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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

SYL-OFF® SL 9176 Anchorage Additive

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 Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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:

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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SYL-OFF® SL 9176 Anchorage Additive

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Dow Corning Australia Pty Ltd (ABN: 36 008 444 166)
Darling Park, Tower 2, Level 20, 201 Sussex Street
Sydney, NSW 2000

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, other names, CAS number, molecular and structural formulae, molecular weight, spectral data, purity, polymer constituents, residual monomers/impurities and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: boiling point, density, vapour pressure, partition co-efficient, absorption/desorption, particle size, flammability limits, flash point, autoignition temperature and explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2008)
Korea (2008)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
SYL-OFF® SL 9176 Anchorage Additive

MOLECULAR WEIGHT
>1000 Da

ANALYTICAL DATA
Reference NMR, IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
All hazardous impurities and residual monomers are present at levels under the concentration cut-offs for classification.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Straw coloured liquid

Property	Value	Data Source/Justification
Boiling Point	>197°C at 101.3 kPa	MSDS
Specific Gravity	1000 kg/m^3 at 25 °C	MSDS
Vapour Pressure	Not determined	Based on the high molecular weight of the polymer the vapour pressure is expected to be low.

Water Solubility	Indeterminable	Hydrolytically unstable
Hydrolysis as a Function of pH	Not determined	Stability tests under acidic and basic conditions indicate that hydrolysis and cross-linking occur rapidly under these conditions
Partition Coefficient (n-octanol/water)	Not determined	Hydrolytically unstable and a meaningful partition coefficient cannot be determined
Adsorption/Desorption	Not determined	Expected to sorb strongly to soil and sediment based on its predominantly hydrophobic structure and the possibility of cross-linking with the soil
Dissociation Constant	Not determined	Does not contain dissociable functionality
Flash Point	139 ºC	MSDS
Autoignition Temperature	Not determined	Not expected to autoignite based on its chemical structure.
Explosive Properties	Not determined	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 contains reactive alkoxysilane and epoxide functional groups and may hydrolyse in water. The polymer is not compatible with strong oxidising agents and at temperatures >150 ºC, may emit formaldehyde.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported into Australia as SYL-OFF® SL 9176 Anchorage Additive (>90% notified polymer)

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<10	<10	<10	<10	<10

PORT OF ENTRY
Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS
Dow Corning Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 20 or 200 L steel drums and transported within Australia by road.

USE
The notified polymer will be used as an adhesion promoter in formulations for coating paper (<2% concentration). Applications include laminate/labelstock, single- and double-sided industrial release films and film liners of technical adhesive tapes.

OPERATION DESCRIPTION
At reformulation sites, the notified polymer will be pumped from imported drums into an enclosed mixing vessel, where it will be blended with other chemicals. The formulation containing <2% notified polymer, will then be transferred to coating heads, where rolls of paper that are being fed automatically through a roller system will be treated. The treated paper will then be carried by conveyor and dried in an oven (*ca*. 120 ºC), prior to distribution to customers.

Equipment used during formulation and application of the notified polymer will be cleaned by washing with water. The resulting liquid waste will be disposed of by licensed contractors.

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)*
Stevedore	1-5	1	5
Transport	1-5	2	5
Warehouse	1-5	5	10
Adhesive preparation/application	5-15	8	72
Cleaning/maintenance of equipment	unspecified	unspecified	unspecified

EXPOSURE DETAILS
Stevedore, transport and warehouse staff may come into contact with the imported product (>90% notified polymer) only in the event of accidental rupture of containers.

The blending and application processes will be largely conducted in automated and enclosed environments. Dermal or ocular exposure to the notified polymer (at >90% concentration as imported or <2% concentration following formulation) may occur whilst opening containers, during connection/disconnection of hoses, during application and cleaning of machinery. Inhalation exposure to the notified polymer should be minimised through the use of enclosed systems and exhaust ventilation. Exposure should be further mitigated by the use of personal protective equipment (PPE: goggles, impervious gloves and protective clothing).

Once cured, the notified polymer is not expected to be bioavailable and further dermal contact should not lead to exposure.

