File No: LTD/1426

December 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

SYL-OFF-SL11 Cross Linker

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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Dow Corning Australia Pty Ltd (ABN 36 008 444 166)
Macquarie University Research Park, 3 Innovation Road
NORTH RYDE NSW 2113

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 Formula, Structural Formula, Molecular Weight, Spectral Data, Purity, Concentration and Identity of Impurities and Additives/Adjuvants, Import Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Vapour pressure, 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
Korea (2007)
Canada (2004)
USA (2003)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
SYL-OFF-SL11 Cross Linker

OTHER NAME(S)
Dimethyl, Methylvinyl Cyclosiloxane with Epoxide
Material Number: 04072154

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	Cyclosiloxanes, Me hydrogen		
CAS No.	68037-53-6	*Weight %*	0.4
Hazardous Properties	R10 (Flammable) R53 (May cause long-term adverse effects in the aquatic environment) (information provided by the notifier)		

Chemical Name	Cyclotetrasiloxane, 2,2,4,4,6,6,8,8-octamethyl-
CAS No.	556-67-2 *Weight %* 0.4
Hazardous Properties	Classification Repr. Cat. 3; R62 (Possible risk of impaired fertility) R53 (May cause long-term adverse effects in the aquatic environment) Concentration cutoffs Conc≥5%: Xn; R62

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: colourless liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Liquid at room temperature
Boiling Point	350°C at 101.3 kPa	Measured
Density	984.8 kg/m^3 at 25°C	Measured
Vapour Pressure	Not determined	The notified polymer is considered to be very slightly volatile given its high molecular weight of > 1000 Da. It is claimed that the vapour pressure will be less than 1.33×10^{-8} kPa.
Water Solubility	0.05 g/L at 40°C and pH 7.0	Measured. Based on the structure of the polymer little or no water solubility is expected. However, silicone polymers in the liquid form could be water dispersible.
Hydrolysis as a Function of pH	Not determined	Stability tests under acidic and basic conditions indicate that hydrolysis of some pendant functional groups might occur in water.
Partition Coefficient (n-octanol/water)	Not determined	The hydrophobic nature of the notified polymer indicates a strong potential to partition into the octanol phase.
Adsorption/Desorption	Not determined	Expected to be relatively immobile in soil based on the highly hydrophobic structure and possibility of cross-linking with soil.
Dissociation Constant	Not determined	Dissociation is not expected under normal conditions since no readily dissociable functions exist in the notified polymer.
Particle Size	Not determined	Liquid
Flash Point	160°C (closed cup)	Measured
Flammability	Not expected to be highly flammable	Based on measured flash point.
Autoignition Temperature	Not determined	Not expected to self-ignite based on its chemical structure.
Explosive Properties	Not determined	The notified polymer contains no functional groups that would imply explosive properties.

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

Reactivity
The notified polymer may partially hydrolyse in water and transform into higher molecular weight polymers. It can react with strong oxidising agent. Thermal breakdown of the notified polymer during fire or very high heat conditions may evolve the following decomposition products: carbon oxides and traces of incompletely burned carbon compounds, silicon dioxide, formaldehyde & hydrogen.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer packed in 20 kg pails will be imported at > 90%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0-1	1-3	3-10	3-10	3-10

PORT OF ENTRY
Sydney

TRANSPORTATION AND PACKAGING
The 20 kg pails of the notified polymer will be stored at the notifier's warehouse and transported by road from the notifier's warehouse to the paper coating company.

USE
The notified polymer (up to 5%) is used as an adhesive in paper coating.

OPERATION DESCRIPTION
At a paper processing plant, workers will mix the notified polymer into solvent less liquid paper coating formulations in a pressure pot. The pot is then used to pump the coating formulation into the nip of a standard five roll coater or into the pan of a standard three roll coater and then onto a substrate. On thermal cure of the applied paper coating, the notified polymer is chemically consumed and becomes part of a larger polymer. The cured polymer will adhere strongly to the treated paper and provide a durable protective coating.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Stevedoring workers	1-5	1	5
Transport	1-5	2	5
Warehouse	1-5	5	10
Adhesive application	1-5	2	20

EXPOSURE DETAILS
Transport and Warehousing
Transport, warehouse and stores personnel will wear protective equipment (overalls/ industrial clothing and gloves as appropriate) when receiving and handling consignments of the imported product containing the notified polymer. The product in drums will be handled in the warehouse by using forklifts. During transport and warehousing, workers are unlikely to be exposed to the notified polymer except when packaging is breached.

