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

PUBLIC REPORT

Polymer in TX15722

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:

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**Director
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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/1775	Ecolab Pty Ltd	Polymer in TX15722	ND*	≤ 30 tonnes per annum	Additive in paper manufacture

*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.

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

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced:
 - Enclosed equipment when spray boom application of the polymer.
- 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]:
 - Avoid skin and eye contact
 - Avoid spills, splashes and aerosol generation that would increase exposure
 - At the tissue manufacturing site, workers should not unnecessarily enter areas where dermal or inhalation exposure is likely.
- 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]:
 - Safety glasses
 - Gloves
 - Overalls

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 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, physical 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 an additive in paper manufacture, 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

This notification has been conducted under the cooperative arrangement with the United States Environmental Protection Agency (US EPA). Information pertaining to the assessment of the notified chemical by the US EPA was provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on the safe use of the notified chemical were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Ecolab Pty Ltd (ABN: 59 000 449 990)
2 Drake Avenue,
Macquarie Park NSW 2113

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ 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 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

US EPA (2009).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

TX15722 (product containing the notified polymer)

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference NMR, IR, GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

>99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear amber liquid (product)

Property	Value	Data Source/Justification
Melting Point	50-70 °C	Measured
Boiling Point	345 °C at 101.3 kPa	Estimated
Density	1060 kg/m ³	Measured (15% in water)
Vapour Pressure	<1.3x10 ⁻⁹ kPa at 25 °C	Estimated

Water Solubility	Fully miscible	Measured
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)	log Pow = -6.8	Estimated
Adsorption/Desorption	Not determined	The notified polymer is expected to be immobile in soil based on its high molecular weight and presence of cationic functionality which will adsorb to soil and sediment.
Dissociation Constant	Not determined	The notified polymer is a salt and will be ionised under environmental conditions (pH 4-9)
Particle Size	Not determined	The notified polymer is introduced as an aqueous solution.
Flash Point	>93.3 °C	MSDS
Autoignition Temperature	Not determined	Expected to be high, based on flash point.
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative 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 into Australia as a component in a formulated product at <5% concentration.

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

Year	1	2	3	4	5
Tonnes	0-10	0-10	10-30	10-30	10-30

PORT OF ENTRY

Melbourne, Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS

Ecolab Pty Ltd

TRANSPORTATION AND PACKAGING

The product (TX15722) containing the notified polymer at <5% will be introduced to Australia via port Melbourne or Sydney in either 220 kg HDPE (High-density polyethylene) drums or 1100 kg HDPE Intermediate Bulk Containers (IBCs). It will be transported from wharf to warehouses by road and rail.

USE

The product containing the notified polymer (at <5%) will be used as a process aid in tissue paper production. Kitchen towels and toilet paper are the major types of tissue product manufactured.

OPERATION DESCRIPTION

The notified polymer will not be manufactured or formulated in Australia. It will be imported in a formulated product at <5% concentration, which will be sold to end-users (paper manufacturers).

Upon delivery to the customer site, the drums or IBCs containing the product will be off-loaded and warehoused until use. The product (containing the notified chemical at < 5%) will be moved to the production area for use in paper manufacturing. The operator will manually connect the hose to the run tank for transfer. The product will be pumped to a spray boom which automatically applies the product evenly on to the drying mechanism. The spray application will occur within enclosed equipment designed to minimise and capture overspray. Plant operators will be involved in cleaning the empty packaging, and will also carry out maintenance and repairs of the equipment.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Notifier Warehouse Personnel	4	6
Transportation	6	12
Customer Warehouse	2	12
Customer Plant Operators	0.25	104

EXPOSURE DETAILS

Transport and warehouse workers may come into contact with the notified polymer (<5% concentration) only in the event of accidental rupture of containers.

The paper manufacturing process at the end-use site will be largely automated and enclosed. However, dermal and ocular exposure of operators to the notified polymer at <5% concentration may occur during handling, connecting hoses to the run tank and during cleaning up product packaging and tank. Inhalation exposure may occur as a result of mists or overspray from the spray boom, however in normal operation the workers will not be in close proximity to the equipment. Exposure may also occur if e.g. a fitting or hose bursts, or from splashes or spills from cleaning of nozzles and replacement of hoses during maintenance.

Exposure to workers will be mitigated through the use of automated/enclosed processes for the machinery used in paper production, and use of personal protective equipment (PPE) such as overalls, safety glasses, and gloves.

6.1.2. Public Exposure

The product containing the notified polymer will only be used for industrial applications and will not be sold to the public. The public may come into contact with finished tissue paper products containing low level of the notified polymer. However, in this finished form the notified polymer will be entrapped within a solid cured polymer/fibre matrix where it is considered immobile and inert. Exposure to the notified polymer in this form will not be expected.

6.2. Human Health Effects Assessment

No toxicity data were submitted on the notified polymer.

An acute oral toxicity study on an analogue (backbone component of the notified polymer) indicated an LD50 of >2000 mg/kg bw.

