

File No: LTD/1965

June 2017

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

PUBLIC REPORT

Polymer in Sika Primer-207

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 and Energy.

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:

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

**Director
NICNAS**

TABLE OF CONTENTS

SUMMARY	3
CONCLUSIONS AND REGULATORY OBLIGATIONS	3
ASSESSMENT DETAILS.....	5
1. APPLICANT AND NOTIFICATION DETAILS.....	5
2. IDENTITY OF CHEMICAL.....	5
3. COMPOSITION.....	5
4. PHYSICAL AND CHEMICAL PROPERTIES	5
5. INTRODUCTION AND USE INFORMATION.....	6
6. HUMAN HEALTH IMPLICATIONS	7
6.1. Exposure Assessment.....	7
6.1.1. Occupational Exposure.....	7
6.1.2. Public Exposure.....	7
6.2. Human Health Effects Assessment	7
6.3. Human Health Risk Characterisation	8
6.3.1. Occupational Health and Safety.....	8
6.3.2. Public Health.....	8
7. ENVIRONMENTAL IMPLICATIONS.....	8
7.1. Environmental Exposure & Fate Assessment	8
7.1.1. Environmental Exposure.....	8
7.1.2. Environmental Fate	9
7.1.3. Predicted Environmental Concentration (PEC).....	9
7.2. Environmental Effects Assessment.....	9
7.2.1. Predicted No-Effect Concentration.....	9
7.3. Environmental Risk Assessment.....	9
BIBLIOGRAPHY	10

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/1965	Sika Australia Pty Limited	Polymer in Sika Primer-207	ND*	≤ 1 tonne per annum	Additive in primer for adhesives and sealants

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As no 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.

Human health risk assessment

Provided that the recommended controls are being adhered to, 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, the notified polymer is not considered to pose an unreasonable risk to public health.

Environmental risk assessment

On the basis of the assessed use pattern, 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:
 - Ensure adequate ventilation during application and curing
- 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:
 - Avoid contact with skin and eyes
 - 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:
 - Coveralls, impervious gloves, 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 polymer. Employers should ensure that the exposure standard for isocyanates (SFA, 2013) is not exceeded for all areas where the notified polymer may be handled or present.
- A copy of the 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.

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.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000;
 - products containing the polymer are made available to the general public for DIY purposes;
 - the polymer is introduced for reformulation in Australia;
- or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from additive in primer for adhesives and sealants, 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.

Safety Data Sheet

The SDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT

Sika Australia Pty Limited (ABN: 12 001 342 329)
55 Elizabeth Street
WETHERILL PARK NSW 2164

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ 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, additives/adjuvants, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME

Sika® Primer-207 (product containing $\leq 15\%$ notified polymer)

MOLECULAR WEIGHT

$> 1,000$ Da

ANALYTICAL DATA

Reference IR spectra was provided.

3. COMPOSITION

DEGREE OF PURITY

$> 88\%$

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: black liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Introduced in organic solvent
Boiling Point	Not determined	Introduced in organic solvent
Density	970 kg/m ³ at 20 °C*	SDS
Vapour Pressure	Not determined	Based on the high molecular weight of the polymer ($> 1,000$ Da), the vapour pressure is expected to be low
Water Solubility	Not determined	Not tested due to the presence of end-groups that readily react with water to form carbon dioxide and insoluble polymeric species
Hydrolysis as a Function of pH	Not determined	Not tested due to the presence of end-groups that readily react with water to form carbon dioxide and insoluble polymeric species

Property	Value	Data Source/Justification
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to react with water and octanol to form carbon dioxide and insoluble polymeric masses
Adsorption/Desorption	Not determined	Expected to bind to negatively charged soil or sediment as the notified polymer contains potential cationic groups
Dissociation Constant	Not determined	The notified polymer contains potential cationic functionalities and is likely to be ionised
Flash Point	Not determined	Introduced in a flammable organic solvent. The notified polymer is not expected to be highly flammable
Autoignition Temperature	Not determined	Not expected to autoignite
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

*For product containing the notified polymer at $\leq 15\%$ concentration in organic solvent

Reactivity

The notified polymer contains terminal isocyanate groups which are expected to react with water and moisture in air to form amines and carbon dioxide. The reaction of terminal isocyanate groups is considered essential for its function.

