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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Siloxanes and Silicones, di-Me, polymers with 3-[(2-aminoethyl)amino]propyl Ph silsesquioxanes, methoxy-terminated

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 and Energy.

This Public Report is 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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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/2101	Wacker Chemie AG	Siloxanes and Silicones, di-Me, polymers with 3-[(2-aminoethyl)amino]propyl Ph silsesquioxanes, methoxy-terminated	ND*	≤ 30 tonnes per annum	Component of industrial coatings

*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.

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 the low hazard and reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid contact with skin and eyes

- 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:
  - Safety glasses
  - Impervious gloves
  - Protective clothing
  - Respiratory protection if inhalation of aerosols are expected

  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, 2015) or relevant State or Territory Code of Practice.

- A copy of the 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.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

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.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

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

(1) Under Section 64(1) of the Act; if
  - the polymer has a number-average molecular weight of less than 1000 g/mol;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a component of industrial coatings, 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.

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

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

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 g/mol

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details exempt from publication include: molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for all physico-chemical endpoints except water extractability.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2014)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Silres HP 2000 (product containing > 85% notified polymer)
Silres HP 2020 (product containing > 90% notified polymer)

CAS NUMBER
477725-72-7

CHEMICAL NAME
Siloxanes and Silicones, di-Me, polymers with 3-[(2-aminoethyl)amino]propyl Ph silsesquioxanes, methoxy-terminated

MOLECULAR WEIGHT
Number average molecular weight (Mn) is > 1,000 g/mol.

ANALYTICAL DATA
Reference SEC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 85%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	Benzene, methyl-		
CAS No.	108-88-3	*Weight %*	0.3
*Hazardous Properties**	H225 (Highly flammable liquid and vapour) H315 (Causes skin irritation) H373 (May cause damage to organs through prolonged or repeated exposure) H360 (May damage fertility or the unborn child) H336 (May cause drowsiness or dizziness) H304 (May be fatal if swallowed and enters airways)		

Chemical Name	1,2-Ethanediamine, *N*-[3-(trimethoxysilyl)propyl]-		
CAS No.	1760-24-3	*Weight %*	9.5
*Hazardous Properties^*	H302 (Harmful if swallowed) H314 (Causes severe skin burns and eye damage) H315 (Causes skin irritation) H317 (May cause an allergic skin reaction) H318 (Causes serious eye damage) H332 (Harmful if inhaled) H335 (May cause respiratory irritation) H373 (May cause damage to organs through prolonged or repeated exposure) H411 (Toxic to aquatic life with long-lasting effects) H412 (Harmful to aquatic life with long-lasting effects)		

Chemical Name	Methanol		
CAS No.	67-56-1	*Weight %*	0.5
*Hazardous Properties**	H225 (Highly flammable liquid and vapour) H331 (Toxic if inhaled) H311 (Toxic in contact with skin) H301 (Toxic if swallowed) H370 (Causes damage to organs)		

Chemical Name	Cyclotetrasiloxane, 2,2,4,4,6,6,8,8-octamethyl-		
CAS No.	556-67-2	*Weight %*	0.3
*Hazardous Properties**	H361f (Suspected of damaging fertility) H413 (May cause long-lasting harmful effects to aquatic life)		

* From HCIS
^ From ECHA C&L Inventory

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)
None

ADDITIVES/ADJUVANTS

Chemical Name	Benzene, ethyl-		
CAS No.	100-41-4	*Weight %*	< 5

Chemical Name	Benzene, dimethyl-		
CAS No.	1330-20-7	*Weight %*	< 10

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellowish liquid*

Property	***Value***	***Data Source/Justification***
Melting Point/Freezing Point	Not determined	Will be used in liquid form
Boiling Point*	140 °C	SDS
Density*	1,120 kg/m^3 at 20 °C	SDS
Vapour Pressure*	0.19 kPa at 20 °C 1.25 kPa at 50 °C	SDS
Water Extractability*	19.6 mg/g at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Expected to hydrolyse in contact with water
Partition Coefficient (n-octanol/water)	Not determined	Not applicable
Adsorption/Desorption	Not determined	Expected to strongly adsorb to solids (NICNAS, 2018)
Dissociation Constant	Not determined	Does not contain functionalities which are expected to dissociate in the environmental pH range of 4 to 9
Flash Point*^	38 °C	SDS

