File No: LTD/1760

October 2014

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

# PUBLIC REPORT

## Polymer 1 in Elastollan SP 9380/9381/9382

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**
**NICNAS**

# TABLE OF CONTENTS

# 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/1760 | P. D. Plastics (Australia) Pty Ltd | Polymer 1 in Elastollan SP 9380/9381/9382 | Yes | ≤ 1 tonne per annum | Component of plastics |

# 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,

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R42: May cause sensitisation by inhalation

**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.
When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

**Environmental risk assessment**
Based on its assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

**Recommendations**

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - R42: May cause sensitisation by inhalation

The above should be used for products/mixtures containing the notified polymer, if applicable, based on the concentration of the notified polymer present and the intended use/exposure scenario.

- Due to the sensitisation properties of the notified polymer, the notifier should consider their obligations under the Australian Dangerous Goods Code.

Health Surveillance

- As the notified polymer is a skin/respiratory sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

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 during manufacture of masterbatches or plastic articles:
  - Enclosed and automated systems
  - Local and general exhaust ventilation

- 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 during manufacture of masterbatches or plastic articles:
  - Avoid skin and eye contact during operations
  - Clean any spills promptly and appropriately

- 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 during manufacture of masterbatches or plastic articles:
  - Coveralls
  - Safety goggles
  - Impervious gloves
  - Respirators

  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

- The notified polymer should be disposed of to landfill.

Storage

- The handling and storage of the notified polymer should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, 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 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 importation volume exceeds one tonne per annum notified polymer;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of plastics, 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 notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

# ASSESSMENT DETAILS

## 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
P. D. Plastics (Australia) Pty Ltd (ABN: 42 091 476 505)
16 Rowsley Road
MOUNT ELIZA VIC 3930

NOTIFICATION CATEGORY
Limited-small volume: Synthetic polymer with Mn < 1,000 Da (1 tonne or less per year).

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, additives/adjuvants, use details 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
Japan (2002)
Korea (2004)

## 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Elastollan SP 9380/9381/9382 (contains < 1% notified polymer)

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference GPC spectra were provided.

## 3. COMPOSITION

DEGREE OF PURITY
> 90%

## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellowish, viscous liquid

| Property | Value | Data Source/Justification |
|---|---|---|
| Melting Point/Freezing Point | < 5 °C | (M)SDS |
| Boiling Point | > 200 °C at 101.3 kPa | (M)SDS |
| Density | 1,080 kg/m$^3$ at 15 °C | (M)SDS |
| Vapour Pressure | $4 \times 10^{-4}$ kPa at 25 °C* | (M)SDS |
| Water Solubility | Not determined | Not tested due to the presence of end-groups that readily react with water to form carbon dioxide and insoluble high molecular weight polymers |
| Hydrolysis as a Function of pH | Not determined | Not tested due to the presence of end-groups that readily react with water to form carbon dioxide and insoluble high molecular weight polymers |

| | | |
|---|---|---|
| Partition Coefficient (n-octanol/water) | Not determined | Expected to react with water and octanol to form carbon dioxide and insoluble high molecular weight polymers |
| Adsorption/Desorption | Not determined | Not tested due to hydrolytic instability. Reaction products are expected to associate with soil/sediment |
| Dissociation Constant | Not determined | Contains functional groups that may form cationic intermediates during reaction with water at environmental pH (4-9) |
| Flash Point | 204.5 °C | (M)SDS |
| Autoignition Temperature | > 250 °C | (M)SDS |
| Explosive Properties | Not determined | Contains no functional groups that imply explosive properties |
| Oxidising Properties | Not determined | Contains no functional groups that imply oxidative properties |

* Value determined for the monomer of the notified polymer.

DISCUSSION OF PROPERTIES

*Reactivity*
The notified polymer contains the reactive isocyanate functional group that readily reacts with substances which contain active hydrogen.

***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 as a component of plastic pellets at < 1% concentration.

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

| *Year* | *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Tonnes* | < 1 | < 1 | < 1 | < 1 | ≤ 1 |

PORT OF ENTRY
Melbourne

IDENTITY OF RECIPIENTS
P. D. Plastics (Australia) Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported as a component of plastic pellets at < 1% concentration in 25 kg bags. The products will be transported by road from the port of entry to clients.

