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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in FennoSize S C30

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/2014	Kemira Australia Pty Ltd	Polymer in FennoSize S C30	ND*	≤ 400 tonnes per annum	Component of surface sizing agent

*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.

As the notified polymer will be used on materials with direct food contact, the public report of this assessment will be forwarded to Food Standards Australia New Zealand (FSANZ) for their information.

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, noting that the formulation may be classified because of hazardous impurities or additives.

  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 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 1,000 g/mol;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of surface sizing agent, 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 g/mol

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, import volume and identity of manufacturer/recipients.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China (2015), Korea (2013)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
FennoSize S C30

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) is > 1,000 g/mol.

ANALYTICAL DATA
Reference GPC report was provided.

3. COMPOSITION

DEGREE OF PURITY
< 25% (prepared in solvent and never isolated)

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: light brown liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-3 °C	SDS*
Boiling Point	Not determined	-
Density	1,000–1,060 kg/m^3	SDS*
Vapour Pressure	2.3 kPa at 25 °C	SDS*. Based on the molecular weight the notified polymer is expected to have very low vapour pressure.
Water Solubility	Miscible	SDS of product containing <25% of notified polymer.
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional groups. However, significant hydrolysis is not expected in the environmental pH range of 4–9.
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition from *n*-octanol to water on the basis of its water miscibility.
Adsorption/Desorption	Not determined	Expected to adsorb to soil, sediment and sludge based on the presence of potential cationic functionalities.

Property	Value	Data Source/Justification
Dissociation Constant	Not determined	Contains potential cationic functionalities and is likely to be ionised in the environmental pH range (4–9).
Particle Size	~ 349 nm	Measured[#]
Flash Point	100–199 °C	SDS
Flammability	Not determined	-
Autoignition Temperature	Not determined	-
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

* Solution containing < 25% of the notified polymer
[#] Only study summary provided

DISCUSSION OF PROPERTIES
The notified polymer is manufactured with water and acetic acid used as solvent. The polymer is never isolated from the solvent and is introduced as a dispersion.

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

Physical hazard classification
Based on the limited information on physico-chemical properties listed 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 as dispersion in end use product at up to 25% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 400	< 400	< 400	< 400	< 400

PORT OF ENTRY
Brisbane, Melbourne, Sydney

TRANSPORTATION AND PACKAGING
The product containing < 25% of the notified polymer will be imported and transported by road to the site of use in bulk in intermediate bulk containers, flexitanks or isotanks.

USE
The product containing the notified polymer will be used as surface sizing agent in paper and cardboard manufacture. The cardboard will be used in packaging non-food and food items.

OPERATION DESCRIPTION
The product containing the notified polymer will be used as is or blended with aluminium sulphate using batch or in-line mixing processes. This will then be mixed with starch and applied to paper/cardboard.

Batch mixing
A measured amount of the product containing < 25% of the notified polymer will be added to an open top tank. This will be done either using a pump or by direct decanting. Aluminium sulphate will be added and mixed using an electric mixer. Once mixed, it will be transferred to intermediate bulk containers for transport to industrial customers.

Inline mixing
Upon delivery, the product containing the notified polymer (< 25% concentration) will be pumped through a pipe and a known amount of aluminium sulphate is metered into the pipe. An inline mixer will be used to ensure complete mixing.

Application
The application to paper surfaces will be automated. The product will be added to starch in the size press machine at a temperature between 60–90 °C. After mixing with starch, the mixture will be pumped into the size press which consists of two rolls through which the paper sheets move. The mixture flows on to either one or both sides of the paper sheet and coats the surface. The paper will be dried by contact with heated cylinders and then rolled up.

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	2–3	30–50
Batch processing (where applicable)	< 10 min	250

EXPOSURE DETAILS
Transport and storage workers are not expected to be exposed to the notified polymer (at a concentration of < 25%) during the importation, transport and storage, except in the unlikely event of an accident where the packaging may be breached or a spill occurs.

Dermal and ocular exposure to the notified polymer (at concentrations of < 25%) may occur during batch processing, and various stages of the application process, during the routine cleaning and maintenance of equipment and during the cleaning up of spills or leaks. Exposure is expected to be minimised through the use of enclosed, automated systems and the use of personal protective equipment (PPE) such as impervious gloves, coveralls and eye protection. Inhalation exposure of the workers to the notified polymer is not expected due to the use of enclosed system and low vapour pressure of the notified polymer.

6.1.2. Public Exposure
The notified polymer is for industrial use only. The public may come in contact with the paper/cardboard substrates coated with the product containing the notified polymer. However, once the polymer is heat cured, it will be bound within the matrix and is not expected to be bioavailable.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

The notified polymer has a high molecular weight (> 1,000 Da), low percentage of low molecular weight species, and low water solubility; hence absorption across biological membranes is expected to be limited. Therefore, systemic toxicity after dermal exposure to the notified polymer is expected to be low.

The notified polymer contains a functional group that has been associated with structural alert for eye and skin corrosion/irritation.

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

The notified polymer contains functional groups with structural alerts for irritation/corrosion. However, the effects are expected to be limited due to the high molecular weight of the notified polymer along with the very low percentage of low molecular weight species (< 1% below 1,000 g/mol).

6.3.1. Occupational Health and Safety

Reformulation and application workers may come in contact with the notified polymer at up to 25% concentration during reformulation and application process. However, minimum exposure will occur due to the process automation, enclosed system and the use of PPE such as coveralls, impervious gloves and safety glasses.

