment and sludge based on its high molecular weight and the presence of a cationic group
Dissociation Constant	Not Determined	The notified polymer is expected to be ionised in the environmental pH range of 4–9 based on its structure
Particle Size	Not determined	Notified polymer will be imported in an aqueous dispersion and will not be separated from the aqueous mixture
Flash Point	Not determined	Notified polymer will be imported in an aqueous dispersion and will not be separated from the aqueous mixture
Flammability	Not flammable	SDS*
Autoignition Temperature	Not determined	Not expected to have autoignition properties (imported in solution)
Explosive Properties	Not explosive	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not oxidising	Contains no functional groups that would imply oxidative properties

* product containing the notified chemical at < 30%.

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 not be manufactured in Australia. It will be imported into Australia at < 30% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 500	< 600	< 700	< 700	< 700

PORT OF ENTRY
Melbourne, Sydney and Brisbane

IDENTITY OF MANUFACTURER/RECIPIENTS
Kemira Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in intermediate bulk containers (IBC), flexitanks, or isotanks and will be transported by road.

USE
The notified polymer will be used as a surface sizing agent in the cardboard manufacturing industry.

OPERATION DESCRIPTION
Batch process:
The imported product containing the notified polymer at < 30% will be measured and blended with other ingredients in a mixing tank. The mixture containing the notified polymer will be mixed using an electric mixer for 30 to 120 minutes, and then decanted into tanks or IBCs which will be delivered to the end use sites.

Inline mixing process:
The imported product containing the notified polymer at < 30% will be pumped through a pipe together with other ingredients. The ingredients including the notified polymer will be mixed using an inline mixer, to give a formulated product ready for use.

Application:
The formulated product containing the notified polymer will be pumped to the size press by pipe and mixed with the starch (at temperatures of 60 °C – 90 °C). This process will be automated with no manual handling expected. The mixture may be applied onto either one or both sides of the paper sheet. After the passing through the size press, the paper sheet will be dried through contact with heated cylinders.

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 warehouse	2-3	10-15
Formulation/blending	< 10 minutes	250

EXPOSURE DETAILS
Transport, warehouse and storage workers are not expected to be exposed to the notified polymer during importation, transport and storage of the containers containing the notified polymer (at < 30% concentration), except in the unlikely event of an accident where the packaging may be breached or a spill occurred.

Dermal and ocular exposure to the notified polymer (at concentrations of < 30%) may occur during batch processing, inline mixing operations, and various stages of the application process, and also during the routine cleaning and maintenance of equipment or cleaning up of spills or leaks. Exposure is expected to be minimised by the use of automated systems and the use of personal protective equipment (PPE) such as safety goggles, PVC or rubber gloves and protective clothing. Inhalation exposure of the workers to the notified chemical is not expected as the notified chemical (at relatively low concentration < 30%) is anticipated to have a low vapour pressure.

6.1.2. Public Exposure
The notified polymer is intended for industrial use only, and will not be sold to the public and hence direct exposure is not expected. However, members of the public may come into contact with cardboard coated with product containing the notified polymer. The notified polymer will be bound within the inert matrix of the cardboard and will not be bioavailable.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

The notified polymer has a high molecular weight (> 10,000 Da), a low percentage of low molecular weight species, and a low solubility; hence absorption across biological membranes is expected to be limited. Systemic toxicity after dermal exposure to the notified polymer is therefore expected to be low.

The notified polymer contains a functional group that has been associated with structural alert for eye and skin corrosion/irritation, however, the risk of irritation effects from exposure to the notified polymer are expected to be limited by the high molecular weight (> 10,000 Da), low percentage of low molecular weight species and low solubility.

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.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer is expected to be of low systemic toxicity; however it has the potential to be an eye and a skin corrosive/irritant due to the presence of a relevant structural alert.

Occupational exposure to the notified chemical is expected to be low due to the use of personal protective equipment (PPE) (eye protection, PVC or rubber gloves and protective clothing), the use of automated processes and the expected low vapour pressure of the polymer.

Overall, the risk to workers health from the use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health
The notified polymer will be for industrial use only and will not be made available to the general public. However, members of the public may come into contact with the dried cardboard coated with product containing the notified chemical. The notified polymer will be bound within the inert matrix of the cardboard; therefore, 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 into Australia and releases of the notified polymer to the environment are not expected from manufacture and reformulation. Accidental spills of the notified polymer during import, transport or storage are expected to be adsorbed onto a suitable material and collected for disposal in accordance with local regulations. Small amounts of the notified polymer may remain as residues in empty containers, which are expected to be disposed of in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE
The notified polymer will be used by a number of paper mills as a processing aid. The notified polymer will be utilised in a completely automated system and will be incorporated in the finished paper products. Based on the cationic nature of the notified polymer, strong binding is expected to occur between the polymer and the paper fibres. No significant release of the notified polymer is expected from the aqueous stream during paper manufacturing. Small spills and leaks may occur and these are to be collected using a suitable adsorbent for disposal to landfill. Some residual polymer may remain in the empty import containers. These will be rinsed and the reinstate will be added to the process stream.

