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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME  
(NICNAS)**

**PUBLIC REPORT**

**Geniosil® LX 678**

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  
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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   |
|----------------------|------------------|------------------------|--------------------|-----------------------|---|
| STD/1691             | Wacker Chemie AG | Geniosil® LX 678       | *ND                | < 10 tonnes per annum | Component of coatings, sealants and adhesives |

\* Not determined

## CONCLUSIONS AND REGULATORY OBLIGATIONS

### **Hazard Classification**

Based on the limited toxicity information 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**

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**

On the basis of the expected low hazard and the assessed use pattern the notified polymer is not expected 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 engineering controls to minimise occupational exposure to the notified polymer during reformulation or final use, and methanol released during curing:
  - Enclosed/automated processes if possible
  - Local exhaust ventilation
  - Adequate general ventilation
- 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 when handling the polymer during reformulation or final use, and methanol released during curing:
  - Avoid contact with skin and eyes
  - Avoid inhalation of aerosols, dusts, mists or vapours
  - Avoid spills
  - Clean up any spills promptly
- 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 during reformulation or final use:
  - Impervious gloves
  - Safety glasses or goggles
  - Respiratory protection if inhalation exposure may occur
  - Protective clothing

- Protective footwear

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

- A copy of the SDS should be easily accessible to employees.
- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (Safe Work Australia, 2015) or relevant State or Territory Code of Practice.
- 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.

#### Storage

- The handling and storage of the notified polymer should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

#### 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
    - Products containing the polymer have become available for consumers to use as a spray;
- or
- (2) Under Section 64(2) of the Act; if
    - the function or use of the polymer has changed from its use as a component of coatings, sealants and adhesives, 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 the notified polymer and products containing the notified polymer provided by the notifier were 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

Wacker Chemie AG (ABN: 11 607 113 062)  
1/35 Dunlop Rd  
MULGRAVE VICTORIA 3170

#### NOTIFICATION CATEGORY

Standard: Synthetic polymer with  $M_n < 1,000$  g/mol (more than 1 tonne per year)

#### EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details exempt from publication include: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, polymer constituents, use details, import volume, and identity of manufacturer/recipients.

#### VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Schedule data requirements are varied for all the end points of physical and chemical properties, human health effects and environmental effects except for water extractability and acute oral toxicity.

#### PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

#### NOTIFICATION IN OTHER COUNTRIES

Canada (2015)  
US (2016)  
China (2012)

### 2. IDENTITY OF CHEMICAL

#### MARKETING NAME(S)

Geniosil LX 678  
Geniosil XT 50 (product containing the notified polymer)  
SILRES BS 6920 (product containing the notified polymer)

#### OTHER NAME(S)

Silicone resin with phenyl and methoxy groups

#### MOLECULAR WEIGHT

Number average molecular weight ( $M_n$ ) is  $> 500$  g/mol

#### ANALYTICAL DATA

Reference GPC spectra were provided

### 3. COMPOSITION

#### DEGREE OF PURITY

$> 95\%$

#### HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

|                              |  |                 |       |
|------------------------------|--|-----------------|-------|
| <i>Chemical Name</i>         | Benzene, (trimethoxysilyl)-  |                 |       |
| <i>CAS No.</i>               | 2996-92-1  | <i>Weight %</i> | $< 2$ |
| <i>Hazardous Properties*</i> | H226 (Flammable liquid and vapour)                                       |                 |       |
|                              | H302 (Harmful if swallowed)  |                 |       |
|                              | H373 (May cause damage to organs through prolonged or repeated exposure) |                 |       |

\* The impurity is not listed in the Safe Work Australia Hazardous Chemical Information System (HCIS). The Hazardous properties listed are based on information available on the European Chemicals Agency website (<https://echa.europa.eu/information-on-chemicals>).