Physical hazard classification

Based on the limited physico-chemical data, 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.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured or reformulated in Australia. It will be imported in end-use products at concentrations $\leq 15\%$.

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

Sydney

TRANSPORTATION AND PACKAGING

The notified polymer will not be manufactured, reformulated or repackaged in Australia. It will be imported in products at concentrations $\leq 15\%$. The products will be packaged in 30 mL to 1L metal cans, packed in cartons. It will be transported and packaged according to the Dangerous Goods requirements.

USE

The notified polymer will be used as a surface primer to promote adhesion of sealants and adhesives. It will be used on a wide range of substrates including float-glass, ceramic-coated glass, plastics, pre-coatings, painted surfaces, E-coat surfaces and metals. The primers containing the notified polymer at $\leq 15\%$ concentration are for industrial use only and not expected to be available to the public for DIY use.

OPERATION DESCRIPTION

The primer containing the notified polymer at $\leq 15\%$ concentration will be used by professionals only. The method of application will be mainly using brush, felt or foam applicator. The application is likely to be conducted in a workshop or in outdoor areas, for installation, repair and maintenance operations. Under normal circumstances, the workers will open the primer containers and dip the applicator (brush, felt or foam) into the primer and apply it to the substrate. Once dry, the primer coating containing the notified polymer will be layered

with adhesive and other substrates. The applicators will be cleaned with suitable solvent for re-use, or disposed of to landfill.

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 and warehousing	1-2	12-24
End-users	0.5	12-24

EXPOSURE DETAILS

Transport and warehouse workers are not expected to be exposed to the notified polymer except in the event of a spill or leak due to container breach. The workers may be exposed to the notified polymer via dermal, ocular and inhalation routes.

Professional end-users may experience dermal, ocular and inhalation exposure to the notified polymer at concentrations $\leq 15\%$ during application of the primers. The high molecular weight of the polymer ($> 1,000$ Da) is expected to reduce the likelihood of inhalation exposure, and aerosols are not expected to be generated during the coating process. According to the notifier, workers are expected to wear personal protective equipment (PPE) such as coveralls, impervious gloves, safety glasses and respiratory protection if required, to reduce exposure to the notified polymer during application and drying of the primer. Respiratory protection is expected to be used in places with poor ventilation to prevent exposure to other hazardous chemicals present in the primer.

Once the primers have dried, the notified polymer is expected to be reacted into the primer matrix, and is not expected to be bioavailable.

6.1.2. Public Exposure

The primers containing the notified polymer are for industrial use only. The public may come in contact with coated articles to which the primer containing the notified polymer has been applied. However the primer layer is expected to be covered by other substrates and the polymer will be reacted into the primer layer. Therefore the notified polymer is not expected to be available for exposure by the public.

6.2. Human Health Effects Assessment

No toxicity data were provided. The notified polymer is not expected to be absorbed across biological membranes to a significant extent based on its high molecular weight ($> 1,000$ Da) and moderate percentage of low molecular weight species ($< 1,000$ Da).

The notified polymer contains isocyanate 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 $\geq 5,000$ 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 expected to be $\ll 5,000$ Da and although its molecular weight is $> 1,000$ Da, the polymer contains a proportion of low molecular weight species; hence, the hazard 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 (HCIS, 2016). Isocyanates may also cause respiratory sensitisation by skin contact (US EPA, 2010).

Health hazard classification

As no 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.

The product containing the notified polymer ($\leq 15\%$) imported into Australia has been classified as hazardous by the notifier, based on the other components present in the product. The hazards include sensitisation via the dermal and inhalation routes.

6.3. Human Health Risk Characterisation**6.3.1. Occupational Health and Safety**

No toxicity studies are available for the notified polymer. 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 $\leq 15\%$ concentration during transfer and application of the primer is expected to be limited by the use of PPE. Due to the expected low volatility of the notified polymer and method of application, significant inhalation exposure is not anticipated. Exposure and risk would be further reduced by safe work practices such as avoiding skin and eye contact, use in a well ventilated area, and prompt clean-up of spills.

