File No: STD/1627

November 2017

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

# PUBLIC REPORT

## GENOPOL AB-2

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**

# TABLE OF CONTENTS

# SUMMARY

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

| ASSESSMENT REFERENCE | APPLICANT | CHEMICAL OR TRADE NAME | HAZARDOUS CHEMICAL | INTRODUCTION VOLUME | USE |
|---|---|---|---|---|---|
| STD/1627 | Cintox Australia Pty Ltd | GENOPOL AB-2 | Yes | < 10 tonnes per annum | Component of industrial inks and coatings |

# CONCLUSIONS AND REGULATORY OBLIGATIONS

**Hazard classification**
Based on the available information, the notified polymer is 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 recommended hazard classification is presented in the following table.

| *Hazard classification* | *Hazard statement* |
|---|---|
| Skin sensitisation (Category 1B) | H317 – May cause an allergic skin reaction |

**Human health risk assessment**
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

As the notified polymer will be used on materials with direct food contact, the public report of this assessment will be forwarded to Food Standards Australia New Zealand (FSANZ) for their information.

**Environmental risk assessment**
On the basis of the low hazard and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

**Recommendations**

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - Skin sensitisation (Category 1B): H317 – May cause an allergic skin reaction

  The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified polymer present.

Health Surveillance

- As the polymer is a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin sensitisation.

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:
  - Enclosed, automated processes, where 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:
  - Avoid skin contact

- 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:
  - Impervious gloves
  - Coveralls

  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 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.

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.

Emergency procedures

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

**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 will be used as a component of coatings for direct food contact;
  - information has become available on reproduction toxicity of the notified polymer;

or

(2) Under Section 64(2) of the Act; if

- the function or use of the polymer has changed from component of industrial inks 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 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)
Cintox Australia Pty Ltd (ABN: 63 122 874 613)
Suite 1, Level 2, 38-40 George Street
PARRAMATTA NSW 2150

NOTIFICATION CATEGORY
Standard: Synthetic polymer with Mn < 1,000 Da (more than 1 tonne per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, use details, polymer constituents, residual monomers, impurities, additives/adjuvants and import volume.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
None

NOTIFICATION IN OTHER COUNTRIES
None

## 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
GENOPOL AB-2

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) is < 1,000 g/mol.

ANALYTICAL DATA
Reference IR, HPLC and GPC spectra were provided.

## 3. COMPOSITION

DEGREE OF PURITY
> 95%

## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Brown, pasty liquid

| Property | Value | Data Source/Justification |
|---|---|---|
| Melting Point | -27.7 °C | Measured |
| Boiling Point | 421.7 °C at 101.3 kPa | Measured |
| Density | 1,149 kg/m$^3$ at 20 °C | Measured |
| Vapour Pressure | $1.3 \times 10^{-7}$ kPa at 20 °C<br>$1.7 \times 10^{-7}$ kPa at 25 °C<br>$5.9 \times 10^{-7}$ kPa at 50 °C | Measured |
| Water Solubility | $1.22 \times 10^{-3}$ g/L at 20 °C | Measured |
| Hydrolysis as a Function of pH | Not determined | The notified polymer contains hydrolysable functional groups. However, due to its limited water solubility, significant hydrolysis is not expected in the environmental pH range of 4 – 9. |

| Property | Value | Data Source/Justification |
|---|---|---|
| Partition Coefficient (n-octanol/water) | Component 1 (4%): log Pow = 2.1 at 25 °C<br>Component 2 (1%): log Pow = 3.6 at 25 °C<br>Component 3 (29%): log Pow = 4.3 at 25 °C<br>Component 4 (64%): log Pow = 6.2 at 25 °C | Measured |
| Surface Tension | 51.6 mN/m | Measured |
| Adsorption/Desorption | log $K_{oc}$ = 0.958 – 4.71 | Measured |
| Dissociation Constant | Not determined | The notified polymer does not contain dissociable functionality |
| Thermal Stability | - 490 J/g | Measured |
| Flash Point | > 300 °C at 100.9 kPa | Measured |
| Flammability | Not determined | Estimated. Predicted to be low based on high flash point |
| Autoignition Temperature | 440 °C | Measured |
| Explosive Properties | Not explosive | Expert statement |
| Oxidising Properties | Not determined | The notified polymer does not contain chemical groups which are associated with oxidising properties |

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 POLYMER (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. The notified polymer will be introduced into Australia in the neat form at > 95% concentration.

