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

PUBLIC REPORT

**Oxirane, 2-methyl-, polymer with oxirane, ether with 2-ethyl-2-(hydroxymethyl)-
1,3-propanediol (3:1), polymer with α -hydro- ω -hydroxypoly[oxy(methyl-1,2-
ethanediyl)] and 1,1'-methylenebis[4-isocyanatocyclohexane]**

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director
NICNAS**

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESS- MENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1757	BASF Australia Ltd	Oxirane, 2-methyl-, polymer with oxirane, ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1), polymer with α -hydro- ω -hydroxypoly[oxy(methyl-1,2-ethanediyl)] and 1,1'-methylenebis[4-isocyanatocyclohexane]	Yes	≤ 20 tonnes per annum	Component of construction waterproofing products

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

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers, provided the recommended controls are in place.

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

Environmental risk assessment

Based on its expected low hazard and 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 engineering controls to minimise occupational exposure to the notified polymer as introduced in products:
 - Good general ventilation, including local ventilation if necessary
- 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 as introduced in products:
 - Avoid contact with skin and eyes
 - Avoid generation of aerosols or mists
 - Avoid inhalation of vapours, mists or aerosols
- 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 polymer as introduced in products:
 - Isocyanate-resistant gloves
 - Protective glasses
 - Coveralls
 - Respiratory protection if inhalation exposure is expected

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 (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

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

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 to be introduced in Australia in a form other than finished products;
 - products containing the notified polymer are intended to be applied by spray.
- or
- (2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of construction waterproofing products 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.

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet

The (M)SDS of the products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

BASF Australia (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place
Southbank VIC 3001

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: structural and molecular formula, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for most physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (2014), Canada (2009) and China (2013)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

SONOGUARD TOP COAT HT GRAY INTNL (product containing the notified polymer)
MasterSeal CR 195 Alu Gry (product containing the notified polymer)
MasterSeal TC 225HT TB INTNL (product containing the notified polymer)

CAS NUMBER

70776-57-7

CHEMICAL NAME

Oxirane, 2-methyl-, polymer with oxirane, ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1), polymer with α -hydro- ω -hydroxypoly[oxy(methyl-1,2-ethanediyl)] and 1,1'-methylenebis[4-isocyanatocyclohexane]

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Liquid (imported in solvent-based liquid products)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Imported in liquid and paste products
Boiling Point	Not determined	Imported in liquid and paste products
Density	1100-1130 kg/m ³ at 20 °C	(M)SDS of the products
Vapour Pressure	Not determined	Imported in liquid and paste products
Water Solubility	Not determined	The notified polymer contains groups that

Hydrolysis as a Function of pH	Not determined	readily react with water to form carbon dioxide and insoluble high molecular weight polymers
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer contains groups that readily react with water to form carbon dioxide and insoluble polymeric masses
Adsorption/Desorption	Not determined	Expected to react with water and octanol to form carbon dioxide and insoluble polymeric masses
Dissociation Constant	Not determined	The notified polymer contains groups that readily react with water to form carbon dioxide and insoluble polymeric masses
Particle Size	Not determined	Contains no dissociable functional groups at environmental pH
Flash Point	Not determined	Imported in liquid and paste products
Autoignition Temperature	Not determined	Imported in liquid and paste products
Explosive Properties	Not determined	Imported in liquid and paste products
Oxidising Properties	Not determined	Contains no functional groups that would imply explosive properties
		Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES

The notified polymer will be imported in polyurethane sealant products. It cannot be isolated without reaction with moisture in the atmosphere, which will cause crosslinking and curing into a solid mass. Therefore it was not practical to measure the physico-chemical properties of the notified polymer.

Reactivity

The 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 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 into Australia in finished products at concentrations < 70%.

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

Year	1	2	3	4	5
Tonnes	≤ 20	≤ 20	≤ 20	≤ 20	≤ 20

PORT OF ENTRY

Sydney, Melbourne and Brisbane

IDENTITY OF MANUFACTURER/RECIPIENTS

BASF Australia Ltd

TRANSPORTATION AND PACKAGING

The products containing the notified polymer will be imported into Australia by sea in 20L metal pails and transported in shipping containers by road for storage in warehouses. The products will be delivered to customers by pallet loads and broken down to smaller loads for distribution to construction sites.

