File No PLC/1349

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in GT-101

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government 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 Australian Government Department of the Environment.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

June 2016

Table of Contents

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1349	Procter & Gamble Australia Pty Ltd Costco Wholesale Australia Pty Ltd	Polymer in GT-101	No	≤ 10 tonnes per annum	Component of automatic dishwashing detergent

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

Environmental Risk Assessment
Based on the PEC/PNEC ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Health and Safety Recommendations

- 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, noting that the formulation may be classified as R43 because of hazardous impurities.

  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 of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency Procedures

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

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 automatic dishwashing detergent, 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 notified 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 products containing the notified polymer were provided by the applicant. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants
Procter & Gamble Australia Pty Ltd (ABN: 91 008 396 245)
Level 4
1 Innovation Road
MACQUARIE PARK NSW 2113

Costco Wholesale Australia Pty Ltd (ABN: 57 104 012 893)
17 – 21 Parramatta Road
LIDCOMBE NSW 2141

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.

2. IDENTITY OF POLYMER

Marketing Name(s)
GT-101 (contains the notified polymer at < 60% concentration in aqueous solution)

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

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	Clear/slight yellow liquid*
Melting Point/Glass Transition Temp	< 10 °C*
Density	1,300 – 1,400 kg/m^3 at 25 °C*
Water Solubility	Soluble
Dissociation Constant	Expected to be ionised under environmental conditions (pH 4-9)
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

*For the notified polymer at < 60% concentration in aqueous solution

5. INTRODUCTION AND USE INFORMATION

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

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

Use
The notified polymer will not be manufactured in Australia. The notified polymer will be imported as a component of automatic dishwashing machine tablets at < 6% concentration.

6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by tests submitted on the following toxicological endpoints.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
Rat, acute oral	LD50 > 5000 mg/kg bw; low toxicity	no	OECD TG 425

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains residual impurities that are classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. These are present in the notified polymer as introduced above the cut off concentrations for classification.

Occupational Health and Safety Risk Assessment
Transport, storage and retail workers may come into contact with the notified polymer (at a concentration of < 6%) only in the event of accidental rupture of packages. Exposure would be limited to dermal or ocular contact and is expected to be limited by the notified polymer being contained within the individual detergent pouches.

Exposure of professional kitchen workers is expected to be of a similar extent to that experienced by consumers using automatic dishwashing pouches containing the notified polymer.

Public Health and Safety Risk Assessment
Public exposure to the notified polymer while adding the dishwashing pouch to the machine is not expected to occur as the detergent (containing the notified polymer at < 6%) is contained in sealed pouches. Exposure to the notified polymer from washed dishes is expected to be low because it is present at a low concentration in the detergent (< 6%) and will be further diluted in the wash water, and is expected to be rinsed off washed articles after two rinse cycles prior to drying.

The public may be exposed during use of automatic dishwashing pouches containing the notified polymer at < 6%. However, given the assumed low hazard, the risk posed by exposure to the notified polymer is not considered unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

Anionic polymers are generally of low toxicity to fish and daphnia, however they are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone, which may apply to the notified polymer.

This is supported by results from ecotoxicological investigations conducted on the notified polymer, which are summarised in the table below. The actual concentrations of the notified polymer in the test media were determined at the start and conclusion of each study. The results of these studies are considered reliable as the validity criteria for all of the tests were satisfied.

Endpoint	Results	Assessment Conclusion
Fish Toxicity		
Pimephales promelas	96 h LC50 > 969 mg/L*	Not harmful to fish
Aquatic Invertebrate Toxicity		
Daphnia magna	48 h EC50 = 580 mg/L*	Not harmful for aquatic invertebrates
Algal Toxicity		
Pseudokirchneriella subcapitata	72 h E_rC50 = 98.1 mg/L*	Harmful to algae

* Based on the active ingredient

Based on the above ecotoxicological endpoints for the notified polymer, it is expected to be harmful to algae, but is not expected to be harmful to fish and aquatic invertebrates. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), the notified polymer is formally classified as "Acute Category 3; Harmful to aquatic life". Based on its lack of ready biodegradability and acute ecotoxicity, the notified polymer is formally classified as "Chronic Category 3; Harmful to aquatic life with long lasting effects" under the GHS.

The notified polymer will be imported into Australia as finished domestic dishwashing machine tablets; the notified polymer will not be reformulated or repackaged in Australia. Release of the notified polymer during transport and storage in Australia is expected to be limited to accidental spills or leaks and residue in import containers. These releases are expected to be collected and disposed of to landfill in accordance with local government regulations. All wastes including container residues are expected to be disposed of to landfill in accordance with local government regulations.

Based on the results of a ready biodegradability test (conducted in accordance with OECD TG 301 B guidelines), the notified polymer is not considered to be readily biodegradable (0% in 28 days). However, based on its high molecular weight the notified polymer is not expected to cross biological membranes, and is therefore not expected to be bioaccumulative.

Based on its use in dishwashing machine tablets, it is expected that the majority of the notified polymer will be released to the aquatic compartment through sewers during use. Up to 50% of the notified polymer is expected to adsorb to sludge and sediment during sewage treatment plant (STP) processes, based on its high molecular weight and anionic properties (Boethling and Nabholz, 1997), with sludge eventually disposed of to landfill or re-used for soil remediation. The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with 100% release of the notified polymer into sewer systems nationwide with no removal in sewage treatment plants.

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

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
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	1.0	
Dilution Factor – Ocean	10.0	
PEC – River	6.057	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 1,000 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 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 6.06 µg/L may potentially result in a soil concentration of approximately 40.38 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymer in the applied soil in 5 and 10 years may be approximately 201.9 µg/kg and 403.8 µg/kg, respectively.

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for algae. A safety factor of 100 was used given endpoints for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC50 (Algae, 72 h)	98.10	mg/L
Assessment Factor	100	
PNEC:	981.00	µg/L

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q – River	6.058	981	0.006
Q – Ocean	0.606	981	0.001

The Risk Quotients (RQ = PEC/PNEC) for discharge of treated effluents containing the notified polymer to the aquatic environment indicate that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. The notified polymer is not expected to be readily biodegradable nor bioaccumulative. In both surface waters and landfill, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon. Therefore, on the basis of the PEC/PNEC ratio, maximum importation volume, and assessed use pattern in dishwashing machine tablets, the notified polymer is not considered to pose an unreasonable risk to the environment.