Property	*Value*	*Data Source/Justification*
Flammability*^	Not determined	The high MW and chemical structure of the notified polymer would suggest a low potential for flammability. It will be introduced in flammable solvent.
Autoignition Temperature*	425 °C	SDS
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidising properties

* Property of the product Silres HP 2000 containing > 85% notified polymer
^ The low flash point is expected to be attributed to the volatile solvent in the product Silres HP 2000

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

Reactivity
The notified polymer is expected to be stable under normal conditions of use.

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. The notified polymer will be imported into Australia at > 85% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 30	≤ 30	≤ 30	≤ 30	≤ 30

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The products (Silres HP 2000 and Silres HP 2020) containing the notified polymer will be imported in 210 kg steel drums, 25 kg steel cans or 2 - 5 L tins and transported within Australia by road.

USE
The notified polymer will be used as a component (< 90%) of the hardener in two-part industrial coatings (top-coat). It will be present at ≤ 50% concentration in the final coating.

OPERATION DESCRIPTION
The imported products (hardener component) are expected to be mixed with other ingredients using a fully enclosed and automated system with local exhaust ventilation as the notified polymer is moisture sensitive. The finished coatings containing the notified polymer at ≤ 50% concentration will then be applied by brush, roller or 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	< 1	240
Reformulation	2 - 4	240
Professional end-users	8	240
Cleaning and waste management	1	240

EXPOSURE DETAILS

Transport and storage
Transport, storage and trade sale workers are not expected to be exposed to the notified polymer except in the unlikely event of accidental rupture of the packaging.

Reformulation and end-use
Dermal, ocular or inhalation exposure to the notified polymer at ≤ 90% concentration may occur during mixing and coating application, and during cleaning and maintenance of equipment. Exposure will be mitigated by the use of engineering controls (including enclosed and automated systems and local exhaust ventilation) and personal protective equipment (PPE: goggles, impervious gloves, protective clothing and respirators during spray operations), as stated by the notifier. Once the coating is cured and dried, the notified polymer will be reacted into the polymer matrix and will not be available for exposure.

6.1.2. Public Exposure
The coatings containing the notified polymer (at ≤ 50% concentration) are intended for industrial use and will not be available to the public. The public may have dermal contact with coatings containing the notified polymer after they have been applied and cured. However, once the coating is cured and dried, the notified polymer will be reacted into the polymer matrix and will not be available for exposure.

6.2. Human Health Effects Assessment
No toxicity data were submitted for the notified polymer. Based on the high molecular weight (> 1,000 g/mol) and low percentage (< 2%) of low molecular weight species (< 500 g/mol), the notified polymer is not expected to be absorbed across biological membranes to a significant extent.

The notified polymer contains a structural alert indicative of possible irritation effects. Therefore, potential for skin and eye irritation of the notified polymer cannot be ruled out.

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.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer may cause skin and eye irritation.

During reformulation and end-use, workers may come into contact with the notified polymer at ≤ 90% concentration during mixing and coating application, and during cleaning and maintenance of equipment. The use of control measures (such as spray booths and ventilated areas) and PPE (goggles, impervious gloves, coveralls and respirators during spray operations), as stated by the notifier, is expected to minimise exposure to the notified polymer and reduce the risk of potential irritation effects.

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.

6.3.2. Public Health

Coatings containing the notified polymer will not be made available to the public. Members of the public may come into contact with articles coated with finished coatings containing the notified polymer. However, the notified polymer in cured coatings is expected to be bound within an inert matrix and will not be available for exposure.

