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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Loctite® PL Premium

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.

This Public Report is 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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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/1866	Henkel Australia Pty Ltd	Polymer in Loctite® PL Premium	ND*	≤ 10 tonnes per annum	Ingredient in single-component construction adhesives

* ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As only limited toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of 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 phrases:

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 with adequate labelling of the products containing the notified polymer, it is not considered to pose an unreasonable risk to public health.

Environmental risk assessment
On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Health Surveillance

- As the notified polymer is a potential respiratory and skin 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 safe work practices to minimise occupational exposure to the notified polymer as introduced in the adhesive product:
  - Ensure good general ventilation during application of adhesives.
  - Avoid breathing vapours.
  - Avoid skin and eye contact.
  - Clean up spills promptly

- 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 as introduced in the adhesive product:

– Impervious gloves
– Overalls
– Safety glasses
– Respiratory protection if inhalation exposure may occur

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

- Where good general ventilation is inadequate, and inhalation exposure may occur, atmospheric monitoring should be conducted to measure workplace concentrations of isocyanates during use of products containing the notified polymers. Employers should ensure that the exposure standard for isocyanates [NOHSC:1003 (1995)] is not exceeded for all areas where the notified polymer may be handled or present.

- 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 of 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.

Public Health

- The following measures should be taken by introducers and marketers:
  – Adequate labelling of adhesive packages containing the notified polymer that are intended for consumer use, detailing hazards and ways to reduce exposure
  – Compliance with the SUSMP (Standard for the Uniform Scheduling of Medicines and Poisons) entry for “ISOCYANATES, free organic”, if the adhesives containing the notified polymer meet the criteria for this category.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Storage

- The handling and storage of the products containing 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 containment, physical 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;
- the polymer is introduced in other than pre-packaged adhesives

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from ingredient of single-component construction adhesives 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 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 ≥ 1,000 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, analytical data, degree of purity, polymer constituents, residual monomers, impurities and additives/adjuvants.

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
USA, Korea, Mexico, Taiwan

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Loctite® PL Premium (contains 21% notified polymer)

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference IR, GPC, UV spectra were provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Tan oily paste*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	The notified polymer is not isolated from solution under normal conditions of use
Boiling Point	172–341°C #	(M)SDS
Density	~1,060 kg/m^3*	(M)SDS
Vapour Pressure	Not determined	Expected to be low based on the high molecular weight >1000 Da
Water Extractability	< 2%	The notified polymer contains reactive functional groups that readily react with water.
Hydrolysis as a Function of pH	Not determined	Test not conducted as the notified polymer contains reactive functional groups that readily react with water. However, the notified polymer contains hydrolysable functionalities, and hydrolysis is expected to be slow under environmental conditions (pH 4–9).
Partition Coefficient (n-octanol/water)	1.3–10.6	Measured. The notified polymer contains reactive functional groups that readily

		react with water.
Adsorption/Desorption	Not determined	Predicted to adsorb to soil from water due to its low water extractability. The notified polymer is also likely to irreversibly combine with soil through chemical reactions that are characteristic of these adhesive polymers.
Dissociation Constant	Not determined	Contains ionisable functionalities. Therefore, the notified polymer is expected to be ionised at the environmental pH range of 4–9.
Particle Size	Not determined	The notified polymer is not isolated from solution under normal conditions of use
Flash Point	121 °C*	(M)SDS
Autoignition Temperature	Not determined	Not expected to be autoignite under normal conditions of use
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

* For a product containing > 70% notified polymer
# For a marketed product containing 21% notified polymer

Reactivity
The notified polymer is expected to react with water (moisture) under normal conditions of use, to form carbon dioxide and insoluble high molecular weight polymers.

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 of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported into Australia as a component of finished construction adhesives at 21% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1–10	1–10	1–10	1–10	1–10

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Henkel Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported as a component of finished construction adhesives (at 21% concentration) in 295 mL foil-lined paper tubes (cartridges) with a plastic nozzle at one end for dispensing. The cartridges will be used in standard caulking guns. The products containing the notified polymer will be imported by sea and then transported by road to various warehouses and stores.

USE
The notified polymer will be used as an ingredient of single-component moisture-cured construction adhesives by professionals and do it yourself (DIY) users. The concentration of the polymer in the adhesives will be 21%. Both interior and exterior application of the adhesives will occur to surfaces such as wood, plywood, concrete, stone, metals and some plastics.

OPERATION DESCRIPTION
The notified polymer will not be manufactured or reformulated in Australia. At end-use sites, the imported adhesives will be applied via the caulking guns to the surface of the substrate to be glued. Application is via a thin bead of approximately 5–8 mm wide and pressure may be applied until the adhesive is cured.

5. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport	4	4
Warehouse	0.5	15
Application	0.25–2	1–10
Disposal	< 1	1–10

EXPOSURE DETAILS

Transport and Storage
Transport and storage workers may come into contact with the notified polymer as a component of construction adhesives (at 21% concentration) only in the unlikely event of rupture of containers.

End-use
Dermal and ocular exposure to the notified polymer (at 21% concentration) may occur when opening the containers and during application of the adhesive, and during cleaning. Exposure should be minimised through the use of personal protective equipment (PPE) including gloves, safety glasses and protective clothing, as specified on the M(SDS). Significant inhalation exposure is not expected due to the estimated low vapour pressure of the notified polymer, and the likelihood that only limited amounts of the adhesive will be used at any one time.

Workers may also be exposed to residues of uncured adhesives containing the notified polymer during cleaning and maintenance of application equipment. Exposure should be minimised by the anticipated use of PPE and by safe work practices such as cleaning up spills promptly, and avoiding contact with the adhesive.

Once the adhesive is cured and dried, the notified polymer will be reacted into the solid polymeric matrix and will not be available for exposure.

6.1.2. Public Exposure
Adhesives containing the notified polymer will be available to consumers for DIY use. Exposure of DIY users is expected to be similar to that experienced by professional workers, but is likely to be less frequent. It is not known whether DIY consumers would use PPE during application and cleaning.

The public may also come into contact with the glued and cured substrates containing the notified polymer. Once the adhesive is cured and dried, the notified polymer will be reacted into the solid polymeric matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

Only acute oral toxicity data were submitted for the notified polymer at > 70%. (See Appendix). Based on this study, the notified polymer at approximately 70% has a LD50 > 2000 mg/kg. Substantial adverse clinical signs were seen at this dosage.

The notified polymer is not expected to be absorbed across biological membranes to a significant extent based on its high molecular weight (Mn > 1,000 Da); however, due to the presence of a substantial percentage of low molecular weight species (<1,000 Da) dermal absorption cannot be ruled out.

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 US EPA specifies that structures with isocyanate equivalent weights of ≥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 expected to be << 5,000 Da and although its molecular weight is >1,000 Da, the polymer contains a substantial proportion of low molecular weight species; hence, the risks cannot be ruled out.

Polymeric isocyanates are less volatile and contain less free isocyanate, and are therefore expected to be less of an inhalation hazard. However, the UK Employment Medical Advisory Service believes polymeric isocyanate aerosols are capable of causing 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). 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 unless there is 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 only limited toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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

The notifier did not classify the notified chemical as hazardous. However the imported product containing the notified polymer is classified by the notifier as follows on the basis of other isocyanate impurities / components of the product:

Hazard classification	*Hazard statement*
Skin irritation (Category 2)	H315 – Causes skin irritation.
Skin sensitiser (Category 1)	H317 – May cause an allergic skin reaction.
Serious eye irritation (Category 2A)	H319 – Causes serious eye irritation.
Acute toxicity Inhalation (Category 4)	H332 – Harmful if inhaled.
Target Organ Systemic Toxicant - Single exposure (Category 3), respiratory tract irritation	H335 – May cause respiratory irritation.
Respiratory sensitiser (Category 1)	H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Carcinogenicity (Category 2)	H351 – Suspected of causing cancer.
Target Organ Systemic Toxicant - Repeated exposure (Category 2)	H373 – May cause damage to organs through prolonged or repeated exposure.

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 21% concentration during application and clean-up of the adhesive is expected to be limited by the use of PPE, as recommended on the (M)SDS. Due to the expected low volatility of the notified polymer, significant inhalation exposure is not anticipated. Exposure and risk would be further reduced by safe work practices such as avoidance of skin and eye contact, use in a well ventilated area, and prompt clean-up of spills.

The adhesives also contain lower molecular weight isocyanate impurities/components which are classified as hazardous. The controls in place to limit exposure to these chemicals would also reduce exposure to the notified polymer.

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 contains isocyanate functional groups that are of concern for irritation, skin and respiratory sensitisation and pulmonary toxicity. Adhesives containing the notified polymer will be used by consumers in a similar way to workers. The public may be exposed to products containing the notified polymer when applying the adhesive and during clean-up procedures. Exposure to the notified polymer during use of the adhesive would be limited by the use of PPE; however, it is not known whether the public would use PPE.

