File No: PLC/305

5 November 2002

# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

# **FULL PUBLIC REPORT**

# **Instant-Lok 3412**

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**Director Chemicals Notification and Assessment** 

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# **FULL PUBLIC REPORT**

# **Instant-Lok 3412**

### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

National Starch & Chemical Pty Ltd (ABN 37 000 351 806), 7 Stanton Road Seven Hills NSW 2047.

NOTIFICATION CATEGORY

The notified polymer meets the PLC criteria.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Part B: Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Spectral Data, Purity, Hazardous and Non-hazardous Impurities/Residual Monomers, Additives/Adjuvants, Manufacture/Import Volume, and Site of Manufacture or Reformulation.

Part D: Identity and Composition of Polymer, Degradation Products and Loss of Monomers, Other Reactants, Additives, and Impurities.

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) Instant-Lok 3412 (Australia) Uni-Rez 2638 (overseas)

### 3. COMPOSITION

DEGREE OF PURITY

Non-Confidential

High.

### 4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS Import.

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

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

USE

A hot melt adhesive used in the manufacture of paper/plastic laminated pet food bags.

### 5. PROCESS AND RELEASE INFORMATION

# 5.1. Distribution, Transport and Storage

PORT OF ENTRY Not stated.

IDENTITY OF MANUFACTURER/RECIPIENTS National Starch & Chemical Pty Ltd

### TRANSPORTATION AND PACKAGING

The notified polymer will be imported as solid granules in paper bags of 23 kg nett weight and transported by road to customer sites for manufacturing laminated pet food bags.

# 5.2. Operation Description

At the customer site, the content of import bags is manually fed into the adhesive application machine of 23 kg capacity. No other materials are added. When the adhesive is applied, the polymer and paper are combined together and the adhesive is sandwiched between the films. Adhesive is softened during the process.

# 5.3. Occupational exposure

Number and Category of Workers

Category of Worker	Number	Exposure Duration	Exposure Frequency
Transport and Storage Workers	4-6	2-3 hours/day	10-15 days/year
Laminating Machine Operators	2-4	6 min/day	50 days/year
End-Use Customers – Pet Food	6-8		
Manufacturers			

### Exposure Details

Transport and storage workers will load and unload 23 kg paper bags, and therefore they would only be exposed to the notified polymer in the event of an accident.

Laminating machine operators will potentially be exposed to the notified polymer when they manually transfer 23 kg bags of the polymer into the adhesive application machine and manually clean the equipment at completion of a run using rags and a water soap mixture. The transfer takes approx 6 min, 3-4 times/day, 50 days/year and the potential exposure is mainly via skin and eye contact. Inhalation is unlikely as no dust is generated from the non-friable granules and mechanical ventilation is available throughout the plant. Precautions are taken against electrostatic charging and thermal burn. Machinery operators will wear safety glasses, impervious gloves, overalls and safety boots. Respiratory and eye protection equipment is available for use if required.

At end use customers such as a pet food manufacturer, exposure to notified polymer would be negligible as it is trapped between layers of impervious polymer or aluminium films.

### 5.4. Release

# RELEASE OF CHEMICAL AT SITE

The notifier estimates up to 50 kg per annum of the notified polymer will be released as a result of machinery cleaning in the pet food bag manufacture and disposal of import bags and residues they contain.

### RELEASE OF CHEMICAL FROM USE

The majority of the notified polymer will be used as an adhesive in laminated pet food bags and release to the environment will occur when these bags are disposed of.

### 5.5. Disposal

Empty import bags and any residual polymer they contain will be disposed of to landfill.

Pet food packaging will eventually be disposed of to landfill via household garbage collection.

# 5.6. Public exposure

There would be little potential for the public to be exposed to the notified polymer as it will not be sold directly to the public. The public will be handling packagings containing the notified polymer, however, no contact will occur since the polymer is sandwiched between two impervious polymer or aluminium films.

### 6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa

Amber solid granules

Melting Point 140°C

Remarks Test report not provided.

**Boiling Point** ~260°C

Remarks Test report not provided.

**Density**  $960 \text{ kg/m}^3 \text{ at } 25^{\circ}\text{C}$ 

Remarks Test report not provided.

**Water Solubility** < 0.02 g/L at 20°C

METHOD EC Directive 92/69/EEC A.6 Water Solubility (Flask Method).

EC Directive 94/37/EEC.

Remarks Test was conducted on an analogue of the notified polymer.

TEST FACILITY Huntingdon Life Sciences Ltd (1997)

**Solubility in Organic Solvents** 10-14 g/L n-octanol at 20°C

< 1 g/L methanol at 20°C

< 1 g/L dimethylformamide at 20°C

Remarks Test was conducted on an analogue of the notified polymer using a gravimetric

method.

TEST FACILITY Huntingdon Life Sciences Ltd (1997)

**Hydrolysis as a Function of pH** Stable at pH 4 and pH 9

Remarks Test was conducted on an analogue of the notified polymer. The test substance (ca.

10~mg) was added to 500~mL~pH~4 and pH~9 buffers, stirred at  $50^{\circ}C$  for 5 days. The IR spectra of the test substance and treated test substance showed no significant differences, indicating the analogue polymer is stable under acidic and

basic conditions.

TEST FACILITY Huntingdon Life Sciences Ltd (1997)

Partition Coefficient (n-octanol/water) Not determined.

Remarks The expected low water solubility and high octanol solubility of the notified

polymer is indicative of partitioning into the organic phase.

