File No: LTD/1653

March 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer PE-PC

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

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:

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Director
NICNAS

TABLE OF CONTENTS

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/1653	Kao Australia Pty Ltd	Polymer PE-PC	ND*	< 10 tonnes per annum	A component of hair styling products

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is not recommended for classification 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
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 chemical itself. However, these should be selected on the basis of all ingredients in the formulation.
- 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

- The notified polymer should be disposed of to landfill.

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 1000;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from use as a component of leave-on hair styling products at < 10% concentration, or is likely to change significantly;
- the amount of polymer being introduced has increased from 10 tonnes per annum, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

(Material) Safety Data Sheet
The (M)SDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Kao Australia Pty Ltd (ABN: 59 054 708 299)
1A The Crescent
KINGSGROVE NSW 2208

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 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, polymer constituents, residual monomers, impurities, additives/adjuvants, 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)
Polymer PE-PC

MOLECULAR WEIGHT

NAMW > 10,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear, brown viscous liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Liquid at ambient temperature
Boiling Point	Not determined	Expected to undergo decomposition prior to boiling
Density	810 kg/m^3 at 25 °C	SDS. For notified polymer at < 10% concentration in ethanol
Vapour Pressure	Not determined	Expected to be low, based on the high molecular weight of the polymer
Water Solubility	Not determined	Expected to be dispersible in water to concentrations > 30% w/w.
Hydrolysis as a Function of pH	Not determined	Contains functionality with the potential to hydrolyse under environmental conditions (pH 4-9)
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to the interface between octanol and water, based on its surfactant properties
Adsorption/Desorption	Not determined	Expected to partition to phase boundaries, based on its surfactant properties
Dissociation Constant	Not determined	Does not contain dissociable functionality
Particle Size	Not determined	The notified polymer is supplied in liquid formulation
Flash Point	Not determined	Polymer with NAMW > 1000 Da
Flammability	Not determined	Not expected to be flammable
Autoignition Temperature	Not determined	Not expected to autoignite
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties

DISCUSSION OF PROPERTIES

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 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 as a solution in ethanol at < 10% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 10	< 10	< 10	< 10	< 10

PORT OF ENTRY
Sydney and Melbourne

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 250 mL plastic containers (packed in cardboard outer boxes) suitable for the packaging of Dangerous Goods Class 3 flammable and will be transported according to the requirements of the Dangerous Goods Code and Regulations.

USE
The notified polymer will be used as a component of leave-on hair styling products at < 10% concentration.

OPERATION DESCRIPTION
The notified polymer will be imported as a component of finished hair styling products at < 10% concentration. The finished product may be used in professional salons and will also be made available to consumers for home use. The finished products will be applied by spray or as an aerosol mousse.

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 warehousing	1-2	24
Retail	8	200
Salon	8	200

EXPOSURE DETAILS
Transport, storage and retail workers may come into contact with the notified polymer at < 10% concentration only in the event of an accidental rupture of containers of the hair styling products.

Professional salon workers may be exposed to the notified polymer via inhalation, dermal and ocular routes when applying the finished hairstyling products containing the notified polymer at < 10% concentration to clients. Salon workers may use some PPE to minimise exposure, and good hygiene practices are expected to be in place. If PPE is not used, exposure of salon workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified polymer.

6.1.2. Public Exposure
There will be widespread and repeated exposure of the public to the notified polymer (at < 10% concentration) through the use of the hair styling products. The principal routes of exposure will be via inhalation, dermal and ocular routes.

6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix A.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics
No toxicokinetic data on the notified polymer were submitted. The notified polymer is of high molecular weight

(> 10,000 Da) and contains a low percentage of low molecular weight species (i.e. < 1% < 1000 Da) hence absorption across biological membranes is not expected. This is supported by the lack of systemic toxicity observed in the acute oral toxicity study.

Acute toxicity.
The notified polymer was found to be of low acute oral toxicity in rats (LD50 > 2,000 mg/kg bw). No acute dermal and inhalation toxicity studies were submitted for the notified polymer. Based on the result of the acute oral toxicity study and high molecular weight, the notified polymer is also expected to be of low acute dermal and inhalation toxicity.