USE
The imported plastic pellets containing the notified polymer will be compounded with other materials to form coloured plastic pellets (masterbatches) which will be used in the manufacture of injection moulded articles. The imported plastic pellets will also be directly used in the manufacture of injection moulded articles. The resulting articles will be used tactile elements on floors for easier orientation by blind people in traffic areas and public buildings. Final plastic articles will contain < 1% notified polymer.

OPERATION DESCRIPTION

*Masterbatch production*
The imported plastic pellets containing the notified polymer will be compounded with other materials to form coloured plastic pellets (masterbatches) through processes involving weighing and transferring into a mixer,

mixing, extruding, QA testing, dispensing of resulted pallets into 25 kg drums, and routine cleaning and maintenance. The mixing and extrusion will be performed in an enclosed system.

*Injection moulding*
The imported plastic pellets containing the notified polymer will also be used in the manufacture of injection moulded articles through processes involving transfer of the base pellets and masterbatches into the injection-moulding machine, where they are melted and injected into a mould before being ejected into suitable receptacles.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1. Exposure Assessment

#### 6.1.1. Occupational Exposure

EXPOSURE DETAILS
Transport and storage workers may come into contact with the notified polymer at < 1% concentration only in the event of an accidental rupture of containers.

*Masterbatch production and injection moulding*
Masterbatch production and injection moulding processes are expected to be largely enclosed and automated; however, workers may be exposed (dermal and ocular) to the notified polymer at < 1% concentration when weighing and transferring the pellets to the mixer or injection moulding machine, during quality control testing and maintenance and cleaning tasks. Exposure will be limited as the notified polymer will be introduced in plastic pellets where it will be bound within the polymer matrix and hence not bioavailable. Inhalation exposure to the notified polymer at < 1% concentration may occur if dust particles are generated from the compounding of the pellets. The notifier has stated that the use of personal protective equipment (PPE) including respiratory protection, chemical resistant gloves, safety googles, safety shoes and protective clothing are expected to be worn by workers, which should mitigate worker exposure.

#### 6.1.2. Public Exposure
Imported plastic pallets containing the notified polymer at < 1% concentration are only for use in industrial settings. The public may come into contact with tactile elements on floors containing < 1% notified polymer; however, the notified polymer will be bound in the polymer matrix of the plastic articles and hence will not be bioavailable.

### 6.2. Human Health Effects Assessment
No toxicity data were submitted. Absorption across biological membranes is expected to be limited by the relatively high molecular weight (> 500 Da) of the notified polymer.

The notified polymer contains the diisocyanate functional group and hence is expected to have the health effects associated with diisocyanates to some extent. Diisocyanates are well known dermal and inhalation sensitisers in the workplace and have been documented to cause asthma, lung damage, and in severe cases, fatal reactions (US EPA 2011b). Apart from the concern for irritation and pulmonary toxicity (Barrett 1994, US EPA 2010, Kirk-Othmer 1995), isocyanates may also cause respiratory sensitisation by skin contact (US EPA, 2010).

As in the case of the notified polymer, polymeric isocyanates tend to be non-volatile and are therefore expected to be less of an inhalation hazard compared to non-polymeric isocyanates. However, aerosols of polymeric isocyanates may cause respiratory sensitisation similar to monomer vapours, and reports have shown that inhalation of relatively non-volatile isocyanates in the form of dusts and spray mists may cause adverse respiratory effects (HSIS, 2008).

***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.

The notified polymer contains isocyanate functional groups. According to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), substances containing isocyanate functional groups should be classified

as hazardous if there is no evidence to indicate that the substance does not cause respiratory hypersensitivity. Therefore, the following risk phrase should apply to the notified polymer:

R42: May cause sensitisation by inhalation

In the MSDS provided by the notifier, the notified polymer is classified as H317- May cause an allergic skin reaction and H334- May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### 6.3. Human Health Risk Characterisation

#### 6.3.1. Occupational Health and Safety

The notified polymer contains reactive isocyanate functional groups which are known to be hazardous and cause potential irritation and sensitisation to the skin and respiratory system.

