File No PLC/716

August 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

EX854, XEP-854, EX861, XEP-861

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 and Water Resources.

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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Niche Creation Network Pty Ltd (ABN: 80 097 370 673)
126A Edinburgh Road
Castlecrag NSW 2068

and

Marubeni Australia Ltd (ABN: 53 000 329 699)
Level 18, 367 Collins Street
Melbourne VIC 3000

NOTIFICATION CATEGORY
Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details, 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
Korea (2006), Japan (2002), US EPA (2002)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
EX854, XEP-854, EX861, XEP-861 (neat notified polymer)
SP521, SP451, SP482, SP474, SP434, SP292, SP295, SP441, J171 (<50% notified polymer)

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >10000

REACTIVE FUNCTIONAL GROUPS
The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met (yes/no/not applicable)*
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	Solid pellets
Melting Point/Glass Transition Temp	Decomposition, without melting, occurred at temperatures >300°C.
Density	1140 kg/m^3 at 21°C
Water Solubility	6-54 mg C/L, as determined using OECD TG 120. However, based on the chemical structure, this is expected to be due to the presence of low molecular weight components.
Dissociation Constant	Not applicable
Particle Size	100% of notified polymer >400 μm
Reactivity	Stable under normal environmental conditions. The notified polymer is not highly flammable, not explosive, non-oxidising, and does not self-ignite at temperatures <400°C.
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	200	400	500	600	600

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will be imported into Melbourne by sea as solid pellets in 25kg paper bags with aluminium and shrink-wrapped in containers. The imported products will contain the notified polymer at neat concentrations or at concentrations <50%.

Reformulation/manufacture processes

Processing of the notified polymer will use conventional fabrication equipment using one of the following techniques: multilayer film co-extrusion, sheet co-extrusion, co-extrusion blow moulding, or co-injection moulding.

At larger facilities, automated systems will be used to feed pellets of the notified polymer into the production line, and to handle the final products (2 – 5% notified polymer) after processing.

At smaller facilities, workers will manually load the pellets into a feed hopper from bags at a rate of 2 or 3 per hour. Following processing, the formed product will emerge from the equipment through dies and be manually guided to the chilled roller or receiving area. The rollers used to collect the formed product will be manually changed using lifting devices. Every 6 – 12 months the equipment will be dismantled, heated in an oven and residues of notified polymer removed manually.

Use

The notified polymer will be used as a processing aid in the manufacture of food packaging material. It will be present in the non-food contact layer of multilayer films used in food packaging materials.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Exposure of workers to the notified polymer during reformulation processes at large facilities is likely to be minimal due to the automated and enclosed nature of the operations.

At smaller facilities, dermal exposure is expected to be the main route of exposure. Inhalation exposure is unlikely to occur, given the large particle size of the notified polymer. Dermal exposure may occur during manual loading of the pellets into the feed hopper (neat concentrations of notified polymer), handling of the final product (2 – 5% notified polymer), and during maintenance/cleaning. However, the high molecular weight of the notified polymer and its low water solubility suggest that it is unlikely to cross biological membranes following exposure. In addition, exposure should be minimised by the local exhaust ventilation present in areas where the product emerges from the machinery, and use of personal protective equipment, including safety glasses and protective clothing during manual transfer into feed hoppers, as well as cotton gloves when handling the final products. Similar personal protective equipment is expected to be worn during cleaning/maintenance operations.

Following processing, the notified polymer will be encapsulated within the product and is unlikely to be biologically available. As such, exposure to the notified polymer during handling of the final product is expected to be negligible.

PUBLIC EXPOSURE

The notified polymer will only be sold to the public in the form of finished food packaging articles (containing the notified polymer at concentrations of 2 – 5%). There is potential for extensive public exposure to such articles, however, the notifier has stated that the notified polymer will only be present in a non-food contact layer of multilayer food packaging films and will be encapsulated within the layer. Hence public exposure to the notified polymer is expected to be low.

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 the minimal exposure to workers and the low intrinsic hazard of the polymer.

PUBLIC HEALTH

The notified polymer will not be available to the public. Members of the public may make dermal contact with products containing the notified polymer. However, the risk to public health will be low because the notified polymer is of low hazard, it will be encapsulated in a layer of the food packaging films, thus unavailable for exposure, and will be present at relatively low concentrations (2 - 5%).

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Estimated environmental release of the notified polymer is summarised in the following table.

Source of release	% Volume	Released to
Residual notified polymer within 25 kg aluminium lined paper bags	<0.5%	Landfill
Accidental spills and equipment cleaning	<1.0%	Landfill
End-of-useful-life disposal of finished articles	>98.5%	Landfill

ENVIRONMENTAL FATE

Notified polymer that is disposed to landfill is expected to be immobile, due to its insolubility in water. Eventually, the notified polymer is expected to degrade via biotic and abiotic mechanisms to simple organic compounds and water. Due to the large molecular weight and low water solubility, the notified polymer is not expected to bioaccumulate.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted. PLCs without significant ionic functionality are of low concern to the aquatic environment.

7.3. Environmental Risk Assessment

Based on the proposed use pattern, the release of the notified polymer to the environment is expected to be very low. The use pattern of the notified polymer in multilayer films will result in limited, if any exposure to the aquatic environment. While no ecotoxicity data are available, due to limited release to water it is unlikely that the polymer would exist at levels that could pose a risk to aquatic organisms. The high molecular weight indicates a low potential for bioaccumulation.

Based on the reported exposure levels and use pattern, the polymer is not considered to pose a risk to the environment when it is stored, transported and used in the proposed manner.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

8.2. Level of Concern for Public Health

There is No Significant Concern to public health when used in the proposed manner.

8.3. Level of Concern for the Environment

The 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 *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.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

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

10.1. Secondary Notification

The Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under subsection 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 subsection 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.