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

FULL PUBLIC REPORT

PRO8600 in Hilti HIT-HY70

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 and Water Resources.

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 334-336 Illawarra Road, Marrickville NSW 2204.

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
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FULL PUBLIC REPORT

PRO8600 in Hilti HIT-HY70

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Hilti Pty Ltd (ABN 44 007 602 100)
23 Egerton Street
Silverwater NSW 2128

NOTIFICATION CATEGORY

Limited: Synthetic polymer with NAMW ≥ 1000 .

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: Chemical Name, Other Name, CAS Number, Molecular Formula, Structural Formula, Molecular Weight, Purity, Hazardous Impurities/Residual Monomers, Additives, Polymer Constituents

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

US: PMN P04-524 (2004), South Korea (2006), Japan (2006)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)

Urethane Methacrylate

MARKETING NAME(S)

PRO8600 (neat polymer)
Hilti HIT-HY70 (imported product)
PRO8469, FOR3112 (polymer blended with diluents)

MOLECULAR WEIGHT

Mn > 1,000 Da

ANALYTICAL DATA

Reference NMR, and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

>95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

All hazardous impurities/residual monomers are present below the relevant cut-offs for classification of the notified chemical as a hazardous substance.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

The polymer is a solid containing low level of impurity and additives. They are not expected to be released into the environment because of the physical properties of the polymer (high molecular weight, solid with negligible vapour pressure) and the conditions of processing and use (incorporated into formulations that are 100% cured (polymerised) using ultraviolet light/electron beam (UV/EB) or peroxide-cure technology).

DEGRADATION PRODUCTS

The polymer is stable under normal conditions. The auto-ignition temperature test shows that the first fumes are emitted at 250°C, the temperature at which the degradation is starting.

At higher temperatures, the polymer may decompose to its starting materials. In extreme conditions, hydrocyanic acid, carbon monoxide, and carbon dioxide may be released.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa

Amber solid (notified polymer)

Light grey, pasty semi-solid with ester-like odour (imported product)

Property	Value	Data Source/Justification
Pour point	79 ± 3°C	Measured
Density	1194.9 kg/m ³ at 20°C	Measured
Vapour Pressure	< 1.3 x 10 ⁻⁴ Pa at 25°C	Measured
Water Solubility	1.22 x 10 ⁻⁵ g/L at 20°C	Measured
Hydrolysis as a Function of pH	Kb for pH > 8 at 25°C: 5.265 x 10 ⁻³ L/mol-sec	Estimated
Partition Coefficient (n-octanol/water)	log Pow at 20°C = 3.71 to > 6.50	Measured
Adsorption/Desorption	log K _{oc} = 4.23 to > 5.63	Measured
Dissociation Constant	Not determined	Polymer contains no dissociable groups
Particle Size	Not determined	The notified polymer is a solid block unsuitable for particle size assessment.
Flash Point	185 ± 2°C at 101.3 kPa	Measured
Flammability	Not highly flammable	Measured
Autoignition Temperature	> 400°C	Measured
Explosive Properties	Not expected to be explosive	Predicted based on the chemical structure.
Oxidising Properties	Not expected to be oxidising	Predicted based on the chemical structure

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity

The notified polymer is expected to be stable under normal conditions.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be imported as a component of products in foil packs (300mL, 500mL and 1400mL) which will contain 15.5% of the notified polymer.

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

The product containing the notified polymer will be arriving in Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS

The polymer is manufactured in the Hilti Villers Saint Paul plant in France and imported to Hilti Australia.

TRANSPORTATION AND PACKAGING

The marketed product containing the notified polymer will be imported into Australia in packages containing the foil packs of 330mL, 500mL and 1400mL volumes and transported by road to the Hilti warehouse and sold to customers.