Considering its high molecular weight (>1000 Da), high water solubility and expected low partition coefficient, the notified polymer is not expected to be absorbed by the dermal route.

The notified polymer contains functional groups of concern for corrosion/irritation and sensitisation. These hazards may be limited by the high molecular weight of the polymer. However some low molecular weight species <1000 are present.

The notified polymer contains a hazardous impurity, below the cut-off concentration for classification.

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

There is limited information available on the hazard of the notified polymer, however it may have irritation and/or sensitising effects. The highest potential for worker exposure to the product containing the notified polymer at <5% would occur at the tissue manufacturing site, in the vicinity of the spray equipment. There is also potential for exposure from spills and drips which may occur during connection and disconnection of hoses from the import containers to the paper manufacturing system. Enclosed systems, safe work practices and use of PPE would reduce worker exposure and risk.

Therefore, provided that adequate control measures are in place to minimise worker exposure, the risk to workers from the use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer will not be available to the general public. Public exposure is not expected during transport or use of the polymer in the manufacturing of tissue paper. Dermal exposure of the public can occur to the tissue paper containing the notified polymer. However, in finished tissue paper the notified polymer is expected to be crosslinked and bound within the paper matrix, and not likely to transfer or leach.

Therefore, the risk to the public health from exposure to tissue paper containing 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 into Australia as a component of formulated aqueous products. There will be no exposure to the environment from manufacture, reformulation or repacking activities as these operations will not take place in Australia. Exposure of the notified polymer to the environment is not expected during transportation except in the event of a spill. Spills are assumed to be contained, collected and disposed to landfill.

RELEASE OF CHEMICAL FROM USE

The notified polymer at 5% will be used by a single Australian customer as a paper processing aid. The notified polymer will be utilised in a completely automatic system and will be incorporated in the finished tissue paper. No environmental release of the notified polymer from the paper manufacturing process is expected. Small spills and leaks that may occur are expected to be washed with water and collected for disposal.

RELEASE OF CHEMICAL FROM DISPOSAL

The notifier stated that, at the paper manufacturing site, the maximum amount of notified polymer released daily to sewer is expected to be 22.5 kg. The amount of the notified polymer released to the sewer is expected to be 7.4 tonnes per annum. All waste from the manufacturing site will be treated by the Carrum Treatment Plant in the Yarra Valley Water sewer system. It is expected that residues in the import containers would be washed out on-site at the paper mill and the rinsates treated in the on-site water treatment facility. It is assumed that 50% of the tissue paper to which the notified chemical is applied will end up in landfill and the remainder will be disposed to the Australian sewage system.

7.1.2. Environmental Fate

The notified polymer is not expected to be readily biodegradable. The notified polymer is expected to be stable to hydrolysis in the environmental pH range of 4–9. Abiotic degradation mediated by hydrolytic mechanisms is therefore expected to be slow.

The notified polymer is not expected to be fully removed from the effluents of waste water treatment plants. Although the notified polymer has a high water solubility, some of notified polymer discharged in treated effluent is expected to partition to sludge and sediment, based on the high molecular weight and presence of cationic moiety in the structure. The rate of abiotic degradation may be slow based on the apparent hydrolytic stability of the notified polymer and it may persist in the water column. Although potentially persistent in the water compartment, the notified polymer is unlikely to bioconcentrate in aquatic organisms based on the low estimated log K_{ow} and the relatively large molecular weight.

Due to the presence of cationic functionality, the notified polymer has the potential to strongly adsorb to soil and sediment in the sludge fraction. Therefore, only a low proportion of the notified polymer is expected to remain in the effluent water from both on-site waste water treatment plants and municipal water treatment plants to which treated effluent may be discharged. Sludge (containing the notified polymer) generated is expected to be sent to landfill for disposal.

In either landfill or water, the notified polymer is expected to be decomposed to water, oxides of carbon, and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

Tissue Paper Manufacture

Considering the high water solubility of the notified polymer, and based on OECD Emission Scenario Documents on Pulp, Paper and Board Industry (ENV/JM/MONO(2009)25) for one individual paper manufacturing mill, the daily release of the notified polymer to waste water (E_{water}) before any treatment plant, whether on-site or off-site, was calculated as follows:

$$\begin{aligned} E_{water} &= C_{wastewater} \times Flow_{wastewater} \\ &= (5/100) \times 450 \times 1000 \\ &= 22,500 \text{ g/day} \end{aligned}$$

E_{water} (g/day): Emission per day to waste water from paper manufacturing process; (OECD, ENV/JM/MONO(2009)25).

$C_{wastewater}$ (%): Concentration of the notified polymer in waste water from paper manufacturing processes.

$Flow_{wastewater}$ (L/day): Waste water generated from the whole plant; provided by the notifier.

