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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Prepolymer MS-21-P6-D1 in Sika Tack GO

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 Sustainability, Environment, Water, Population and Communities.

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:

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

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1526	Sika Australia Pty Limited	Prepolymer MS-21-P6- D1 in Sika Tack GO	Yes	≤ 80 tonnes per annum	Component of a sealant for automotive windscreen replacement

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the presence of the isocyanate functional group in the notified polymer, the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:.

Xn; R42 May cause sensitisation by inhalation.

The classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	Hazard statement
Respiratory sensitisation	1	May cause allergy or asthma symptoms or breathing difficulties if inhaled

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

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 Hazard Classification and Labelling

- Use the following risk phrases for products/mixtures containing the notified polymer:
 - Conc ≥ 1%: R42

Health Surveillance

 As the notified polymer contains isocyanate functional groups, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a history of isocyanate sensitivity, asthma or other pulmonary condition and who may be adversely affected by isocyanate exposure.

CONTROL MEASURES

Occupational Health and Safety

• Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified polymer during application/use:

- Good general ventilation during curing including local exhaust ventilation if necessary.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid contact with skin and eyes
 - Clean spills immediately, taking care to avoid inhalation
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
 - Organic vapour respirator if inhalation exposure is likely to occur
 - Isocyanate resistant gloves, coveralls and goggles

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

- A short term exposure limit (STEL) of 0.07 mg/m3 and long term time-weighted-average (TWA) exposure limit of 0.02 mg/m3 applies for the airborne concentration of all isocyanates in the workplace [NOHSC: 1003(1995)]. Employers should ensure that this exposure standard for isocyanates is not exceeded for all areas of the adhesive application site.
- 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 of to landfill.

Storage

- The following precautions should be taken regarding storage of the notified polymer:
 - Check all containers against leakage
 - Store in a ventilated area.

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;
- if products containing the notified polymer are made available to the public.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from as a component of a polyurethane sealant/adhesive, or is likely to change significantly;
 - the amount of polymer being introduced has increased from eighty tonnes per annum, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Sika Australia Pty Limited (ABN 12 001 342 329)
55 Elizabeth Street,
Wetherill Park NSW 2164

NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn ≥1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, polymer constituents, residual monomers, 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 required physico-chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES US EPA (1999)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Sika Tack GO (contains notified polymer up to 10%)

OTHER NAME(S)

MS-21-P6-D1

MOLECULAR WEIGHT

Mn Value > 10,000 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

The notified polymer contains a residual monomer that is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC: 1008 (2004)]. The impurity is present in the notified polymer at levels above the cut off concentrations for hazard classification.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None identified

ADDITIVES/ADJUVANTS

None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES Not expected to occur under normal conditions of use.

DEGRADATION PRODUCTS

Not expected to occur under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Black viscous liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	The notified polymer is liquid.
Boiling Point	Not determined	Expected to decompose prior to boiling
Density*	$\sim 1000 \text{ kg/m}^3 \text{ at } 20^{\circ}\text{C}$	MSDS
Vapour Pressure	$< 1.3 \times 10^{-9} \mathrm{kPa}$	Estimated based on the NAMW > 1,000 Da (US EPA, 2007). The vapour pressure of the residual MDI is 7.2×10^{-7} kPa at 20°C.
Water Solubility	Not determined	Not tested due to the presence of end- groups that readily react with water to form carbon dioxide and insoluble high molecular weight polymers
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 high molecular weight polymers. The backbone of the notified polymer contains groups that are expected to hydrolyse very slowly in the environmental pH range (4-9).
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to react with water and octanol to form carbon dioxide and insoluble high molecular weight polymers
Adsorption/Desorption	Not determined	Not tested due to hydrolytic instability. Likely to adsorb to sludge, soil and sediment based on its high molecular weight.
Dissociation Constant	Not determined	The notified polymer does not contain any dissociable functional groups at environmental pH
Particle Size	Not determined	The notified polymer is liquid.
Flash Point*	>150°C at 101 kPa (closed cup)	MSDS
Flammability	Not determined	Not expected to be flammable.
Autoignition Temperature	Not determined	Not expected to undergo autoignition.

