File No: LTD/2074

May 2019

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

# PUBLIC REPORT

## Polymer in Hostaperm Yellow H3G 50

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/2074 | Clariant (Australia) Pty Ltd | Polymer in Hostaperm Yellow H3G 50 | ND* | ≤ 10 tonne per annum | Component of paints and 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.

**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 polymers are 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:
  - Local exhaust ventilation
  - Enclosed, automated systems where possible.

- 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 end use:
  - Use of spray booths for spray applications, where possible.

- 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 and end use:
  - Avoid inhalation exposure

- 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 and end use:
  - Appropriate respiratory protection (with particulate filter) if inhalation exposure may occur

  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 1,000 g/mol;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of paints and 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 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)
Clariant (Australia) Pty Ltd (ABN: 30 069 435 552)
Level 3, Olympus Building
3 Acacia Place
296 – 324 Ferntree Gully Road
NOTTING HILL VIC 3168

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: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, use details and import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for physico-chemical endpoints except melting point, boiling point, water solubility, and partition coefficient.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China and Korea

## 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Hostaperm Yellow H3G 50 (formulation containing the notified polymer at ≤ 30% concentration)

MOLECULAR WEIGHT
Number average molecular weight (Mn) is > 10,000 g/mol.

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

## 3. COMPOSITION

DEGREE OF PURITY
> 99%

## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: yellow powder*

| *Property* | *Value* | *Data Source/Justification* |
|---|---|---|
| Melting Point | 356 °C | Measured |
| Boiling Point | Decomposes without boiling | Measured |
| Density | 1,590 kg/m$^3$ at 20 °C | Product SDS* |
| Vapour Pressure | Not determined | Estimated to be low based on high molecular weight |
| Water Solubility | < 0.003 g/L at 23 °C | Measured |
| n-Octanol Solubility | Miscible with n-octanol at every ratio | Measured |
| Hydrolysis as a Function of pH | Stable at pH 1.2, 4.0, 7.0, 9.0 at 40°C | Measured |

| *Property* | *Value* | *Data Source/Justification* |
|---|---|---|
| Partition Coefficient (n-octanol/water) | log $P_{ow}$ > 5.5 at 20 °C | Calculated from individual solubilities in water and in n-octanol |
| Adsorption/Desorption | Not determined | Expected to have low mobility in soil based on its low water solubility, high log $P_{ow}$ and cationic functionality |
| Dissociation Constant | Not determined | Contains cationic functionalities, but significant dissociation in the environmental pH range of 4-9 is not expected due to its low water solubility |
| Particle Size | D50 = 2 µm | Product SDS* |
| Flash Point | Not determined | Not expected to form flammable vapours |
| Flammability | Not determined | Not expected to be flammable |
| Autoignition Temperature | Not determined | Not expected to autoignite |
| Explosive Properties | Not determined | Contains no functional groups that imply explosive properties |
| Oxidising Properties | Not determined | Contains no functional groups that imply oxidative properties |

* Formulation containing the notified polymer at ≤ 30% concentration

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 and it will be imported into Australia as a pigment powder formulation containing the notified polymer at ≤ 30% concentration.

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

| *Year* | *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Tonnes* | 0.5 – 10 | 1 – 10 | 1 – 10 | 1 – 10 | 1 – 10 |

PORT OF ENTRY
Melbourne and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Clariant (Australia) Pty Ltd

TRANSPORTATION AND PACKAGING
The powder formulation containing the notified polymer (at ≤ 30% concentration) will be imported in 10 kg paper bags in cardboard boxes or mesh transport boxes, or in 1.2 L polyethylene (PE) bottles. These containers will be transported to warehouses for storage, and then delivered to the reformulation sites.

USE
The notified polymer will be used as a component of paints and coatings at ≤ 1.5% concentration.

OPERATION DESCRIPTION

*Reformulation*
At the reformulation site, the containers of the powder formulation containing the notified polymer at ≤ 30% concentration will be opened and weighed in a fume hood. The required quantity of the powder formulation will be manually loaded into a 10,000 L blending tank, to which other ingredients will be added. The mixture will be blended by high speed dispersion and mixing under local exhaust ventilation. After the blending is completed, the reformulated coating product will be transferred to the filling machine and pumped into steel containers such as 5 L to 20 L pails or 205 L drums.

