File No: LTD/2059

February 2019

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Acrylic Polymer in Sikaflex Adhesives and Sealants

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

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/2059	Sika Australia Pty Ltd	Acrylic Polymer in Sikaflex Adhesives and Sealants	Yes	< 1 tonne per annum	Component of industrial adhesives and sealants

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Skin irritation (Category 2)	H315 – Causes skin irritation
Eye irritation (Category 2A)	H319 – Causes serious eye irritation

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, the notified polymer is not considered to pose an unreasonable risk to public health.

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

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - Skin irritation (Category 2): H315 – Causes skin irritation
  - Eye irritation (Category 2): H319 – Causes serious eye irritation

  The above should be used for products/mixtures containing the notified polymer, if applicable, based on the concentration of the notified polymer present.

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 during handling of the notified polymer:
  - Avoid contact with skin

- 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:
  - Impervious gloves

- Protective clothing

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

- 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.

Storage

- The handling and storage of 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 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 importation volume exceeds one tonne per annum notified polymer;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of industrial 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 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(S)
Sika Australia Pty Ltd (ABN: 12 001 342 329)
55 Elizabeth Street
WETHERILL PARK NSW 2164

NOTIFICATION CATEGORY
Limited-small volume: Synthetic polymer with Mn < 1,000 g/mol (1 tonne or less per year)

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, spectral data, degree of purity, polymer constituents, residual monomers, impurities, use details, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for all physico-chemical endpoints except boiling point, density, water solubility and flash point

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME
Acrylic Polymer in Sikaflex Adhesives and Sealants

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) is < 1,000 g/mol.

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

3. COMPOSITION

DEGREE OF PURITY
> 98%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless liquid

Property	Value	Data Source/Justification
Freezing Point	Not determined	Expected to be < 0 °C
Boiling Point	> 50 °C at 101.3 kPa	SDS
Density	1,135 kg/m^3 at 25 °C	SDS
Vapour Pressure	7.01 × 10^{-8} kPa	Calculated using MPBPVP (v1.43)
Water Solubility	0.495 g/L at 23 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities but significant hydrolysis is not expected in the environmental pH range of 4-9
Partition Coefficient (n-octanol/water)	log P_{ow} = 6.16	Calculated using KOWWIN v1.68
Adsorption/Desorption	log K_{oc} = 4.20 (log K_{ow} method)	Calculated using KOCWIN v2.00

	log K_{oc} = 8.92 (MCI method)	
Dissociation Constant	Not determined	Does not contain dissociable functionalities
Flash Point	> 93.3 °C	SDS
Flammability	Not determined	Not expected to be flammable based on flash point
Autoignition Temperature	Not determined	Not expected to undergo autoignition
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

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

Reactivity
The notified polymer contains pendent acrylate functional groups and, when mixed with other components of the adhesive, is expected to undergo further polymerisation reactions to form a solid matrix. The reactions are intended by design as part of use patterns.

Physical hazard classification
Based on the limited physico-chemical data depicted in the above table, 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.

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 within Australia. It will be imported as a component of finished adhesive and sealant products at ≤ 2% concentration.

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

IDENTITY OF MANUFACTURER/RECIPIENTS
Sika Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The finished adhesive and sealant products containing the notified polymer at ≤ 2% concentration will be imported into Australia by sea and transported by road in sealed 300 mL cartridges. The products containing the notified polymer will be distributed to industrial users in the construction sector.

USE
The notified polymer will be used as a hardener in one-pack moisture-cured polyurethane adhesive/sealants at ≤ 2% concentration.

OPERATION DESCRIPTION
The imported adhesive/sealant products containing the notified polymer at ≤ 2% concentration will be supplied in 300 mL cartridges. The products will be applied to surfaces or cavities using either a manual application gun or a compressed air-assisted gun. Any excess product will be removed using a scraper and cloth. The adhesive/sealant cures with 2-4 hours.

6. 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 and warehousing	2 – 4	12 – 14
Applicators	8	100 – 200

EXPOSURE DETAILS

Transport and storage
Transport and storage workers may come into contact with the notified polymer at ≤ 2% concentration only in the unlikely event of an accidental breach of the cartridges.

End use
At end use sites, dermal and perhaps accidental ocular exposure to the notified polymer at ≤ 2% concentration may occur during application of adhesives/sealants containing the notified polymer. Inhalation exposure is not expected given the calculated low vapour pressure of the notified polymer and high viscosity of the adhesives/sealants. The potential for exposure to the notified polymer should be minimised through the use of personal protective equipment (PPE) including coveralls, gloves, and goggles.

Once the product containing the notified polymer has cured, the notified polymer will be bound within a polymer matrix and is not expected to be available for exposure.

6.1.2. Public Exposure
Products containing the notified polymer at ≤ 2% concentration are for industrial use only, and will not be available to the public. The public may come into contact with the cured adhesives/sealants containing the notified polymer after application. However, once the adhesives/sealants are cured, the notified polymer will be bound within a polymer matrix and is not expected to be available for exposure.

6.2. Human Health Effects Assessment
No toxicity data were submitted.

Toxicokinetics, metabolism and distribution
No toxicokinetic data were submitted. Based on the relatively low molecular weight (Mn < 1,000 g/mol) and significant levels (> 30%) of low molecular weight species < 500 g/mol of the notified polymer, absorption across biological membranes may occur. However, dermal absorption may be limited given the lipophilic nature of the notified polymer (calculated log Pow = 6.16).

The notified polymer contains acrylate functional groups. Once absorbed, acrylates are expected to be detoxified predominantly via conjugation with glutathione via the Michael addition reaction or glutathione-*S*-transferase. The acrylates are also likely to be hydrolysed via carboxylesterases (Patty's Toxicology, 2012).

