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

FULL PUBLIC REPORT

Isocyanate Polymer in Pur-Fect Lok 91-834A

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, Water, Heritage and the Arts.

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 Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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**

TABLE OF CONTENTS

<u>FULL PUBLIC REPORT</u>	3
1. APPLICANT AND NOTIFICATION DETAILS.....	3
2. IDENTITY OF CHEMICAL	3
3. COMPOSITION.....	3
4. PHYSICAL AND CHEMICAL PROPERTIES.....	4
5. INTRODUCTION AND USE INFORMATION.....	4
6. HUMAN HEALTH IMPLICATIONS.....	5
6.1 Exposure assessment.....	5
6.1.1 Occupational exposure.....	5
6.1.2 Public exposure.....	6
6.2 Human health effects assessment.....	6
6.3 Human health risk characterisation.....	6
6.3.1 Occupational health and safety	6
6.3.2 Public health.....	7
7. ENVIRONMENTAL IMPLICATIONS	7
7.1 Environmental Exposure & Fate Assessment.....	7
7.1.1 Environmental Exposure.....	7
7.1.2 Environmental fate.....	7
7.1.3 Predicted Environmental Concentration (PEC)	8
7.2 Environmental effects assessment	8
7.2.1 Predicted No-Effect Concentration	8
7.3 Environmental risk assessment	8
8. CONCLUSIONS AND REGULATORY OBLIGATIONS.....	8
<u>BIBLIOGRAPHY</u>	11

FULL PUBLIC REPORT**Isocyanate Polymer in Pur-Fect Lok 91-834A****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 $M_n \geq 1000$ Da.

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, polymer constituents, residual monomers/impurities, use details, import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Melting/boiling point, water solubility, vapour pressure, hydrolysis as a function of pH, adsorption/desorption, dissociation constant, autoignition temperature

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

CEC/775

NOTIFICATION IN OTHER COUNTRIES

USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Pur-Fect Lok 91-834A (containing < 65% notified polymer)

OTHER NAME(S)

Isocyanate-terminated urethane polymer

ANALYTICAL DATA

Reference NMR, GPC and DSC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

The notified polymer contains a residual monomer that is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC: 1008 (2004)]. The impurity is present in the notified polymer at levels above the cut off concentrations for hazard classification.

ADDITIVES/ADJUVANTS None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Stable under normal conditions of use. Reacts as part of intended use as an adhesive.

DEGRADATION PRODUCTS

None under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: White semi-solid (highly viscous)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	> 20°C	Estimated
Thermal transition	Exothermic transition observed in the differential scanning calorimetry trace of the notified polymer at ~48°C. This may be the crystallisation temperature of the notified polymer.	Measured
Density	1070 kg/m ³ at 20°C (imported product)	MSDS
Vapour Pressure	< 1.3 x 10 ⁻⁹ kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2007)
Water Solubility	Not tested*	Expected to be water dispersible, based on the presence of hydrophilic moieties in the chemical structure.
Hydrolysis as a Function of pH	Not tested*	The core of the notified polymer contains groups that are expected to hydrolyse only very slowly in the environmental pH range (4–9) at ambient temperature.
Partition Coefficient (n-octanol/water)	Not tested*	The notified polymer and the insoluble polymeric masses are not expected to be bioavailable based on their high molecular weight.
Adsorption/Desorption	Not tested*	-
Dissociation Constant	Not determined	The notified polymer has no dissociable functions
Particle Size	Not determined	Notified polymer is a semi-solid at room temperature
Flash Point	> 160°C (Cleveland open cup) (imported product)	MSDS
Autoignition Temperature	Not determined	The notifier has stated that the notified polymer is not expected to autoignite at ambient temperatures based on experience in use.
Explosive Properties	Not determined	The notified polymer does not contain explosives.

* Not tested due to the presence of end-groups that readily react with water or octanol to form insoluble polymeric masses.

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer is stable under normal storage and handling conditions. It reacts as part of its intended use as an adhesive.

Dangerous Goods classification

Based on the limited physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported by airfreight or ship (Melbourne or Sydney) as a component (<65%) of a hot melt adhesive.

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>	10-20	10-20	10-20	10-20	10-20

PORT OF ENTRY

Melbourne and Sydney

IDENTITY OF RECIPIENTS

Henkel Australia Pty Ltd
135 – 141 Canterbury Rd
Kilsyth Vic 3137

TRANSPORTATION AND PACKAGING

The notified polymer will be imported in sealed 25 kg or 200 kg steel drums and transported by road to the end user site.