*End Use*
The notified polymer at ≤ 1.5% will be available in paints and coating products for professional use and for the general public. In an industrial setting, the paint and coating products will be predominantly applied using spray equipment within a spray booth. Do-it-yourself (DIY) users will typically apply the paint products by brush, roller or air-less 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 – 2 | 24 |
| Reformulation workers | 8 | 50 |
| Painters and tradesmen | 8 | 250 |

EXPOSURE DETAILS

*Transport and Storage*
Transport and storage workers may come into contact with the notified polymer at ≤ 30% concentration (as imported) or ≤ 1.5% concentration (in end use products) only in the unlikely event of accidental breaching of containers.

*Reformulation*
At reformulation sites, dermal, ocular and inhalation exposure to the notified polymer at up to ≤ 30% concentration may occur when weighing and transferring the notified polymer in powder form to the blending tank or during equipment cleaning and maintenance. Exposure to the notified polymer during reformulation is expected to be minimised through the use of enclosed and automated systems, local exhaust ventilation and personal protective equipment (PPE), including gloves, safety goggles, coveralls and respiratory protection if dust exposure is likely to occur.

*End use*
At end use sites, dermal, ocular and inhalation exposure to paints and coatings containing the notified polymer at ≤ 1.5% concentration may occur during transfer, application and cleaning processes. During use in industrial sites, the potential for exposure should be minimised through the use of engineering controls such as spray booths and PPE, including coveralls, gloves and goggles, as well as appropriate respiratory protection where ventilation is inadequate.

Once dried and cured, the notified polymer will be bound within a polymer matrix and is not expected to be available for exposure.

#### 6.1.2. Public Exposure
The paint and coating products containing the notified polymer (at ≤ 1.5% concentration) will be accessible to do-it-yourself (DIY) users. Dermal, ocular and inhalation exposure to the notified polymer may occur when applying the notified polymer at up to at ≤ 1.5% concentration. The frequency and extent of exposure for DIY users are expected to be lower than industrial users. By following the safe use instructions and use of appropriate

PPE as recommended on the product labels, the potential for exposure to the notified polymer is expected to be further reduced.
Members of the public may come into contact with surfaces coated with the finished paint and coating products containing the notified polymer. However, once dried and cured, the notified polymer is expected to be bound into the polymer matrix and will not be available for exposure.

### 6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

| *Endpoint* | *Result and Assessment Conclusion* |
|---|---|
| Acute oral toxicity – rat | LD50 > 2,000 mg/kg bw; low toxicity |
| Skin irritation (*in vitro* reconstructed human epidermis test) | Non-irritating |
| Eye irritation (*in vitro* BCOP Test) | Non-irritating |

*Toxicokinetics, metabolism and distribution*
No information on the toxicokinetics, metabolism and distribution of the notified polymer was provided. Based on the high molecular weight (> 10,000 Da), absorption of the notified polymer across the skin or biological membranes is expected to be limited.

*Acute toxicity*
The notified polymer was found to have low acute oral toxicity in rats. No information was submitted on acute dermal or inhalation toxicity.

*Irritation and Sensitisation*
The notified polymer was not considered to be a skin irritant based on the results of an *in vitro* human skin test using the EpiDerm Reconstructed Human Epidermis Model. The notified polymer was not considered to be an eye irritant based on the results of an *in vitro* bovine corneal opacity and permeability test (BCOP Test).

No information on skin sensitisation was provided. There were no structural alerts identified in the notified polymer indicative of skin sensitisation potential.

*Lung overloading*
It is noted that the notified polymer is expected to be water-insoluble with molecule weight > 10,000 g/mol. Inhalation of polymers with molecular weights > 70,000 g/mol has been linked with irreversible lung damage due to lung overloading and impaired clearance of particles from the lung, particularly following repeated exposure (US EPA, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new, accessed on March 2019). There is a data gap for polymers with MW between 10,000 and 70,000 g/mol, and uncertainty may exist.

***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

*Reformulation*
Reformulation workers may come into contact with to the notified polymer in powder form at concentrations ≤ 30%. The use of engineering controls, such as enclosed/automated processes and local exhaust ventilation, and suitable PPE, is expected to minimise the exposure and hence reduce the risk of inhalation and lung overloading effects.

*End Use*
During end use, professional workers may come into contact with the notified polymer at up to ≤ 1.5% concentration. At this low concentration in end use products and use of spray booths and PPE are expected to minimise the exposure and hence reduce the risk to workers.

