

File No: LTD/1651

April 2013

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

PUBLIC REPORT

Polymer in Liofol UR 3833

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 Sustainability, Environment, Water, Population and Communities.

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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

**Director
NICNAS**

TABLE OF CONTENTS

SUMMARY	3
CONCLUSIONS AND REGULATORY OBLIGATIONS	3
ASSESSMENT DETAILS	5
1. APPLICANT AND NOTIFICATION DETAILS	5
2. IDENTITY OF CHEMICAL	5
3. COMPOSITION	6
4. PHYSICAL AND CHEMICAL PROPERTIES	6
5. INTRODUCTION AND USE INFORMATION	7
6. HUMAN HEALTH IMPLICATIONS	7
6.1. Exposure Assessment	7
6.2. Human Health Effects Assessment	8
6.3. Human Health Risk Characterisation	8
7. ENVIRONMENTAL IMPLICATIONS	9
7.1. Environmental Exposure & Fate Assessment	9
7.2. Environmental Effects Assessment	9
7.3. Environmental Risk Assessment	10
BIBLIOGRAPHY	11

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/1651	Henkel Australia Pty Ltd	Polymer in Liofol UR 3833	Yes	< 100 tonnes per annum	Component of a two part adhesive system for food packaging

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 presence of the isocyanate functional group in the notified polymer, 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

Provided the recommended control measures are in place, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

The risk to occupational health and safety is not considered unreasonable provided that the notified polymer is only used under controlled conditions by trained workers wearing PPE.

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

Environmental risk assessment

On the basis of the assessed use pattern and assumed low hazard, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

Health Surveillance

- As the notified polymer contains functional groups of concern, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a history of sensitivity, asthma or other pulmonary condition and who may be adversely affected by isocyanate exposure.

CONTROL MEASURES

Occupational Health and Safety

- 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 (< 50% concentration):
 - Do not breathe vapours/spray
 - Avoid contact with skin and eyes
- A person conducting a business or undertaking at a workplace should implement the following safe engineering controls to minimise occupational exposure during handling of the notified polymer (< 50% concentration):

- Ventilation system, including local exhaust ventilation
- 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 (< 50% concentration):
 - Safety glasses
 - Coveralls
 - Gloves
 - Respirator

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

- Atmospheric monitoring should be conducted to measure workplace concentrations of isocyanates during use of products containing the notified polymer. Employers should ensure that the exposure standard for isocyanates [NOHSC: 1003(1995)] is not exceeded for all areas where the notified polymer will be handled.
- 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.

Public Health

- The following measures should be taken by the notifier to minimise public exposure to the notified polymer:
 - the food packaging film, which contains the notified polymer, should be fully cured.

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.
- The following precautions should be taken regarding storage of the notified polymer:
 - Product should be stored indoors in a cool, dry, well-ventilated area.
 - Containers should be sealed when not in use.
 - Protect from physical damage and store according to relevant Dangerous Goods Storage Requirements.

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 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 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 polymer has a number-average molecular weight of less than 1000;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of a two-part adhesive system for use in food packaging, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 100 tonnes per annum, 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 chemical/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 product containing the notified polymer provided by the notifier was 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)

Henkel Australia Pty Ltd (ABN: 82 001 302 996)
135-141 Canterbury Road
KILSYTH VIC 3137

NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn ≥1000 Da.

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, analytical data, degree of purity, polymer constituents, residual monomers, impurities, use details, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physico-chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Polymer in Liofol UR 3833 (contains notified polymer at < 80% concentration)

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference FTIR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

One hazardous impurity is present at a level above the concentration cut-off for classification. The impurity is present at a concentration of > 1% and may result in carcinogenicity (Cat. 3) and skin and respiratory sensitisation (HSIS classification: R40; R42/43).

DEGRADATION PRODUCTS

The notified polymer is stable under normal conditions. No degradation expected under normal storage and handling conditions.

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Expected to be liquid at room temperature
Density	1060 kg/m ³ at 20 °C	(M)SDS*
Vapour Pressure	Not determined	Expected to be low based on molecular weight
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	Not determined	Expected to be high based on high molecular weight
Flammability	Not determined	Not expected to be flammable
Autoignition Temperature	Not determined	Expected to be high
Explosive Properties	Predicted negative	Contains no functional groups that would infer explosive properties
Oxidising Properties	Predicted negative	Contains no functional groups that would infer oxidising properties

*MSDS for product containing < 80% notified polymer.

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer reacts readily with water.

Physical hazard classification

Based on the submitted physical-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 solvent solution at < 80% concentration.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	< 100	< 100	< 100	< 100	< 100

PORT OF ENTRY

Sydney or Melbourne.

IDENTITY OF RECIPIENT

Henkel Australia Pty Ltd

TRANSPORTATION AND PACKAGING

The notified polymer will be imported at < 80% concentration in 200 L closed head mild steel drums and 20 L steel cans and transported within Australia by road.

USE

The notified polymer will be used as a component (at < 80% concentration) of two-part adhesives for use in film lamination for food packaging.

OPERATION DESCRIPTION

The notified polymer at < 80% concentration will be manually mixed in a bucket with the other component of the two-part adhesive system and diluted with solvent. The mixed adhesive solution (containing < 50% notified polymer) will be poured into the coating machine and then applied by roller to the film, which then passes through a curing oven. The cured film will be distributed to customers for use in food packaging.

6. HUMAN HEALTH IMPLICATIONS**6.1. Exposure Assessment****6.1.1. Occupational Exposure****CATEGORY OF WORKERS**

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Warehouse	1-2	150-240
Transport	1-2	6-12
Application	2-6	150-240
Disposal	1-4	1-6

EXPOSURE DETAILS*Transport and Storage*

Transport and storage workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident.