Therefore, under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health

The notified polymer is for industrial use only. The general public may come in contact with the articles coated with the notified polymer. However, by this time the notified polymer will be cured in the matrix and is not expected to be bioavailable.

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

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 as dispersion in end use product at up to 25% concentration. 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 government regulations.

RELEASE OF CHEMICAL FROM USE

At the industrial customers' site, the formulated product containing the notified polymer will be transported to the size press by pipe and added to the starch. This process will be automated with no manual handling required and therefore, no significant release of the notified polymer is expected during this process.

Residual dispersion containing notified polymer in containers, on equipment is estimated to account for less than 0.5% of the total usage.

RELEASE OF CHEMICAL FROM DISPOSAL

The notifier estimates up to 0.5% of the annual import volume of the notified polymer may remain as residues in empty containers. The empty containers will be taken to approved waste handling sites for recycling or disposal.

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified polymer. Most of the notified polymer is expected to share the fate of the paper and cardboard to which it is applied, to be either disposed of to landfill or enter paper recycling. The notified polymer disposed of to landfill along with used paper and cardboard is not expected to be mobile based on its potential cationic properties and high molecular weight. According to the recent Australian National Waste Report (DoEE and Blue Environment Ltd., 2016), 60% of the waste paper and cardboard treated with the notified polymer is expected to be recycled domestically with the remaining 40% expected to end up in landfill. During recycling processes, waste paper and 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 wastewater from paper recycling processes is expected to be effectively removed through adsorption to sludge or by flocculation at wastewater 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 potential cationic functions and is not expected to

be mobile in the environment (Boethling and Nabholz, 1997). The notified polymer is not expected to be bioaccumulated in aquatic life given its high molecular weight and it contains no significant percentage of low molecular weight constituents. The notified polymer is expected to undergo degradation by biotic and abiotic processes, eventually forming water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer is a potential cationic polymer with molecular weight greater than 1,000 g/mol. Based on Boethling et al. (1997) and Guiney et al. (1997), 95% of the notified polymer is expected to be removed by partition to sludge at wastewater treatment plants. As paper recycling is to be processed at facilities located throughout Australia, it is anticipated that such releases will occur nationwide over 260 working days per annum. 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	400,000	kg/year
Proportion expected to be released to sewer	60%	
Annual quantity of chemical released to sewer	240,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	923	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	95%	
Daily effluent production:	4,877	ML
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC - River:	9.46	µg/L
PEC - Ocean:	0.95	µg/L

STP 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 chemical 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 9.46 µg/L may potentially result in a soil concentration of approximately 63 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of the notified chemical in the applied soil in 5 and 10 years may be approximately 315 µg/kg and 630 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicological data were submitted by the notifier. The aquatic toxicity of the notified polymer has been estimated based on structure activity relationships (SARs) equations for polycationics (Boethling and Nabholz, 1997), and summarised in the table below.

Endpoint	*Result*	*Comment*
Acute Fish Toxicity	96 h EC50 = 42.47 mg/L	Predicted to be harmful to fish
Acute Daphnia Toxicity	48 h EC50 = 42.39 mg/L	Predicted to be harmful to aquatic invertebrates
Acute Algal Toxicity	72 h EC50 = 7.18 mg/L	Predicted to be toxic to alga
Chronic Fish Toxicity	ChV = 2.36 mg/L	Predicted to not cause long lasting harmful effects to fish
Chronic Daphnia Toxicity	ChV = 2.36 mg/L	Predicted to not cause long lasting harmful effects to aquatic invertebrates
Chronic Algal Toxicity	ChV = 1.89 mg/L	Predicted to not cause long lasting harmful effects to alga

The estimated toxicity values indicate that the notified polymer potentially causes acute toxicity to aquatic organisms in environmental waters, but it is predicted to not cause long lasting harmful effects to aquatic life. The SAR estimation 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 above ecotoxicity estimation on the notified polymer is 72h EC50 for alga, and this was selected for the calculation of the predicted no-effect concentration (PNEC). An assessment factor of 500 was used in this case given SAR calculated acute and chronic endpoints for three trophic levels are available as a general indication of potential toxicity.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Alga 72 h EC 50	7.18	mg/L
Assessment Factor	500	
Mitigation Factor	1.00	
PNEC:	14.36	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	9.46	14.36	**0.66**
Q - Ocean	0.95	14.36	**0.07**

The conservative 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. The notified polymer is not expected to be bioaccumulative based on its high molecular weight. Therefore, on the basis of the predicted PEC/PNEC ratio, the maximum annual importation volume, and the assessed use pattern as a surface sizing agent in paper and cardboard manufacture, the notified polymer is not expected to pose an unreasonable risk to the aquatic environment.

BIBLIOGRAPHY

Boethling, RS & Nabholz VJ (1997) Chapter 10 Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton, JD Sutcliffe R ed. Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, 1st ed. New York, Van Nostrand Reinhold, pp 187-234.

Department of the Environment and Energy (DoEE) and Blue Environment Pty Ltd (2016) Australian National Waste Report 2016. Canberra, Australia.

Guiney PD, McLaughlin JE, Hamilton JD & Reinert KH (1997) Chapter 8 Dispersion Polymer In: Hamilton, JD Sutcliffe R ed. Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, 1st ed. New York, Van Nostrand Reinhold, pp 147-165.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >