NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Silicone Antifoam Agent S 371

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 and Heritage.

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Director
Chemicals Notification and Assessment
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1. **APPLICANT AND NOTIFICATION DETAILS**

**APPLICANT(S)**
Wacker Chemicals Australia Pty Ltd of Suite 3, 11 Leicester Avenue, Glen Waverley, Victoria 3150 (ABN 42 005 712 489)

**EXEMPT INFORMATION (SECTION 75 OF THE ACT)**
Data items and details claimed exempt from publication:
Chemical name, CAS number, molecular and structural formula, means of identification, molecular weight details, charge density, polymer constituents, residual monomers and impurities, reactive functional groups (including FGEW), purity.

**VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)**
No variation to the schedule of data requirements is claimed.

**PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)**
None

**NOTIFICATION IN OTHER COUNTRIES**

2. **IDENTITY OF CHEMICAL**

**MARKETING NAME(S)**
Silicone Antifoam Agent S 371

3. **COMPOSITION**

**POLYMER CONSTITUENTS**
The notified polymer is composed of monomers listed on AICS.

**PLC CRITERIA JUSTIFICATION**

<table>
<thead>
<tr>
<th>Molecular Weight</th>
<th>The notified polymer meets the molecular weight criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactive Functional Groups</td>
<td>The notified polymer contains only low concern (OH) groups</td>
</tr>
<tr>
<td>Charge Density</td>
<td>The notified polymer has low charge density.</td>
</tr>
<tr>
<td>Elemental Criteria</td>
<td>The notified polymer contains only approved elements.</td>
</tr>
<tr>
<td>Degradability</td>
<td>The notified polymer is not biodegradable.</td>
</tr>
<tr>
<td>Water Absorbing</td>
<td>The notified polymer is not a water-absorbing polymer.</td>
</tr>
<tr>
<td>Residual Monomers</td>
<td>All residual monomers are below the relevant cut-off concentration.</td>
</tr>
<tr>
<td>Hazard Category</td>
<td>The notified polymer is not classified as a hazardous substance.</td>
</tr>
</tbody>
</table>

The notified polymer meets the PLC criteria.

4. **INTRODUCTION AND USE INFORMATION**

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

<table>
<thead>
<tr>
<th>Year</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
USE
The notified polymer is a component of the product, Wacker Silicone Antifoam Agent S 370, which is used as an antifoam agent for aqueous system in manufacture and processing of dispersions, paints and surface coatings, adhesives, cooling lubricants and textile applications. The notified polymer will not be introduced as S 371, but rather as a minor component in some mortar additives. Other products containing the notified polymer in the range 0.02-0.5% may be introduced later.

6. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance at 20°C and 101.3 kPa</td>
<td>Colourless, medium viscous liquid with mild odour.</td>
</tr>
<tr>
<td>Melting Point/Glass Transition Temp</td>
<td>Not provided</td>
</tr>
<tr>
<td>Density</td>
<td>990 kg/m³</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>In accordance with OECD 105, a preliminary test was performed by mixing certain amounts of the test substance with deionised water. The mixtures were stirred at 24°C and analysed for undissolved particles. The approximate solubility of the test substance was found to be &lt;0.0025 g/L.</td>
</tr>
<tr>
<td>Particle Size</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Degradation Products</td>
<td>Not provided</td>
</tr>
<tr>
<td>Loss of monomers, other reactants, additives impurities</td>
<td>Not provided</td>
</tr>
</tbody>
</table>