Adhesive Formulation

The possible routes of exposure to the notified polymer (> 90%) are dermal and ocular during attachment and detachment of pumping lines to the steel drums. Dermal and ocular exposure may also occur during cleaning of the mixing tanks after formulation. Exposure to significant amounts of the notified polymer should be limited because of the engineering controls and the personal protective equipment (PPE) worn by workers. Engineering controls include either local exhaust ventilation, good general ventilation or forced mechanical ventilation. PPE includes safety glasses, gloves, and coveralls.

Application of Adhesive
The possible routes of exposure to the notified polymer (up to 5%) are dermal and ocular during application of the adhesive to various surfaces. Exposure during application should be minimised by the use of PPE including safety glasses, gloves, and coveralls. Engineering controls (local exhaust ventilation or forced mechanical ventilation) will further minimise exposure to the notified polymer during application. Once the adhesive is dried (by air) the notified polymer is cured into an inert matrix and not available for exposure.

6.1.2. Public exposure
Public exposure to the notified polymer is not expected under normal use conditions as it is used only in industrial settings. Exposure to the notified polymer could occur if an accident occurred in transport. Although the public may have contact with articles to which the adhesive has been applied, the notified polymer will be part of a solid matrix and not available for exposure.

6.2. Human health effects assessment

No toxicity data for the notified polymer or an acceptable analogue polymer were submitted.

Toxicokinetics and Distribution
Based on the high molecular weight (Mn > 1000 Da), low water solubility and expected high lipophilicity, absorption across biological membranes is expected to be low. Systemic toxicity after dermal exposure to the notified polymer is therefore expected to be low.

Irritation and Sensitisation
The notified polymer contains an epoxide group that is a structural alert for irritation and sensitisation (Barratt et al. 1994, Gerner et al. 2004 and Hulzebos et al. 2005). Given the notified polymer contains a moderate percentage of low molecular weight species (< 1000 Da) it may possess some irritating and sensitising properties.

Health hazard classification

Based on the information provided, the notified polymer cannot be classified as a hazardous substance according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

However, based on a structural alert and moderate percentage of low molecular weight species, the notified polymer may have irritation and sensitisation properties.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The notified polymer may have the potential to cause irritation and sensitisation.

There is a possibility of ocular and dermal exposure to the notified polymer at > 90% during connection of pumping lines to the steel drums in adhesive formulation, and up to 5% during cleaning of mixing tanks and adhesive application. However, the expected use of PPE by workers should minimise exposure during these activities.

Overall, provided workers wear PPE, the risk to workers health from use of the notified polymer is not considered unacceptable.

6.3.2. Public health

As no exposure is expected from the cured printed material, the risk to the public from the use of the notified polymer is low.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured or reformulated in Australia, and therefore, there will be no releases from these activities.

RELEASE OF CHEMICAL FROM USE

The majority of the notified polymer will get thermally cured and become crosslinked in paper coatings, and is therefore not expected to be released to the environment. During the use of the industrial adhesives (for paper coating) containing the notified polymer, releases may occur from cleaning of application equipment and in the form of residues in empty containers. The wash-water generated during equipment cleaning will be collected for disposal. Residues in empty containers will be left to harden before disposal.

RELEASE OF CHEMICAL FROM DISPOSAL

Cleaning wash-water will be disposed of via a licensed waste contractor who will treat the effluent and subsequently send any solids containing the notified polymer to landfill. Containers, and hardened adhesive, will be disposed of to landfill.

Most of the imported quantity of notified polymer will be incorporated into the inert matrix of paper coatings after application and share the environmental fate of the paper substrates.