6.1.2. Public exposure
The notified polymer is intended for industrial use only, therefore the public may be exposed to the imported product (>90% notified polymer) only in the event of a transport accident. The public will come into contact with manufactured products containing the cured adhesive. However, as the notified polymer will be cured and crosslinked to form an inert matrix, it will be unavailable for exposure.

6.2. Human health effects assessment

The results from toxicological investigations conducted on an analogue of the notified polymer are summarised in the table below. Although the analogue polymer contains some structural similarity to the notified polymer, the use of the data is limited by the absence of functional groups present in the notified polymer.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >2,000 mg/kg bw; low toxicity
Rabbit, acute dermal toxicity	LD50 >2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	mutagenic

Based on the high molecular weight (>1000 Da) of the notified polymer, the potential of the notified polymer to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure is limited. However, the polymer contains a significant proportion of low molecular weight species (<1000 Da) that may be absorbed.

The notified polymer contains structural alerts for the epoxide and alkoxysilane functional groups (with pendant methoxysilane groups present). The alkoxysilane functional group presents a concern for lung toxicity from inhalation of vapours or aerosols and the epoxide functional group presents a concern for carcinogenicity, reproductive toxicity, skin irritation and sensitisation (Barratt *et al.*, 1994; Gerner *et al*., 2004; Hulzebos *et al*., 2005; US EPA, 2010). However, for reproductive and carcinogenicity effects, there is greater concern for primary epoxides than epoxides with substitutions on both epoxy carbons, as is the case with the notified polymer (US EPA, 2010).

No toxicity data is available for the notified polymer. Studies conducted on an analogue polymer that contains epoxy but not alkoxysilane functionality were provided by the notifier. The analogue polymer was of low acute oral toxicity in rats, low acute dermal toxicity in rabbits, was not a skin or eye irritant in rabbits and was not a skin sensitiser in guinea pigs (Magnus-Kligman method). The analogue polymer was mutagenic in a bacterial reverse mutation study [a dose-related, statistically significant increase in the number of revertant colonies was noted for one of the 5 strains tested (*Salmonella Typhimurium:* TA1535) with and without metabolic activation].

Therefore, based on studies involving an analogue polymer, the notified polymer may be mutagenic. In addition, while the high molecular weight of the notified polymer is expected to preclude many of the abovementioned concerns posed by the presence of functional groups with structural alerts, the presence of a significant proportion of low molecular weight species (<1000 Da) means that these effects cannot be ruled out.

In summary, based on the results of an analogue polymer, the notified polymer may be mutagenic and based on structural alerts and a high percentage of low molecular weight species, may have potential for irritation and/or sensitisation, reproductive effects and lung toxicity.

Health hazard classification
Due to the lack of toxicity data/information, the notified polymer cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). However, based on the results of an analogue polymer, the notified polymer may be mutagenic.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
No toxicological data are provided for the notified polymer. However, based on data provided for an analogue polymer, it may be mutagenic. In addition, the potential for irritation, sensitisation or reproductive effects following contact with the notified polymer cannot be excluded. Due to the presence of low molecular weight species, and the presence of a structural alert associated with lung toxicity, inhalation of the vapour should be avoided.

Due to the control measures in place to reduce exposure, including enclosed, automated processes and the use of PPE, the overall risk of exposure to the notified polymer is expected to be low. Hence, provided these control measures are in place, the risk to the health of workers from use of the notified polymer is not considered to be unacceptable.

6.3.2. Public health
The notified polymer is intended for use in industrial applications by qualified operators. The public may be exposed to products manufactured using the polymer-containing adhesive. However, the polymer will be cured and unavailable for exposure. Therefore, when used in the proposed manner, the risk to public health is not considered to be unacceptable.