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

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

ADDITIVES/ADJUVANTS  
None

#### 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Liquid

| <i>Property</i>                            | <i>Value</i>                    | <i>Data Source/Justification</i>                                    |
|--|---------------------------------|---|
| Melting Point/Freezing Point               | Not determined                  | No data available   |
| Boiling Point                              | 331 °C at 101.3 kPa             | SDS   |
| Density                                    | 1182 kg/m <sup>3</sup> at 20 °C | SDS   |
| Vapour Pressure                            | 0.382 kPa at 25 °C (or 20 °C)   | SDS   |
| Water Extractability                       | 42 mg/g at 20 °C                | Measured  |
| Hydrolysis as a Function of pH             | Not determined                  | No data available   |
| Partition Coefficient<br>(n-octanol/water) | Not determined                  | No data available   |
| Adsorption/Desorption                      | Not determined                  | No data available   |
| Dissociation Constant                      | Not determined                  | No data available   |
| Flash Point                                | 162 °C                          | SDS   |
| Flammability                               | Not determined                  | No data available   |
| Autoignition Temperature                   | 415 °C                          | 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

For details of the water extractability test, refer to Appendix A.

#### *Reactivity*

The notified polymer contains methoxy groups that are able to be hydrolysed in the presence of water or moisture. The polymer will react with water and cross-link to form insoluble mass, releasing small amounts of methanol.

#### *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.

The notified polymer has a flash point of 162 °C which is greater than 93 °C. Based on *Australian Standard AS1940* definitions for combustible liquid, the notified polymer may be considered as a Class C2 combustible liquid if the polymer has a fire point below the boiling point.

#### 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 formulated products at ≤ 85% concentration.

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

| <i>Year</i>   | <i>1</i> | <i>2</i> | <i>3</i> | <i>4</i> | <i>5</i> |
|---------------|----------|----------|----------|----------|----------|
| <i>Tonnes</i> | < 10     | < 10     | < 10     | < 10     | < 10     |

## PORT OF ENTRY

Melbourne

## TRANSPORTATION AND PACKAGING

The notified polymer will be imported into Australia in neat form in steel drums or pails of 220 kg or 30 kg in size. The notified polymer will also be imported into Australia in formulated products (at up to 85% concentration) in packaging suitable for retail sale. The products will be transported by road to the notifier's warehouse for storage and then distributed to reformulation or retail sites. End-use products containing the notified polymer (at concentrations  $\leq 85\%$ ) will be in packaging suitable for retail sale ( $\leq 20$  L).

## USE

The notified polymer will be used as a binder and cross-linker in coatings, sealants and adhesives applied to building and construction materials. It is estimated that approximately 70% of the imported notified polymer will be used in industrial applications and approximately 30% of the notified polymer will be used in products for Do-It-Yourself (DIY) use. When imported in neat form (for industrial use only), the notified polymer will be reformulated into end-use products. The concentration of the notified polymer in end-use products will vary between 5% and 85%, with a concentration of  $\leq 75\%$  in non-spray applications, and  $\leq 85\%$  in spray applications. The notifier anticipates that up to 10% of the imported polymer will be reformulated for spray applications for industrial use only. No spray products containing the notified polymer will be available for DIY use.

## OPERATION DESCRIPTION

*Reformulation*

It is expected that the reformulation process will involve transfer and blending operations that will be highly automated and occur under closed conditions (with adequate workplace ventilation), followed by automated filling of the reformulated finished products into containers of various sizes. The finished end use products will contain the notified polymer at concentrations between 5% and 85%.

*End use*

The finished end use products containing the notified polymer will be used by professional and DIY users. For DIY use the end use products are expected to be in packaging  $\leq 5$  L and for professional use the end use products are expected to be in packaging  $\leq 30$  kg. End use products available to professional users will contain the notified polymer at  $\leq 85\%$  concentration and are expected to be applied by tube, caulking gun, brush, roller or spray apparatus. End use products available to DIY users will contain the notified polymer at  $\leq 75\%$  concentration and are expected to be applied by tube, caulking gun, brush, or roller. No spray products will be available for DIY use.