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

The notified polymer will be imported into Australia for reformulation into a two-component protective top coating. Environmental release may occur during the transport and storage of the notified polymer, and accidental spills are to be contained and collected using an inert absorbent material and disposed of to landfill in accordance with local government regulations.

The notified polymer is sensitive to water, so reformulation operations are expected to be carried out in a fully enclosed system (performed under nitrogen or vacuum). Release during reformulation is therefore expected to be negligible. Solvent used for equipment washing, containing residues of the notified polymer, is expected to be disposed of via accredited waste disposal contractors. Wastes and spills during reformulation activities are expected to be contained on-site and disposed of in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

Coatings containing the notified polymer will be applied to surfaces in industrial or commercial settings (no DIY users) mainly by spray, but brushes and rollers may also be used. The main release of the notified polymer is expected to be from overspray, estimated by the notifier to account for up to 1.5% of the total annual import volume. During spraying the notified chemical is expected to be incorporated within the developing polymer matrix of the top coating. Therefore, overspray will lead to diffuse release of the top coating but the notified chemical is expected to be retained within the developing polymer matrix and will not be bioavailable. Once the topcoat is applied to surfaces, it cures (cross-links) and the notified chemical is irreversibly incorporated within the polymer matrix.

The notifier has indicated that top coatings containing the notified chemical will be applied to a variety of macrostructures including buildings, bridges and offshore platforms. In each application, the notified chemical is expected to be fully cured within the polymer matrix so release is not expected; minimal release is essential to the weather-resistant function of the top coat.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical is expected to share the fate of the material to which it has been applied, and be disposed of to landfill at the end of its useful life or destroyed during metal reclamation processes. Residues in import containers are expected to cross-link under ambient conditions to form solid waste that will be disposed of in accordance with local regulations.

Offshore installations fall under strict legislative requirements, especially for waste disposal, which is required to be done onshore. There are no chemical waste processing facilities on board offshore platforms. Therefore any waste generated at offshore locations which contains the notified chemical is expected to be disposed of in accordance with these requirements.

7.1.2. Environmental Fate

As a result of its use pattern, the majority of the notified polymer is expected to be either subjected to metal reclamation or disposed of to landfill. During metal reclamation, the notified polymer will thermally decompose to form water vapour and oxides of carbon and silicon. In landfill, the notified polymer will be present as cured solids and will be neither bioavailable nor mobile. Thus, release of the notified polymer from the assessed use pattern is not expected to lead to ecotoxicologically significant concentrations in the aquatic environment. In

landfill, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon, nitrogen and silicon by analogy with other siloxanes (NICNAS, 2018).

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated because significant release of the notified polymer to the aquatic environment is not expected based on the reported use pattern.

7.2. Environmental Effects Assessment

The results from an ecotoxicological investigation conducted on the notified chemical are summarised in the table below. Details of this study can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Algal Toxicity	72 h ErL50 > 100 mg/L (WSF)	Not harmful to algae up to the limit of its water solubility

WSF: Water Soluble Fraction

Based on the study 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 or chronic 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) for the aquatic compartment has not been calculated, since the notified chemical is not harmful to aquatic life up to the limit of its solubility in water.

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) for the aquatic compartment has not been calculated as release of the notified polymer to the aquatic environment will be limited to minimal amounts released from overspray during the coating of structures in the vicinity of the aquatic environment. Upon release, the notified chemical is expected to hydrolyse when in contact with water, forming an insoluble, cross-linked polymeric mass which is not toxic to algae up to the limit of the water solubility of the notified polymer.

