

File No.: LTD/2077

May 2019

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

**PUBLIC REPORT**

**RESYDROL VAL 5547w**

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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## SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

| ASSESSMENT REFERENCE | APPLICANT                       | CHEMICAL OR TRADE NAME | HAZARDOUS CHEMICAL | INTRODUCTION VOLUME    | USE                   |
|----------------------|---------------------------------|------------------------|--------------------|------------------------|-----------------------|
| LTD/2077             | Allnex Resins Australia Pty Ltd | RESYDROL VAL 5547w     | ND*                | ≤ 220 tonnes per annum | Component of coatings |

\*ND = not determined

## CONCLUSIONS AND REGULATORY OBLIGATIONS

### 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.

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

| <i>Hazard Classification</i> | <i>Hazard Statement</i>                                  |
|------------------------------|--|
| Acute Category 3             | H402 – Harmful to aquatic life                           |
| Chronic Category 3           | H412 – Harmful to aquatic life with long lasting effects |

### 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 PEC/PNEC ratio, 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 engineering controls to minimise occupational exposure to the notified polymer during reformulation:
  - Enclosed/automated processes if possible
  - Local exhaust ventilation
- 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 during reformulation:
  - 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 during reformulation:

- Impervious gloves
- Safety glasses or goggles
- Protective clothing

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.
- If products and mixtures containing the notified chemical/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 chemical/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;
  - the end use concentration of the notified polymer exceeds 15% for public /DIY use;or
- (2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a component of 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 chemical/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 provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

## ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemical were carried out by NICNAS.

### 1. APPLICANT AND NOTIFICATION DETAILS

#### APPLICANT

Allnex Resins Australia Pty Ltd (ABN: 25 000 045 572)  
49 – 61 Stephen Road  
BOTANY NSW 2019

#### NOTIFICATION CATEGORY

Limited: Synthetic polymer with  $M_n \geq 1,000$  g/mol

#### 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, residual monomers, impurities, additives/adjuvants, 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 physico-chemical endpoints.

#### PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT

None

#### NOTIFICATION IN OTHER COUNTRIES

Canada (2016)

### 2. IDENTITY OF CHEMICAL

#### MARKETING NAME

RESYDROL VAL 5547w

#### MOLECULAR WEIGHT

Number average molecular weight ( $M_n$ ) is  $> 1,000$  g/mol

#### ANALYTICAL DATA

Reference GPC spectrum were provided.

### 3. COMPOSITION

#### DEGREE OF PURITY

93 - 98%

### 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellow-brown liquid

| <i>Property</i> | <i>Value</i>                     | <i>Data Source/Justification</i>   |
|-----------------|----------------------------------|--|
| Melting Point   | Not determined                   | Liquid at room temperature   |
| Boiling Point   | Not determined                   | Not expected to boil based on high molecular weight. At elevated temperatures, the notified polymer decomposes |
| Density         | 1,020 kg/m <sup>3</sup> at 20 °C | SDS  |
| Vapour Pressure | Not determined                   | Expected to be low based on high molecular weight  |

| <b>Property</b>                         | <b>Value</b>       | <b>Data Source/Justification</b>   |
|---|--------------------|--|
| Water Solubility                        | Not determined     | Expected to be dispersible in water based on its use in water-based coatings   |
| Hydrolysis as a Function of pH          | Not determined     | Stable. Contains hydrolysable functionality however, the substance is a complex polymeric material which forms an inseparable emulsion when mixed with water                         |
| Partition Coefficient (n-octanol/water) | Not determined     | The notified polymer is surface active and estimations may not adequately characterise the partitioning behaviour. The notified polymer is expected to partition to phase boundaries |
| Surface Tension                         | 36.8 mN/m at 23 °C | Measured. As surface tension < 60 mN/m, the notified polymer is considered surface active  |
| Adsorption/Desorption                   | Not determined     | Dispersible in water and is expected to be mobile, however, high molecular weight polymers adsorb to soil and sediment and thus have limited mobility                                |
| Dissociation Constant                   | Not determined     | Contains dissociable functionality which is expected to dissociate at environmental pH 4-9   |
| Flash Point                             | > 100 °C           | SDS  |
| Flammability                            | Not determined     | Not expected to be flammable based on flash point.   |
| Autoignition Temperature                | Not determined     | Not expected to autoignite   |
| Explosive Properties                    | Not determined     | Contains no functional groups that would imply explosive properties  |
| Oxidising Properties                    | Not determined     | Contains no functional groups that would imply oxidising properties  |

