File No: LTD/1814

April 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Eka SP CE 28

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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

SUMMARY 3
CONCLUSIONS AND REGULATORY OBLIGATIONS 3
ASSESSMENT DETAILS 5
1. APPLICANT AND NOTIFICATION DETAILS 5
2. IDENTITY OF CHEMICAL 5
3. COMPOSITION 5
4. PHYSICAL AND CHEMICAL PROPERTIES 5
5. INTRODUCTION AND USE INFORMATION 6
6. HUMAN HEALTH IMPLICATIONS 7
6.1. Exposure Assessment 7
6.1.1. Occupational Exposure 7
6.1.2. Public Exposure 7
6.2. Human Health Effects Assessment 7
6.3. Human Health Risk Characterisation 8
6.3.1. Occupational Health and Safety 8
6.3.2. Public Health 8
7. ENVIRONMENTAL IMPLICATIONS 8
7.1. Environmental Exposure & Fate Assessment 8
7.1.1. Environmental Exposure 8
7.1.2. Environmental Fate 9
7.1.3. Predicted Environmental Concentration (PEC) 9
7.2. Environmental Effects Assessment 9
7.2.1. Predicted No-Effect Concentration 10
7.3. Environmental Risk Assessment 10
BIBLIOGRAPHY 11

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/1814	Akzo Nobel Pulp and Performance Chemicals (Australia) Pty Ltd	Polymer in Eka SP CE 28	ND*	< 500 tonnes per annum	Additive in paper and 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 for the 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 chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

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 polymer:
  - Closed and automated processes where possible

- 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 polymer as introduced and during paper/cardboard manufacturing:
  - Avoid skin and eye contact
  - Avoid generation of aerosols

- 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 polymer as introduced and during paper/cardboard manufacturing:
  - Impervious gloves
  - Coveralls
  - Eye protection such as safety glasses or goggles

  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 notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the 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 chemical 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 chemical 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(2) of the Act; if
  - the function or use of the polymer has changed from additive in paper and 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.

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet
The (M)SDS of the product containing 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)
Akzo Nobel Pulp and Performance Chemicals (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, CAS number, molecular and structural formulae, molecular weight, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, site of reformulation/production 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)
Eka SP CE 28 (product containing the notified polymer at < 40%)

MOLECULAR WEIGHT
> 10,000 Da

ANALYTICAL DATA
Reference NMR and GPC were provided.

3. COMPOSITION

DEGREE OF PURITY
> 50%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: light brown dispersion with pungent odour

Property	Value	Data Source/Justification
Melting Point	-3°C	(M)SDS*
Boiling Point	100°C	(M)SDS*
Density	1027 kg/m^3	(M)SDS*
Vapour Pressure	2.3 kPa at 25 °C	(M)SDS*
Water Solubility	Expected to be dispersible	The notified polymer contains both hydrophilic and hydrophobic groups, and may have surfactant properties.
Hydrolysis as a Function of pH	Not Determined	The notified polymer contains hydrolysable functionality, but hydrolysis is not expected to occur within the environmental pH range of 4-9.
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, given the presence of a cationic group.
Dissociation Constant	Not Determined	The notified polymer is expected to be ionised in the environment due to the presence of ionic moieties.
Particle Size	Not determined	Imported in liquid product
Flash Point	100-199°C	(M)SDS*
Flammability	Not expected to be flammable	(M)SDS*
Autoignition Temperature	Not determined	Not expected to autoignite
Explosive Properties	Predicted negative	Contains no functional groups that would infer explosive properties
Oxidising Properties	Predicted negative	Contains no functional groups that would infer oxidising properties
Viscosity	< 50 mPa.s at 20°C	(M)SDS*

*For Eka SP CE 28 (product containing the notified polymer at < 40%)

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer as a component in the formulated product 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 for the 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 at < 40% as an aqueous solution.