Explosive Properties Not determined The structural formula contains no explosophores.

DISCUSSION OF PROPERTIES

The notified polymer is an intermediate which will be imported in a polyurethane adhesive/sealant. It could not 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 physio-chemical properties of the notified polymer.

Reactivity:

The notified polymer is stable under normal storage and handling conditions. As stated above, the notified polymer contains reactive isocyanate functional groups, which will react with atmospheric moisture causing it to crosslink and form a solid.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer is an intermediate component which will be imported in a finished polyurethane sealant/adhesive product at a concentration of up to 10%.

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

Year	1	2	3	4	5
Tonnes	40-80	40-80	40-80	40-80	40-80

PORT OF ENTRY Sydney

IDENTITY OF RECIPIENTS Sika Australia Pty Limited 55 Elizabeth Street, Wetherill Park NSW 2164

TRANSPORTATION AND PACKAGING

The finished product containing the notified polymer will be imported in sealed 310 ml aluminium cartridges or 600 ml aluminium polyester laminated "sausages" designed to fit into special applicator guns. Each carton will contain 12 cartridges or 20 "sausages". From the dockside, the finished product will be off-loaded and transported by road to the notifier's warehouse facilities and then to the designated distributor, or may be sent directly to the end-users, i.e., auto-glass installation companies.

USE

The notified polymer will be used in a sealant (up to 10% concentration) for automotive windscreen replacement. The sealant will be predominantly used in after-market automotive industry.

OPERATION DESCRIPTION

The notified polymer will be imported as a component (up to 10%) of a finished polyurethane sealant/adhesive product and will be used by automotive repair workers for replacement of windscreen glass. The sealant/adhesive will be applied using conventional pumping equipment (i.e. caulking type guns). The cartridge or sausage will be fitted into the caulking gun and the adhesive applied to a localised area around the perimeter of the automotive windshield groove prior to installation of the automotive replacement glass. The polymer material reacts with atmospheric moisture at the time of application to form an inert solid matrix. Any excess adhesive will be cleaned using a specially formulated cleaning product and a cloth.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

^{*}For product containing up to 10% notified polymer

NUMBER AND CATEGORY OF WORKERS

Category of Worker	Number	Exposure Duration (hours/day)	Exposure Frequency (days/year)
Transport and Warehouse Workers	4-8	2	20
Auto-glass Installation Companies and	100	8	200
Glass Replacement Tradesmen			

EXPOSURE DETAILS

Exposure of transport and storage workers is not expected except in the event of accidental breach of packaging. As the sealant is applied manually with a caulking gun, dermal exposure to the notified polymer is possible during application and manipulation of the automotive windscreen. Ocular exposure, though less likely, is also possible from splatter during application. Inhalation exposure would be limited by the expected low vapour pressure ($< 1.3 \times 10^{-9}$ kPa) of the notified polymer and the low level of low molecular weight species.

Exposure to the notified polymer will be minimised by the use of safety glasses, impervious (neoprene) gloves, coveralls and safety boots. Typically, the windscreen repair operation is carried out in an outdoor area or within an automotive repair workshop which is a large area with good natural ventilation. However, local exhaust ventilation or mechanical ventilation may be used where general ventilation is inadequate to prevent inhalation exposure to workers. Once the sealant has cured, the notified polymer becomes bound within a polymer matrix and hence, is unavailable for exposure.

6.1.2. Public Exposure

The product containing the notified polymer will only be available to industrial end users and will not be sold to the general public. The potential for general public exposure to the notified polymer during transportation of the imported product containing the notified polymer is likely to be negligible and would only occur in the event of an accident.

After curing, the notified polymer is expected to be irreversibly bound to the substrate and will not be bioavailable for exposure.