The majority of the notified polymer will be disposed of to landfill as a cured polymer matrix in coated articles or destroyed during metal reclamation processes. In landfill, the notified polymer which is bound to coated articles is unlikely to be bioavailable or mobile. On the basis of the low aquatic toxicity and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Extractability 19.6 mg/g at 20 °C

Method	OECD TG 120 Solution/Extraction Behaviour of Polymers in Water
Remarks	The solubility/extractability of the notified polymer was estimated by measuring the difference in the dry weight of test substance (containing 85% (w/w) of the notified polymer) before and after extraction with water. After extraction the residual test substance was dried at 105 °C instead of the 40 °C recommended by the guidelines. No chemical analysis of the aqueous phase was performed, but it is known that the test substance hydrolyses in water, releasing methanol (water soluble) and forming an insoluble, cross-linked, polymeric mass. Therefore, the measured change in mass is likely due to the loss of methanol to the aqueous phase during extraction rather than due to solubilised polymer. The test substance also contains 15% impurities (not the notified polymer). If impurities partition to the aqueous phase during extraction this would also contribute to the change in mass. This was not considered in the test report (in contrast to the recommendations of the study guidelines). Therefore the water solubility value has not be delineated from the hydrolysis and impurities in the notified polymer.
Test Facility	Wacker Chemie (2014)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Algal Growth Inhibition Test

TEST SUBSTANCE	Product containing 85 % (w/w) notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test
Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration	Nominal: 100 mg/L
Auxiliary Solvent	None
Water Hardness	Not determined
Analytical Monitoring	None
Remarks – Method	Based on the results of a range finding test, a limit test was performed using a Water Soluble Fraction (WSF) of the test substance. The WSF was prepared by stirring solid test substance in water (at a nominal concentration of 100 mg/L) for 24 hours followed by a 24 hour settling period. The middle fraction of the aqueous layer was siphoned, and filtered through a 0.45 µm membrane filter to give the WSF. Static conditions were used. Nominal concentrations (at 0 hours) are reported (instead of measured concentrations), consistent with the OECD guidelines for difficult to test substances (OECD, 2019). A positive control test was run separately using potassium dichromate. All other test guidelines were adhered to.

RESULTS

Biomass		*Growth*	
EyL50 (mg/L at 72 h)	*NOELR (mg/L)*	*ErL50 (mg/L at 72 h)*	*NOELR (mg/L)*
> 100	100	> 100	100

NOELR = No Observed Effect Loading Rate

Remarks – Results	All validity criteria were satisfied. The cell concentration of the control cultures increased by a factor of 177 after 72 hours. The 72 h ErC50 for the positive control was 0.341 mg/L which is within the normal range for this reference item. The test item hydrolyses in contact with water to form a cross-linked, insoluble polymeric mass. Therefore, the WSF probably contained a very low concentration of the notified polymer but this was not confirmed with analytical monitoring. The test substance contains impurities which are hazardous to aquatic life. No harmful effects from these impurities were observed during the test duration.
CONCLUSION	The test substance is not harmful to algae up to its water solubility limit.
TEST FACILITY	Noack-Laboratorien (2014)

BIBLIOGRAPHY

NICNAS (2018). IMAP: Cyclic Volatile Methyl Siloxanes: Environment Tier II Assessment. NICNAS. Retrieved from https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-ii-environment-assessments/cvms

Noack-Laboratorien (2014) Algal Growth Inhibition Test with SILRES® HP 2000 (Study No: SPO15915, July, 2014). Műnchen, Germany, Dr. U. Noack-Laboratorien (Unpublished report submitted by the notifier).

OECD (2019) Guidance Document on Aqueous-Phase Aquatic Toxicity Testing of Difficult Test Chemicals. Organisation for Economic Co-operation and Development. Retrieved from https://www.oecd.org/env/guidance-document-on-aquatic-toxicity-testing-of-difficult-substances-and-mixtures-0ed2f88e-en.htm.

SWA (2015) Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, https://www.safeworkaustralia.gov.au/doc/model-code-practice-spray-painting-and-powder-coating.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >

Wacker Chemie (2014) Solution/Extraction Behaviour of SILRES® HP 2000 (Study No: N-0002106333, June, 2014). Burghausen, Germany, Wacker Chemie AG (Unpublished report submitted by the notifier).