Application

Dermal, ocular or even inhalation exposure may occur when mixing the adhesive containing notified polymer (at < 80% concentration) with the other component or when pouring the uncured adhesive into the coating machine. Exposure will be minimised by the use of ventilation and the use of PPE (including organic

respirator, safety glasses and impermeable gloves). The notified polymer is expected to fully react with the second component, therefore once cured, the notified polymer will be trapped in an inert polymer matrix and will be unavailable for exposure.

6.1.2. Public Exposure

The product containing the notified polymer at < 80% concentration will not be available to the general public. Cured films containing the notified polymer will be used for food packaging but direct food contact to the cured adhesive is not expected because it will be fixed between layers of film. Additionally, once cured, the notified polymer is expected to fully react and will be unavailable for exposure.

6.2. Human Health Effects Assessment

No toxicity data were provided for the notified polymer.

The notified polymer is not expected to be absorbed across biological membranes to a significant extent, based on its high molecular weight ($M_n > 1,000$ Da). However, the polymer contains a relatively low percentage of low molecular weight species (< 1,000 Da) that may be absorbed.

The notified polymer contains isocyanate functional groups that are of concern for irritation, dermal and respiratory sensitisation, and pulmonary toxicity (Barrett 1994, US EPA 2010, Kirk-Othmer 1995).

The USEPA specifies that structures with isocyanate equivalent weights of $\geq 5,000$ Da are presumed not to pose a hazard under any conditions. In addition, concerns are generally confined to species with molecular weights < 1,000 Da. The isocyanate functional group equivalent weight of the notified polymer is < 5,000 Da and although its molecular weight is > 1,000 Da, the polymer contains a proportion of low molecular weight species, hence the risks cannot be ruled out.

Polymeric isocyanates tend to be non-volatile and are therefore expected to be less of an inhalation hazard compared to non-polymeric isocyanates. However, polymeric isocyanate aerosols 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 could cause adverse respiratory effects (HSIS, 2008). Isocyanates may also cause respiratory sensitisation by skin contact (US EPA, 2010).

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. Thus, the following risk phrase should be applied to the notified polymer:

R42: May cause sensitisation by inhalation

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.

Based on the presence of the isocyanate functional group in the notified polymer, 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.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymer contains isocyanate functional groups that are of concern for irritation, skin and respiratory sensitisation and pulmonary toxicity. Dermal and ocular exposure to the notified polymer at < 80% concentration during transfer and application of the adhesive is expected to be limited by the use of PPE. Due to the expected low volatility of the notified polymer and given the expected use of exhaust ventilation, inhalation exposure is not anticipated. Therefore, provided control measures are in place to reduce exposure, the risk to the health of workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer is intended for use in industrial applications only. The public may be exposed to food packaging manufactured using the notified polymer. The notifier has advised that exposure is not likely as the notified polymer is not expected to migrate from the adhesive as it will be fully reacted into an inert matrix. The manufacturer of the food packaging is responsible for ensuring the adhesive containing the notified polymer has fully cured so that the levels of reactive, low molecular weight species are below the limits of detection. Therefore provided end-users i.e. food packaging manufacturers employ good manufacturing processes to ensure complete curing of the adhesive the risk to public health is not considered to be unreasonable.

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, no release of the notified polymer to the environment is expected from this activity. In the event of accidental spills and leaks at storage sites and during mixing with the adhesive components, the notified polymer is expected to cure to form a solid mass. The cured solid mass is expected to be collected and disposed of to landfill. Any spills during transportation are not expected to result in significant release to aquatic environments as the notified polymer will react with water and atmospheric moisture to form an insoluble solid that can subsequently be collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified polymer will be applied to the substrates using a roller. A small amount of the notified polymer is expected to be released to the environment due to wastes from spills and cleaning of application equipment. The notified polymer in these wastes is expected to cure to an inert solid on exposure to ambient conditions and the cured mass will be contained and disposed to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer will be incorporated in a polymer matrix and bound to the surface of substrates after application. It is expected to share the fate of the substrate to which it has been applied and is predominantly expected to be disposed of to landfill. Residual notified polymer in empty import containers is expected to be cured into an inert solid matrix and be disposed of to landfill along with the empty containers.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified polymer is expected to be disposed of to landfill as cured waste, residues in empty containers, and coated articles at the end of their useful life. Uncured notified polymer disposed of to landfill is expected to react with water and atmospheric moisture to form an insoluble solid polymer matrix. The solid polymer matrix as waste and cured onto articles 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)

A predicted environmental concentration (PEC) was not calculated because the notified polymer is not expected to persist in the aquatic compartment due to its hydrolytic instability. Furthermore, the notified polymer is never isolated from the adhesive. The notified polymer rapidly reacts with water and other components of the adhesive product to form insoluble, non-bioavailable, high molecular weight solids. Moreover, very limited aquatic exposure to the notified polymer or its hydrolysis products is expected when the notified polymer is used as proposed.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. The notified polymer is not expected to persist in water due to its hydrolytic instability. In addition, the notified polymer is never isolated from the adhesive and reacts with water to form insoluble, non-bioavailable, high molecular weight solids. Therefore, the notified polymer is expected to be of low concern to aquatic organisms.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for the notified polymer has not been calculated as no ecotoxicity data for the polymer 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 ($Q = \text{PEC}/\text{PNEC}$) for the notified polymer has not been calculated as release to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern as a component of an adhesive. The majority of the notified polymer will be disposed of to landfill as a cured polymer matrix. The notified polymer is irreversibly bound in the inert polymer matrix, and is unlikely to be bioavailable or mobile in this form. On the basis of the assessed use pattern and assumed low hazard, 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 (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/newchemicals/pubs/npcchemicalcategories.pdf>