File No: LTD/1935

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in FennoSize S C28

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/1935	Kemira Australia Pty Ltd	Polymer in FennoSize S C28	ND*	< 800 tonnes per annum	A surface sizing agent 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, 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 PEC/PNEC ratio and the assessed 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 (M)SDS should be easily accessible to employees.

- If products and mixtures containing the 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, 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;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a surface sizing agent 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.

(Material) Safety Data Sheet
The (M)SDS of the product containing the notified chemical 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)
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 C28 (containing notified polymer at < 30%)

MOLECULAR WEIGHT
> 10,000 Da

ANALYTICAL DATA
Reference SEC spectra 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 25 °C AND 101.3 kPa: Light brown liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-3 °C	(M)SDS*
Boiling Point	100 °C at 101.3 kPa	(M)SDS*
Density	1,000 – 1,060 kg/m^3	(M)SDS*
Vapour Pressure	2.3 kPa at 25 °C	(M)SDS*, for the product, based on the molecular weight the notified chemical

		would be expected to have negligible vapour pressure.
Water Solubility	Miscible	(M)SDS
Hydrolysis as a Function of pH	Not Determined	Significant hydrolysis is not expected at the environmental pH range of 4-9 based on its structure
Partition Coefficient (n-octanol/water)	Not Determined	Expected to partition to the interface between octanol and water based on its amphiphilic structure.
Adsorption/Desorption	Not Determined	The notified polymer is expected to adsorb strongly onto soil sediment from water based on the presence of a cationic group and potential surface activity.
Dissociation Constant	Not Determined	The notified polymer is a salt is expected to be ionised in the environment
Particle Size	Not determined	The notified polymer will be only imported in miscible solution
Flash Point	< 100 °C	(M)SDS*, due to other components of product rather than the notified polymer.
Flammability	Not flammable	(M)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 in intermediate bulk containers (IBC), flexitanks, or isotanks.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 300	< 500	< 600	< 700	< 800

PORT OF ENTRY
Melbourne, Sydney, and Brisbane

IDENTITY OF MANUFACTURER/RECIPIENTS
Kemira Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The imported product containing the notified polymer will be transported by road to the notifier warehouses and stored in IBCs, flexitanks or isotanks for reformulation and repackaging.

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 inline using an inline mixer, to give a formulated product ready for use.

Application:
The formulated product containing the notified polymer will be transported to the size press by pipe and added to the starch (at temperature of 60 ºC – 90 ºC). This process will be automated with no manual handling required. The mixture will be flowing into and coating either on one side or on both sides of the paper sheet. After the size press, the paper sheet will be dried by contact with heated cylinders and then rolled up into a large roll of paper.

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 and warehouse/storage workers are not expected to be exposed to the notified polymer (at a concentration of < 30%) 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 < 30%) 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 automated systems and the use of personal protective equipment (PPE) such as eye protection, 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 expected to have a low vapour pressure.

6.1.2. Public Exposure
The notified polymer will be 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.

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
The notified polymer has the potential to be an eye and a skin corrosion/irritation due to the presence of a relevant structural alert. However, the risk of irritation effects from exposure to the notified polymer may be limited by the high molecular weight (> 10,000 Da), low percentage of low molecular weight species and low solubility.

Occupational exposure to the notified chemical is expected to be minimal due to the use of PPE (eye protection, PVC or rubber gloves and protective clothing) and automated process.

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

6.3.2. Public Health
The product containing the notified chemical will not be made available to the general public. However, 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 as dispersion for use as a surface sizing agent in paper and cardboard manufacturing. No significant release of the notified polymer to the environment is expected from transport and storage processes. In the case of accidental spillage, spills containing the notified polymer are expected to be physically contained, absorbed on inert material and be disposed of to landfill or be discharged in accordance with local 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 waste dispersion containing notified polymer is expected to be flushed down into the PM sump and recycled into the water loop. It is expected that up to 0.5% of the dispersion containing notified polymer may remain in packaging as residues. Empty containers are to be taken to an approved waste handling site for recycling or disposal.

It is assumed that 50% of the cardboard to which the notified polymer is applied will end up in landfill and the remainder will undergo paper recycling processes.

7.1.2. Environmental Fate
No environmental fate data were submitted. The notified polymer is not expected to be readily biodegradable given it is a highly-crossed acrylate polymer without any readily biodegradable functionalities. The notified polymer has a molecular weight > 1000 Da and does not contain significant amount of low molecular weight constituents. The notified polymer is not expected to be bioaccumulative due to high molecular weight.

It is assumed that 50% of the waste cardboard treated with the notified polymer will 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 is expected to be efficiently removed in waste water treatment plants through adsorption of the cationic polymer to sludge or by flocculation (Boethling and Nabholz, 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)

It is assumed that that 50% of the cardboard containing the notified polymer would be recycled and be released to sewers. The notified polymer is a cationic polymer with molecular weight > 1000 Da and 90% of the notified polymer is expected to be removed by partition to sludge at the sewage treatment plants (Boethling and Nabholz, 1997). 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	800,000	kg/year
Proportion expected to be released to sewer	50 %	
Annual quantity of polymer released to sewer	400,000	kg/year
Days per year where release occurs	260	days/year
Daily polymer release:	1538.46	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	**Mitigation**
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	< 34.02	µg/L
PEC - Ocean:	< 3.40	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 34.018 µg/L may potentially result in a soil concentration of approximately 0.2268 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 1.134 mg/kg and 2.268 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 1.94%. 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	96 LC50 = 2.04 mg/L	Predicted to be toxic to fish
Daphnia Toxicity	48 LC50 = 3.29 mg/L	Predicted to be toxic to aquatic invertebrates
Algal Toxicity	72 h EC50 = 0.48 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 23 was applied to the above calculated toxicity values and the mitigated endpoints are summarised as under (Boethling and Nabholz, 1997):

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 LC50 = 46.92 mg/L	Predicted to be harmful to fish
Daphnia Toxicity	48 LC50 = 75.67 mg/L	Predicted to be harmful to aquatic invertebrates
Algal Toxicity	72 h EC50 = 11.04 mg/L	Predicted to harmful to algae

The mitigated toxicity values indicate that the notified polymer is harmful to aquatic life in environmental waters. The QSAR 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 although acute endpoints for three trophic levels are available as a general indication of potential toxicity, these endpoints are predicted by SARs calculations

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Algae)	11.04	mg/L
Assessment Factor	250	
PNEC:	44.16	µg/L

7.3. Environmental Risk Assessment

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

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	< 34.02	44.16	**< 0.77**
Q - Ocean	< 3.40	44.16	**< 0.077**

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 higher 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 paper and cardboard manufacturing, the notified polymer is not expected to pose an unreasonable risk to the environment.

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