Dermal and ocular exposure to the notified polymer during the manufacture of masterbatches or plastic articles is expected to be low due to its introduction at < 1% concentration in plastic pellets where it will be bound within the polymer matrix and hence not bioavailable. There is the potential for inhalation exposure by workers if dust particles containing < 1% notified polymer are generated from the compounding of the pellets. The notifier has stated that PPE including respiratory protection is expected to be used and hence inhalation exposure is expected to be limited. Therefore given the expected low exposure, the risk to the health of workers from the use of the notified polymer is not considered to be unreasonable

#### 6.3.2. Public Health

The public have the potential to be exposed to plastic articles containing the notified polymer at < 1% concentration. However, the notified polymer will be bound in the polymer matrix of the plastic articles and hence will not be bioavailable. Therefore, the notified polymer is not considered to pose an unreasonable risk to public health.

## 7. ENVIRONMENTAL IMPLICATIONS

### 7.1. Environmental Exposure & Fate Assessment

#### 7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured in Australia. Therefore, release of the notified polymer to the environment is not expected from this activity. The notified polymer in plastic pellets will be blended with other ingredients to form coloured plastic pellets (masterbatches). In the event of accidental spills at storage sites and the generated waste of the notified polymer during blending is expected to be collected and reused.

RELEASE OF CHEMICAL FROM USE

The imported plastic pellets containing the notified polymer and the reformulated coloured plastic pellets (masterbatches) will be used in manufacture of injection moulded articles. The resulting articles will be used as tactile elements for floors for easier orientation by blind people in traffic areas and public buildings. Wastes of the plastic pellets containing the notified polymer during manufacturing of various injection-moulded articles are expected to be collected and reused. Release of the plastic pellets containing the notified polymer to the aquatic environment is not expected.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues of the notified polymer in empty containers are expected to be collected by waste management contractors for disposal by thermal decomposition or recycling. The notified polymer will be incorporated in moulded article. The plastic articles at the end of their useful lives are expected to share the fate of the plastic articles, and be disposed of to landfill.

#### 7.1.2. Environmental Fate

No environmental fate data were submitted. The notified polymer will be physically incorporated within the inert polymer matrix. All wastes including import container residues and empty containers are expected to be disposed of to landfill. At the end of their useful life, the articles containing the notified polymer are expected to be disposed of to landfill. The solid polymer matrix as waste is not expected to be mobile, bioavailable or

readily biodegradable in this form. The notified polymer will eventually degrade biotically or abiotically in landfill to form water and oxides of carbon and nitrogen.

#### 7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) for the notified polymer has not been calculated since no significant release to the environment is expected based on its reported use pattern.

### 7.2. Environmental Effects Assessment

No ecotoxicological data were submitted. The notified polymer is not expected to persist in water due to its hydrolytic instability. In addition, the notified polymer is not expected to be isolated from plastic articles and be bioavailable. Therefore, the notified polymer is expected to be of low concern to aquatic organisms.

#### 7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) for the notified polymer has not been calculated as no ecotoxicological data were submitted and the notified polymer is not expected to pose an unreasonable risk to the aquatic environment.

### 7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified polymer has not been calculated as release to the aquatic environment is not expected based on its reported use pattern as a component of plastic moulded articles. The notified polymer is irreversibly bound in the inert polymer matrix, and is unlikely to be bioavailable or mobile in this form. Therefore, based on its assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

# BIBLIOGRAPHY

Barratt MD, Basketter DA, Chamberlain M, Admans GD and Langowski JJ (1994), An Expert System Rulebase for Identifying Contact Allergens. Toxicology In Vitro 8(5), 1053-1060

HSIS (2008) Isocyanates Exposure Standard Documentation. Safe Work Australia. Accessed online 1st September, 2010.

Kirk-Othmer Encyclopedia of Chemical Technology, 4th edition (1995) M Howe-Grant (ed). Vol 14, p.902 (Richter RH and Priester RD contributors). New York, John Wiley and Sons.

NOHSC (1990) Isocyanates. National Occupational Health and Safety Commission, Canberra, Worksafe Australia.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html.

US EPA (2010) TSCA New Chemicals Program (NCP) Chemical Categories. Washington, D. C., http://www.epa.gov/oppt/newchems/pubs/npcchemicalcategories.pdf.

US EPA (2011) Methylene Diphenyl Diisocyanate (MDI) and Related Compounds Action Plan (RIN 2070-ZA15, April, 2011), United States Environmental Protection Agency. Washington, DC, USA.