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July 2008

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

FULL PUBLIC REPORT

Silquest A-1170 Silane

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

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

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

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**Director
NICNAS**

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FULL PUBLIC REPORT**Silquest A-1170 Silane****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Sika Australia Pty Ltd (ABN 12 001 342 329)
55 Elizabeth St
Wetherill Park NSW 2164

NOTIFICATION CATEGORY

Limited-small volume: Chemical other than polymer (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: Other name, use details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Water solubility, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, particle size, flammability limits, autoignition temperature, explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Silquest A 1170, Dynasytan 1124, Bis(trimethoxysilylpropyl)amine (name used on product MSDS)

CAS NUMBER

82985-35-1

CHEMICAL NAME

1-Propanamine, 3-(trimethoxysilyl)-N-[3-(trimethoxysilyl)propyl]-

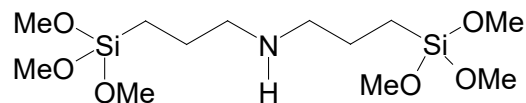
OTHER NAME(S)

Bis[3-(trimethoxysilyl)propyl]amine
Bis(γ -trimethoxysilylpropyl)amine
Bis[trimethoxysilylpropyl]amine
N,N-Bis[3-(trimethoxysilyl)propyl]amine

MOLECULAR FORMULA

C₁₂H₃₁NO₆Si₂

STRUCTURAL FORMULA



MOLECULAR WEIGHT

341.50

ANALYTICAL METHOD Infrared
 Remarks 1622, 1563, 1402, 1150, 1031 cm⁻¹ (refer to Figure 5b in the publication below)
 TEST FACILITY D. Zhu and W. J. Van Ooij, Structural characterisation of bis-[3-(trimethoxysilyl)propyl]amine silanes by Fourier-transform infrared spectroscopy and electrochemical impedance spectroscopy, J. Adhesion Sci. Technol., 16(9), 1235 – 1260 (2002).

3. COMPOSITION

DEGREE OF PURITY 90-95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name Methanol
CAS No. 67-56-1 *Weight %* <1
Hazardous Properties T (Toxic), Xn (Irritant); F (Highly flammable)
 Conc≥20%: T; R23/24/25; R39/23/24/25
 10% ≤ Conc < 20%: T; R20/21/22; R39/23/24/25
 3% ≤ Conc < 10%: Xn; R20/21/22; R68/20/21/22
 (HSIS 2008)

Chemical Name Gamma-Aminopropyltrimethoxysilane
CAS No. 13822-56-5 *Weight %* 1-5
Hazardous Properties R41 51/53 (Classified by the notifier)

Chemical Name Tris(trimethoxysilylpropyl)amine
CAS No. 82984-64-3 *Weight %* 1-5
Hazardous Properties R41 51/53 (Classified by the notifier)

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

ADDITIVES/ADJUVANTS
 None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Colourless to yellow liquid

Property	Value	Data Source/Justification
Melting Point	< -38°C	MSDS
Boiling Point	285-288°C at 101.3 kPa	MSDS
Density	1004 kg/m ³ at 20°C	MSDS
Vapour Pressure	0.01 kPa at 20°C	MSDS
Water Solubility	Not determined	Notified chemical readily reacts with water
Hydrolysis as a Function of pH	Not determined	Notified chemical contains functionalities that hydrolyse rapidly in water, which is supported by the literature.
Partition Coefficient (n-octanol/water)	Not determined	Notified chemical readily reacts with water. A logK _{OW} of -3.73 is estimated by EPIWIN 3.2.
Adsorption/Desorption	Not determined	Notified chemical readily reacts with water. A logK _{OC} of 6.26 is estimated by EPIWIN 3.2.
Dissociation Constant	Not determined	Notified chemical contains a functionality group that is expected to have a pK _a in range of 9 - 11.
Particle Size	Not determined	The notified chemical is in liquid form.
Flash Point	> 100°C	MSDS
Flammability	Not determined	Not expected to be flammable under normal conditions of use.
Autoignition Temperature	Not determined	Not expected to autoignite under normal

Explosive Properties	Not determined	environmental and use conditions. Not expected to be explosive based on absence of structural alerts.
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DISCUSSION OF PROPERTIES

Reactivity

Stable under normal conditions of use.

Reacts rapidly with water to form methanol (highly flammable) and siloxane gel.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical is imported as part of a finished product.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	0.95	0.95	0.95	0.95	0.95

PORT OF ENTRY

Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS

Imported by the notifier.