**6. HUMAN HEALTH IMPLICATIONS****6.1. Exposure Assessment****6.1.1. Occupational Exposure**

## CATEGORY OF WORKERS

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

## EXPOSURE DETAILS

*Transport and storage*

Transport and storage workers may come into contact with the notified polymer in its neat form, or at a concentration of  $\leq 85\%$  as a component of formulated and end-use products only in the event of an accidental rupture of containers. In the event of a leak, workers may also be exposed to methanol vapours released from the notified polymer through reactions with moisture in the air. The notifier states that such exposure will be minimised



through the use of personal protective equipment (PPE) including protective coveralls, chemical resistant gloves, safety glasses, and appropriate respiratory protection (such as a respirator with a full face mask and ABEK gas filter).

#### *Reformulation workers*

The reformulation process is expected to be fully enclosed and automated. Dermal and ocular exposure of workers to the notified polymer (in neat form or at  $\leq 85\%$  concentration) may occur during transfer, quality control analysis, and cleaning and maintenance of equipment. Inhalation exposure to methanol vapours formed from the notified polymer through contact with moisture in the air may also occur. The notifier states that exposure is expected to be minimised through the use of PPE such as protective coveralls, chemical resistant gloves, safety glasses, engineering controls and the presence of adequate local exhaust ventilation and respiratory protection (such as a respirator with a full face mask and ABEK gas filter).

#### *End users*

Dermal and ocular exposure to the notified polymer at  $\leq 85\%$  concentration may occur when applying coating, sealant and adhesive products containing the notified polymer. The products containing the polymer may be applied by spray, hence inhalation exposure to the polymer is also possible. In addition, users may potentially be exposed to a small amount of methanol released from the notified polymer during the curing process. The notifier states that workers are expected to wear appropriate PPE including protective coveralls, chemical resistant gloves, safety glasses and respiratory protection such as a respirator with a full face mask and ABEK gas filter as required and use safe work practices to minimise exposure. Once the end use product is cured the notified polymer will be incorporated into an inert matrix and will not be available for exposure.

### **6.1.2. Public Exposure**

The notifier has indicated that 30% of the notified polymer introduced will be used in sealant, adhesive and coating products for DIY applications at concentration  $\leq 75\%$ ; however, no spray products will be available to the public. Dermal and ocular exposure to the notified polymer may occur during use. As no spray products containing the notified polymer will be available for DIY use, inhalation exposure to the polymer is not expected. Inhalation exposure to a small amount of methanol released from the notified polymer during the curing process may be possible.

However, public exposure to the notified polymer is expected to be of low frequency and small scale. After the sealant, adhesive and coating products containing the notified polymer have been applied, the polymer will be cured into an inert matrix and will not be available for exposure.

### **6.2. Human Health Effects Assessment**

Only study data for acute oral toxicity were submitted for the notified polymer. For details of the study, refer to Appendix B.

| <i>Endpoint</i>           | <i>Result and Assessment Conclusion</i> |
|---------------------------|---|
| Acute oral toxicity – rat | LD50 > 2000 mg/kg bw; low toxicity      |

No toxicokinetic data on the notified polymer were submitted. For dermal and gastrointestinal absorption, molecular weights below 100 g/mol are favourable for absorption and molecular weights above 500 g/mol do not favour absorption (ECHA, 2017). Dermal uptake is likely to be low to moderate if the water solubility/extractability is between 1-100 mg/L. Based on the molecular weight of the notified polymer ( $M_n > 500$  g/mol), the potential of the notified polymer to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure is expected to be limited. However, the notified polymer contains a significant proportion (> 30%) of low molecular weight species (< 500 g/mol) that may be absorbed.

The notified polymer is expected to have low acute oral toxicity based on a study conducted in rats with a LD50 > 2000 mg/kg bw. No other toxicity study data were submitted for the polymer.

