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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

SILRES® IC 368 Polymer

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

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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 CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1881	Wacker Chemie AG	SILRES® IC 368 Polymer	ND*	≤ 50 tonnes per annum	Component of coatings, adhesives and sealants

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment
Provided that the recommended controls are being adhered to, 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.

No environmental fate data or degradation studies were provided by the notifier. The degradants of the notified polymer may lead to precursors of potentially persistent cyclosiloxanes. The assessed use pattern of the notified polymer does not control the release of breakdown products into the environment during use and after disposal and the long-term environmental risk profile of cyclosiloxanes is currently unknown. Consequently, the long-term risk profile for the notified polymer and its degradation products is unknown.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer and methanol released during curing:
  - Enclosed and automated processes during reformulation, where possible
  - Local exhaust ventilation and/or good general ventilation
  - Spray booths, where possible

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified polymer and methanol released during curing:
  - Avoid breathing in vapours, mists or aerosols

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer and methanol released during curing:

- Impervious gloves
- Respiratory protection, where vapours, mists or aerosols may be formed

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012) or relevant State or Territory Code of Practice.

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

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 1,000;

or

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

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

(Material) Safety Data Sheet
The (M)SDS of the notified polymer and a product containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with the United States Environmental Protection Agency (US EPA). Information pertaining to the assessment of the notified polymer by the US EPA was provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on the safe use of the notified polymer were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Wacker Chemie AG (ABN: 11 607 113 062)
1/35 Dunlop Road
MULGRAVE VIC 3170

NOTIFICATION CATEGORY
Limited (Reduced fee notification): Synthetic polymer with Mn ≥ 1,000 Da – chemical assessed by comparable agency

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, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants and import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2010)
Canada (2014)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
SILRES® IC 368 Polymer

OTHER NAME(S)
GENIOSIL XB 502 (product containing the notified polymer at < 70% concentration)

MOLECULAR WEIGHT
≥ 1,000 Da

ANALYTICAL DATA
Reference GPC data were provided

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Liquid at ambient temperature
Boiling Point	> 300 °C	(M)SDS
Density	1,200 kg/m^3 at 20 °C	(M)SDS

Property	Value	Data Source/Justification
Vapour Pressure	Not determined	Expected to be low based on high molecular weight
Water Extractability	11.73 mg/g	Measured. Determined at neutral pH only as the polymer readily reacts with water under acidic and basic conditions
Hydrolysis as a Function of pH	Not determined	The notified polymer reacts with water to form methanol and an insoluble polymeric mass. The rate of hydrolysis increases under acidic and basic conditions
Partition Coefficient (n-octanol/water)	Not determined	Reacts with water
Adsorption/Desorption	Not determined	Reacts with water
Dissociation Constant	Not determined	Reacts with water
Flash Point	137 °C	(M)SDS
Flammability	Not determined	Not a flammable liquid based on flash point
Autoignition Temperature	424 °C	(M)SDS
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES

Reactivity
The notified polymer reacts with moisture to release methanol and form a water insoluble polymeric mass.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. It will be imported in neat form and in a formulated product, GENIOSIL XB 502, at < 70% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 10	≤ 15	≤ 30	≤ 40	≤ 50

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The notified polymer and GENIOSIL XB 502 containing the notified polymer will be imported in 200 L drums and 1,000 L IBCs and transported by road for distribution to Australian formulators.

The finished adhesives and sealants containing the notified polymer will be packaged in tubes, cartridges and sausage packs up to 600 mL in size. The formulated coating products containing the notified polymer will be mainly contained in 200 L steel drums for supply to commercial facilities, while 25 L pails may be also used for industrial trial purposes.

USE
The notified polymer will be used as a component of adhesives, sealants and coatings. It is estimated that > 95% of the imported notified polymer will be used in industrial applications and < 5% of the notified polymer will be used in products for DIY applications (adhesives and sealants only). The finished products will contain the notified polymer at < 70% concentration.

OPERATION DESCRIPTION

Reformulation
The imported notified polymer or the product GENIOSIL XB 502 containing the notified polymer at < 70% concentration will be reformulated into finished coating, adhesive and sealant products. As the notified polymer is moisture sensitive, the reformulation process including transfer, mixing and packaging steps are expected to be fully enclosed and automated with local exhaust ventilation.

End Use
The finished adhesive and sealant products containing the notified polymer will be used by both professionals and DIY users. For DIY use, finished products will be in small pack sizes expected to be in the range of 20 mL tube to 300 mL cartridge. For professional use, finished products will be in pack sizes up to 600 mL sausage. The adhesives and sealants will be applied to substrates directly from the packaging.