Irritation and sensitisation.
The notified polymer is of high molecular weight and does not contain any structural alerts for irritation and sensitisation; hence the notified polymer is not expected to be irritating or sensitising. This is supported in a guinea pig maximisation test that showed the notified polymer to be not a skin sensitiser at a challenge concentration of 10%.

Mutagenicity/Genotoxicity.
The notified polymer was not mutagenic in a bacterial reverse mutation study using two strains of bacteria (TA 98 and TA 100).

Health hazard classification
Based on the available information, the notified polymer is not recommended for classification 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
Salon workers may be exposed to the notified polymer when applying hairstyling products containing the notified polymer at < 10% concentration. The risk to these workers is expected to be of a similar or lesser extent than that experienced by consumers using hairstyling products containing the notified polymer (for details of the public health risk assessment, see Section 6.3.2.).

6.3.2. Public Health
Toxicological studies have been provided for the notified polymer that show that it is of low acute oral toxicity, not a skin sensitiser and not mutagenic in a bacterial reverse mutation assay. No repeat dose toxicity studies have been provided, however, based on the high molecular weight and low percentage of low molecular species absorption across biological membranes is not expected. Furthermore, similar polymers currently used in cosmetic applications are noted for their low toxicity (Fruijtier-Pölloth, 2005).

The hairstyling products will be applied by spray hence inhalation exposure is expected. Absorption across the lungs is not expected to occur and given the relatively high water solubility the notified polymer is expected to be rapidly cleared from the lungs via the mucociliary mechanism if inhaled.

Therefore, the risk associated with the use of the notified polymer at up to 10% concentration in hairstyling products is not considered 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 component of finished hair styling products. The notified polymer will not be manufactured or reformulated in Australia; therefore no release is expected from these activities. Accidental spills during transport are expected to be collected with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified polymer is a component in hair styling products. Therefore, it is expected that the majority of the imported quantity of notified polymer will eventually be washed off the hair and be released to sewer.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues of the notified polymer in the empty end-use containers are expected to account for up to 1% of the total import volume of the notified polymer. These residues are expected to either share the fate of the container and be disposed of to landfill, or to be washed to sewer when containers are rinsed before recycling

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified polymer. The majority of the notified polymer is expected to be released to sewer during use in hair styling products. During waste water treatment processes in sewage treatment plants (STPs), a proportion of the notified polymer is expected to be removed from waste waters due to its likelihood to partition to phase boundaries. The notified polymer that partitions to sludge will be removed with the sludge for disposal to landfill or used on land for soil remediation. The notified polymer that is released to surface waters is expected to partition to suspended solids and organic matter and disperse. Based on its surface activity and water dispersibility, the notified polymer is not expected to bioaccumulate. Block copolymers, such as the notified polymer, are not expected to be readily biodegradable and whilst primary biodegradability is possible, it may also be limited. Degradation is expected to be slow due to its high molecular weight and degradation is likely to proceed by sequential cleavage of the terminal groups (Madsen *et al*. 2001). As sequential cleavage of the terminal groups is expected, the degradation products of the notified polymer are likely to be structurally similar to the parent polymer, just with fewer repeating units and lower molecular weight. Therefore, degradation products are expected to have a similar environmental fate to the parent polymer. Ultimately, the notified polymer is expected to degrade via biotic and abiotic processes in soil and surface waters to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the predicted environmental concentration (PEC) is summarised in the table below. Based on the reported use in hair styling products, it is assumed that 100% of the notified polymer will be released to sewer on a nationwide basis over 365 days per year. It is also assumed under a worst-case scenario that there is no removal of the notified polymer during STP processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.40	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	6.06	µg/L
PEC - Ocean:	0.606	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 6.06 µg/L may potentially result in a soil concentration of approximately 40.4 µg/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 202 µg/kg and 404 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymer. Block copolymers, such as the notified polymer and potential degradation products, are reported to be some of the least toxic types of non-ionic surfactants (Madsen *et al.* 2001). Toxicity to fish and aquatic invertebrates is reported to have median effect concentrations (EC50) values greater than 100 mg/L. Even considering the expected lack of ready biodegradability, block copolymers are not expected to be harmful to aquatic life. Therefore, the notified polymer is not expected to be harmful to aquatic life and is not formally classified under the Globally Harmonised System of Classification of Chemicals (GHS; United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The predicted no-effect co concentration (PNEC) was calculated using the lowest available value for toxicity to aquatic organisms, that is, EC50 > 100 mg/L. An assessment factor of 1000 was used as no measured toxicity data for the notified polymer is available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50	> 100	mg/L
Assessment Factor	1000	
PNEC:	> 100	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	6.06	> 100	< 0.061
- Ocean	0.606	> 100	< 0.0061