6.2 Human Health Effects Assessment

No toxicity data were submitted 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 (Mn > 1000 Da).

The notified polymer contains isocyanate functional groups that are of concern for irritation, dermal and respiratory sensitisation and pulmonary toxicity (Barratt 1994, USEPA 2010, Kirk-Othmer 1995).

The USEPA specifies that structures with isocyanate equivalent weights of \geq 5,000 are presumed not to pose a hazard under any conditions. In addition, concerns are generally confined to species with molecular weights <1,000. The isocyanate functional group equivalent weight of the notified polymer is <5,000, however, its molecular weight is >1,000. A relatively low proportion of low molecular weight species are present in the notified polymer. At such levels health concerns of the notified polymer associated with the isocyanate functionality 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). Isocyanates may also cause respiratory sensitisation by skin contact (US EPA 2010).

According to the Approved Criteria (NOHSC 2004), substances containing isocyanate functional groups should be classified as hazardous 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.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Toxicological data was not supplied for the notified polymer. On the basis of the presence of isocyanate functional groups, the notified polymer may cause irritation, dermal and respiratory sensitisation and pulmonary toxicity. Such effects cannot be ruled out, though they are expected to be reduced by the relatively low proportion of low molecular weight species present in the notified polymer.

Dermal exposure is the main potential route of worker exposure to the notified polymer (< 10% concentration) during the application of the sealant. The potential for inhalation exposure to the notified polymer will be limited by its expected low volatility and will vary with the ventilation controls available at the sites of application. The notifier has recommended engineering controls such as local exhaust ventilation if vapours containing the notified polymer are generated. Workplace controls required to reduce exposure to MDI would also protect against exposure to the notified polymer. In summary, the risk to workers associated with exposure to the notified polymer is not considered unreasonable assuming that the stated engineering controls, safe work practices and appropriate PPE are used.

6.3.2. Public Health

The sealant for automotive windscreen replacements, which contains the notified polymer, will only be used by qualified workers. There is no expected public exposure to the notified polymer, which will be cured and will only be present in inert form in the frame of automobile windscreens.

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 as a component of finished products and further reformulation or repackaging of the notified polymer in Australia is not expected. In the event of an accidental spill during transport, distribution or storage, the notified polymer is expected to cure in the presence of atmospheric moisture to form a solid mass which is expected to be collected and disposed of to landfill. Similarly, damaged cartridges are expected to cure in the atmosphere prior to disposal to landfill.

RELEASE OF CHEMICAL FROM USE

The sealant will be used by industrial end users. Therefore, following application of the notified polymer, any residual inert material around the perimeter of the windshield will be cleaned off using a solvent formulation and a cloth, or if cured, cut-off and disposed of to landfill by licensed waste disposal contractors. Cleaning cloths are expected to be disposed of to landfill. Any residual in application cartridges, estimated to be 2% of total import volume, will react with atmospheric moisture to form an inert material and is expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer will reside on the frame of motor vehicle windscreens after application. At the end of the vehicle's useful life, the glass windscreens and windscreen support frames containing the inert polymer are expected to be either recycled for glass and metal reclamation, or disposed of to landfill.

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 generated during use, residues in empty containers and articles at the end of their useful life. Small quantities of notified polymer in sealant on metal substrates may be sent to metal reclamation or glass recycling facilities. 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. The notified polymer will eventually degrade biotically or abiotically in landfill, or by thermal decomposition during metal reclamation or glass recycling, to generate water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

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. Further, the notified polymer is never isolated from sealant products containing the polymer, which rapidly reacts with moisture (water) to form insoluble, non-bioavailable, high molecular weight solids. 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. Additionally, the notified polymer is never isolated from the sealant, which reacts 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 = PEC/PNEC) for the notified polymer has not been calculated as release to the aquatic environment is not expected based on its reported use pattern as a component of automotive windscreen sealants. The majority of the notified polymer will be disposed of to landfill as cured sealant. In the cured sealant 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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