USE

The notified polymer is a component of a two-part adhesive mortar product for anchor and rebar fastenings. The imported product (Hilti HIT-HY70) is used in the construction industry as a chemical injection fastening system for all types of masonry base materials: hollow and solid, made from clay bricks, sand-lime stones, concrete blocks and aerated light-weight concrete, as well as for natural stones. The main applications are:

- Wall ties
- Horizontal and vertical overhead applications
- Scaffoldings
- Aerated facades
- Balconies
- Refurbishments
- Fastenings and fittings of sanitary components
- Elevator rails
- Cable trays
- Pipe fixings
- Brackets

OPERATION DESCRIPTION

The imported adhesive mortar is packed in two foil packs joined together. The curing process is initiated by combining Component A (15.5% notified polymer) and Component B (hardener) within the mixing nozzle (mixing ratio is A:B = 3:1) using the specialised dispenser equipment. The mortar which is formed (11.5% notified polymer) is directly injected into the borehole using the same dispenser. There is no clean up involved, as the foil packs and mixing nozzle are disposable.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

EXPOSURE DETAILS

Transport and Storage

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

Application

The typical users of the product containing the notified polymer will be professionals of companies with skilled craftsmen belonging to the following sectors: building and construction, mechanical, electrical, steel and metal, wood, interior finishing, industrial and government. The adhesive mortar will be directly injected to the area of application using the specialised dispenser system, which allows dosing and controls the flow of the injection. The supplier recommends the use of safety glasses, rubber gloves and protective clothing. When handled in this way, exposure of the workers to the notified polymer is expected to be low.

Once the notified polymer has been cured, it is fixed into the polymer matrix and is no longer bioavailable. Exposure to the notified polymer after curing is therefore negligible.

6.1.2. Public exposure

The notified polymer will not be sold to the public and it is unlikely that the public will come into contact with the adhesive mortar after use. However, if contact were to occur, exposure to the notified polymer would be negligible, as the polymer will have been cured into the matrix at this stage.

The public may be exposed to the notified polymer as the result of an accident during transport, however, this is considered to be unlikely and exposure would be minimised by the type and size of packaging used.

6.2. Human health effects assessment

No toxicity data were submitted. The notified polymer has $M_n > 1000$ Da so is unlikely to cross biological membranes. However, there is significant amount (>40%) of low MW species (<1000 Da). The notified polymer contains reactive functional groups which are a structural alert for irritation and sensitisation. However, the notified polymer would not be expected to exhibit sensitisation based on its MW. The notifier has therefore classified the polymer as an irritant carrying the risk phrases R36/38 (Irritating to eyes and skin).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Although the notified polymer is classified as irritating to the eyes and skin, the risk of dermal and ocular exposure in workers applying the adhesive mortar would be reduced due to the provision of the dispenser system, the use of personal protective equipment (PPE), and the low concentration ($\leq 15.5\%$) of the notified polymer in the imported product.

The risk of adverse health effects arising from exposure to the notified polymer after its use and curing is negligible, as the polymer will be 100% cured.

6.3.2. Public health

The risk to public health is considered to be negligible, based on the negligible public exposure expected, and the expected low hazard of the imported product ($\leq 15.5\%$ notified polymer).

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

There is little chance for release of the adhesive containing the notified polymer until the foil pack is broken allowing the adhesive to flow around the metal bolt. It is possible that some of the adhesive could be pushed out of the hole as the metal bolt is inserted, but this could be wiped away with rags or paper towels and disposed of with rubble and other construction waste. The excess material on the cloth or paper would crosslink into a solid mass.

RELEASE OF CHEMICAL FROM USE

It is likely that old rags or paper towels used to wipe away excess of the adhesive containing the notified polymer would be either placed into landfill or possibly be incinerated. In a landfill the cross linked material would be immobile and would be unlikely to leach into groundwater. Over time it could be expected to be slowly degraded as a result of slow biological and abiotic processes operative in these facilities, with production of water, methane, ammonia, oxides of nitrogen and carbon monoxide and dioxide. Incineration would destroy the material with production of water vapour and oxides of carbon and nitrogen.

Most of the material will become an integral part of masonry structures, and its fate will be that of the building rubble resulting from demolition of the old buildings. It is likely that this will be deposited into landfill.