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

Similar to professional painters, DIY users may come into contact with the notified polymer at ≤ 1.5% concentration via dermal, ocular and inhalation routes during application of paints by brush, roller or air-less spray. Given that the paints contain a relatively low concentration of the notified polymer and the paint products will be used less frequently and in much smaller scales by DIY users compared to professional users, the extent of exposure is expected to be low. Therefore, the risk to the health of DIY users from the notified polymer is not considered to be unreasonable.

Members of the public may come into contact with articles or surfaces which have been treated with paints or coatings containing the notified polymer. However, the notified polymer will 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 in a pigment powder formulation for reformulation into finished paints and coatings. The reformulation processes involve blending operation in an enclosed environment, followed by automated filling of the finished paints into end-use containers. The notifier estimates that liquid waste from reformulation including cleaning of equipment may account for 2% of the import volume of the notified polymer, which is expected to be treated at an onsite wastewater treatment plant before release to sewers. Residual notified polymer in empty import containers is expected to be disposed of to landfill, in accordance with local government regulations. Accidental spills of the products containing the notified polymer during import, reformulation, transport or storage are expected to adsorb onto a suitable material and collected for disposal in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The finished paints and coatings containing the notified polymer will be available for use by professional users and the general public. In an industrial setting, the paint and coating products will be predominantly applied using spray equipment within a spray booth. The overspray is expected to be trapped onto spray booth filters before disposal to landfill. Liquid waste from cleaning of application equipment is expected to be collected and treated before disposal, in accordance with local government regulations.

DIY users will typically apply the paint products by brush, roller or air-less spray. Generally spills will be collected using suitable materials before disposal to landfill, however some incorrect disposal to sewer may occur.

Once dried and cured, the notified polymer will be bound within a polymer matrix and is not expected to be available for environmental exposure.

RELEASE OF CHEMICAL FROM DISPOSAL

As a result of its use pattern, most of the notified polymer is expected to share the fate of the substrate to which it has been applied, to be disposed of to landfill at the end of their useful lives. Residual notified polymer in empty end use containers is expected to be cured into an inert solid matrix and be disposed of to landfill.

It is assumed that up to 5% of the paints and coatings containing the notified polymer at ≤ 1.5 concentration 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

Results of a biodegradation test conducted on the notified polymer shows that it is not readily biodegradable (3% degradation over 28 days in OECD 301F test). For details of the biodegradation study, refer to Appendix C.

Most of the notified polymer is expected to share the fate of the article to which it has been applied, to be disposed of to landfill at the end of their useful lives. In landfill, the notified polymer will be present as cured solids and will be neither bioavailable nor mobile. A small proportion of the paint used by DIY users may be incorrectly disposed of to sewers. Based on its low water solubility (< 0.003 g/L), high low $P_{ow}$ (> 5.5) and cationic functionality, the notified polymer is expected to be effectively removed through adsorption to sludge at sewage treatment plants (STPs). Sludge containing the notified polymer will be sent to landfill for disposal or agricultural land for remediation. The notified polymer is expected to have low mobility in soil and sludge due to its low water solubility, high log $P_{ow}$ and cationic functionality. The notified polymer is not expected to bioaccumulate based on its high molecular weight. In landfill, soil, sludge and water, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon, nitrogen and sulphur.

### 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 in paints for professional and DIY users, a conservative release of 5% of the annual import volume to sewers on a nationwide basis over 365 days per year is used for the notified polymer. It is also assumed under the worst-case scenario that there is no removal of the notified polymer during sewage treatment processes.

| Predicted Environmental Concentration (PEC) for the Aquatic Compartment | | |
|---|---|---|
| Total Annual Import Volume | 10,000 | kg/year |
| Proportion expected to be released to sewer | 5 | % |
| Annual quantity of chemical released to sewer | 500 | kg/year |
| Days per year where release occurs | 365 | days/year |
| Daily chemical release | 1.37 | kg/day |
| Water use | 200 | L/person/day |
| Population of Australia | 24.386 | Million |
| Removal within STP | 0 | % |
| Daily effluent production | 4,877 | ML |
| Dilution Factor – River | 1 | |
| Dilution Factor – Ocean | 10 | |
| PEC – River | 0.28 | µg/L |
| PEC – Ocean | 0.03 | µg/L |

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/$m^2$/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/$m^3$). Using these assumptions, irrigation with a concentration of 0.28 µg/L may potentially result in a soil concentration of approximately 1.87 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 9.36 µg/kg and 18.7 µg/kg, respectively.