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

| *Year* | *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Tonnes* | < 10 | < 10 | < 10 | < 10 | < 10 |

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The neat notified polymer in 200 L steel drums will be transported by road from the port wharf to the notifier's warehouse then to the notifier's customers' sites for reformulation. The reformulated inks or coatings containing the notified polymer at ≤ 15% concentration will be then transported by road in 20 L pails or 200 L drums to end users.

USE
The notified polymer will be used as a component in UV-curable inks and coatings at ≤ 15% concentration for commercial printing/coating on metal, paper, cardboard, wood and plastic substrates. Some uses of the finished inks and coatings will be for the exterior surfaces of food packaging.

OPERATION DESCRIPTION
The notified polymer will not be manufactured in Australia. It will be introduced in neat form for reformulation into UV-curable inks and coatings. At the reformulation site, the notified polymer will be manually weighed and added to the blending vessel to be mixed with other components of inks or coatings. The reformulated ink or

coating containing the notified polymer at ≤ 15% concentration will be then piped into an automated filling system which will dispense the reformulated ink or coating into 20 L pails or 200 L drums for distribution to end users. Laboratory technicians will conduct quality control testing on the notified polymer and the reformulated inks and coatings.

*End-Use*
Reformulated inks or coatings containing the notified polymer at ≤ 15% concentration will be applied to metal, paper or plastic substrates using standing automated printing or coating techniques. Once applied, the inks or coatings will be cured by exposure to UV light. During the curing process, the notified polymer is partially consumed. The remaining polymer will be bound within the ink or coating matrix, and subsequently not expected to be available for release.

## 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 | 2 -3 | 10 - 15 |
| Blending operations | 8 | 50 |
| Laboratory: quality control and research and development | 1 | 20 |
| Printing/coating operators | 4 | 365 |

EXPOSURE DETAILS
*Transport and storage*
Exposure to the neat notified polymer at > 95% concentration is not expected to occur during transport and storage except in the unlikely event of an accident where the packaging is breached.

*Reformulation*
Dermal and ocular exposure to the neat notified polymer or formulated polymer at ≤ 15% concentration may occur during manually weighing, charging the blending vessels, sampling, and cleaning. Inhalation exposure to the notified polymer during reformulation is unlikely due to the use of local exhaust ventilation and the use of closed systems. Exposure of workers to the notified polymer will be further reduced by the stated use by the notifier of PPE such as coveralls, gloves and protective goggles. Respiratory protection may be used if conditions are dusty or high vapour concentrations are present.

*End-use*
Dermal and ocular exposure to the notified polymer at ≤ 15% concentration may occur during the printing or coating process (which involves manual handling of inks/coatings containing the notified polymer) and during maintenance processes. Workers are expected to wear PPE (coveralls, PVC coated cotton gloves and protective goggles) as stated by the notifier while handling the inks or coatings which should minimise exposure. Inhalation exposure is not expected unless mists/aerosols are generated during the printing/coating processes. This is expected to be minimised by the stated use of local exhaust ventilation installed in areas surrounding the printing machines to remove solvent and any other airborne ink components.

Exposure is not anticipated for workers who might make dermal contact with the notified polymer when handling the cured end products, as the notified polymer will be incorporated into the polymer matrix and will not be bioavailable.

#### 6.1.2. Public Exposure
The UV-curable ink/coating products containing the notified polymer will be for industrial use only and will not be available to the public. The public may come into dermal contact with substrates on which the ink or coating is applied. However, once the coating is dried and cured, the notified polymer will be bound within the ink/coating matrix and will not be bioavailable.