In the event of accidental release of the non-cross linked material which contains 15.5% of the notified polymer (eg as a result of transport accident) it is expected the notified polymer would adsorb onto soils and be immobilised. The small pack size should limit release in an accident situation, and in the event of material reaching the water compartment the notified polymer is likely to become associated with the sediments. However, the M_n is greater than 1,000 Da, the notified polymer molecules would not therefore easily cross biological membranes and is not expected to bioaccumulate significantly.

RELEASE OF CHEMICAL FROM DISPOSAL

The total import volume of the notified chemical will ultimately be disposed as normal waste that will end up in either landfill or be incinerated. Used cartridges may be sent to recycling and disposal centres. In this scenario, the cartridges will be broken down into component parts for recycling.

The notified polymer that is incinerated is expected to thermally decompose to form predominantly simple organic and nitrogen based compounds and various salts. Similarly, the notified polymer that is disposed of to landfill should eventually degrade.

7.1.2 Environmental fate

No environmental fate data were submitted.

7.1.3 Predicted Environmental Concentration (PEC)

As there is no deliberate release to the aquatic environment, no PEC can be calculated.

7.2. Environmental effects assessment

No ecotoxicity data were submitted.

7.2.1 Predicted No-Effect Concentration

No ecotoxicological data were provided.

7.3. Environmental risk assessment

The environmental hazard from the notified polymer is expected to be limited when the material is used in the indicated manner. The polymer is imported in foil packs which also contain the hardening agent contained within a fragile vial in the centre of the pack, and most of the material will become part of a solid cross linked resin mass embedded in masonry structures, and will have little exposure to the environment. Most residual material resulting from application of the notified polymer will be deposited into landfill, although some may be incinerated. In a landfill situation the notified polymer will be immobile and is expected to undergo slow biological and abiotic degradation, while incineration will destroy the notified material with production of oxides of nitrogen and oxygen.

If accidentally released before it has been cross-linked into a solid mass, the polymer would associate with soils and sediments.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the presence of reactive functional groups, the notified polymer is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

R36/38 – Irritating to eyes and skin

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 2003) 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>
Skin irritant	2	Causes skin irritation
Eye irritant	2	Causes eye irritation

Human health risk assessment

Under the conditions of the occupational settings described, the risk to workers is considered to be [acceptable](#).

When used in the proposed manner the risk to the public is considered to be [acceptable](#).

Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- Use the following risk phrases for products/mixtures containing the notified polymer:
 - Conc \geq 20% R36/38
- The following safety phrases should appear on the MSDS and label for the product containing the notified polymer:
 - S24/25: Avoid contact with skin and eyes
 - S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
 - S37/39: Wear suitable gloves and eye/face protection

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer in the product Hilti HIT HY-70:
 - Avoid contact with skin, eyes or clothing
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer in the product Hilti HIT HY-70:
 - Tightly sealed safety goggles
 - Protective gloves - nitrile rubber gloves
 - Protective work clothing

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

- 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 to landfill.

Storage

- Store in a cool (5-25°C), dark and well-ventilated area away from sources of heat and ignition. Protect from heat and sunlight. Store away from foodstuffs.

Emergency procedures

- Do not allow spilled material to enter drainage, surface or ground water. Clean the accident area with organic solvents. Dispose of the collected material to landfill.

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 Da.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from component of a two-part adhesive mortar product for anchor and rebar fastenings, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 1 tonne, or is likely to increase, significantly;
 - if the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical 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 the product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Pour Point $79 \pm 3^{\circ}\text{C}$

Method OECD TG 102 Melting Point/Melting Range.
Remarks No significant protocol deviations. GLP compliance.
Test Facility SafePharm Laboratories (2007a).

Density 1194.9 kg/m^3 at 20°C

Method OECD TG 109 Density of Liquids and Solids.
Remarks Density was measured using a gas comparison pycnometer. No significant protocol deviations. GLP compliance.
Test Facility SafePharm Laboratories (2007a).