### 7.2. Environmental Effects Assessment

Results from the Daphnia toxicity investigation conducted on the notified polymer are summarised in the table below. Details of the study can be found in Appendix C.

| *Endpoint* | *Result* | *Assessment Conclusion* |
|---|---|---|
| Daphnia Toxicity | 48h EC50 > 100 mg WAF*/L | Not harmful to aquatic invertebrates up to its water solubility limit |

* WAF: Water Accommodated Fraction

Based on the above ecotoxicological endpoint for the notified polymer, it is not expected to be harmful to aquatic invertebrates up to its water solubility limit. As only one ecotoxicological endpoint was provided, the notified polymer is not classified according to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

### 7.2.1. Predicted No-Effect Concentration (PNEC)

Although the toxicity test above shows that the notified polymer is not harmful to Daphnia up to its water solubility limit, the toxicity of the notified polymer to other aquatic organisms such as fish or alga is still unknown. Therefore, the predicted no-effects concentration (PNEC) has been calculated based on a single endpoint for Daphnia as shown in the table below. An assessment factor of 1000 was used given endpoint for only one trophic level was available.

| Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment | | |
|---|---|---|
| 48h EC50 for Daphnia | > 100 | mg/L |
| Assessment Factor | 1,000 | |
| Mitigation Factor | 1.00 | |
| PNEC | > 100 | µg/L |

### 7.3. Environmental Risk Assessment

Based on the above predicted PEC and PNEC, the following Risk Quotient (Q = PEC/PNEC) has been calculated.

| Risk Assessment | PEC (µg/L) | PNEC (µg/L) | Q |
|---|---|---|---|
| Q – River | 0.28 | > 100 | **< 0.01** |
| Q – Ocean | 0.03 | > 100 | **< 0.001** |

The risk quotient for discharge of effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on its annual importation quantity and reported use pattern. Therefore, on the basis of the predicted PEC/PNEC ratio, the maximum annual importation volume, and the assessed use pattern as a component of paints and coatings, the notified polymer is not expected to pose an unreasonable risk to the environment.

## APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

**Melting Point** 356 °C at 101.3 kPa

Method OECD TG 102 Melting Point/Melting Range
Remarks Differential scanning calorimetry (DSC) was used.
Test Facility Clariant (2017a)

**Boiling Point** Decomposes without boiling

Method OECD TG 103 Boiling Point
Remarks Differential scanning calorimetry (DSC) was used. The mean onset of decomposition was 382 °C.
Test Facility Clariant (2017b)

**Water Solubility** < 0.003 g/L at 23 °C

Method OECD TG 105 Water Solubility
EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks Flask Method; the notified polymer could not be pulverised as instructed in the test guideline as it is very sticky and crystalline.
Test Facility Clariant (2017c)

**n-Octanol Solubility** Miscible with n-octanol at every ratio

Method OECD TG 105 adapted for n-Octanol
Remarks Flask Method
Test Facility Clariant (2017d)

**Hydrolysis as a Function of pH**

Method Korean Polymer Stability Test Guideline

| *pH* | *T (°C)* | $t_{½}$ *(year)* |
|---|---|---|
| 4 | 40 | > 1 |
| 7 | 40 | > 1 |
| 9 | 40 | > 1 |

Remarks The test substance was not water soluble and the content of degradation products in the aqueous phase was negligible after the test periods: pH 1.2 (24 h) and pH 4.0, pH 7.0, pH 9.0 for 14 days.
Test Facility Clariant (2017e)

# APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

## B.1. Acute Oral Toxicity – Rat, Fixed Dose Procedure

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 420 Acute Oral Toxicity – Fixed Dose Method<br>EC Council Regulation No 440/2008 B.1 bis Acute toxicity (oral) fixed dose method |
| Species/Strain | Rat/Wistar (RccHan: WIST) |
| Vehicle | Hexane |
| Remarks – Method | GLP certificate<br>The study plan originally intended to follow OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method, and was subsequently adjusted. |

