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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Polymer in Laundry Detergent A

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 the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full 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: | 334 - 336 Illawarra Road MARRICKVILLE NSW 2204, 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**

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FULL PUBLIC REPORT**Polymer in Laundry Detergent A****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Kao (Australia) Marketing Pty. Ltd. (ABN: 59 054 708 299)

NOTIFICATION CATEGORY

Polymer of Low Concern

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, Polymer Constituents, Residual Monomers/Impurities, Use Details, and Import Volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Polymer in Laundry Detergent A

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) > 1,000 Da

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION*Criterion**Criterion met*

Molecular Weight Requirements

Yes

Functional Group Equivalent Weight (FGEW) Requirements

Yes

Low Charge Density

Yes

Approved Elements Only

Yes

Stable Under Normal Conditions of Use

Yes

Not Water Absorbing

Yes

Not a Hazard Substance or Dangerous Good

Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:

Rubbery solid (manufactured as solution in propylene glycol and water)

Melting Point/Glass Transition Temp

Not determined as polymer is in solution.

Density

ca. 1000 kg/m³ at 20 °C (for the polymer solution).

Water Solubility

>400 g/L at 20°C.

No test report provided. The notified polymer is expected to be water

| | |
|-----------------------|---|
| Dissociation Constant | soluble based on its predominantly hydrophilic chemical structure. pKa = ~5. No test report provided. The notified polymer is expected to be ionised in the environmental pH range (4-9). |
| Reactivity | Stable under normal environmental conditions. The notified polymer is not expected to hydrolyse under normal environmental conditions. |
| Degradation Products | None under normal conditions of use. |

5. INTRODUCTION AND USE INFORMATION

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

| <i>Year</i> | <i>1</i> | <i>2</i> | <i>3</i> | <i>4</i> | <i>5</i> |
|-------------|----------|----------|----------|----------|----------|
| Tonnes | <40 | <50 | <50 | <50 | <50 |

Use

The notified polymer will be used as a component of laundry liquid (<5%, for use by the general public).

Mode of Introduction and Disposal

The laundry liquid containing the notified polymer will be imported into Australia in 400 mL plastic bottles *via* Sydney, Melbourne, Brisbane and Perth ports. Reformulation and/or repackaging will not be carried out in Australia. The laundry liquid will be distributed (by road) to supermarkets and retail stores for sale to the general public.

6. HUMAN HEALTH IMPLICATIONS

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the notified polymer or analogue chemical. In solution, if free amine is present a hazard classification may be appropriate.

| <i>Endpoint</i> | <i>Result</i> | <i>Effects Observed?</i> | <i>Test Guideline</i> |
|---|-------------------------------|--------------------------|---|
| Rat, acute oral | LD50 >2000 mg/kg bw | no | OECD TG 423 (modified protocol) |
| Skin sensitisation - adjuvant test | no evidence of sensitisation. | no | Maximisation test (guideline not specified) |
| Genotoxicity - bacterial reverse mutation | non mutagenic | no | OECD TG 471 (modified protocol) |
| Genotoxicity – in vitro mammalian chromosome aberration test* | non genotoxic | no | Guideline not specified |

*Study performed on an analogue of the notified polymer.

All results were indicative of low hazard.

The polymer contains hazardous impurities, which have the potential to cause irritation and/or sensitisation. However, the concentration of these impurities in the finished laundry liquid will be very low and below the cut-off concentration to cause irritation/sensitization.

Occupational Health and Safety Risk Assessment

While reformulation and/or repackaging will not be carried out in Australia, dermal and ocular exposure may potentially occur as a result of accidental spillage during transport or storage. However, exposure to significant amounts of the notified polymer would likely be limited due to its low concentration in the laundry liquid.

Overall, the OHS risk presented by the notified polymer is expected to be low, based on the minimal exposure to workers and the assumed low hazard of the polymer.

Public Health Risk Assessment

The notified polymer will be available to the general public as a component of laundry liquid. Dermal and ocular exposure may occur as a result of accidental spillage or splashing. However, exposure to significant amounts of the notified polymer would be limited due to its low concentration in the laundry liquid.

While the polymer contains hazardous impurities, which have the potential to cause irritation and/or sensitisation, the concentration of these impurities in the finished laundry liquid will be very low and below the cut-off concentration to cause any irritation/sensitisation.