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

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

PORT OF ENTRY

Melbourne, Sydney, Brisbane

IDENTITY OF RECIPIENTS

Akzo Nobel Pulp and Performance Chemicals (Australia) Pty Ltd

TRANSPORTATION AND PACKAGING

The product containing the notified polymer will be imported, transported and stored in IBCs (intermediate bulk containers).

USE

The notified polymer will be used as a surface sizing agent in paper and cardboard manufacturing.

OPERATION DESCRIPTION

The notified polymer will be imported in dispersion at < 40% concentration (in water). The dispersion will either be transported to the cardboard or paper manufacturing site (end-use site), or will be blended with metal salt in an open tank using an electric mixer at the notifier's production site. In the latter scenario, the imported dispersion will be decanted into the mixing tank either by gravity flow or pump. The resulting blended product will be decanted into a closed tank or IBC before delivery to the end-use site. Addition to the tank will take place either manually or using a pump.

At the end-use site, the dispersion will be mixed with metal salt using an inline mixer. The mixture will be pumped into the size press along with starch at <100ºC using an automated system. At this stage the solution containing the notified polymer (at < 5% concentration), starch and other additives will flow onto paper or cardboard sheet as a coating. It will then be dried, sized and spooled onto rollers to produce finished paper or cardboard product containing the notified polymer at < 5% concentration.

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	2-3	10-15
Reformulation	2-3	100
Quality control	1	100
Cleaning and maintenance	1	100

EXPOSURE DETAILS

Transport and Storage

Waterside, storage and transport workers may come into contact with the product containing the notified polymer, only in the unlikely event of an accident.

Reformulation and end-use

At reformulation and end-use sites, workers may have dermal and/or ocular exposure to the notified polymer (at < 40% concentration) from spills and drips during connection and disconnection of hoses from the import containers to the formulation tank or paper manufacturing system, and during quality control analysis. Inhalation exposure is not expected as the notifier stated that the aerosols are unlikely to be generated during processing, and the polymer is not expected to vaporise.

Once the mixture containing the notified polymer at < 5% is fed into the paper/cardboard manufacturing system, worker exposure is expected to be limited as the system will be closed and operators are not required to be in the area. Dermal exposure may occur during the maintenance and cleaning of the paper making machines. Exposure is expected to be minimised by the use of PPE such as gloves and goggles.

Users of paper/cardboard

Users of the dried and set paper or cardboard, such as office or warehouse workers, are expected to experience very low exposure, as the notified polymer will be incorporated into the size coating matrix, and is not expected to be bioavailable.

6.1.2. Public Exposure

The paper and cardboard may be widely used by the public. However, the exposure of the public is likely to be very low because the notified polymer will be incorporated within the size coating matrix and is not expected to be bioavailable.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer. It contains functional groups of concern that may be associated with irritation/corrosion and skin sensitisation. The potential for irritation is likely to be reduced by the high molecular weight (>10,000 Da).

Dermal absorption is likely to be limited by the high molecular weight (>10,000 Da) and the low levels of low molecular weight species, however it is noted that the polymer may be surface active. If so, this may enhance the potential for dermal absorption of the polymer itself and other substances.

Health hazard classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the 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

Based on the structure of the notified polymer, it may have irritation and sensitisation potential. At various stages of the processing of the polymer into cardboard or paper, there is potential for exposure of workers to the notified polymer at up to 40%. These include transfer processes, quality control analysis and cleaning and maintenance tasks. The notifier has stated that worker exposure is expected to be minimised through the use of personal protective equipment (PPE; e.g. gloves, goggles and protective clothing) and, at later stages of the process, the use of enclosed, automated processes. Safe work practices would further reduce the potential worker exposure.

Users of the finished paper and cardboard are expected to experience very low exposure to the notified polymer, as it will be incorporated into the size coating matrix and is not expected to be bioavailable.