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 in Australia. Blending of the notified polymer will occur on-site. In the event of an accidental spill during transport or blending, the notified polymer is expected to be absorbed with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
The notified polymer is an adhesion promoter for paper coatings and will be blended with other components prior to application to rolls of paper from a roller system. The majority of the notified polymer will become irreversibly cross-linked as the adhesive is heat cured after application to the paper. A small proportion of the imported quantity of notified polymer (<1%) may be released through the cleaning of application equipment. Wash-water containing the notified polymer, from the cleaning of equipment, will be disposed of by a licensed waste contractor. In wash-water, the notified polymer is likely to hydrolyse and cross-link to form solids which will be disposed of to landfill. Residues in empty import containers will be left to cross-link and harden before disposal to landfill. In the event of an accidental spill during the paper coating process, the notified polymer is expected to be absorbed with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL
Due to the film-like nature of the coated paper liners, they are not likely to enter the paper recycling process at significant levels, but are expected to be disposed of to landfill. Hence, the majority of the imported quantity of notified polymer will eventually be disposed of to landfill.

7.1.2 Environmental fate

No environmental fate data were submitted. The majority of the notified polymer will enter landfill as part of an inert cross-linked matrix on paper. In landfill, the notified polymer is not expected to be bioavailable or mobile due to its cross-linked structure. In landfill and soil the notified polymer may undergo soil-catalysed degradation into lower molecular weight compounds. These degradants will further oxidise, both biotically and abiotically, to form water, and oxides of carbon and silica (Dow Corning, 1997).

7.1.3 Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) for the notified polymer has not been calculated as no significant release to the aquatic 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. The notified polymer will tend to form insoluble cross-linked solids in water that will have low bioavailability. The notified polymer is therefore not expected to pose a toxic hazard to aquatic life.

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 are available.

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

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Due to the lack of toxicity data/information, the notified polymer cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Based on the results of an analogue polymer, the notified polymer may be mutagenic and based on structural alerts and a high percentage of low molecular weight species, may have potential for irritation and/or sensitisation, reproductive effects and lung toxicity.

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 engineering controls to minimise occupational exposure to the notified polymer (as introduced at >90% concentration and when using at <2% concentration):
  - Enclosed, automated processes during reformulation
  - Exhaust ventilation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer (as introduced at >90% concentration and when using at <2% concentration):
  - Avoid skin and eye contact
  - Avoid inhalation of vapour

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer (as introduced at >90% concentration and when using at <2% concentration):
  - Coveralls, gloves, goggles
  - Respiratory protection (if exhaust ventilation is not available)

  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 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.

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(1) of the Act; if
- the polymer has a number-average molecular weight of less than 1000;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of adhesive used at work places for paper coating (at <2%) or is likely to change significantly;
- the amount of polymer being introduced has increased from 10 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 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. However, the hazard identifications section should be amended to read "Not Determined/no test data" given the potential concerns of the notified polymer.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility Indeterminable

Method Attempts were made to measure the water solubility of lower molecular weight fractions of the notified polymer (NAMW = 636) using a modification of OECD TG 120. Solutions of the test substance in deionised water or buffer solutions of pH 2, 7 and 9 (2 g/200 mL) were shaken at 40ºC. After 24 h, aliquots were filtered and analysed for total organic carbon.

Remarks The interpretation of the results of this test were confounded by the reactivity of this liquid polymer in water. Based on the results of stability tests conducted under similar conditions, the notified polymer undergoes rapid cross linking reactions which are thought to involve reactive intermediates formed by hydrolysis. The water solubility of the notified polymer is therefore an indeterminable property in this case.

Test Facility Dow Corning (2008)

Hydrolysis as a Function of pH Not determined

Remarks The stability in water of a lower molecular weight fraction of the notified polymer (NAMW = 586) was investigated. Solutions of the test material were agitated in water at pH 1.2 at 40°C for 1 day, and pH 4, 7 and 9 at 40°C for 14 days. After this time, the water insoluble fraction was characterised by GPC and FT-IR to investigate changes in the molecular weight (MW) and structure of the polymer.

Solids were isolated from test mixtures which had reduced solubility in the GPC solvent, THF, as compared with the starting liquid notified polymer, which indicates a chemical transformation of the polymer under the test conditions. A GPC analysis of the THF soluble components of the solid material also showed measurable increases in the MW in samples treated under acidic and basic conditions, in particular. The MW increase of polymers in these solutions and the formation of insoluble solids in the aqueous test mixtures is interpreted as the result of cross-linking/chain extension of the polymer through hydrolytic condensation. Changes in the polymer structure were also observable by FT-IR.

Test Facility Dow Corning (2008)

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