Irritation and sensitisation
No data were provided for the notified polymer on eye or skin irritation, or skin sensitisation.

The notified polymer contains acrylate functional groups which are known to have potential to cause skin and eye irritation, and skin sensitisation (US EPA, 2010). Based on the *Guide to the Classification & Labelling of UV/EB Acrylates* published by European Chemical Industry Council (Cefic, 2011), polymeric acrylates are recommended for classifications for eye and skin irritation in the absence of toxicological data.

The potential for the notified polymer to cause skin sensitisation may be reduced by the limited potential for the notified polymer to be dermally absorbed.

Mutagenicity/Genotoxicity
Results of a number of mutagenicity studies on acrylate and methacrylate compounds have been evaluated (Johannsen *et al*., 2008). In general, it was found that these compounds were negative in bacterial reverse mutation assays and other *in vitro* mammalian point mutation assays. While some positive results were observed in *in vitro* mammalian clastogenicity assays, the results from *in vivo* assays were all negative. Therefore, based on the available information, the notified polymer is not likely to be genotoxic.

Health hazard classification
Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Skin irritation (Category 2)	H315 – Causes skin irritation
Eye irritation (Category 2A)	H319 – Causes serious eye irritation

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer is a skin and eye irritant, and may have the potential to cause skin sensitisation.

Workers may be at risk of sensitisation from the notified polymer when applying the adhesive and sealant products containing the notified polymer at ≤ 2% concentration. The stated use by the notifier of PPE by workers including protective clothing and gloves should minimise this risk.

Therefore, under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health
The adhesive and sealant products containing the notified polymer are intended for industrial use only and will not be available to the public. The public may come into contact with the cured sealants/adhesives containing the notified polymer after application. However, once the sealants/adhesives are cured, the notified polymer will be bound within a polymer matrix and is not expected to be available for exposure.

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

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 of finished adhesive and sealant products; no reformulation or repackaging will occur in Australia. Spills or accidental release of the products containing the notified polymer during import, storage, and transport will only occur if the cartridges are breached and are expected to be collected by suitable absorbents and disposed of to landfill, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE
Products containing the notified polymer in cartridges will be applied to surfaces or cavities using either a manual application gun or a compressed air-assisted gun. Once the sealant/adhesive is applied they will cure in 2 - 4 hours. As estimated by the notifier, cured waste during application may account for up to 5% of import volume of the notified polymer which will be disposed of to landfill, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

As a result of its use pattern, the majority of the notified polymer is expected to share the fate of the substrates to which it has been applied; to be disposed of to landfill at the end of their useful lives. As estimated by the notifier, residual notified polymer in empty end-use cartridges may account for up to 5% of import volume of the notified polymer, which is expected to be cured into an inert solid matrix and be disposed of to landfill along with the empty cartridges.

7.1.2. Environmental Fate

No environmental fate data were submitted. Most of the notified polymer is expected to share the fate of the substrates to which it has been applied, to be disposed of to landfill at the end of their useful lives. In landfill, the notified polymer will be present as cured solids and will be neither bioavailable nor mobile. In landfill, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the notified polymer to the aquatic environment will be limited based on its reported use pattern as a component of industrial adhesive and sealant products.

7.2. Environmental Effects Assessment

No ecotoxicological data were submitted for the notified polymer. The notified polymer is neutral with Mn < 1,000 g/mol, and therefore has the potential to be adsorbed through biological membranes of aquatic organisms in environmental waters.

7.2.1. Predicted No-Effect Concentration (PNEC)

The Predicted No-Effect Concentration (PNEC) has not been calculated since no ecotoxicological data are available.

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) for the aquatic compartment has not been calculated as no ecotoxicological data are available and release of the notified polymer to the aquatic environment will be limited based on its reported use pattern. On the basis of the reported use pattern as a component of industrial adhesive and sealant products, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 0.495 g/L at 23 °C

Method	In-house modified flask method: 10 g of the sample were added to 100 mL of water and the suspension was shaken for 4 h at 23 °C. Afterwards the suspension was filtered (unspecified size) and the water was evaporated. The residue was weighed until weight constancy.
Test Facility	Sika (2018)

BIBLIOGRAPHY

Cefic (2011) Guide to the Classification and Labelling of Acrylates, 4th edition. European Chemical Industry Council (CEFIC), Brussels, Belgium, UV/EB Acrylate Resin Sector Group, https://hnlkg4f5wdw34kx1a1e9ygem-wpengine.netdna-ssl.com/wp-content/uploads/2017/09/4_Guide-to-the-Classification-and-Labelling-of-UV-EB-Acrylates.pdf

Johannsen, F. R.; Vogt, B.; Waite, M.; Deskin, R. (2008) Mutagenicity assessment of acrylate and methacrylate compounds and implications for regulatory toxicology requirements. Regulatory Toxicology and Pharmacology, 50: 322-335.

Patty's Toxicology (2012) Bingham, E. and Cohrssen, B. (eds.) Patty's Toxicology: Volume 4 (Chapter 57). 6th ed. New York: John Wiley Sons, 1999-2012.

Sika (2018) Determination of the Water Solubility of [Notified Polymer] (Report CAS-2018-0459, June, 2018). Zurich, Switzerland, Sika Technology AG.

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, https://www.safeworkaustralia.gov.au/doc/model-code-practice-managing-risks-hazardous-chemicals-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., http://www.epa.gov/oppt/newchems/pubs/npcchemicalcategories.pdf

US EPA (2012) Estimation Programs Interface (EPI) SuiteTM for Microsoft® Windows, v 4.10. United States Environmental Protection Agency. Washington DC, USA.