TRANSPORTATION AND PACKAGING

The finished products containing the notified chemical are imported in sealed 250 ml aluminium containers. These are shipped in cartons and stored in corrugated cardboard or fibreboard boxes that are wrapped in plastic on pallets. The cartons are transported from the wharf by road.

USE

A component of an adhesion promoter (<10%) for polyurethane adhesives.

OPERATION DESCRIPTION

The product containing the notified chemical is not locally manufactured or reformulated. OEMs, automotive repair shops and specialists in window glass replacement will use the finished products. Application involves cleaning the bond face with a cloth or absorbent paper towel and applying the product to the glass using a paintbrush. The paintbrush is cleaned after use each day.

6. HUMAN HEALTH IMPLICATIONS**6.1 Exposure assessment****6.1.1 Occupational exposure**

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Waterside, Transport, Warehouse	20	1	50
Applicators at glass replacement workshops	500	4	200

EXPOSURE DETAILS

Exposure of transport and storage workers is not expected except in the event of accidental spillage or breach of packaging.

Applicators

As the activator is applied manually, dermal exposure to the notified chemical is possible during application and manipulation of the automotive windscreen. Ocular exposure, though less likely, is also possible from splatter during application. Inhalation exposure is unlikely due the low vapour pressure (0.01 kPa) of the

notified chemical.

Exposure to the notified chemical will be minimised as applicators are expected to wear personal protective equipment consisting of impervious overalls, gloves, safety boots and eye protection goggles. Local exhaust ventilation is expected to be available to prevent any inhalation exposure to workers.

Once the activator and adhesive cure, the notified chemical becomes bound within a matrix and is unavailable for exposure.

6.1.2. Public exposure

The imported product containing the notified chemical will not be sold to the general public, but only used by industrial customers. The public may come into contact with the notified chemical only after it has been applied to, and becomes an inert part in the frame of automobile windscreens. In this form, the notified chemical is unlikely to be bioavailable.

6.2. Human health effects assessment

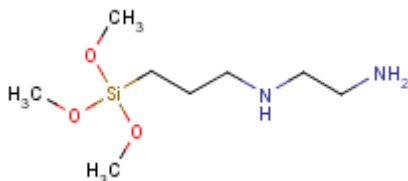
No toxicity data were submitted on the notified chemical; therefore the health assessment is based on the known hazards of alkoxy silane (especially trimethoxysilane), publicly available information on the notified chemical and published toxicological data on an analogue proposed by the notifier, N-[3-(trimethoxysilyl)propyl]ethylenediamine.

N-[3-(trimethoxysilyl)propyl]ethylenediamine

IUPAC name 1,2-Ethanediamine, N-[3-(trimethoxysilyl)propyl]-

CAS number 1760-24-3

Structural formula



Molecular Weight	222 Da
Melting Point	< -36°C
Boiling Point	264°C at 101.3 kPa
Density	1030 kg/m ³ at 25°C
Vapour Pressure	0.04 kPa at 20°C

Toxicological data on the analogue are summarised in the table below. Details of these studies can be found in the IUCLID Dataset (IUCLID 2004) and OECD SIDS report (OECD 2003).

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	oral LD50 > 2000 mg/kg bw low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation – adjuvant test	evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 500 mg/kg
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro (Hamster ovary HGPRT assay)	non genotoxic
Genotoxicity – in vivo (Mouse micronucleus assay)	non genotoxic
Developmental and reproductive toxicity	NOAEL = 500 mg/kg/day.

The notified chemical has a relatively low molecular weight (341.5 Da) and rapidly hydrolyses to form methanol and siloxane gel. Due to this reaction, the notified chemical is expected to undergo hydrolysis if in contact with mucous membranes lining the respiratory system, eyes and to a lesser extent the skin.

The notified chemical contains the trimethoxysilane functionality and has a molecular weight of less than 1000. This class of chemical has been flagged as a potential concern for lung toxicity from inhalation of vapours or aerosols (EPA 2002). The vapour pressure of the notified chemical is very low (0.01 kPa) and therefore inhalation of the vapour of the notified chemical is not expected to occur under normal environmental

conditions. However, methanol vapour (which is highly flammable and toxic by inhalation and in contact with skin) may be generated under humid conditions, or if the notified chemical is mixed with water.

Acute toxicity

The oral LD₅₀ in rats for the analogue is above 2000 mg/kg bw and is considered to be of low toxicity via the oral route (IUCLID 2004). Published information on the notified chemical report that the rat oral LD₅₀ is 3.6 ml/kg and the test animals showed evidence of general depressed activity, changes in motor activity and gastrointestinal changes (RTECS 1998).