RELEASE OF CHEMICAL FROM DISPOSAL

It is expected that up to 0.5% of the notified polymer may remain in empty import containers. Empty containers will to be taken to an approved waste handling site for recycling or disposal.

According to the recent Australian paper packaging recycling rate (APC, 2015), 76% of the cardboard to which the notified polymer is applied is expected to undergo paper recycling processes, and the remaining 24% is assumed to end up in landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted. The notified polymer is not expected to be readily biodegradable based on its structure. The notified polymer is not expected to be bioaccumulated in aquatic life given its molecular weight is greater than 10,000 Da and it contains no significant percentage of low molecular weight constituents.

Most of the notified polymer is expected to share the fate of the cardboard on which it applied to, to be either disposed of to landfill or subject for paper recycling. The notified polymer disposed of to landfill along with used cardboard is not expected to be mobile, based on its cationic properties and high molecular weight. According to Australian paper packaging recycling rate (APC, 2015), 76% of the waste cardboard treated with the notified polymer is expected to be recycled domestically. During recycling processes, waste cardboard is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks and coatings from the fibres. The notified polymer discharged to waste water from paper recycling processes is expected to be efficiently removed through adsorption of the cationic polymer to sludge or by flocculation at waste water treatment plants (Boethling and Nabholz, 1997; Guiney et al., 1997).

Sludge containing the notified polymer will be sent to landfill for disposal or agricultural land for remediation. The notified polymer will be bound to soil or sludge due to its cationic functions and is not expected to be mobile in the environment (Boethling and Nabholz, 1997). The notified polymer is expected to undergo slow degradation by biotic and abiotic processes, eventually forming water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

Based on Australian paper packaging recycling rate (APC, 2015), 76% of the waste cardboard containing the notified polymer would be recycled and be potentially released to sewers. The notified polymer is a cationic polymer with molecular weight > 1000 Da, and based on information provided by the notifier and previous study results, 95% of the notified polymer is expected to be removed by partition to sludge at sewage treatment plants (Boethling and Nabholz, 1997; Guiney et al., 1997). As paper recycling is to be processed at facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume. The resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	700,000	kg/year
Proportion expected to be released to sewer	76*	%
Annual quantity of chemical released to sewer	532,000*	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	2,046	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22,613	million
Removal within STP	95%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	22.62	µg/L
PEC - Ocean:	2.26	µg/L

*the worst case scenario

Sewage treatment plant effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 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 1,500 kg/m^3). Using these assumptions,

irrigation with a concentration of 22.62 µg/L may potentially result in a soil concentration of approximately 0.15 mg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 0.75 mg/kg and 1.51 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicological data were submitted for the notified polymer. The aquatic toxicity of the notified polymer has been estimated based on structure activity relationships (SARs) equations (Boethling and Nabholz, 1997). The charge density for the notified polymer, measured as percent amine-nitrogen, was determined to be 2.17%. Using this value, and noting that the percent amine-nitrogen is less than 3.5, the acute toxicity of the notified polymer was calculated and summarised in the table below:

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96h LC50 = 1.61 mg/L	Predicted to be toxic to fish
Daphnia Toxicity	48h LC50 = 1.77 mg/L	Predicted to be toxic to aquatic invertebrates
Algal Toxicity	96h EC50 = 0.29 mg/L	Predicted to be very toxic to algae

Based on the calculated values in the above table, the notified polymer is likely to be very toxic to aquatic life. However, surface waters tend to have higher total organic content and the toxicity of the notified polymer in the environment is expected to be mitigated by the presence of dissolved organic content. Based on the charge density of the notified polymer, a calculated mitigation factor of 27 was applied to the above calculated toxicity values and the mitigated endpoints are summarised below (Boethling and Nabholz, 1997):

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96h LC50 = 43.60 mg/L	Predicted to be harmful to fish
Daphnia Toxicity	48h LC50 = 47.96 mg/L	Predicted to be harmful to aquatic invertebrates
Algal Toxicity	96h EC50 = 7.89 mg/L	Predicted to be toxic to algae

The mitigated toxicity values indicate that the notified polymer is potentially toxic to aquatic life in environmental waters. The SAR estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the notified polymer. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified polymer to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The most sensitive endpoint from the ecotoxicity calculations on the notified polymer is for algae and this was selected for the calculation of the predicted no-effect concentration (PNEC). A more conservative assessment factor of 250 is appropriate in this case as SAR calculated acute endpoints for three trophic levels are available as a general indication of potential toxicity.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Algae)	7.89	mg/L
Assessment Factor	250	
Mitigation Factor	1.00	
PNEC:	31.56	µg/L

7.3. Environmental Risk Assessment

Based on the above predicted PEC and PNEC, the following Risk Quotient (Q = PEC/PNEC) has been calculated:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	22.62	31.56	**0.717**
Q - Ocean	2.26	31.56	**0.072**

The risk quotient for discharge of effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on its annual importation quantity. Due to cationicity and high molecular weight of the notified polymer, it is not expected to be bioaccumulative. Therefore, on the basis of the PEC/PNEC ratio, the maximum annual importation volume

and assessed use pattern as a sizing agent in cardboard manufacturing, the notified polymer is not expected to pose an unreasonable risk to the environment.

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