### 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* |
|---|---|
| Rat, acute oral toxicity | LD50 > 2000 mg/kg bw; low toxicity |
| Rat, acute dermal toxicity | LD50 > 2000 mg/kg bw; low toxicity |
| Rabbit, skin irritation | slightly irritating |
| Eye irritation (*in vitro* isolated chicken eye test) | non-irritating |
| Mouse, skin sensitisation – Local lymph node assay (LLNA) | evidence of sensitisation (EC3 = 32.8%) |
| Rat, repeat dose oral toxicity – 28 days | NOAEL = 100 mg/kg bw/day |
| Mutagenicity – bacterial reverse mutation | non mutagenic |
| Genotoxicity – *in vitro* mammalian cell chromosome aberration test | non genotoxic |
| Genotoxicity – *in vitro* mammalian cell gene mutation assay | non genotoxic |

*Toxicokinetics*

Given the moderately high molecular weight of the notified polymer (> 800 g/mol) and low percentage (< 5%) of low molecular weight species < 500 g/mol, absorption across biological membranes is expected to be limited.

*Acute toxicity*

The notified polymer was found to be of low acute oral and dermal toxicity in studies conducted in rats.

*Irritation and sensitisation*

Based on a study conducted in rabbits, the notified polymer is slightly irritating to skin. All animals displayed well defined erythema at 24 and 48 hours after treatment. All signs of irritation were resolved by the 10 day observation time-point.

Based on an *in vitro* isolated chicken eye test, the notified polymer is considered not irritating to eyes.

In a mouse LLNA study, the notified polymer was determined to be a weak sensitiser with an estimated concentration required to produce a 3-fold increase in lymph-node cell stimulation (EC3) of 32.8%.

*Repeated dose toxicity*

In a 28-day repeated dose oral (gavage) toxicity study, rats were treated with the notified polymer at 0, 100, 300 or 1000 mg/kg bw/day. Test substance-related adverse effects observed at 1000 mg/kg bw/day included lower mean cholesterol concentrations, pale and nutmeg-like patterned liver, hepatic lipidosis, small male reproductive organs/tissues (testes, epididymes, seminal vesicle and prostate), yellowish-grey epididymal foci, reduced weights of testes, epididymes and seminal vesicle, decreased spermatogenesis, lack of spermatozoa, focal dilation of epididymal tubules and decreased amount of secretum in the seminal vesicle and prostate. Adverse effects in the testes and epididymes (including effects on spermatozoa and spermatogenesis) persisted throughout the recovery period.

Treatment- related adverse effects observed at 300 mg/kg bw/day included decreased mean cholesterol concentrations, pale liver and hepatic lipidosis in females, and yellowish-grey epididymal foci and focal dilation of epididymal tubules in males.

The No Observed (Adverse) Effect Level (NO(A)EL) was established for systemic toxicity for the notified polymer as 100 mg/kg bw/day based on the effects observed in the liver in males and females, as well as the changes observed on the male reproduction organs.

*Mutagenicity/Genotoxicity*

The notified polymer tested negative in a bacterial reverse mutation assay, an *in vitro* mammalian cell chromosome aberration test and in an *in vitro* mammalian cell gene mutation test. Based on these results, the notified polymer is not considered to be genotoxic.

***Health hazard classification***

Based on the available information, the notified polymer is 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 recommended hazard classification is presented in the following table.

| *Hazard classification* | *Hazard statement* |
|---|---|
| Skin sensitisation (Category 1B) | H317 – May cause an allergic skin reaction |

### 6.3. Human Health Risk Characterisation

#### 6.3.1. Occupational Health and Safety

Based on the available information the critical health effect of the notified polymer is skin sensitisation.