A dermal toxicity test of the analogue in rats resulted in one death when two animals were dosed at 16.0 ml/kg. There were no signs of toxicity but there was gross pathological evidence of congested lungs, liver and spleen and pale kidneys (IUCLID 2004). Published data on the notified chemical report that the rabbit dermal LD₅₀ is 11.3 ml/kg (Union Carbide and Plastics Company 1992). Although there is insufficient detailed information, these results indicate the notified chemical is likely to be of low toxicity via the dermal route.

Eye Irritation

An acute eye irritation test found that the analogue was an irritant with irreversible effects, based on significant conjunctival chemosis, enanthema (eruption on a mucous membrane) and persistent iridial congestion and corneal opacity more than 21 days after exposure to the test substance (IUCLID 2004).

A summary report on an eye irritation test of the notified chemical using the draize score has recorded the notified chemical as causing 'severe irritation' to the eyes of rabbits (Union Carbide Chemicals and Plastics Company Inc 1992).

The trimethoxysilane group of chemicals have previously been associated with occupational eye irritation in exposed workers who experienced severe inflammation of the cornea (Grant 1986).

Based on the collective information, the notified chemical is considered to be a severe irritant to the eyes.

Skin Irritation

A semi-occlusive skin irritation study performed on the analogue using the OECD 404 guidelines noted that slight erythema and oedema was evident on the skin of rabbits, but that all lesions observed at the 72-hour observation point had resolved by the Day 14 reading. Based on the average scores, the test substance was considered to be non-irritating. An additional study performed on rabbit skin using the occlusive method found that exposure produced minor to moderate erythema on 6 of 6 rabbits tested and desquamation on 3 animals within 3 to 7 days. The average Draize scores indicated that the analogue test substance was slightly irritating (IUCLID 2004).

A summary report on the skin irritation effects of the notified chemical noted a 'moderate' reaction when rabbits were exposed to a 0.5ml dose (Union Carbide Chemicals and Plastics Company Inc 1992). No study details were available and therefore it is not known whether the test was conducted to OECD guidelines or even if the test method used semi-occlusive or occlusive dressing.

Finally, it has been previously stated that alkoxysilane groups that rapidly hydrolyse when in contact with water (such as the notified chemical), result in metabolites that may only cause mild skin irritation (Hulzebos et al 2005).

Although there appears to be signs of irritation under different test conditions, based on the available information, the notified chemical cannot be classified as a skin irritant.

Sensitisation

Amine-functional methoxysilanes have previously been implicated as a cause of occupational contact dermatitis, often as a result of repeated skin exposure with workers involved in the manufacture or use of the resins containing the chemical during fibreglass production (Hughes 2001; Toffoletto 1994).

The guinea pig maximisation test on the analogue resulted in signs of irritation to the test substance during induction as well as sensitisation reactions after the first challenge on 30% of the animals tested. However there was also evidence of slight irritation in one control animal.

Based on the analogue data and information on methoxysilanes, the possibility of the notified chemical to cause

skin sensitisation cannot be ruled out.

Repeated Dose Toxicity

The NOAEL for oral dosing for a 28-day study on the analogue was considered to be 500 mg/kg bw/day. Clinical signs included temporary weight loss, perioral soiling, increased nasal sounds, laboured respiration and salivation prior to and after dosing. There were no significant changes to organ weights, motor activity, haematology and serum chemistry values. No changes were observed at necropsy. The investigators noted a clear dose-related resistance to dosing by the control and treatment groups, and determined that many of the clinical findings were anticipated based on the amine-functionality of the test substance to cause irritation.

Based on the analogue data the notified chemical is considered unlikely to cause significant systemic toxicity, although local irritation may be observed.

Mutagenicity

The analogue was not found to be mutagenic to any of the bacterial strains used in the Ames test. The analogue did not cause genotoxicity in an *in vitro* test on Chinese Hamster Ovary cells.

Therefore it is considered unlikely that the notified chemical is mutagenic or genotoxic.

Toxicity for reproduction

As part of the repeated dose study (OECD TG 422) conducted on the analogue, female rats exposed to the test substance by gavage for up to 39 days and up to 500 mg/kg/day were observed for reproductive effects. There were no effects in any of the reproductive parameters evaluated. Two females in the 500 mg/kg/day group were sacrificed or found dead but the deaths were attributed to dosing-related errors. Two high dose (500 mg/kg/day) and one low dose (25 mg/kg/day) females did not produce litters despite positive evidence of copulation. All other females, including high dose group females, produced litters that were similar to the control. No adverse effects or abnormalities were detected in the litter produced by exposed rats. Based on the results, the NOAEL for developmental and maternal systemic toxicity in rats was determined to be 500 mg/kg bw/day. Based on the analogue data the notified chemical is considered unlikely to cause significant reproductive toxicity.