The notified polymer does not contain functional groups associated with irritation or sensitisation effects.

The notified polymer contains methanol as an impurity at a concentration < 0.5% and also releases methanol vapour during end-use due to reaction with moisture. Methanol is known to be toxic and flammable (see Section 3 Composition).

**Health Hazard Classification**

As only limited 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.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains impurities including methanol and benzene, (trimethoxysilyl)- that are classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. However the concentrations of these impurities in the polymer are below the cut-off concentration for hazard classification.

**6.3. Human Health Risk Characterisation**

The main health concern for the notified polymer is the potential for effects to lungs and mucous membranes from inhalation. Given the low vapour pressure of the notified polymer, inhalation exposure is only expected where aerosols are formed, which may occur during spray applications of products containing the polymer.

**6.3.1. Occupational Health and Safety**

Inhalation exposure to the notified polymer in neat form is not expected given the reformulation process is largely enclosed and automated. Inhalation exposure to the notified polymer at  $\leq 85\%$  concentration may occur during the spray applications of coatings containing the polymer. The use of appropriate PPE (such as protective coveralls, chemical resistant gloves, safety glasses, and respiratory protection as required, including face mask, respirator and ABEK gas filter) and engineering controls including local exhaust ventilation and adequate general ventilation should minimise the potential for exposure.

Under the conditions of the occupational settings described, and with proper respiratory protection, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

**6.3.2. Public Health**

Retail products containing the notified polymer at  $\leq 75\%$  concentration will be available for public use in DIY applications. According to the notifier, retail products containing the notified polymer will be applied by brush, roller, or from ready-to-use packs. No spray products will be available for DIY use. Dermal and ocular exposure may occur. Users may also be exposed to a small amount of methanol vapour released from the notified polymer during the curing process. However, such exposure is expected to be of low frequency and small scale. Provided individuals use appropriate PPE and apply the end use products in well ventilated areas, the risk to the public is not considered to be unreasonable.

The public may come into contact with the cured sealants, adhesives and coatings containing the notified polymer after applications. However, once the products are cured, the notified polymer will be bound within a polymer matrix and is not expected to 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**

The notified polymer is not manufactured in Australia. 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.

Reformulation of the notified polymer is to occur in an automated enclosed system with engineering controls. Equipment washings are to be collected and disposed of via a licensed waste contractor in accordance with local government regulations.

**RELEASE OF CHEMICAL FROM USE**

The coatings, sealants and adhesives containing the notified polymer will be used mainly in industrial processes and applications with < 30% introduction volume to be used by DIY consumers. Limited environmental release is expected from the use of the notified polymer as it will be cured into a cross-linked polymer matrix. However, small amounts of the notified polymer may be released to sewer from incorrect disposal by DIY consumers, which are expected to be cured into cross-linked polymer matrix by moisture contact.

**RELEASE OF CHEMICAL FROM DISPOSAL**

Residues of the notified polymer will remain in the transport containers (or commercial bottles). Empty containers are to be collected for recycling at licensed waste disposal facilities. In cases where recycling is not appropriate, the empty containers are to be disposed of to landfill.

**7.1.2. Environmental Fate**

No environmental fate data were submitted. The notified polymer is a component of binding agents, coatings and sealants which is expected to share the fate of the articles which it is applied to. Under the proposed use pattern only limited quantities are expected to be disposed of improperly as a consequence of DIY use.

The majority of the notified polymer is expected to share the fate of the articles which it is applied to, which will eventually be disposed of to landfill as a part of the cured polymer matrix and is not expected to be mobile, bioavailable or readily biodegradable in this form. In landfill, the notified polymer is expected to ultimately degrade via biotic or abiotic processes to form water and oxides of carbon and silicon.

