File No SAPLC/75

September 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

X-22-3701 E

This Self Assessment has been compiled by the applicant and adopted by NICNAS 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), administered by the Department of Health and Ageing and the Department of the Environment and Water Resources has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

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:

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Director
NICNAS

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FULL PUBLIC REPORT

1. APPLICANT AND NOTIFICATION DETAILS

1.1 APPLICANT
Toyota Tsusho (Australasia) Pty Ltd (ABN 24 056 847 315) of Level 19, 44 Market Street, Sydney, NSW, 2000

1.2 NOTIFICATION CATEGORY
Self Assessment: Polymer of Low Concern

1.3 EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, Other Names, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details, Manufacture/Import Volume, and Site of Manufacture/Reformulation.

1.4 PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

1.5 NOTIFICATION IN OTHER COUNTRIES
USA – date unknown

2. IDENTITY OF CHEMICAL

2.3 MARKETING NAME(S)
X-22-3701 E

2.7b MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (NAMW) >1000 Da

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

4.1	**Appearance at 20°C and 101.3 kPa**	Light yellow hazy liquid
4.2	**Melting Point/Glass Transition Temp**	Not applicable. The notified polymer is not isolated from the imported product.
4.3	**Density**	970 to 990 kg/m^3 at 25°C
4.4	**Water Solubility**	The notified polymer is expected to have low water solubility due to it containing a predominance of

		hydrophobic groups.
4.5	**Dissociation Constant**	The notified polymer contains a low concentration of acid groups that will exhibit typical acidity.
4.7	**Reactivity**	Expected to be stable under normal environmental conditions (pH 4-9).
4.8	**Degradation Products**	None under normal conditions of use.

5. INTRODUCTION AND USE INFORMATION

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

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

5.2 USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will not be manufactured in Australia. The solid polymer product containing the notified polymer (<0.1% w/w) will be imported by sea in 1,000 kg Bulka bags. Upon arrival at ports in Sydney the product containing the notified polymer will be transported by road to the notifier's warehouse where it will be stored under cover until such time that it is transported to customers in Sydney.

Reformulation/manufacture processes

No reformulation of the imported polymer will take place in Australia.

Use

The imported polymer product containing the notified polymer will be used in the manufacture of nappies. Approximately 10 g of the imported polymer product containing <0.01 g of the notified polymer will be sandwiched within each nappy's outer material covering.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Transport and warehousing workers may come into dermal, inhalation and ocular contact with the notified polymer through accidental leaks and spillages from imported polymer Bulka bags.

During manufacture of nappies, plant workers will transfer the imported polymer product containing the notified polymer via mechanical means to a hopper. From the hopper the imported polymer product containing the notified polymer will be transferred by an enclosed automated system and mixed with other components before being added to nappies during the automated manufacturing process. Potential exposure will mainly be via dermal and inhalation contact during transfer from Bulka bags. However, exposure will be minimised by workers wearing impermeable gloves, eye protection, coveralls and dust masks. Additionally, local exhaust ventilation adjacent to the hopper unit will minimise exposure via inhalation.

Following manufacture of the nappies, the notified polymer will be contained within the nappy covering and hence, the notified polymer no longer be available for exposure.

PUBLIC EXPOSURE

The notified polymer will not be sold to the public. The public will come into contact with nappies containing the notified polymer. However, the notified polymer will be contained within the nappy covering and will not be readily available for exposure.

6.2. Toxicological Hazard Characterisation

No toxicological data were submitted. The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

The OHS risk presented by the notified polymer is expected to be low, based on low hazard and low exposure levels as well as the engineering controls and personal protective equipment used by workers.

PUBLIC HEALTH

The notified polymer will not be sold to the public. The public will come into contact with nappies containing the notified polymer at low concentrations. However, the notified polymer will be contained within the nappy covering and will not be readily available to cause exposure. Any health risk to the public is considered to be low.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Release to the environment during shipping, transport and warehousing will only occur through accidental spills or leaks. It is estimated that approximately 1% of the imported polymer product containing the notified polymer will remain as residues in "empty" Bulka bags.

The notified polymer will be used in dedicated manufacturing lines and thus waste generated from cleaning will be negligible. The empty Bulka bags and cleaning residues will be disposed of to licensed waste landfill sites.

The remainder of the notified polymer will be contained in nappies and the majority will be disposed of to licensed waste landfill sites after use.

7 ENVIRONMENTAL FATE

The vast majority of the notified polymer will be disposed of to landfill. The notified polymer is expected to be hydrolytically stable and to not be readily biodegradable. Due to its hydrophobic nature, it is expected that the notified polymer in landfill will associate with organic phases of soil and sediments, and slowly degrade to simple carbon and silicon compounds.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted. Anionic polymers 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 is unlikely to apply to the notified polymer.

7.3. Environmental Risk Assessment

No aquatic exposure is anticipated during nappy manufacturing processes and end use of the notified polymer. Virtually all of the notified polymer will be disposed of to landfill. Use of nappies will be widespread throughout Australia and concentrations of the notified polymer in landfill are expected to be low. The notified polymer will not be mobile and will degrade slowly by biotic and abiotic processes and not pose a significant risk to the environment.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

The risk to occupational health and safety is considered to be acceptable under the conditions of the occupational settings described.

8.2. Level of Concern for Public Health

The risk to public health is considered to be acceptable when used in the proposed manner.

8.3. Level of Concern for the Environment

The notified polymer is not considered to pose a risk to the environment based on its reported use

pattern.

9. MATERIAL SAFETY DATA SHEET

9.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

10. 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.

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

- 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of to landfill.
- Empty containers should be sent to local recycling or waste disposal facilities.

Emergency procedures

- Spills/release of the imported product containing the notified polymer should not be allowed into drains or waterways. Spills should be taken up mechanically and put into suitable container for disposal.

11. 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 chemical 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 chemical has changed from a component of polymers in nappies, or is likely to change significantly;
- the amount of chemical being introduced has increased from 10 tonnes, or is likely to increase, significantly;
- if the chemical 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.