#### DISCUSSION OF PROPERTIES

For details of the test on surface tension refer to Appendix A.

#### Reactivity

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

#### Physical Hazard Classification

Based on the limited physico-chemical data depicted in the above table, the notified polymer cannot be 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 neat for reformulation into water-based wood coatings containing the notified polymer at ≤ 15% 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> | ≤ 20     | ≤ 50     | ≤ 100    | ≤ 180    | ≤ 220    |

#### PORT OF ENTRY

Sydney, Melbourne and Brisbane

## TRANSPORTATION AND PACKAGING

The notified polymer will be imported by ship in 20 L pails, 200 L drums and 1 tonne intermediate bulk containers. The water-based wood coatings containing the notified polymer at  $\leq 15\%$  concentration will be packaged in containers suitable for retail sale.

## USE

The notified polymer will be used as a component of water-based wood coatings at  $\leq 15\%$  concentration.

## OPERATION DESCRIPTION

*Reformulation*

At the reformulation sites, the notified polymer will be combined using typical blending processes with other components into finished water-based wood coatings containing the notified polymer at  $\leq 15\%$  concentration. The reformulation process is expected to be fully automated and performed under enclosed and controlled conditions.

*End Use*

The water-based wood coatings containing the notified polymer at  $\leq 15\%$  concentration will be applied by professional painters and do-it-yourself (DIY) users by brush or roller to exterior wood surfaces. Application by spray is not anticipated.

**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     | 1-2                                  | 20                                    |
| Warehouse/store           | 8                                    | 30                                    |
| Dispatch                  | < 1                                  | 365                                   |
| Reformulation             | 2                                    | 50                                    |
| Quality Control           | 1                                    | 50                                    |
| Retailers                 | 1                                    | 30                                    |
| Professional painters     | 8                                    | 50                                    |

## EXPOSURE DETAILS

Transport and storage workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident or container rupture.

*Reformulation*

Dermal and ocular exposure to the notified polymer at  $\leq 100\%$  concentration may occur during the blending process, and cleaning and maintenance of equipment. Exposure should be minimised through the use of personal protective equipment (PPE: goggles, impervious gloves, protective clothing), as stated by the notifier. The use of automated and enclosed systems during the reformulation process should further minimise exposure to the notified polymer. Inhalation exposure to the notified polymer is not expected due to its assumed low vapour pressure and the use of enclosed systems.

*End Use – Professionals*

Dermal and ocular exposure to the notified polymer at  $\leq 15\%$  concentration may occur during application of the wood coatings by brush or roller. Exposure should be minimised through the use of PPE (goggles, impervious gloves, protective clothing), as stated by the notifier. Inhalation exposure to the notified polymer is not expected as the coatings will not be applied by spray, in addition to the expected low vapour pressure of the notified polymer. Once the coatings are dried, the notified polymer will be bound within an inert solid matrix and will not be available for exposure.

### 6.1.2. Public Exposure

Finished wood coatings containing the notified polymer at  $\leq 15\%$  concentration will be sold to the general public for DIY use. Dermal and ocular exposure to the notified polymer at  $\leq 15\%$  concentration may occur during application of the wood coatings by brush or roller. It is expected that exposure to the notified polymer (at  $\leq 15\%$  concentration) by DIY users will be lower than professional end users due to the relatively infrequent use of wood coatings and smaller scale of application. Inhalation exposure to the notified polymer is not expected as the coatings will not be applied by spray, in addition to the expected low vapour pressure of the notified polymer.