The primer is classified as hazardous based on the other hazardous components present in the product. The controls proposed to limit worker exposure to these components 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 is intended for use by professionals only. The public may be exposed to products on which the notified polymer containing primer has been applied. Once the primer is cured and dried, the notified polymer will be reacted into the polymeric matrix and is not expected to be available for exposure. Therefore, when used as proposed, 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**

No manufacturing or reformulation of the notified polymer will take place in Australia. The most likely release of the notified polymer to the environment during these activities will be a transport accident. However, the capacity and specifications of the import containers are likely to minimise the extent of any such releases. Releases that do occur as a result of accidents are expected to be physically contained, absorbed on inert material and sent for disposal to landfill.

RELEASE OF CHEMICAL FROM USE

The product containing the notified polymer will be used to treat surfaces using brush, felt or foam. It will be used for industrial use only and is not expected to be available to the general public. During industrial use of the notified polymer, releases to the environment could occur as a result of residual in empty containers, spills and leaks, disposal of the applicators and cleaning of the brushes. Empty containers and used applicators will be disposed of to landfill. Any spills will be cleaned using a cloth which will also be disposed of to landfill. Brushes will be cleaned using solvent, which will be wiped onto newspaper or paper towelling and this will be disposed of to landfill. No significant release to sewer is expected to occur.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer will share the fate of articles to which it has been applied and therefore is expected to be disposed of to landfill or thermally decomposed during metals reclamation processes.

7.1.2. Environmental Fate

No environmental fate data were submitted. The notified polymer is expected to rapidly hydrolyse and degrade based on its structure and functional groups. The notified polymer is of high molecular weight (> 1000 Da), and therefore, is not expected to cross biological membranes for bioaccumulation.

The majority of the notified polymer is expected to be cured into the polymeric matrix as part of its use in coating systems. The notified polymer bound into the matrix is not expected to be bioavailable or bioaccumulate. In landfill the notified polymer is expected to degrade by biotic and abiotic processes to form water and oxides of carbon, nitrogen, sulphur and phosphorus.

Based on its use pattern, a significant amount of the notified polymer is not expected to be released to the aquatic environment. However, if residues are washed to sewer from cleaning of application equipment, the notified polymer is expected to partition from the water column to sediment as it reacts rapidly with water to form carbon dioxide and insoluble inert polymerised compounds.

7.1.3. Predicted Environmental Concentration (PEC)

A predicted environmental concentration (PEC) was not determined because no significant aquatic exposure of the notified polymer is expected based on its reported use pattern. Moreover, on contact with water the notified polymer is expected to react rapidly with water to form carbon dioxide and insoluble inert polymerised compounds.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. The notified polymer is expected to react rapidly with water to form carbon dioxide and insoluble inert polymerised compounds. Therefore, in the unlikely event that the notified polymer is released to the aquatic compartment, it is expected to be of low concern to the aquatic environment.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer 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 significant release to the aquatic environment is not expected based on its reported use pattern. The majority of the notified polymer will ultimately be cured into an inert matrix. In its cured state, the notified polymer is irreversibly bound within an inert matrix, and is not expected to be bioavailable or mobile. Based on its limited environmental exposure, the notified polymer is not considered to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

- Barratt MD, Basketter DA, Chamberlain M, Admans GD and Langkowski JJ (1994), An Expert System Rulebase for Identifying Contact Allergens. *Toxicology In Vitro* 8(5), 1053-1060.
- HCIS (2016) Isocyanate: Exposure Standard Documentation <<http://hcis.safeworkaustralia.gov.au/ExposureStandards/Document?exposureStandardID=1013>> (accessed 5th April 2017).
- Kirk-Othmer Encyclopedia of Chemical technology, 4th edition (1995) M Howe-grant (ed). Vol 14, p902 (Richter RH and Priester RD contributors). New York, John Wiley and Sons
- SFA (2013) Workplace Exposure Standards for Airborne Contaminants. <<http://www.safeworkaustralia.gov.au/sites/SWA/about/Publications/Documents/772/Workplace-exposure-standards-airborne-contaminants.pdf>>
- SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, <http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace>.
- United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html>.
- US EPA (2010) TSCA New Chemicals Program (NCP) Chemical Categories. Washington, D.C., https://www.epa.gov/sites/production/files/2014-10/documents/ncp_chemical_categories_august_2010_version_0.pdf