USE

Component of hot melt adhesive (< 65% concentration) for use in laminating/bonding of sandwich panels for caravans.

OPERATION DESCRIPTION

The seal of import drums will be broken and the product containing the notified polymer (< 65% concentration) will be heated to 120°C and applied using a fully automated volumetric dispensing system whereby the exact volume required will be deposited. The product will be applied to the substrate (expanded polystyrene, wood or aluminium) using a roll to roll laminator. Once applied, the laminated material will then be allowed to cure through reaction with atmospheric moisture or absorption onto the surface of the substrate.

At the end of the application process the remaining adhesive in the melting unit will be drained out and allowed to cure.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and Storage	1-5	1	200
Application Operators	2	6	100
Cleaning and Maintenance	1	0.5	100
Quality Inspector	1	2	40

EXPOSURE DETAILS

Exposure of transport workers to the notified polymer is not expected to occur except in the event of an accident.

Exposure of workers to the notified polymer (< 65% concentration) may occur via the dermal route and perhaps the ocular and inhalation route (though aerosols are not expected to be generated) during the opening of containers, application of the adhesive, handling of the substrate, cleaning operations and during curing. Such exposure is expected to be minimised by the fully automated nature of the application process, the ventilation hoods present in the heating/application area, and the wearing of personal protective equipment by workers, including gloves, goggles, overalls, and respiratory protection. In addition, curing of the substrate will

take place in areas with natural ventilation and following curing the adhesive will be inert and not bioavailable.

It is also noted that, due to the presence of other hazardous substances in the product containing the notified polymer, there are expected to be controls in place during its handling that are appropriate for these hazards. These controls are expected to also reduce exposure of workers to the notified polymer.

6.1.2. Public exposure

The public will only be exposed to the notified polymer after it has been cured on an inert matrix and is no longer bioavailable, or in the case of an accident during transportation.

6.2. Human health effects assessment

No toxicity data were submitted 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 ($M_n > 1000$ Da).

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

The USEPA specifies that structures with isocyanate equivalent weights of $\geq 5,000$ are presumed not to pose a hazard under any conditions. In addition, concerns are generally confined to species with molecular weights $< 1,000$. The isocyanate functional group equivalent weight of the notified polymer is $< 5,000$, however, its molecular weight is $> 1,000$. A relatively low proportion of low molecular weight species are present in the notified polymer. At such levels health concerns of the notified polymer associated with the isocyanate functionality 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 (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

Based on the presence of the isocyanate functional group the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

Xn; R42 May cause sensitisation by inhalation.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Toxicological data was not supplied for the notified polymer. On the basis of the presence of isocyanate functional groups, the notified polymer may cause irritation, dermal and respiratory sensitisation and pulmonary toxicity. Such effects cannot be ruled out, though they are expected to be reduced by the relatively low proportion of low molecular weight species present in the notified polymer.

Dermal exposure is the main potential route of worker exposure to the notified polymer ($< 65\%$ concentration) during the process of applying the product to substrates. Irritation and sensitisation may occur as a result of dermal exposure. Dermal exposure is expected to be minimised by the automated processes in place for many of the handling and application operations, the ventilation hoods present in the application area, and the wearing of personal protective equipment by workers, including gloves, goggles, and overalls.

Inhalation exposure of workers to the notified polymer may also occur, however, the expected low vapour pressure of the notified polymer may limit this route of exposure and in addition, generation of aerosols is not

expected. Adverse effects resulting from repeated inhalation exposure to the notified polymer may include respiratory sensitisation and pulmonary toxicity. The short term exposure limit (STEL) of 0.07 mg/m³ and long term time-weighted-average (TWA) exposure limit of 0.02 mg/m³ is set for the airborne concentration of all isocyanates in the workplace [NOHSC: 1003(1995)]. Airborne levels of isocyanates should remain below these levels at all areas of the adhesive processing site, including the hot melt, application and curing areas. The engineering controls in place to reduce exposure to vapours of the adhesives, such as the automated operations, adequate local exhaust ventilation, the use of respiratory protection, and the general ventilation present during curing, are expected to lower potential inhalation exposure to the notified polymer. Respiratory protection should be used, as deemed appropriate, during handling procedures involving the notified polymer and if significant amounts of the notified polymer or residual monomers remain uncured. Such respiratory protection should consist of an appropriately fitted and maintained air-line respirator or self-contained breathing apparatus complying with the appropriate Australian Standard.

It is noted that the measures in place to minimise risks involved in handling the hazardous substances present in the product containing the notified polymer are expected to correspondingly reduce the risk associated with handling of the notified polymer.