Health hazard classification

Based on the eye irritation studies on the notified chemical and the analogue, the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Xi; R41 – Risk of Serious Damage to Eyes

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Workers may experience dermal exposure and accidental ocular exposure to the finished product containing <10% of the notified chemical during manual application. Exposure is expected to be limited with the use of personal protective equipment that prevents eye exposure (protective glasses) and covers the skin (gloves, coveralls). Although exposure to the vapour of the notified chemical is unlikely, engineering controls such as local exhaust ventilation are expected to prevent inhalation of volatile compounds such as methanol that may be generated during use of the product. Therefore, although the notified chemical is a severe eye irritant and the potential for skin sensitisation cannot be ruled out, under the proposed occupational setting, the notified chemical is not likely to pose a significant health risk for workers.

6.3.2. Public health

The notified chemical is not available to the public, except after the product has been applied and cured and the notified chemical becomes bound within a matrix. The notified chemical is not available for exposure hence the risk to the public is negligible.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as finished products in sealed 250 mL aluminium tins and sold directly to customers. Further reformulation or repackaging of the notified chemical in Australia is not expected. Therefore, release at site for reformulation of the notified chemical in Australia is not expected.

RELEASE OF CHEMICAL FROM USE

Some notified chemical may be released to the environment as small incidental spills during application (< 5%), or as residues left on the perimeter of the windshield after application (< 5%). A small amount (< 2%) may remain as residue in the import cans. In total it is anticipated that < 12% of the notified chemical will be released each year through spills and residues. These will form an inert insoluble compound when it comes into contact with atmospheric moisture, which can be easily collected for disposal. It is expected that the waste chemical will be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical will reside on the frame of motor vehicle windcreens after application. At the end of the vehicle's useful life, the glass windcreens and windscreen support frames containing the inert chemical will either be recycled for glass and steel reclamation, or disposed to landfill. Any spills during application and residues remaining in containers or from scrapped automobiles are also likely to be disposed of in landfill.

7.1.2 Environmental fate

No environmental fate data were submitted.

The mixture containing the notified chemical reacts or cures on contact with atmospheric moisture to form an inert solid. Most of the notified chemical will be fixed with the glass bonding adhesives to the window frame at the customer sites, and will remain on the automotive window frame until the vehicle or glass reach the end of their lifespan. Therefore, this part of the notified chemical will be either disposed of to landfill, or be recycled for glass and steel reclamation. Any releases from use and residues in the imported containers will also be disposed of to landfill.

The notified chemical in landfill is not expected to leach, since it is in the form of an inert solid after reacting with moisture. The solid material will be subject to slow processes of biotic and abiotic degradation.

The notified chemical, either going to landfill or going to recycle processes for glass or metal reclamation, will finally decompose into water, oxides of nitrogen, carbon and silicon.

7.1.3 Predicted Environmental Concentration (PEC)

The calculation of PEC is not necessary since no release to the water environment is expected based on the reported use pattern.

7.2. Environmental effects assessment

No ecotoxicity data were submitted.

7.3. Environmental risk assessment

The calculation of PEC/PNEC is not possible due to the unavailability of the ecotoxicity data. However, the notified chemical is not considered to pose an unacceptable risk to the aquatic environment since no release of the notified chemical is expected according to its reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

Xi; R41 – Risk of Serious Damage to Eyes

Human health risk assessment

Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

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

Environmental risk assessment

On the basis of the reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
 - Avoid dermal and eye contact during application
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
 - Eye protection glasses
 - Chemical-resistant gloves
 - Coveralls

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

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical 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 chemical should be disposed of to landfill.

Storage

- The following precautions should be taken regarding storage of the notified chemical:
 - Storage in a cool dry location

Emergency procedures

- Spills or accidental release of the notified chemical 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 chemical is listed on the Australian Inventory of Chemical Substances (AICS).

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

- (1) Under Section 64(1) of the Act; if
 - the importation volume exceeds one tonne per annum notified chemical;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from an adhesion promoter for polyurethane adhesives, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 1 tonne, or is likely to increase, significantly;
 - the concentration of the chemical used in a product exceeds 10 %;
 - if the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

Material Safety Data Sheet

The MSDS of the notified chemical and product containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

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