Based on the described use scenario and proposed controls, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The public may have contact with finished paper or cardboard, in which the polymer is incorporated into the size coating matrix and is not expected to be bioavailable. Therefore based on very low exposure, the risk to the public from the proposed use of the notified polymer 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 a dispersion for use as a surface sizing agent in paper and cardboard manufacturing. The dispersion containing notified polymer will be used as is or blended with a metal salt. At the cardboard manufacturing site the concentration of the notified polymer in the size press solution is <5%. No significant release of the notified polymer to the environment is expected from transport and storage processes. In the case of an accidental spill, the notified polymer is expected to be physically contained, absorbed on inert material or flushed down into the paper machine (PM) sump and recycled into the water loop. The PM sump is a drain or linked drains, usually located in the basement of a paper-machine, that is expected to terminate in an on-site controlled waste/effluent treatment facility.

RELEASE OF CHEMICAL FROM USE

At the industrial customer's site, the dispersion containing the notified polymer will be pumped into a storage tank. The amount of waste dispersion containing the notified polymer is expected to be small, with possible release postulated to occur when connecting the IBC to the pump or during decanting. The dispersion containing the notified polymer is fully miscible with water and any drips will be flushed down into the PM sump and recycled into the water loop. Residual dispersion containing notified polymer in containers or 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 30% 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. Since the notified polymer has a molecular weight much greater than 1000 Da. and no significant percentage of low molecular weight constituents, it is not expected to be able to cross biological membranes and therefore is not expected to bioaccumulate.

It is assumed that 70% 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 would be 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). The notified polymer is therefore expected to be concentrated in the sludge fraction of on-site or municipal waste water treatment plants. Sludge generated during the washing process will be sent to landfill for disposal or agricultural land for remediation. The notified polymer will be bound to soil and 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)

A preliminary calculation of the PEC was carried out assuming that 70% of the cardboard containing the notified polymer would be recycled and released to sewers with no mitigation. The calculation indicated that the PEC exceeded the PNEC (Predicted No Effect Concentration), hence a more realistic exposure scenario was calculated such that 90% of the notified polymer was assumed to partition to sludge in STPs due to its net positive charge (Boethling and Nabholz, 1997). The results of the calculation with the mitigation included are shown in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	500,000	kg/year
Proportion expected to be released to sewer	70%	
Annual quantity of chemical released to sewer	350,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1346.15	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	
Dilution Factor - Ocean	10	
PEC - River:	29.77	µg/L
PEC - Ocean:	2.98	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 chemical 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 29.77 µg/L may potentially result in a soil concentration of approximately 0.198 mg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 0.992 mg/kg and 1.984 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicological data were submitted for the notified polymer. The cationicity of the notified polymer may contribute ecotoxicity to aquatic life. Therefore, the ecotoxicological endpoints for the notified polymer were calculated based on Structure Activity Relationships (SARs) equations for estimating the toxicity of polycationic polymers (Boethling and Nabholz, 1997). The endpoints are summarised in the table below. As a worst case scenario, the toxicity values predicted by SARs have not been modified by mitigation factors to reflect the actual toxicity in the natural aquatic environments, to account for the anticipated binding of the polymer with organic carbon in surface waters.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) = 12.21 mg/L	Predicted to be harmful to fish
Daphnia Toxicity	EC50 (48 h) = 333.40 mg/L	Predicted to be not harmful to aquatic invertebrates
Algal Toxicity	EC50 (96 h) = 20.52 mg/L	Predicted to be harmful to algae

The notified polymer is expected to be harmful to fish and algae and not harmful to aquatic invertebrates in environmental waters with typical levels of total organic carbon. 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 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 fish and this was selected for the calculation of the predicted no-effect concentration (PNEC) below. 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		
LC50 (Fish).	12.21	mg/L
Assessment Factor	250	
PNEC:	48.84	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:	29.77	48.84	0.609
Q - Ocean:	2.98	48.84	0.061

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.

BIBLIOGRAPHY

Boethling, RS & Nabholz VJ (1997) 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.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

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 >.