7.1.2 Environmental fate

No environmental fate data were submitted. Since the notified polymer has a molecular weight greater than 1000 Da and limited percentage of low molecular weight constituents, it is not expected to be able to cross biological membranes, due to molecular size, making bioaccumulation unlikely. The notified polymer is not considered to be bioaccumulative.

It is assumed that 50% of the waste paper to which the notified polymer is applied will end up in landfill and the rest will undergo paper recycling processes. During recycling processes, waste paper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks and coatings from the fibres. Very little of the notified polymer is expected to partition to the supernatant water, due to its highly hydrophobic nature, which is released to the sewer. Sludge generated during the washing process will be sent to landfill for disposal. In landfill, the notified polymer will be bound to soil and sludge based on its hydrophobicity and will be slowly degraded, eventually forming water and oxides of carbon and silicon.

7.1.3 Predicted Environmental Concentration (PEC)

The PEC for the notified polymer has not been calculated since no significant release to the environment is expected based on its reported use pattern.

7.2. Environmental effects assessment

No ecotoxicity data for the notified polymer or any acceptable analogue polymer were submitted. High molecular weight non-ionic polymers are a class of substances that are generally assumed to be of low environmental concern.

7.2.1 Predicted No-Effect Concentration

The PNEC has not been calculated since no ecotoxicity data are available for the notified polymer.

7.3. Environmental risk assessment

The notified polymer is used for a specific application in the paper coating industry. The overwhelming majority of the imported quantity of the notified polymer will be irreversibly cross-linked into inert coatings on paper that will ultimately be disposed of to landfill. As there is very limited potential for aquatic exposure to the notified polymer based on the reported use pattern, the polymer is not expected to pose a risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified polymer cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

However, based on a structural alert, the notified polymer may have potential for irritation and sensitisation properties.

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

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

Environmental risk assessment
On the basis of the reported use pattern, the notified polymer is not expected 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 polymer in adhesive formulation:
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during connecting pumping lines to the steel drums, cleaning the mixing tanks and adhesive application activities:
  - Protective gloves
  - Long-sleeved protective clothing
  - Safety glasses

  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 polymer should be disposed of to landfill.

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 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(2) of the Act; if
- the function or use of the chemical has changed from an adhesive in paper coating, or is likely to change significantly;
- the amount of chemical being introduced has increased from 10 tonne per year, or is likely to increase, significantly;
- 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.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of the notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point 350ºC at 101.3 kPa

Method Boiling point at Reflux (In-house Method)
Remarks Report was not sighted.

Density 984.8 kg/m^3 at 25ºC

Method Standard weighing cup/pyncnometer method (In-house Method)
Remarks Report was not sighted.

Water Solubility 0.05 g/L at 40ºC and pH 7.0

Method OECD TG 120 Solution/Extraction Behaviour of Polymers in Water
Remarks Analytical method: total carbon analysis. A flask method was used, and the mixture of the notified polymer in water (10,000 mg/L, nominal) was filtered by a syringe-filter (0.45µm) after 24 hours agitation at 40ºC. The solubility at pH 2.0, 7.0 and 9.1 was determined to be 41, 54 and 34 mg/L, respectively. Based on the structure of the polymer little or no water solubility is expected. However, silicone polymers in the liquid form could be water dispersible.
Test Facility KOPTRI (2007)

Hydrolysis as a Function of pH

Method OECD TG 120 Solution/Extraction Behaviour of Polymers in Water

Remarks A stability test of the notified polymer was conducted at 40˚C for 24 hours at pH 1.2, and 2 weeks at pH 7.0 & pH 9.0. The notified polymer became insoluble in THF (used for GPC analysis) after each of the three exposure experiments. This may indicate that hydrolysis, probably of some pendant functional groups, occurred during the test, despite no notable changes in the FT-IR spectra.
Test Facility KOPTRI (2007)

Flash Point 160ºC (pressure unknown)

Method Pensky Marten Closed Cup - Automatic Flash Tester Method. This method is very similar to Seta closed cup Flash Point Method (In-house Method)
Cleveland Open Cup Flash point value for this polymer is 210ºC.
Remarks Report was not sighted.

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