COMMENTS ON ADDITIONAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrolysis as a Function of pH</td>
<td>Not determined</td>
</tr>
<tr>
<td>Remarks</td>
<td>The notified polymer contains Si-O bond that could be expected to undergo hydrolysis. However, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely to occur.</td>
</tr>
<tr>
<td>Partition Coefficient (n-octanol/water)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Remarks</td>
<td>The notified polymer’s low water solubility and its hydrophobic nature is indicative of partitioning into the octanol phase.</td>
</tr>
<tr>
<td>Adsorption/Desorption</td>
<td>Not determined</td>
</tr>
<tr>
<td>Remarks</td>
<td>The notified polymer is expected to be relatively immobile in soil due its low water solubility. Polydimethylsiloxanes were tested concerning adsorption on sludge and degradability. Wastewater treatment plants monitoring and simulation studies have confirmed that polydimethylsiloxanes which enters treatment plants are largely removed by sorption to sludge (Fendinger et al 1997). Experiments in several soils and under different test conditions demonstrated that polydimethylsiloxanes will degrade in soil. (Lehmann et al 1994(a, b); Carpenter et al 1995).</td>
</tr>
<tr>
<td>Dissociation Constant</td>
<td>Not determined</td>
</tr>
<tr>
<td>Remarks</td>
<td>The notified polymer does not contain any groups that are expected to dissociate.</td>
</tr>
</tbody>
</table>
7. **HUMAN HEALTH IMPLICATIONS**

7.1 **Toxicology**

7.1.1 **Toxicological Investigations**

In toxicological data provided to the government agency in Canada for a similar polymer, the following results are available:

- **Acute oral toxicity (rat)**: LD50 >2007 mg/kg (Limit test without mortality and other signs of toxicity)
- **Skin irritation (Rabbit, 4h)**: non-irritating
- **Patch test (human)**: non-hazardous in accordance with EEC/OSHA guidelines
- **Eye irritation (Rabbit)**: mild irritant
- **Skin sensitisation (guinea-pig; Magnusson-Kligmann)**: not sensitising
- **Bacterial reverse mutation assay** (*Salmonella typhimurium*): not mutagenic

7.1.2 **Human Health Hazard Assessment**

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by the toxicological data for a similar polymer.

7.2 **Occupational Health**

7.2.1 **Occupational Exposure**

- The notified polymer will be used in a variety of production processes, by an unknown number of workers.
- The concentration of the notified polymer in finished products will be 0.02-5.0%.
- Standard safety procedures for the handling of chemicals will be observed.

7.2.2 **Exposure Assessment**

Dermal and ocular exposure can occur during formulation processes. However, exposure to significant amounts of the notified polymer is limited due to the low concentration of notified polymer in the imported product, the engineering controls in place and personal protective equipment worn by workers.

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

7.3 **Public Health**

7.3.1 **Public Exposure**

- Members of the public may have contact with products (e.g. paints, coolants) containing the notified polymer.

7.3.2 **Exposure Assessment**

Products containing the notified polymer will be sold to the general public. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified polymer. However, exposure will be low because the notified polymer is present at low concentrations.

8. **ENVIRONMENTAL IMPLICATIONS**

8.1 **Ecotoxicology**

8.1.1 **Ecotoxicological Investigations**

No toxicological data were provided.

8.1.2 **Environmental Hazard Assessment**

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.
8.2 Environmental Contamination
8.2.1 Environmental Exposure
The notified polymer will be imported as part of a variety of mortar/adhesive formulations. The concentrations of the notified polymer in the various uses are as follows: 2-6% in construction adhesives, 1-6% in repair mortars and screeds, and 2-6% for modification of gypsum. The concentration of the notified polymer in the final product is therefore <0.02% and most of the notified polymer will remain bound in the mortar/adhesives. Thus the notified polymer will only be released to the drain as a consequence of the cleaning of the application equipments. No re-packaging or reformulation to the product will occur in Australia as they will be imported as 25 kg paper bags. The product is protected in paper bags with a PE inliner and the bags are packed into a sturdy cardboard. The product is unlikely to be spilled when it is transported in this way.

The major use of the product will be as part of vinyl acetate-ethylene based polymer at a concentration of 0.33% of the notified polymer. The product is used by a limited number of customers in Australia in a dry-mix application. The product is mixed (usually at 2%, max 4%, in very exceptional cases 8%) with other dry powder component and packed in 25 kg paper bags in bagging machines. The main application of these dry-mixes is in self-levelling cement floors. Because this type of floor is generally very large (shopping complexes and factory floors), generally very little remains from use and in the machine. The amounts of the notified polymer that could end up in drains from cleaning are relatively small. When cleaning does occur, the estimated dilution of the dry-mix in water is about 1 in 20. This means the maximum concentration of the notified polymer in the draining water is 0.33% x 2% x 5% = 0.00033% or 3.3 ppm.