**7.1.3. Predicted Environmental Concentration (PEC)**

The predicted environment concentration (PEC) was calculated assuming 1.5% of the notified polymer would be improperly disposed of into the environment (5% of the DIY products which comprises 30% of total import volume:  $5\% \times 30\% = 1.5\%$ ). The extent to which the notified polymer is removed from the effluent in STP processes based on its properties has not been considered for this worst-case scenario.

| <i><b>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</b></i> |        |              |
|---|--------|--------------|
| Total Annual Import/Manufactured Volume   | 10,000 | kg/year      |
| Proportion expected to be released to sewer   | 1.5%   |              |
| Annual quantity of chemical released to sewer   | 150    | kg/year      |
| Days per year where release occurs  | 365    | days/year    |
| Daily chemical release:   | 0.41   | kg/day       |
| Water use   | 200    | L/person/day |
| Population of Australia (Millions)  | 24.386 | million      |
| Removal within STP  | 0%     |              |
| Daily effluent production:  | 4,877  | ML           |
| Dilution Factor - River   | 1.0    |              |
| Dilution Factor - Ocean   | 10.0   |              |
| PEC - River:  | 0.08   | µg/L         |
| PEC - Ocean:  | 0.01   | µg/L         |

**7.2. Environmental Effects Assessment**

No ecotoxicity data were submitted. The results from an algal toxicity investigation conducted on an acceptable analogue of the notified polymer are summarised in the table below. Details of this study can be found in the report for NICNAS notification LTD/1881. Additionally, ecotoxicity endpoints for fish and daphnia were provided in the SDS for the product containing > 90% concentration of the notified polymer.

| <i><b>Endpoint</b></i> | <i><b>Result</b></i>  | <i><b>Assessment Conclusion</b></i>   |
|------------------------|---|---|
| Fish Toxicity          | 96 h EC50 > 0.074 mg/L<br>(maximum achievable concentration)  | Notified polymer is not harmful to fish up to the limit of its solubility in water (SDS)    |
| Daphnia Toxicity       | 48 h EC50 > 0.0029 mg/L<br>(maximum achievable concentration) | Notified polymer is not harmful to daphnia up to the limit of its solubility in water (SDS) |
| Algal Toxicity         | 72 h EC50 > 100 mg/L (WAF)                                    | Analogue is not harmful to algae up to the limit of its solubility in water (LTD/1881)      |

The notified polymer is not expected to be harmful to algae, fish or aquatic invertebrates up to the limit of its water solubility based on the analogue data and the SDS for the product containing the notified polymer.

**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 the limit of its 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.

**APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES****Water Solubility** 42 mg/g at 25 °C

|               |  |
|---------------|--|
| Method        | OECD TG 120 Solution/Extraction Behaviour of Polymers in Water |
| Remarks       | Gravimetric method   |
| Test Facility | Wacker Chemie (2015)   |

**APPENDIX B: TOXICOLOGICAL INVESTIGATIONS****B.1. Acute Oral Toxicity – Rat**

|                  |   |
|------------------|---|
| TEST SUBSTANCE   | Notified polymer  |
| METHOD           | OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method<br>EC Council Regulation No 440/2008 B.1 Acute Toxicity (Oral) |
| Species/Strain   | Rat, WISTAR CrI: WI(Han)  |
| Vehicle          | Corn oil  |
| Remarks – Method | GLP compliant<br>No significant protocol deviations   |

## RESULTS

| <i>Group</i> | <i>Number and Sex of Animals</i> | <i>Dose (mg/kg bw)</i> | <i>Mortality</i> |
|--------------|----------------------------------|------------------------|------------------|
| 1            | 3 F                              | 2,000                  | 0/3              |
| 2            | 3 F                              | 2,000                  | 0/3              |

|                   |   |
|-------------------|---|
| LD50              | > 2,000 mg/kg bw  |
| Signs of Toxicity | None recorded   |
| Effects in Organs | None recorded   |
| Remarks – Results | No mortality occurred. All animals made the expected body weight gains. |

CONCLUSION The notified polymer is of low acute toxicity via the oral route.

TEST FACILITY BSL (2016)

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