Vapour Pressure $< 1.3 \times 10^{-4} \text{ Pa}$ at 25°C

Method OECD TG 104 Vapour Pressure.
Remarks The vapour pressure was determined using a vapour pressure balance at $90\text{--}100^{\circ}\text{C}$. No statistical analysis was performed because the balance readings were too low and variable for a line of best fit to have any meaning. Instead a regression slope was imposed on a single data point from the last run to provide an estimate of the maximum value for the vapour pressure at 25°C . GLP compliance.
Test Facility SafePharm Laboratories (2007b).

Water Solubility $1.22 \times 10^{-5} \text{ g/L}$ at 20°C

Method OECD TG 105 Water Solubility.
Remarks EC Directive 92/69/EEC A.6 Water Solubility.
In the preliminary test an aliquot (0.1003 of the test material) was diluted to 550 mL with glass double-distilled water. After shaking at 30°C for 5 hours and standing at 20°C for 67 hours, the solution was centrifuged at 13500 rpm for 20 minutes and analysed by HPLC.
Test Facility SafePharm Laboratories (2007a).

Hydrolysis as a Function of pH Kb for $\text{pH} > 8$ at 25°C : $5.265 \times 10^{-3} \text{ L/mol-sec}$ for simplest molecule

Method
Remarks Based on the chemical structure of the notified polymer, it is likely that hydrolysis will occur since there are numerous groups that will be prone to hydrolysis. The estimated hydrolysis rate was determined by computer-based estimation software, HYDROWIN vl.67© 2000, U.S.Environmental Protection Agency.
Test Facility SafePharm Laboratories (2007a).

Partition Coefficient (n-octanol/water) $\log \text{Pow}$ at $20^{\circ}\text{C} = 3.71$ to > 6.50

Method OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks EC Directive 92/69/EEC A.8 Partition Coefficient.
HPLC Method. A 6 series of peaks were found which eluted from the column to beyond that of the highest of 13 reference materials (DDT).
Test Facility SafePharm Laboratories (2007a).

Adsorption/Desorption $\log K_{\text{oc}} = 4.23$ to > 5.63
– screening test

Method OECD TG 121 Estimation of the Adsorption Coefficient (K_{oc}) on Soil and Sewage Sludge using High Pressure Liquid Chromatography.

Remarks The method guideline states that measurement of adsorption coefficient should be carried out on substances in their ionised and non-ionised forms. In the absence of any environmentally relevant dissociating groups, the absorption/desorption was carried out at approximately neutral pH on the test material in its non-ionised form. A 6 series of peaks were found which eluted from the column to beyond that of the highest of 13 reference materials (DDT).

Test Facility SafePharm Laboratories (2007a).

Dissociation Constant Not determined

Remarks The test material is a complex mixture. Method OECD TG 112 is not applicable to material of this nature, Also there are no dissociable groups in the normal environmental pH range of 4-9.

Flash Point $185 \pm 2^{\circ}\text{C}$ at 101.3 kPa

Method EC Directive 92/69/EEC A.9 Flash Point.

Remarks Determined using a closed cup equilibrium method. No significant protocol deviations. GLP compliance.

Test Facility SafePharm Laboratories (2007b).

Flammability Not highly flammable

Method EC Directive 92/69/EEC A.10 Flammability (Solids).

Remarks No significant protocol deviations. GLP compliance. The pile ignited with a small orange flame which self-extinguished 12 seconds after the Bunsen flame was removed, without propagating combustion.

Test Facility SafePharm Laboratories (2007b).

Autoignition Temperature $> 400^{\circ}\text{C}$

Method 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).

Remarks No significant protocol deviations. GLP compliance.

Test Facility SafePharm Laboratories (2007b).

BIBLIOGRAPHY

- FORS (Federal Office of Road Safety) (1998) Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 6th Edition, Canberra, Australian Government Publishing Service
- NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- Safepharma Laboratories Limited (2007a) PRO8600,: SPL Project Number 2387/0001, Determination of general physico-chemical properties. Shardlow business park, Shardlow, Derbyshire, DE72 2GD, U.K.
- Safepharma Laboratories Limited (2007b) PRO8600,: SPL Project Number 2387/0002, Determination of hazardous physico-chemical properties. Shardlow business park, Shardlow, Derbyshire, DE72 2GD, U.K.
- United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.