The notified polymer is a silicone which has been tested concerning adsorption on sludge and degradability. In accordance with test results with different types of polysiloxanes, >90% of the notified polymer is effectively removed from the aqueous stream with the sludge. Wastewater treatment plants monitoring and simulation studies have confirmed that polysiloxanes which enter treatment plants are largely removed by adsorption to sludge and will almost completely absent from treated effluent. Polysiloxanes did not impact the freshwater treatment process. Due to its high molecular weight and low water solubility, the notified polymer is not expected to bioaccumulate (Connell 1990).

If the sludge is composted some hydrolysis of the polysiloxanes may occur. The major product from degradation of polysiloxanes in soil is silanediol which further degrades to carbon dioxide and silica. The sludge is likely to be used as solid amendment or to be incinerated. High temperature incineration will result in complete degradation to inorganic silica, water and carbon dioxide.

Approximately 0.16% of the imported volume of the mortar additives containing the notified polymer would be disposed of as residues in the used container. This corresponds to 0.0005% of the notified polymer being disposed of as industrial waste, which is likely to be landfilled. Treated concrete at the end of its useful life is likely to be landfilled as builders’ rubble.

8.2.2 Exposure Assessment
The notified polymer is a high molecular weight polymer which is essentially non-volatile and loss to the atmosphere is unlikely to be significant from sewers and aquatic environment from its use in concrete dry-mixes. The notified polymer in waste from application equipment cleaning may be disposed of into the sewer. Empty import container containing the residual polymer is likely to be disposed of into landfill. During cleaning of the equipment following its use, only small quantities of the notified polymer will discharge into the drain and ultimately to wastewater treatment plants.

The notified polymer is likely to persist in sludge resulting from wastewater treatment because of its tendency to bind particulate matter. Should such wastes be placed in landfill, the polymer is not expected to leach due to its low water solubility and its likely degradation ultimately to carbon dioxide, water and silica in soil. Alternatively, incineration may be used to dispose of these wastes.

The main environmental hazard would arise through spillage in transport accidents that may release quantities of the polymer to drains or waterways. However, the polymer is expected to sink to sediments and remain immobile due to the low solubility of the substance. The MSDS contains adequate directions for dealing with such spills.
9. RISK ASSESSMENT

9.1. Environment
Following its proposed uses, majority of the notified polymer will remain bound in the mortar/adhesive. Only very small quantities of the notified polymer will discharge to drains as a result of the cleaning of the application equipments. Because of its low water solubility and its affinity to particulate matters, it is not likely to be mobile in the aquatic or terrestrial compartments. Most of the notified polymer will adhere to sludge after wastewater treatment and be incinerated. Waste polymer disposed of to landfill will degrade in soil. Based on the limited environmental exposure, the likely risk to the environment is expected to be low.

9.2. Occupational health and safety
The OHS risk presented by the notified polymer is expected to be low.

9.3 Public health
As the public will only be exposed to the notified polymer at low concentrations in products, and as the polymer is unlikely to be bioavailable due to its high molecular weight, the risk to the public is expected to be low.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.2. Environmental risk assessment
The polymer is not considered to pose a risk to the environment based on its proposed use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety
There is No Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health
There is Negligible Concern to public health when used at the concentrations indicated.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet
The notifier has provided MSDS in accordance with the schedule item B 12 of the ICNA Act. The accuracy of the information on the MSDS remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

• No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.

  – 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 NOHSC Approved Criteria for Classifying Hazardous
Substances, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment
- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified polymer:
  - Do not pour leftover product down the drain. Waste generated during use should be landfilled or incinerated accordingly.

Disposal
- The notified polymer should be disposed of in landfill or be destroyed through incineration

Emergency procedures
- Spills/release of the notified polymer should be handled in the case of small amounts: Absorb with a liquid binding material such as diatomaceous earth and dispose of according to local/state/federal regulations. Contain larger amounts and pump up into suitable containers. Clean any slippery coating that remains using a cold cleaner (eg water surfactant blend)

12.1. Secondary notification
The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under subsection 64(1) of the Act; if
  - the notified polymer is introduced as the neat polymer, or
  - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

(2) Under subsection 64(2) of the Act;
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

13. BIBLIOGRAPHY