The Risk Quotients (Q = PEC/PNEC) for a conservative discharge scenario have been calculated to be < 1 for the river and ocean compartments. The notified polymer is not expected to be rapidly biodegradable in the environment however it is not expected to bioaccumulate based on its potential to partition to phase boundaries. The notified polymer has the potential to degrade; however the degradation products are likely to be structurally similar to the notified polymer. Therefore, the notified polymer and its degradation products are not expected to pose an unreasonable risk to the environment based on the assessed use pattern.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/SD [Crl: CD (SD)], SPF
Vehicle	Purified water
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
Remarks - Results	None
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	Saitama Laboratories (2009)

A.2. Skin sensitisation

TEST SUBSTANCE	Notified polymer
METHOD	Similar to OECD TG 406 Skin Sensitisation – Guinea Pig Maximisation Test.
Species/Strain	Guinea pig/Hartley (Std: Hartley), clean
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 0.3% topical: > 10%
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 1% topical: 10%
Signs of Irritation	Signs of irritation during induction were not reported. A 10% mixture of sodium dodecyl sulfate in vaseline was applied to the intradermal injection site on Day 7.
CHALLENGE PHASE	
1st challenge	topical: 0.5 - 10%
Remarks - Method	The notified polymer was supplied as a 10% solution in ethanol. This solution was diluted with distilled water to give the desired test concentrations of the notified polymer.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	0%*	0/10	0/10	-	-
	0.5%	0/10	0/10	-	-
	1%	0/10	0/10	-	-

	3%	0/10	0/10	-	-
	5%	0/10	0/10	-	-
	10%	0/10	0/10	-	-
Control Group	0%*	0/5	0/5	-	-
	0.5%	0/5	0/5	-	-
	1%	0/5	0/5	-	-
	3%	0/5	0/5	-	-
	5%	0/5	0/5	-	-
	10%	0/5	0/5	-	-

* 90% ethanol in water

Remarks - Results: There were no signs of irritation at any test concentration during challenge.

CONCLUSION: There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

TEST FACILITY: Saitama Laboratories (2010)

A.3. Genotoxicity – bacteria

TEST SUBSTANCE: Notified polymer

METHOD: Similar to OECD TG 471 Bacterial Reverse Mutation Test - Pre incubation procedure

Species/Strain: *S. typhimurium*: TA98, TA100

Metabolic Activation System: S9 fraction from phenobarbital/5,6-benzoflavone induced rat liver

Concentration Range in Main Test: a) With metabolic activation: 313 – 5000 µg/plate; b) Without metabolic activation: 313 – 5000 µg/plate

Vehicle: Water

Remarks – Method: No significant deviation was made from the standard protocol except:

- only two strains of bacteria (TA98 and TA100) were used rather than 5 strains as recommended in the OECD guidance; and
- the tests were performed in duplicate rather than triplicate.

2-(2-Furyl)-3-(5-nitro-2-furyl)acrylamide (without metabolic activation) and benzo[a]pyrene (with metabolic activation) were used concurrently as the positive controls.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	> 5000	Negative
Present				
Test 1	> 5000	> 5000	> 5000	Negative

Remarks - Results: No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation.

All the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains

CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BML (2010)

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