The public may come into contact with surfaces applied with the wood coatings containing the notified polymer at  $\leq 15\%$  concentration. However, once the coatings are dried, the notified polymer will be bound within an inert solid matrix and will not be available for exposure.

### 6.2. Human Health Effects Assessment

The results from a toxicological investigation conducted on the notified polymer is summarised in the following table. For full details of this study, refer to Appendix B.

| <i>Endpoint</i>           | <i>Result and Assessment Conclusion</i> |
|---------------------------|---|
| Acute oral toxicity – rat | LD50 > 2,000 mg/kg bw; low toxicity     |

The notified polymer is of high molecular weight ( $> 1,000$  g/mol) and contains low levels ( $< 1\%$ ) of low molecular weight species  $< 500$  g/mol, therefore absorption across biological membranes is expected to be limited.

The notified polymer is of low acute oral toxicity based on a study conducted in rats.

The notified polymer is an anionic surfactant. Anionic surfactants have the potential to cause skin and eye irritation. The notified polymer also contains pendant methacrylate groups which have toxicity concerns associated with skin irritation, and skin and respiratory sensitisation. Given absorption of the notified polymer is expected to be limited, the potential for skin and respiratory sensitisation is expected to be low.

#### *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.

### 6.3. Human Health Risk Characterisation

#### 6.3.1. Occupational Health and Safety

Based on the structure of the notified polymer, it may have the potential to cause skin and eye irritation, and skin and respiratory sensitisation. However, the potential for skin and respiratory sensitisation is expected to be low. Systemic effects are not expected due to limited absorption of the notified polymer.

#### *Reformulation*

During reformulation workers may be at risk of skin and eye irritation, and skin and respiratory sensitisation effects when handling the notified polymer at  $\leq 100\%$  concentration. However the risk is expected to be minimised by the use of enclosed and automated processes and PPE by workers.

#### *End-use*

During end-use, workers may be dermally exposed to the notified polymer at  $\leq 15\%$  concentration during application of coatings containing the notified polymer by brush or roller. Inhalation exposure is not expected given the assumed low vapour pressure of the notified polymer and spray application is not expected. Given the relatively low use concentration of the notified polymer in finished coatings and limited absorption of the notified polymer, the potential for skin and respiratory sensitisation is not expected. The risk of irritation is also expected to be reduced by the proposed low use concentration and application methods (brush and roller). Workers using PPE (goggles, impervious gloves, protective clothing) will further reduce the potential for irritation and sensitisation.

Therefore, 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

DIY users may be dermally exposed to the notified polymer at  $\leq 15\%$  concentration during application of coatings containing the notified polymer by brush or roller. Inhalation exposure is not expected given the expected low vapour pressure of the notified polymer and spray application is not expected.

Given the relatively low use concentration of the notified polymer in finished coatings and limited absorption of the notified polymer, the potential for skin and respiratory sensitisation is not expected. The risk of irritation is also expected to be reduced by the proposed low use concentration and application methods (brush and roller).

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 will be imported neat for reformulation into water-based wood coatings. There is unlikely to be any significant release to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the notified polymer is expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve blending operations that will be highly automated, and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified polymer to the environment from this process is not expected. The reformulation process will be followed by automated filling of the formulated coatings into containers suitable for end use. Blending equipment will be cleaned with solvents, with waste liquids containing the notified polymer to be collected for disposal through licensed trade waste management services. Empty import containers are expected to be recycled or disposed of through licensed waste management services.

##### RELEASE OF CHEMICAL FROM USE

Coatings containing the notified polymer will be used by both professional and DIY users. During use, coatings containing the notified polymer are expected to be applied by brush and/or roller techniques.

During use, the notified polymer may also be released to the environment as accidental spills and container residues. These releases are expected to be collected and disposed of to landfill in accordance with local government regulations.

##### RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer in coatings is expected to share the fate of the substrate to which it has been applied, and is therefore predominantly expected to be disposed of to landfill.