*Reformulation*

During reformulation, workers may be at risk of skin sensitisation when handling the notified polymer as introduced and in reformulated products. The notifier anticipates that worker exposure will be limited through the use of engineering controls such as enclosed systems, automated processes and local exhaust ventilation. The use of appropriate PPE (coveralls, imperious gloves and eye protection) will also be used to limit worker exposure.

*End-Use*

Printing and coating workers may be at risk of sensitisation when handling inks and coatings containing the notified polymer at ≤ 15% concentration. The notifier anticipates that worker exposure will be limited through the use of engineering controls such as enclosed systems, automated processes and local exhaust ventilation (to remove solvent and any other airborne ink components). The use of appropriate PPE (coveralls, imperious gloves and eye protection) will also be used to limit worker exposure.

Exposure is not anticipated for workers who might make dermal contact with the notified polymer when handling cured end products, as the notified polymer will be incorporated into the polymer matrix and will not be bioavailable.

Therefore, under the occupational settings described, the risk to the health of workers from use of the notified polymer is not considered to be unreasonable.

#### 6.3.2. Public Health

The notified polymer is intended for use in industrial applications only. The public may come into dermal contact with substrates on which the ink or coating is applied. However, once the coating is dried and cured, the notified polymer will be bound within the ink/coating matrix and will not be bioavailable.

As some uses of the notified polymer will be for the exterior of food packaging, it is possible that indirect food contact may occur. The notifier has advised that the notified polymer is not expected to migrate from the cured ink or coating as it will be fully reacted into an inert matrix. The manufacturer of the food packaging is responsible for ensuring the ink or coating containing the notified polymer has fully cured so that the levels of reactive, low molecular weight species are below the limits of detection. Therefore provided end-users (i.e. food packaging manufacturers) employ good manufacturing processes to ensure complete curing of the ink or coating the risk to public health is not considered to be unreasonable.

The product flyer for a series of ink products containing the notified polymer at ≤ 15% concentration (UltraCURA® Sens Plas series) states that “a migration test according to DIN EN 14338 was made and has shown that under the conditions of the test no migration was observed”. Though the migration test was unable to be provided by the notifier upon request, a food packaging suitability certificate (certificate of compliance) for the ink was supplied. The certificate was issued by ISEGA Forschungs- und Untersuchungsgesellschaft mbH (Aschaffenburg, Germany) and states that the ink “is used for the printing of the exterior surfaces of primary packaging materials made of board for the packaging of dry, non-fatty foodstuffs”.

The public report of this assessment will be forwarded to Food Standards Australia and New Zealand (FSANZ) for their information.

# 7. ENVIRONMENTAL IMPLICATIONS

## 7.1. Environmental Exposure & Fate Assessment

### 7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia in neat form for reformulation into UV-curable inks coatings, and varnishes. The reformulation process will occur in an enclosed area, and involve transferring the neat notified polymer to a mixing vessel, where it will be blended with other ingredients. The finished ink formulations will then be filled into end use containers automatically. Liquid waste from cleaning of the reformulation equipment will either be reused or disposed of through an approved waste management facility. Release of the notified polymer to the environment in the event of accidental spills or leaks during reformulation, storage and transport is expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations. Empty drums containing up to 1% of the import volume of the notified polymer, as estimated by the notifier, will either be recycled or disposed of through an approved waste management facility.

RELEASE OF CHEMICAL FROM USE

The finished inks, coatings or varnishes containing the notified polymer at up to 15% concentration will be applied to metal, paper or plastic substrates using standard automated printing or coating techniques. Once applied, the inks, varnishes or coatings will be cured by exposure to UV light. During the curing process, the notified polymer is partially consumed and the remaining polymer will be bound within the ink, varnish or coating matrix. As estimated by the notifier, up to 0.5% of the inks or coatings containing the notified polymer may be lost through spillage during transferring to reservoirs in the printing or coating machines.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the notified polymer is expected to share the fate of the substrate to which it has been applied, to be either disposed of to landfill, recycled for substrate reclamation or incinerated. Residual notified polymer in empty end-use containers is expected to be cured into an inert solid matrix and be disposed of to landfill or incinerated along with the empty containers.