The coating products containing the notified polymer will be distributed in mainly 200 L steel drums, used in industrial settings only and applied by brush, roller or airless spray.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage workers	< 0.1	240
Reformulation workers	7	240
End users	4	240

EXPOSURE DETAILS

Transport and Storage Workers
Transport and storage workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident. In the event of a leak, workers may also be exposed to methanol vapours released from the notified polymer through contact with moisture in the air. During clean up, workers are expected to wear appropriate PPE including respiratory protection as advised in the SDS.

Reformulation Workers
The reformulation process is expected to be fully enclosed and automated hence exposure to the notified polymer is not expected. Dermal and ocular exposure to the notified polymer may occur during equipment maintenance and cleaning. Exposure to methanol vapours formed from the notified polymer through contact with moisture in the air may also occur. The notifier states that good ventilation will be in place. Workers are expected to wear appropriate PPE as advised in the SDS.

End Users
Dermal and ocular exposure to the notified polymer at < 70% concentration may occur when applying sealants and adhesives containing the notified polymer. In addition, users may have potential for exposure to methanol released from the notified polymer during the curing process. Workers are expected to wear appropriate PPE and use safe work practices to minimise exposure. Once the adhesive and sealant is cured, the notified polymer will be incorporated into the matrix and will not be available for exposure.

Workers using the coating products containing the notified polymer may come into contact with the polymer at < 70% concentration through dermal, ocular and inhalation routes. Potential exposure to methanol released during the curing process may also occur. Based on the application method used, appropriate PPE and engineering controls are expected to be in place to minimise the potential for exposure. Protective measures against hazardous solvents in the coatings will also reduce the possibilities for workers to come into contact with the notified polymer.

6.1.2. Public Exposure

The notifier has indicated that < 5% of the notified polymer will be used in adhesive and sealant products for DIY applications. Dermal and ocular exposure to the notified polymer at concentrations at < 70% concentration may occur during end use. Users may also have potential for exposure to methanol released from the notified polymer during the curing process. However, exposure is expected to be of low frequency and small scale. Once the adhesive and sealant is cured, the notified polymer will be incorporated into the matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

The notified polymer contains a significant amount of low molecular weight species; however, absorption is expected to be limited by all routes based on physico-chemical properties. There is a concern for irritation of lungs and mucous membranes based on the reactivity of the notified polymer.

The notified polymer also releases toxic and flammable vapour (methanol) during end-use.

Health hazard classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

The main health concern for the notified polymer is the potential for irritation of lungs and mucous membranes from inhalation. Given the expected low vapour pressure of the notified polymer based on its high molecular weight, inhalation exposure is only expected where vapours, mists or aerosols are formed. The notified polymer also releases a toxic and flammable vapour (methanol) during end-use.

6.3.1. Occupational Health and Safety

During reformulation inhalation exposure to the notified polymer is not expected given the process is expected to be largely enclosed and automated. During end-use there is potential for inhalation exposure when applying coatings containing the notified polymer by spray application. Inhalation exposure is not expected during use of sealants/adhesives containing the notified polymer given the viscous nature of the products. Workers may also have potential for exposure to methanol released from the notified polymer during curing of the adhesive, sealant and coating products.

Therefore, provided control measures are in place to minimise inhalation exposure to the notified polymer and methanol released during curing (i.e. appropriate respiratory protection and good general ventilation), the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

Approximately 5% of the imported notified polymer will be used in adhesive and sealant products for DIY applications. Inhalation exposure to the notified polymer is not expected given the viscous nature of the adhesive/sealant products. DIY users may have potential for exposure to methanol released from the notified polymer during the curing process. However, exposure is expected to be of low frequency and small scale. Once the adhesive and sealant is cured, the notified polymer will be incorporated into the matrix and will not be available for exposure. Therefore when used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

No manufacturing of the notified polymer will take place in Australia. Release of the notified polymer to the environment during importation, storage, and transport is unlikely. The most likely source of a release to the environment during these activities will be a transport accident. In the event of a spill, the notified polymer is

expected to be contained and collected with an inert absorbent material and disposed of in accordance with local regulations.

Reformulation of the notified polymer occurs in a closed system and release to the atmosphere is expected to be negligible. Solvent used for equipment washing, containing residues of the notified polymer, is expected to be recycled for reuse on site or disposed of via accredited waste disposal contractors. Wastes and spills (1% of annual import volume) during reformulation activities are expected to be contained on-site and disposed of in accordance with local regulations. Residues in import containers are expected to be disposed of in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

The coatings, sealants and adhesives containing the notified polymer will be used mainly in industrial processes and applications. However, a minor amount (< 5%) of the notified polymer is expected to be used by DIY consumers. Limited environmental exposure is expected during use as once the products containing the notified polymer are cured, the notified polymer will be irreversibly cross-linked into a solid polymer matrix and is not expected to be mobile. The notified polymer may be released to sewer as a result of cleaning application equipment. Spills and drips during use are expected to be collected and be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer is expected to share the fate of the substrate and is expected to be disposed of to landfill at the end of its useful life. The empty import containers are expected to be sent to a packaging recycler. Any cured polymer remaining in the empty containers will be disposed of to landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted. A significant aquatic exposure to the notified polymer is not expected when it is used as proposed in coatings, sealants and adhesives. A minor amount of the notified polymer maybe washed to the sewerage system following spills, or cleaning of residues from application equipment. In water, the notified polymer is expected to hydrolyse to form an insoluble high molecular weight solid, and is therefore not expected to bioaccumulate.