Residues containing the notified polymer on application equipment are expected to be rinsed into containers, and then allowed to cure before disposal as solid wastes to landfill. As a worst case scenario, it is assumed that up to 5% of the coatings containing the notified polymer used by DIY users may be incorrectly disposed of to the sewer, drains, or ground from waste and washing of application equipment.

#### 7.1.2. Environmental Fate

The majority of the notified polymer is expected to be cured within an inert coating matrix and is expected to share the fate of the articles to which it has been applied and will involve eventual disposal to landfill. Once cured the notified polymer is not expected to be bioavailable or bioaccumulative. The notified polymer is also expected to enter landfill as collected wastes and residues.

Bioaccumulation of the uncured notified polymer is unlikely, based on its high molecular weight. The notified polymer is dispersible in water and is expected to be mobile in soil, however, the polymer has potential to adsorb to soil and sediment based on its high molecular weight and anionic properties. Therefore, a significant portion of the notified polymer ( $> 50\%$ ) is expected to partition to sludge and sediment (Boethling and Nabholz, 1997) during wastewater treatment processes in sewage treatment plants (STPs). In surface waters and in landfill, the

notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and nitrogen.

### 7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the predicted environmental concentration (PEC) is summarised in the table below. Based on the reported use coatings for professional and DIY-users, a conservative release of 5% to sewers on a nationwide basis over 365 days per year is used for the notified polymer. It also assumes a worst case scenario where none of the notified polymer is removed during STP processes.

| Predicted Environmental Concentration (PEC) for the Aquatic Compartment |         |              |
|---|---------|--------------|
| Total Annual Import/Manufactured Volume                                 | 200,000 | kg/year      |
| Proportion expected to be released to sewer                             | 5.000   | %            |
| Annual quantity of chemical released to sewer                           | 10,000  | kg/year      |
| Days per year where release occurs                                      | 365     | days/year    |
| Daily chemical release:   | 27.40   | 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:  | 5.62    | µg/L         |
| PEC – Ocean:  | 0.56    | µg/L         |

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m<sup>2</sup>/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<sup>3</sup>). Using these assumptions, irrigation with a concentration of 5.62 µg/L may potentially result in a soil concentration of approximately 37.45 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymer in the applied soil in 5 and 10 years may be approximately 187.3 µg/kg and 374.5 µg/kg, respectively.

## 7.2. Environmental Effects Assessment

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

| <i>Endpoint</i> | <i>Result</i>           | <i>Assessment Conclusion</i> |
|-----------------|-------------------------|------------------------------|
| Algal Toxicity  | 72 h ErC50 = 37.20 mg/L | Harmful to algae             |

Based on the above ecotoxicological endpoint for the notified polymer, it is expected to be harmful to algae. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified polymer is formally classified as ‘Acute Category 3; Harmful to aquatic life’. Based on the above acute ecotoxicity and unknown degradability, the notified polymer is formally classified as ‘Chronic Category 3; Harmful to aquatic life with long lasting effects’ under the GHS.

### 7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for algae. A safety factor of 500 was used since an acute endpoint for only one trophic level was available.

| Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment |        |      |
|--|--------|------|
| ErC50 (Algae, 72 h)  | 37.20  | mg/L |
| Assessment Factor  | 500.00 |      |
| Mitigation Factor  | 1.00   |      |
| PNEC   | 74.40  | µg/L |

### 7.3. Environmental Risk Assessment

The Risk Quotient ( $Q = \text{PEC}/\text{PNEC}$ ) has been calculated based on the predicted PEC and PNEC.

| Risk Assessment | PEC ( $\mu\text{g}/\text{L}$ ) | PNEC ( $\mu\text{g}/\text{L}$ ) | Q            |
|-----------------|--------------------------------|---------------------------------|--------------|
| Q – River       | 5.62                           | 74.4                            | <b>0.076</b> |
| Q – Ocean       | 0.56                           | 74.4                            | <b>0.008</b> |

The risk quotient for discharge of treated effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. The notified polymer is not expected to be bioaccumulative based on its high molecular weight. On the basis of the maximum annual importation volume and assessed use pattern as a component of water-based wood coatings, the notified polymer is not expected to pose an unreasonable risk to the environment.

**APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES****Surface Tension** 36.8 mN/m at 23 °C

|               |   |
|---------------|---|
| Method        | OECD TG 115 Surface Tension of Aqueous Solutions  |
| Remarks       | Concentration: 10% w/w aqueous saturated solution |
| Test Facility | Allnex (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 |
| Species/Strain   | Rat/Wistar   |
| Vehicle          | Olive oil  |
| Remarks – Method | 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            | 3F                               | 2,000                  | 0/3              |
| 2            | 3F                               | 2,000                  | 0/3              |

|                   |  |
|-------------------|--|
| LD50              | > 2,000 mg/kg bw   |
| Signs of Toxicity | No clinical signs of toxicity were noted. All animals gained the expected body weight. |
| Effects in Organs | There were no macroscopic findings observed at necropsy.                               |

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

TEST FACILITY Hameln rds (2016)

## APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

### C.1. Ecotoxicological Investigations

#### C.2.1. Algal Growth Inhibition Test

|                       |  |
|-----------------------|--|
| TEST SUBSTANCE        | Notified polymer   |
| METHOD                | OECD TG 201 Alga, Growth Inhibition Test<br>EC Council Regulation No 440/2008 C.3 Algal Inhibition Test  |
| Species               | <i>Desmodesmus subspicatus</i>   |
| Exposure Period       | 72 hours   |
| Concentration Range   | Nominal: 1.0 – 100 mg/L<br>Actual: 2.0 – 77.4 mg/L   |
| Auxiliary Solvent     | None   |
| Water Hardness        | Not reported   |
| Analytical Monitoring | The content of the test item in the test solutions was estimated by calculation based on the total organic carbon (TOC) of the test item and dissolved organic carbon (DOC) measurement (where DOC = TC (total carbon) - IC (inorganic carbon)).   |
| Remarks – Method      | A stock solution with a nominal loading rate of 100.5 mg/L was prepared by stirring the test substance in algal medium. The definitive test was conducted at the nominal loading rates of 1.0, 3.2, 10, 32, and 100 mg/L of the test substance. The test was conducted in accordance with the test guideline above, with some deviations from the protocol reported. The temperature in the experiment was not within the required range of 21.0 – 24.0 °C (actual range was 22.1 – 24.6 °C) and more than ±2 °C. However, as normal growth was observed, this deviation was deemed by the study authors as uncritical. The stock solutions were autoclaved for 20 minutes instead of the required 15 minutes. This was considered by the study authors as uncritical, as the goal of sterility was achieved. Mistakenly, no algae were added in the lowest concentrated treatment, hence this data was not used for evaluation. |

#### RESULTS

|                                     | <i>Biomass</i>             |                                     | <i>Growth</i>              |
|-------------------------------------|----------------------------|-------------------------------------|----------------------------|
| <i>EyC50</i><br><i>mg/L at 72 h</i> | <i>NOEC</i><br><i>mg/L</i> | <i>ErC50</i><br><i>mg/L at 72 h</i> | <i>NOEC</i><br><i>mg/L</i> |
| 4.87                                | < 2.00                     | 37.20                               | 2.00                       |

Remarks – Results

All validity criteria for the test were satisfied. The 72h ErC50 and EyC50 values of the positive control potassium dichromate were 0.79 mg/L and 0.39 mg/L respectively and showed sufficient statistical correspondence of the data with the dose-response-equation. The values were within the range of the laboratory. For the notified chemical, the test solutions were not renewed during the 72 h test period. The measured concentrations of the test substance lay between 74% and 162% (162% in lowest concentrated treatment) of the nominal concentrations at the beginning of the test and between 0% and 67% of the nominal concentrations at the end of the test. Therefore the biological results were based on the geometric mean of the measured concentrations.

CONCLUSION The test substance is considered to be harmful to algae.

TEST FACILITY LAUS GmbH (2018)

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