### 7.1.2. Environmental Fate

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 either disposed of to landfill, recycled for substrate reclamation or incinerated. In landfill, the notified polymer will be present as cured solids and will be neither bioavailable nor mobile. During metal reclamation, the notified polymer will thermally decompose to form water vapour and oxides of carbon and nitrogen. During paper recycling process, waste paper is repulped using a variety of chemical treatments which, amongst other things, enhance ink detachment from the fibres. Wastewater from paper recycling processes containing the notified polymer is expected to be treated at an onsite wastewater treatment plant before potential release to sewers or surface waters. A ready biodegradability test conducted on the notified polymer shows that it is not readily biodegradable (no degradation after 28 days), for details of the biodegradability study, please refer to Appendix C. Based on its limited water solubility, the majority of the notified polymer is expected to be removed through adsorption to sludge at wastewater treatment plants. The waste sludge containing the notified polymer will be sent to landfill for disposal of or agricultural land for remediation. The notified polymer is expected to be bound to soil or sludge due to its limited water solubility. 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 and nitrogen.

### 7.1.3. Predicted Environmental Concentration (PEC)

As information on expected percentage of import volume of the notified polymer to be used on each material (paper, wood, metal and plastic) is not available, the predicted environmental concentration (PEC) has been calculated to assume the worst case scenario that 100% of the import volume of the notified polymer will be used on paper substrate and 76% would be potentially released to sewers through paper recycling processes (APC, 2015). As paper recycling is to be processed at facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume. It is also assumed under the worst-case scenario that there is no removal of the notified polymer during sewage treatment processes. Similarly as the amount of unreacted polymer in the cured inks, coatings or varnishes is unknown, it is assumed that 100% is available for release.

| Predicted Environmental Concentration (PEC) for the Aquatic Compartment | | |
|---|---|---|
| Total Annual Import/Manufactured Volume | 10,000 | kg/year |
| Proportion expected to be released to sewer | 76% | |
| Annual quantity of chemical released to sewer | 7,600 | kg/year |
| Days per year where release occurs | 260 | days/year |
| Daily chemical release: | 29.23 | kg/day |
| Water use | 200.0 | 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: | 5.99 | µg/L |
| PEC - Ocean: | 0.60 | µg/L |

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m2/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 1500 kg/m3). Using these assumptions, irrigation with a concentration of 75.99µg/L may potentially result in a soil concentration of approximately 39.96 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 0.20 mg/kg and 0.39 mg/kg, respectively.

### 7.2. Environmental Effects Assessment

The results from the ecotoxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C.

| *Endpoint* | *Result* | *Assessment Conclusion* |
|---|---|---|
| Fish Toxicity* | EC50 > 1.9 mg/L† | Not harmful to fish up to its water solubility limit |
| Daphnia Toxicity* | EC50 > 2.1 mg/L† | Not harmful to aquatic invertebrates up to its water solubility limit |
| Algal Toxicity* | EC50 > 1.9 mg/L† | Not harmful to alga up to its water solubility limit |
| Inhibition of Bacterial Respiration | EC50 > 1,000 mg/L (nominal concentration) | Does not inhibit microbial activity in wastewater treatment plants |

*Auxiliary solvent used
† Mean measured

Based on the above ecotoxicological endpoints for the notified polymer, it is not expected to be harmful to aquatic life up to the limit of its water solubility. Therefore, the notified polymer is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) for acute and chronic toxicities (United Nations, 2009).

#### 7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated as the notified polymer is not considered to be harmful to aquatic organisms.

### 7.3. Environmental Risk Assessment

The Risk Quotients (Q = PEC/PNEC) have not been calculated since the PNEC was not calculated. The notified polymer is not expected to be harmful to aquatic life. Therefore, based on the low toxicity to aquatic life and the assessed use pattern in UV-curable inks and coatings, the notified polymer is not expected to pose an unreasonable risk to the aquatic environment.

## APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

**Melting Point** -27.7 °C

| | |
|---|---|
| Method | OECD TG 102 Melting Point/Melting Range (1995)<br>EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature |
| Remarks | Melting point measured using differential scanning calorimetry. As only a small endothermic effect was observed at -30 to -10 °C the phase transformation of the test item is regarded as softening, rather than melting. |
| Test Facility | consilab (2016a) |

**Boiling Point** 421.7 °C at 101.3 kPa

| | |
|---|---|
| Method | OECD TG 103 Boiling Point (1995)<br>EC Council Regulation No 440/2008 A.2 Boiling Temperature |
| Remarks | Boiling point measured using differential scanning calorimetry. |
| Test Facility | consilab (2016a) |

**Density** $1.149\times 10^3$ kg/m$^3$ at 20 °C

| | |
|---|---|
| Method | OECD TG 109 Density of Liquids and Solids (2012)<br>EC Council Regulation No 440/2008 A.3 Relative Density |
| Remarks | Gas comparison pycnometer method used at 20 °C. |
| Test Facility | consilab (2016b) |

**Vapour Pressure** $1.3 \times 10^{-7}$ kPa at 20 °C<br>$1.7 \times 10^{-7}$ kPa at 25 °C<br>$5.9 \times 10^{-7}$ kPa at 50 °C

| | |
|---|---|
| Method | OECD TG 104 Vapour Pressure (2006)EC Council Regulation No 440/2008 A.4 Vapour Pressure |
| Remarks | Differential Scanning Calorimetry (DSC) method. Vapour pressure measured using the Knudsen cell effusion method at 60 to 140 °C. The vapour pressure of the test item at 20 °C, 25 °C and 50 °C was extrapolated from a curve formed from the data obtained in this study. |
| Test Facility | consilab (2016c) |

**Water Solubility** $1.22 \times 10^{-3}$ g/L at 20 °C

| | |
|---|---|
| Method | OECD TG 105 Water Solubility<br>EC Council Regulation No 440/2008 A.6 Water Solubility |
| Remarks | Column Elution Method |
| Test Facility | consilab (2016d) |

**Partition Coefficient (n-octanol/water)** Component 1 (4%): log $P_{ow}$ = 2.1 at 25 °C<br>Component 2 (1%): log $P_{ow}$ = 3.6 at 25 °C<br>Component 3 (29%): log $P_{ow}$ = 4.3 at 25 °C<br>Component 4 (64%): log $P_{ow}$ = 6.2 at 25 °C

| | |
|---|---|
| Method | OECD TG 117 Partition Coefficient (n-octanol/water).<br>EC Council Regulation No 440/2008 A.8 Partition Coefficient. |
| Remarks | HPLC Method was used. The test substance (notified polymer) is surface active. |
| Test Facility | consilab (2016e) |

**Surface Tension** 51.6 mN/m

| | |
|---|---|
| Method | OECD TG 115 Surface Tension of Aqueous Solutions (1995)<br>EC Council Regulation No 440/2008 A.5 Surface Tension |
| Remarks | Ring method (Du Noüy-ring) was used. Concentration: 1 g/L saturated solution.<br>Based on the result of this study, the test item is to be regarded as surface active. |
| Test Facility | consilab (2017a) |

**Adsorption/Desorption** log $K_{oc}$ = 0.958 – 4.71

| | |
|---|---|
| Method | OECD TG 121 Adsorption - Desorption Using HPLC Method.<br>EC Council Regulation No 440/2008 C.19 Adsorption - Desorption Using HPLC Method |
| Remarks | The test substance (notified polymer) is surface active. |
| Test Facility | EAG laboratories (2017a) |

**Thermal Stability** - 490 J/g

| | |
|---|---|
| Method | OECD TG 113 Screening Test for Thermal Stability (1981) |
| Remarks | Thermal stability measured using differential scanning calorimetry (determined as exothermal decomposition energy) in a closed glass crucible under nitrogen heated up to at least 500 °C. |
| Test Facility | consilab (2016a) |