USE

The notified polymer will be imported to Australia at < 70% concentration for use as a component of waterproofing products used in construction.

OPERATION DESCRIPTION

End use

The notified polymer will not be manufactured or reformulated in Australia. It will be imported as a component of finished waterproofing construction products.

The waterproofing products will be directly applied by professional construction operators from the metal pails to surfaces and structural joinery. Application will generally take place outdoors using roller, squeegee or trowel. Once applied the products containing the notified polymer will be allowed to cure and dry overnight or for up to 48 hours.

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>
Transport	3	10-20
Storage	1	50-60
Professional construction applicators	5	150

EXPOSURE DETAILS

Transport and storage workers may come in contact with the imported products containing the notified polymer (at < 70%) only in the unlikely event of an accident.

Dermal and ocular exposure of the notified polymer at concentrations less than 70% may occur during application and cleaning processes, particularly from splashes and spills. The vapour pressure of the notified polymer is unknown and there are low molecular weight species present which may contribute to inhalation exposure. However the products will not be applied by spray therefore it is not expected that the handling and application processes will generate aerosols that would lead to considerable inhalation exposure.

The products containing the notified polymer also contain hazardous impurities of the notified polymer and other hazardous ingredients. The notifier states that operators will be equipped with personal protective equipment such as masks, gloves and protective glasses. Generally, applications will be conducted outdoors however local exhaust ventilation or individual respirators will also be available for workers when products are used in poorly ventilated areas.

Once the products are cured and dried the notified polymer will be reacted into a resin matrix and will not be available for further exposure.

6.1.2. Public Exposure

The finished products containing the notified polymer will not be available for sale to the general public. The products will be applied by professional construction operators. The public may come in contact with surfaces coated with products containing the notified polymer however once the coatings are cured and dried the notified polymer will be reacted into the coating matrix and will not be available 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 notified polymer contains a significant 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 concerns 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; SWA, 2013). 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 sensitising by inhalation 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, dermal and respiratory sensitisation and pulmonary toxicity. The products containing the notified polymer also contain residual isocyanate impurities of the notified polymer and other hazardous ingredients.

The notifier states that workers who handle the products containing the notified polymer will be equipped with appropriate personal protective equipment (PPE) including masks, gloves, and protective glasses to reduce exposure to the notified polymer. If application of the finished products occurs in poorly ventilated areas, local exhaust ventilation or self-contained breathing apparatus will be used to reduce inhalation exposure.

It is expected that control measures will also be in place to minimise exposure to other hazardous ingredients of the products containing the notified polymer. Therefore, provided that the recommended engineering controls and PPE are being adhered to, the risk of the notified polymer to the workers is not expected to be unreasonable.

6.3.2. Public Health

The products containing the notified polymer will not be available to the public. The public may come into contact with surfaces of cured and dried products containing the notified polymer. The notified polymer will be reacted into the resin matrix and will not be bioavailable for exposure. Therefore the risk to the public from the use of the notified polymer is not expected 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. If release does occur as a result of an accident during transport, it is expected to be contained, collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified polymer is expected to be applied to construction substrates by professional operators. It is estimated that up to 1% of the total annual import volume of the notified polymer is expected to be released to the environment due to wastes from spills and leaks. The notified polymer in these wastes is expected to form an inert solid matrix on exposure to ambient conditions and the cured mass will be disposed of 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 the substrates after application. It is expected to share the fate of the substrate and eventually 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 substrates at the end of their useful life. 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 in this form. The notified polymer is expected to eventually degrade biotically or abiotically in landfill into water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer rapidly reacts with moisture (water) to form insoluble, non-bioavailable, high molecular weight solids. A predicted environmental concentration (PEC) was not determined because the notified polymer is not expected to persist in the aquatic compartment due to its hydrolytic instability. The notified polymer is never isolated from construction substrates containing the notified polymer. 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. In addition, the notified polymer, which is never isolated from the construction substrates, is expected to react with moisture (water) to form insoluble, non-bioavailable, high molecular weight solids. Therefore, the notified polymer is expected to be of low 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 the notified polymer is expected to be of low concern 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 is not expected based on its reported use pattern. The majority of the notified polymer will be disposed of to landfill as cured matrix. The notified polymer is irreversibly bound into a solid inert matrix, and is

unlikely to be bioavailable or mobile in this form. Therefore, based on its expected low hazard and assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

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