The waste water containing the notified polymer released to sewer is expected to be treated at the public sewage treatment plant (STP). The log P_{ow} of 0 was estimated by SimpleTreat (EC, 2003) and that up to 3% of the notified polymer will remain in the water column in the STP with 0% removed in sludge. Therefore, the daily release of the notified chemical to surface water (E_{STP_water}) from an individual STP was calculated as following:

$$\begin{aligned} E_{STP_water} &= E_{water} \times F_{STP_water} \\ &= 22,500 \times 0.03 \\ &= 675 \text{ g/day} \end{aligned}$$

E_{STP_water} (g/day): Emission to surface water from STP effluent;

F_{STP_water} (unitless): Fraction of notified polymer remaining in water after STP treatment.

For a conservative scenario, it is assumed that waste water will be released to a moderately-sized STP and be diluted by the daily average water flow at the STP. The resultant predicted environmental concentration (PEC) in river was calculated as following:

$$\begin{aligned} PEC_{river} &= E_{STP_water} \div F_{daily_individual\ STP_flow} \\ &= 675 \div 358 \\ &= 1.88 \text{ } \mu\text{g/L} \end{aligned}$$

PEC_{river} (μg/L): Predicted environmental concentration in river

$F_{daily_individual\ STP_flow}$ (ML/day): Individual STP daily average water flow (358ML, Eastern Treatment Plant, Victoria).

Based on the above calculated PEC of 1.88 μg/L for river water, the PEC for seawater can be calculated as 0.19 μg/L by dividing by a factor of 10.

Tissue Paper General Use.

The notified polymer is used as a process aid in tissue paper production. It is assumed that 50% of the tissue paper to which the notified chemical is applied will end up in landfill and the remainder will be disposed to the Australian sewage system. The predicted environmental concentration (PEC) was calculated assuming that the 90% of the notified polymer is removed from influent during sewage treatment processes (STPs) processes by adsorption to sediment and sludge (Boethling & Nabholz, 1997). It is assumed that release of the notified polymer to surface waters occurs from general use on a nationwide basis over 365 days per year.

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>		
Total Annual Import/Manufactured Volume	30,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	15,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	41.10	kg/day
Water use	200	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:	0.91	µg/L
PEC - Ocean:	0.09	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 81.7 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m³ and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 0.5 mg/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 2.7 mg/kg and 5.4 mg/kg, respectively.

Based on the above calculations, the maximum PEC for the notified polymer in surface water is 2.79 µg/L (= 1.88 + 0.91) for river waters and 0.28 µg/L (= 0.19 + 0.09) for ocean waters receiving combined effluents from tissue paper manufacturing and general use of tissue paper.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymer. The notifier has submitted ecotoxicity studies based on an unidentified analogue which is considered to be the back bone of the notified polymer. However, the analogue was not specifically defined and therefore the studies were not evaluated for validity.

Ecotoxicological endpoints for the notified polymer were calculated based on structure-activity relationship (SAR) equations assuming a worst case cation charge density for the polymer (Boethling and Nabholz, 1997). The endpoints are summarised in the table below and have been modified by mitigation factors to account for the anticipated binding of the polymer with organic carbon in surface waters.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
<i>Acute Toxicity</i>		
Fish Toxicity (96 hour)	LC50 = 30.8 mg/L	Harmful
Daphnia Toxicity (48 hour)	EC50 = 11.0 mg/L	Harmful
Algal Toxicity (96 hour)	EC50 = 4.4mg/L	Toxic
<i>Chronic Toxicity</i>		
Fish Toxicity	ChV = 1.71 mg/L	Not harmful
Daphnia Toxicity	ChV = 0.61 mg/L	Toxic
Algae Toxicity	ChV = 0.2.2 mg/L	Not harmful

Based on the worst case SAR estimations, the notified polymer is potentially harmful or toxic to aquatic organisms 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 for the purposes of risk assessment. 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 estimated hazard data for the notified polymer indicates that, after allowing for the mitigating effects of organic carbon in surface waters, the most sensitive ecotoxicological endpoint is for daphnia. The endpoint for daphnia was therefore selected for the calculation of the PNEC below. An assessment factor of 50 was used as a worst-case calculated chronic endpoint was used for determination of the PNEC.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Algae (ChV)	0.61	mg/L
Assessment Factor	50	
PNEC:	12.2	µg/L

7.3. Environmental risk assessment

<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC µg/L</i>	<i>Q</i>
Q - River:	2.79	12.2	0.23
Q - Ocean:	0.28	12.2	0.023

The risk quotient ($Q = PEC/PNEC$) for aquatic exposure is calculated to be < 1 based on the above calculated PEC and PNEC. The Q value of < 1 indicates the notified polymer is not expected to pose an unreasonable risk to the aquatic environment from its proposed use pattern at the proposed maximum import volume.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Analogue
METHOD	OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure.
Species/Strain	Rat/Female Wistar
Vehicle	Water
Remarks - Method	No protocol deviation. (Up and Down Procedure (UDP) method)

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5 F	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	Instances of soiling of the anogenital area were noted in one animal
Effects in Organs	2/5 animals lost a slight amount of body weight from day 7 to day 14
Remarks - Results	

CONCLUSION	The notified polymer is of low toxicity via the oral route.
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TEST FACILITY	MB Laboratories (2007)
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