Adsorption/Desorption Not determined.

Remarks The notified polymer is expected to be relatively immobile in soil due to its low

water solubility.

**Dissociation Constant** 

Not determined.

Remarks

The notified polymer does not contain any chemical groups which are expected to dissociate in the environmental pH range of 4-9.

**Particle Size** 

Beads are round-to-slightly-oval.

Range (mm)	Mass (%)
4.75	0.1%
3.35	83.8%
2.40	15.7%
2.00	0.4%
1.40	0.0%

Remarks

Size distribution was measured by sieves method. The notified polymer is not likely to produce dust.

**Flammability** 

Not determined

Remarks

The notified polymer is a solid with <0.13 Pa vapour pressure at 20°C. It has negligible volatiles. Many polyamides of this type pass Underwriters Laboratories flame resistance tests as "self-extinguishing".

# **Autoignition Temperature**

Not determined.

Remarks

The notified polymer has a high MW with a COC flash point of 271°C, so the autoignition temperature is expected to be high.

# **Explosive Properties**

Not determined.

Remarks

Not expected to be explosive on structural grounds.

Reactivity

Stable under normal use conditions.

Remarks

Hazardous polymerisation will not occur. No known reactions with water and other chemicals.

### 7. TOXICOLOGICAL INVESTIGATIONS

No toxicological data were submitted.

# 8. ENVIRONMENT

No ecotoxicological data were submitted.

### 9. RISK ASSESSMENT

# 9.1. Environment

# 9.1.1. Environment – exposure assessment

The majority of the notified polymer will be used in manufacturing pet food bags which, at the end of their useful lives, will be disposed of to landfill. Wastes from pet food bag manufacture will also be disposed of to landfill, together with empty import containers and any residual polymer they contain.

In landfill, the notified polymer is expected to become associated with the soil matrix and will not leach into the aquatic compartment due to its low water solubility. Although not expected to be readily biodegradable, the polymer will eventually degrade through biotic and abiotic processes to give water vapour and oxides of carbon and nitrogen. Overall, under normal usage there will be no release to aquatic environment.

# 9.1.2. Environment – hazard assessment

The notified polymer is not expected to cross biological membranes due to its high molecular weight and is therefore not expected to bioaccumulate. Ecotoxicity would not be expected.

#### 9.1.3. Environment – risk characterisation

The notified polymer will follow the fate of pet food bags in which it is incorporated and eventually be disposed of to landfill as will wastes containing the notified polymer from the manufacturing process. As a consequence, the notified polymer is not likely to present a risk to the environment when it is stored, transported and used in the proposed manner.

### 9.2. Human health

### 9.2.1. Occupational health and safety – exposure assessment

Dermal and ocular exposure can occur during certain manufacturing processes. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers. Observation of safe work practice is also required to protect workers against electrostatic charging and thermal burn.

During transport and storage, workers are unlikely to be exposed to the notified polymer. In the event of an accident, spills will be removed according to the MSDS and government regulations.

### 9.2.2. Public health – exposure assessment

The notified polymer will not be sold to the public except in the form of finished packaging articles. There is potential for extensive public exposure to packaging bags comprised wholly or partly of the notified polymer. However, at this stage the polymer is incorporated in the adhesive film sandwiched between two impervious layers, and hence no contact would be expected.

### 9.2.3. Human health - effects assessment

The notified polymer meets the PLC criteria and therefore it can be considered to be of low hazard

# 9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified polymer is expected to be low, given the low hazard of the polymer, the automated process and engineering controls, and safety measures including use of appropriate personal protective equipment by workers.

The notified polymer may be present in formulations containing hazardous ingredients. If these formulations are classified as hazardous to health in accordance with the *NOHSC Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

# 9.2.5. Public health – risk characterisation

The notified polymer will not be available to the public in raw forms. Members of the public may make dermal contact with products containing the notified polymer. However, the notified polymer contained therein should not be bioavailable and the public health risk is therefore low.

# 10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

### 10.1. Hazard classification

The notified polymer meets the PLC criteria and thus it is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

### 10.2. Environmental risk assessment

On the basis of the information available, the polymer is not considered to pose a risk to the environment based on its reported use pattern.

### 10.3. Human health risk assessment

### 10.3.1. Occupational health and safety

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

### 10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

### 11. MATERIAL SAFETY DATA SHEET

### 11.1. Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

### 11.2. Label

The label for the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

### 12. 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.
- Plant operators in manufacturing pet food bags should wear suitable industrial clothing, safety glasses and protective gloves. Hot processes and equipment involving the notified polymer necessitate the use of overalls and heat resistant gloves.
- Engineering controls such as ventilation and process automation should be implemented to reduce worker exposure to dust.
- 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 in landfill.

### Emergency procedures

• Spills/release of the notified polymer should be handled as outlined in the MSDS.

### 12.1. Secondary notification

The Director of Chemicals Notification and Assessment 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 any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

# 13. BIBLIOGRAPHY

- Huntingdon Life Sciences Ltd (1997) [Analogue of the notified polyamide resin] physicochemical properties: Water solubility, solubility in organic solvents, and stability in acidic and basic conditions. Cambridgeshire, England, Huntingdon Life Sciences Ltd.
- NOHSC (1994a) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (1994b) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (1995) Exposure Standards for Atmospheric Contaminants in the Occupational Environment [NOHSC:3008(1995)] & [NOHSC:1003(1995)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. National Occupational Health and Safety Commission, Canberra, AusInfo.