The majority of the notified polymer is expected to eventually be disposed of to landfill fixed in a solid polymer matrix, and is therefore not expected to be mobile, bioavailable or readily biodegradable in this form. In landfill, the notified polymer is expected to ultimately degrade biotically or abiotically to form water and oxides of carbon and silicon. It should be noted that the degradation of the notified polymer may also lead to the formation of precursors of cyclosiloxanes that has potential to persist in water (Environment Canada, 2008).

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) is calculated assuming a worst-case scenario that there is no removal of the notified polymer during sewage treatment plants (STP) processes and 5% of the notified polymer will be washed into sewers per year.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	50,000	kg/year
Proportion expected to be released to sewer	5 %	
Annual quantity of chemical released to sewer	2,500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	9.62	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	2.13	µg/L
PEC - Ocean:	0.21	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m^2/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m^3). Using these assumptions, irrigation with a

concentration of 2.126 µg/L may potentially result in a soil concentration of approximately 0.0142 mg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 70.87 µg/kg and 141.7 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result*	*Assessment Conclusion*
Algae Toxicity	72 h ErC50 > 100 mg/L (WAF)	Not harmful to algae up to the limit of solubility

WAF: water accommodated fraction

Based on the studies provided, the notified polymer is not considered to be harmful to algae up to the limit of its solubility in water. Therefore, the notified polymer is not classified for acute aquatic hazard under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as no effects to aquatic organisms are expected up to its limit of solubility in water.

7.3. Environmental Risk Assessment

The Risk Quotient, Q (= PEC/PNEC), has not been calculated since a PNEC is not available. The majority of the notified polymer will be incorporated in a polymer matrix and bound to the substrate after application, and is not expected to be exposed to the aquatic environment. The notified polymer is not expected to bioaccumulate or be harmful to aquatic organisms up to its limit of solubility in water. Therefore, based on its expected low hazard and the assessed use pattern the notified polymer is not expected to pose an unreasonable risk to the environment.

CONCLUSIONS

On the basis of its expected low hazard and assessed use pattern, the notified polymer is not considered to pose an unreasonable short-term risk to the environment. However, when the notified polymer is disposed of to landfill, it is expected to very slowly degrade and, may form the potentially persistent cyclosiloxanes. The assessed use pattern of the notified polymer does not control the release of breakdown products into the environment after disposal and the long-term environmental risk profile of cyclosiloxanes is currently unknown. Consequently, the long-term risk profile for the notified polymer and its degradation products is unknown.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Extractability 11.73 mg/g

Method	OECD TG 1120 Water Solubility EC test guideline A.20, Canadian NSN Technical Guidance Series - Water Extractability of Polymers
Remarks	Gravimetric determination. For scientific reasons the extraction behaviour was only determined at neutral pH, because under acidic and basic conditions certain functional groups are readily hydrolysed.
Test Facility	Wacker Chemie AG (2013)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Ecotoxicological Investigations

B.1.1. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test EC Council Regulation No 440/2008 C.3 Algal Inhibition Test
Species	*Desmodesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 9.9, 17.9, 32.3, 56.4, and 100.4 mg/L
Auxiliary Solvent	None reported.
Water Hardness	None reported.
Analytical Monitoring	ICP-OES-Method for the determination of Silicon. High performance liquid chromatography using UV detection (HPLC-UV)
Remarks - Method	The water-accommodated fractions (WAF) of the test item in algal medium were prepared for the test. For determination of the presence of dissolved test item in the test solutions, silicone was measured at the start and the end of the test. As the test item is a polymer with a distribution of molecular weights, it is most likely that molecules with low weight and low silicone content were dissolved. Therefore, it was not possible to calculate test item concentrations from the measured silicone concentrations. The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.

RESULTS

Biomass (mg/L at 72h)		*Growth (mg/L at 72h)*	
E_yC50	NOE_yC	E_yC50	NOE_yC
> 100	56	> 100	56

Remarks - Results	Marginal but statistical significant inhibition of algal growth was only observed in the highest treatment of 100 mg/L nominal concentration.
CONCLUSION	The notified polymer is not harmful to algae.
TEST FACILITY	LAUS GmbH (2014)

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