Therefore, although the public may be exposed to incidental amounts of the notified polymer during use of the laundry liquid, the risk to public health is considered to be low due to the predicted low hazard of the notified polymer and low exposure.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by environmental endpoints observed in testing conducted on an analogue polymer.

| <i>Endpoint</i> | <i>Result</i> | <i>Effects Observed?</i> | <i>Test Guideline</i> |
|--------------------------|--------------------------------------|--------------------------|-----------------------|
| Fish Toxicity | LC50 (96 h) >1000 mg/L | yes* | OECD TG 203 |
| Daphnia Toxicity | EC50 (48 h) = 530 mg/L | no | OECD TG 202 |
| Algal Toxicity - Rate | E _r C50 (96 h) = 130 mg/L | yes** | OECD TG 201 |
| Algal Toxicity - Biomass | E _b C50 (96 h) = 35 mg/L | yes** | OECD TG 201 |

*Sub-lethal effects were observed at 3 h, however this was reported to be probably due to the difference in the pH of the test culture to the holding tanks.

**A regrowth test indicated that the test substance has algistatic effects.

The analogue polymer is the undissociated acid form of the notified polymer and is therefore an acceptable surrogate on which to conduct ecotoxicological investigations. Whilst the analogue polymer demonstrates algal biomass inhibition (E_bC50 (96 h) = 35 mg/L) the growth rate endpoint (E_rC50) is preferred as it is independent of test design. Also, the toxicity measured in standard tests is often an overestimate of algal toxicity in most natural surface waters due to the prevailing water hardness. Therefore, the results are indicative of low hazard.

Study Summaries

Acute toxicity to fish

After a range finding test, a limit test at a nominal concentration of 1000 mg analogue polymer/L was conducted in accordance with the *OECD TG 203 Fish, Acute Toxicity Test – Semi-static*. In the range finding test, sub-lethal effects such as lethargy, swimming at the surface and loss of equilibrium, were observed at 3 hours, however, the effects were reported to be probably due to the test organisms adjusting to a drop in pH compared to the holding tank. There was no mortality of rainbow trout exposed to a concentration of 1000 mg polymer/L for 96 h in the limit test. There was no mortality in the control, thus validating the test. The 96 h LC50 was >1000 mg/L and the 96 h NOEC was 1000 mg/L.

Acute toxicity to aquatic invertebrates

A definitive test at concentrations of 10-1000 mg analogue polymer/L was conducted in accordance with the *OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static*. There was no mortality of *D. magna* in the control, thus validating the test. The 48 h EC50 was 530 mg polymer/L with 95% confidence limits of 380-840 mg/L, and the 48 h NOEC was 56 mg/L.

Algal growth inhibition test

After a range finding test, a definitive test at concentrations of 10-1000 mg analogue polymer/L with an initial algal density of 10³ cells/mL was conducted in accordance with the *OECD TG 201 Alga, Growth Inhibition Test*. A concentration dependant pH decline was reported to be due to an intrinsic property of the test substance. The pH deviation in the control cultures (7.2-7.6) was <1.5 units and was therefore within the guideline limits. Cell density of the control increased 149-fold over 96 hours, thus validating the test. A regrowth test showed the test substance to be algistatic in effect. The 96 h E_rC50 was 130 mg polymer/L with 95% confidence limits of 110-150 mg/L, the 96 h E_bC50 was 35 mg polymer/L (95% CI: 30-42 mg/L) and the NOEC for both rate and biomass inhibition was 10 mg/L.

Environmental Risk Assessment

The notified polymer will be imported as a finished liquid laundry detergent. The majority of the imported volume is expected to be released to the sewer as a result of its use, and a small proportion will be disposed of to landfill as residue in empty containers. The notified polymer is not expected to bioaccumulate based on its high molecular weight. It is expected to slowly degrade biotically and abiotically to form water and oxides of carbon. As a worst case scenario, it is assumed that 100% of the annual import volume of the notified polymer is disposed of to the sewer nationwide over 365 days/year to give a predicted environmental concentration (PEC_{river}) of 32.4 $\mu\text{g/L}$ (i.e. $50,000 \text{ kg/annum} \div (21.16 \text{ million people} \times 200\text{L/day} \times 365 \text{ days/year})$). Using the conservative endpoint of the most sensitive species, E_5C50 (alga) = 35 mg/L, and assessment factor of 100 as endpoints for three trophic levels are available, the predicted no-effect concentration (PNEC) is determined to be 350 $\mu\text{g/L}$ (i.e. $35 \text{ mg/L} \div 100$). As the resulting risk quotient ($Q = PEC/PNEC$) is < 1 (i.e. $Q_{\text{river}} = 32.4 \mu\text{g/L} \div 350 \mu\text{g/L} = 0.092$), the notified polymer is not expected to pose a risk to the aquatic environment.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental risk assessment

Based on the reported use pattern and the PEC/PNEC ratio, the notified polymer is not expected to pose a 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.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe removal.

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 polymer 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 polymer, 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 notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component of laundry liquid, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
 - the notified polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical 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 MSDS of a product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.