RESULTS

Main Study

| *Group* | *Number and Sex of Animals* | *Dose (mg/kg bw)* | *Mortality* |
|---|---|---|---|
| 1 | 1 F | 300 | 0/1 |
| 2 | 1 F | 2,000 | 0/1 |
| 3 | 4 F | 2,000 | 0/4 |

| | |
|---|---|
| LD50 | > 2,000 mg/kg bw |
| Signs of Toxicity | In the 2,000 mg/kg bw group, diarrhoea was noted in one animal after dosing and hunched posture was observed in four animals during the day of dosing.<br><br>No signs of systemic toxicity were observed. |
| Effects in Organs | No abnormalities were noted. |
| Remarks - Results | The animals showed expected body weight gain over the observation period. |

| | |
|---|---|
| CONCLUSION | The notified polymer is of low acute toxicity via the oral route. |
| TEST FACILITY | Envigo (2018) |

## B.2. Skin Irritation – *In Vitro* (*in vitro* reconstructed human epidermis test)

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 439 *In vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method |
| Vehicle | None. The notified polymer was wetted with 25 µL Dulbecco's phosphate buffered saline (DPBS). |
| Remarks – Method | GLP certificate<br>EpiDerm Model<br>Negative control (DPBS) and positive control (5% sodium dodecyl sulfate) were run concurrently with the notified polymer.<br>No significant protocol deviations |

RESULTS

| *Test Material* | *Mean $OD_{570}$ of Triplicate Tissues* | *Relative Mean Viability (%)* | *SD of Relative Mean Viability* |
|---|---|---|---|
| *Negative control* | 1.569 | 100 | 10.3 |
| *Test substance* | 2.152 | 137.2 | 9.0 |
| *Positive control* | 0.048 | 3.1 | 0.1 |

OD = optical density; SD = standard deviation

| | |
|---|---|
| Remarks – Results | The test substance did not reduce MTT and it did not change colour when mixed with deionised water.<br><br>The positive and negative controls gave satisfactory responses confirming the validity of the test system and quality of the tissues. |
| CONCLUSION | Based on the mean tissue viability of > 50%, the notified polymer is not classified as a skin irritant according to the GHS criteria. |
| TEST FACILITY | Envigo CRS (2018a) |

**B.3. Eye Irritation – *In Vitro* (in vitro bovine corneal opacity and permeability test)**

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage |
| Vehicle | Saline |
| Remarks – Method | GLP certificate<br>No protocol deviations |

RESULTS

| *Test Material* | *Mean Opacities of Triplicate Tissues* | *Mean Permeabilities of Triplicate Tissues* | *IVIS* |
|---|---|---|---|
| *Vehicle control* | 0 | 0.082 | 1.24 |
| *Test substance** | 0.33 | 0.007 | 0.44 |
| *Positive control** | 104 | 0.217 | 107.58 |

SD = Standard deviation; IVIS = *in vitro* irritancy score
*Corrected for background values

| | |
|---|---|
| Remarks – Results | The notified polymer did not induce ocular irritation according to the test guideline as its IVIS is ≤ 3.<br><br>The IVIS from the vehicle control and positive control were within the historical control means. |
| CONCLUSION | The notified polymer is not classifiable as an eye irritant according to the GHS criteria. |
| TEST FACILITY | Envigo CRS (2018b) |

# APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

## C.1. Environmental Fate

### C.1.1. Ready Biodegradability

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test |
| Inoculum | Activated sludge from a municipal STP |
| Exposure Period | 28 days |
| Auxiliary Solvent | Acetone |
| Analytical Monitoring | Oxygen consumption by OxiTop® |
| Remarks – Method | No major deviations from the test guidelines were reported. A stock solution of the test substance (50 g/L) was made in acetone. The stock solution (100 µL) was pipetted onto sea sand (7g). The sand was allowed to dry overnight and pounded in a mortar before introducing into the test vessels. A toxicity control was run. |

RESULTS

| *Test Substance* | | *Sodium benzoate* | |
|---|---|---|---|
| *Day* | *% Degradation* | *Day* | *% Degradation* |
| 7 | 1 | 7 | 84 |
| 14 | 1 | 14 | 92 |
| 21 | 1 | 21 | 93 |
| 28 | 3 | 28 | 95 |

| | |
|---|---|
| Remarks – Results | All validity criteria for the test were satisfied. The toxicity control exceeded 25% biodegradation after 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance after 28 days was 3%. |
| CONCLUSION | The test substance is not readily biodegradable |
| TEST FACILITY | Noack (2018a) |