In summary, the risk to workers associated with exposure to the notified polymer is not considered unacceptable assuming that the stated engineering controls, safe work practices and appropriately fitted and maintained PPE (particularly respiratory protection) are used.

6.3.2. Public health

As no public exposure to the notified polymer is expected from the cured coated material, the risk to the public from the use of the notified polymer is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported as a component in ready-to-use polyurethane hot-melt adhesive. The notified polymer will not be manufactured or reformulated in Australia. Accidental spills during transport are expected to be collected, cured and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The formulated adhesive containing the notified polymer will be used in commercial settings to laminate/bond sandwich panels for caravans. Molten adhesive will be applied to expanded polystyrene, wood or aluminium substrates by a fully automated dispensing system. The adhesive will cure on exposure to atmospheric moisture to form a solid inert matrix. Up to 2% of the annual import volume of notified polymer is expected to be released to landfill as waste collected from the cleaning of manufacturing equipment and the residue remaining in empty import containers. The residues of the formulated product will be allowed to cure before disposal to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer will share the fate of the articles to which it has been applied. At the end of their useful life most of the articles will be sent to landfill. Additionally, some metal substrates may be sent to recycling facilities.

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 from the cleaning of manufacturing equipment, residues in empty import containers, and articles at the end of their useful life. Small quantities of notified polymer in adhesive on metal substrates may be sent to metal reclamation facilities. The notified polymer will be irreversibly cross-linked into a solid polymer matrix as part of its normal use pattern and is therefore not expected to be mobile, bioavailable or readily biodegradable. The notified polymer will eventually degrade biotically or abiotically in landfill, or by thermal decomposition during metal reclamation, to generate water and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

A predicted environmental concentration (PEC) was not determined because the notified polymer is not expected to persist in water due to its hydrolytic instability. Additionally, the notified polymer is never isolated from the hot-melt adhesive, which reacts with moisture (water) 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 ecotoxicological data were submitted. The notified polymer is not expected to persist in water due to its hydrolytic instability. Additionally, the notified polymer is never isolated from the hot-melt adhesive, which reacts with moisture (water) to form insoluble, non-bioavailable, high molecular weight solids. Therefore, the notified polymer is not expected to pose a concern to the aquatic environment.

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 for the polymer were submitted, and as no significant aquatic exposure is expected based on its reported use pattern.

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 is not expected based on its reported use pattern as a component in industrial ready-to-use hot-melt adhesive in a controlled factory environment. The majority of the notified polymer will be disposed of to landfill as cured adhesive. In the cured adhesive the notified polymer is irreversibly bound into a solid inert resin matrix, and is unlikely to be bioavailable or leach in this form. Due to its limited environmental exposure, the risk of the notified polymer to the environment is expected to be low based on its reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], with the following risk phrase:

Xn; R42 May cause sensitisation by inhalation

and

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	<i>Hazard category</i>	<i>Hazard statement</i>
Respiratory sensitisation	1	May cause allergy or asthma symptoms or breathing difficulties if inhaled

Human health risk assessment

Under the conditions of the occupational settings described where sufficient controls are in place to minimise inhalation exposure when necessary, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

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

Environmental risk assessment

On the basis of the reported use pattern, the notified polymer is not expected to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- Safe Work Australia, should consider the following health hazard classification for the notified polymer:
 - Conc \geq 1%: R42 may cause sensitisation by inhalation

Health Surveillance

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

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified polymer during application/use:
 - Ventilation system including local exhaust ventilation during application, and good general ventilation during curing.
 - Automated processes and closed systems, where possible.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Keep containers securely sealed and check regularly for spills and leaks.
 - Avoid inhalation of vapours, mists and aerosols.
 - Avoid contact with skin and eyes.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymers:
 - Isocyanate-resistant gloves
 - Overalls
 - Safety glasses
 - Appropriately fitted air-line respirators or self-contained breathing apparatus complying with the relevant Australian Standard for cleaning and maintenance workers, or in other circumstances when inhalation exposure may occur.

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 volatile adhesive components during use of the notified polymer. Employers should ensure that the exposure standard for isocyanates [NOHSC: 1003(1995)] is not exceeded for all areas of the adhesive application site.
- 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.

Storage

- The following precautions should be taken regarding storage of the notified polymer:
 - Check all containers against leakage and ensure lids and caps are tightly sealed
 - Store in a ventilated area.

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 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 polymer has a number-average molecular weight of less than 1000;
 - the polymer is used in a process where aerosols are formed;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of industrial hot melt adhesive (< 65% concentration) for use in laminating/bonding, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 20 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 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 MSDS of a product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

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