It is not clear whether the notified polymer meets the criteria for inclusion in the SUSMP (Standard for the Uniform Scheduling of Medicines and Poisons) as “ISOCYANATES, free organic” as it may meet the exemption criteria for this category. However, the label of the imported adhesive contains warnings and instructions for use, based on the presence of other hazardous components of the product. Adherence to this advice would reduce the exposure and risk of consumers using the adhesives. Label advice includes the following statements:

- Warning
- Individuals with lung or breathing problems or prior sensitization to isocyanates should not use this product.
- Avoid breathing vapours
- Avoid contact with eyes and skin
- Prolonged or repeated exposure may cause dermal or respiratory sensitization, effects may be permanent.
- Gloves recommended

First aid instructions are also included.

Once the adhesive is cured and dried, the notified polymer will be reacted into the adhesive polymeric matrix and will not be available for exposure.

Provided that the public has adequate label instructions regarding the hazard of the notifier and ways to reduce exposure during DIY use of the adhesives, the risk to public health from use of the notified polymer is not considered unreasonable.

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 into Australia as a component in finished products, comprising polyurethane based moisture curing construction adhesives. These will be used for interior and exterior applications to bond different substrates; wood, plywood, concrete, stone, metals and some plastics. No reformulation of the notified polymer is expected to occur in Australia. Minor releases can be expected from accidental spills and leaks during transport only, which are expected to be physically contained for disposal to landfill.

RELEASE OF CHEMICAL FROM USE

The adhesives containing the notified polymer will be used by both the Do-It-Yourself (DIY) consumers and professionals. The products containing the notified polymer are expected to be applied to substrates using a caulking gun. Upon application as an adhesive, the notified polymer will react rapidly and become part of the cured inert adhesive matrix. No significant release of the notified polymer to the aquatic compartment is expected from use. Small amounts of accidental spills and leaks are expected to be physically contained for disposal to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Adhesives containing the notified polymer are expected to be applied predominantly to polyurethane, masonry, concrete, metal, stone, plasterboard and timber articles. The notified polymer applied to substrates is expected to adhere to the surface to which it has been applied. At the end of the useful life, the articles are expected to be sent to landfill or thermally recycled for reuse of the plastics or metal material. Empty containers are expected to be sent to landfill, and the residual notified chemical in the containers is expected to be fully cured prior to disposal. Therefore, no environmental release of notified chemical is expected from disposal.

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified polymer. The notified polymer is expected to readily react with water. The majority of the notified polymer is expected to be associated with substrate surfaces as part of the adhesive matrix. Since the notified polymer is expected to be cured upon application and become an inert part of the adhesives matrix, it is not expected to be bioavailable to aquatic organisms.

The majority of the notified polymer is expected to be sent to landfill with the articles at the end of their useful life, or collected as spills/leaks and residues in containers. The remainder may be thermally decomposed in the processes for plastic or metal articles recycling. In either way, the notified polymer is expected to be degraded/decomposed into water, and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

Calculation of the Predicted Environmental Concentration (PEC) is not considered necessary since no significant release of the notified polymer to the aquatic environment is expected from the proposed use pattern.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. This is considered acceptable given no significant release of the notified polymer to the aquatic environment is expected from the proposed use pattern. However, it should be noted that some functional groups of the notified polymer would generate potentially cationic end groups when exposed to water.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) has not been calculated since no significant release of the notified polymer to the aquatic environment is expected from the proposed use pattern.

7.3. Environmental Risk Assessment

A Risk Quotient (PEC/PNEC) has not been calculated since no significant release of the notified polymer to the aquatic environment is expected from the proposed use pattern and no ecotoxicity data is available for the notified polymer.

Since there is expected to be very limited exposure to aquatic organisms, the notified polymer is therefore not considered to pose an unreasonable risk to the aquatic environment based on the assessed use pattern.

APPENDIX : TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer at > 70%
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar
Vehicle	
Remarks - Method	GLP certificate. There were no significant deviations from method used.
RESULTS	Under the conditions of this study the median lethal dose of notified polymer after oral administration was found to be greater than 2000 mg/kg body weight in rats.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 F	2000	No mortality
2	3 F	2000	No mortality

LD50	2000 mg/kg bw
Signs of Toxicity	No clinical observations in the first test group were observed. In the second test group, two of three animals revealed impaired general state, dyspnoea, piloerection, staggering, reduced faeces, respiration sounds and exsiccosis. Most findings occurred from day 6 or day 13, and persisted to the end of the 14 day study period. In one animal, respiration sounds were noted from 3 hours after administration.
Effects in Organs	The stomach of all animals contained light brown or red brown rubber-like or hardened and rubber-like conglomerates of the test substance. In one animal this was seen in conjunction with mucus, gaseous stomach and dark green discolouration of contents.
Remarks - Results	No mortality occurred.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	GmbH (2008) , Germany

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