## C.2. Ecotoxicological Investigations

### C.2.1. Acute Toxicity to Aquatic Invertebrates

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static |
| Species | *Daphnia magna* |
| Exposure Period | 48 hours |
| Auxiliary Solvent | None |
| Water Hardness | 274 mg $CaCO_3$/L |
| Analytical Monitoring | None |
| Remarks – Method | No major deviations from the test guidelines were reported. A test solution with a loading rate of 100 mg/L was prepared and stirred for 72 hours before stabilisation for 1 hour. The Water Accommodated Fraction (WAF) was then siphoned from the centre of the water body for use as the highest test concentration. Lower test concentrations were obtained by further dilution of the highest test concentration. A reference test with potassium dichromate was run. |

RESULTS

| *Nominal concentration (mg WAF/L)* | *Number of D. magna* | *Number Immobilised 48 h* |
|---|---|---|
| Control | 20 | 0 |
| 10 | 20 | 0 |
| 17.8 | 20 | 0 |
| 31.7 | 20 | 0 |
| 56.4 | 20 | 0 |
| 100 | 20 | 0 |

| | |
|---|---|
| EC50 | > 100 mg WAF/L at 48 hours |
| Remarks – Results | All validity criteria for the test were satisfied. The dissolved oxygen concentration was > 8.1 mg/L at 19°C (> 87%; USGS, 2011) during the test. The 48h LC50 for *Daphnia* exposed to potassium dichromate was 2 mg/L which is within the historical range. |
| CONCLUSION | The test substance is not harmful to aquatic invertebrates up to its water solubility limit. |
| TEST FACILITY | Noack (2018b) |

# BIBLIOGRAPHY

Clariant (2017a) [Notified polymer] Melting Point (Report No. 17-008754-2, July, 2017). Frankfurt, Germany, Clariant Produkte (Deutschland) GmbH. (Unpublished report submitted by the notifier).

Clariant (2017b) [Notified polymer] Decomposition (Report No. 17-008754-2, July, 2017). Frankfurt, Germany, Clariant Produkte (Deutschland) GmbH. (Unpublished report submitted by the notifier).

Clariant (2017c) [Notified polymer] Water Solubility (Report No. 17-008754-2/2, May, 2017). Frankfurt, Germany, Clariant Produkte (Deutschland) GmbH. (Unpublished report submitted by the notifier).

Clariant (2017d) [Notified polymer] Solubility in n-Octanol (Report No. 17-008754-2/3, May, 2017). Frankfurt, Germany, Clariant Produkte (Deutschland) GmbH. (Unpublished report submitted by the notifier).

Clariant (2017e) [Notified polymer] Stability test of polymer (Report No. 17-008754-2/5, May, 2017). Frankfurt, Germany, Clariant Produkte (Deutschland) GmbH. (Unpublished report submitted by the notifier).

Envigo (2018) [Notified polymer]: Acute Oral Toxicity in the Rat – Fixed Dose Procedure (Study No. DM04TC, June, 2017). Shardlow, UK, Envigo Research Limited. (Unpublished report submitted by the notifier).

Envigo CRS (2018a) [Notified polymer]: *in vitro* Skin Irritation Test: Human Skin Model Test – OECD 439 (Study No. 1881903, April, 2010). Rossdorf, Germany, Envigo CRS GmbH. (Unpublished report submitted by the notifier).

Envigo CRS (2018b) [Notified polymer]: Bovine Corneal Opacity and Permeability Assay (BCOP) – OECD 437 (Study No. 1881904, March, 2017). Rossdorf, Germany, Envigo CRS GmbH. (Unpublished report submitted by the notifier).

Noack (2018a) [Notified polymer] Ready Biodegradability Manometric Respirometry Test (Study ID. 171128CG/ARE18064, May, 2018). Sarstedt, Germany, Dr U Noack Laboratorien GmbH (Unpublished report submitted by the notifier).

Noack (2018b) [Notified polymer] Acute Immobilisation Test to *Daphnia Magna*, Static, 48 hours (Study ID. 171128CG/DAI18064, August, 2018). Sarstedt, Germany, Dr U Noack Laboratorien GmbH (Unpublished report submitted by the notifier).

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

USGS (2011) U.S. Geological Survey, Change to solubility equations for oxygen in water: Office of Water Quality Technical Memorandum 2011.03, accessed https://water.usgs.gov/software/DOTABLES/ v 3.5, 8 January 2018