**Flash Point** > 300 °C at 100.8 kPa

| | |
|---|---|
| Method | EC Council Regulation No 440/2008 A.9 Flash Point |
| Remarks | Closed cup method used. Result was based on preliminary findings. As no flash point was observed during the preliminary test, the main test was not performed. |
| Test Facility | consilab (2016f) |

**Autoignition Temperature** 440 °C

| | |
|---|---|
| Method | EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases)<br>DIN 51794: Determination of Ignition Temperature (2003) |
| Remarks | A preliminary test was conducted to determine the lowest auto-ignition temperature of the test item (453 °C). The main test was started at the lowest auto-ignition temperature determined from the preliminary test, then decreased in intervals of 3 – 4 K. |
| Test Facility | consilab (2017b) |

**Explosive Properties** Not explosive

| | |
|---|---|
| Method | EC Council Regulation No 440/2008 A.14 Explosive Properties. |
| Remarks | According to United Nations (2015), if the exothermal decomposition energy is < -500 J/g, further tests to investigate explosivity do not need to be performed. |
| Test Facility | consilab (2016a) |

# APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

## B.1. Acute toxicity – oral

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method (2001)<br>EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method (1996) |
| Species/Strain | Rat/HanBrl: WIST (SPF) |
| Vehicle | PEG300 |
| Remarks - Method | No significant protocol deviations |

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Mortality* |
|---|---|---|---|
| 1 | 3F | 2000 | 0/3 |
| 1 | 3F | 2000 | 0/3 |

| | |
|---|---|
| LD50 | > 2000 mg/kg bw |
| Signs of Toxicity | None |
| Effects in Organs | No abnormalities detected at post-mortem. |
| Remarks - Results | No mortality occurred. All animals made expected body weight gains during the study. |

| | |
|---|---|
| CONCLUSION | The notified polymer is of low acute toxicity via the oral route. |
| TEST FACILITY | RCC (2004a) |

## B.2. Acute toxicity – dermal

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 402 Acute Dermal Toxicity – Limit Test (1987)<br>EC Council Regulation No 440/2008 B.3 Acute Toxicity (Dermal) – Limit Test (2008) |
| Species/Strain | Rat/Wistar (Crl:WI) |
| Vehicle | None |
| Type of dressing | Occlusive |
| Remarks - Method | A preliminary study was conducted prior to the main study. No deaths were observed in the preliminary study at 50, 200, 1000 and 2000 mg/kg bw. Based on this result, 2000 mg/kg bw was the dose for the main study. |

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Mortality* |
|---|---|---|---|
| 1 | 5M | 2000 | 0/5 |
| 2 | 5F | 2000 | 0/5 |

| | |
|---|---|
| LD50 | > 2000 mg/kg bw |
| Signs of Toxicity - Local | 6/10 animals displayed very slight to well defined erythema on the treatment site from day 1 to day 2 following 24 hour exposure to the test substance. No oedema was noted. |
| Signs of Toxicity - Systemic | None observed during the study. |
| Effects in Organs | During post-mortem examination, one female displayed moderate hydrometra and another female displayed severe hydrometra. The authors of this study note that these findings are physiological (not pathological) |

| | |
|---|---|
| | and relate to the cycle of the animal. |
| Remarks - Results | No impairments in body weight development were observed during the study. |
| CONCLUSION | The notified polymer is of low acute toxicity via the dermal route. |
| TEST FACILITY | Toxi-Coop (2016a) |

**B.3. Irritation – skin**

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 404 Acute Dermal Irritation/Corrosion (2002)<br>EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation) (1992) |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 |
| Vehicle | None |
| Observation Period | 10 days |
| Type of Dressing | Semi-occlusive |
| Remarks - Method | No significant protocol deviations |

RESULTS

| *Lesion* | *Mean Score* Animal No.* | | | *Maximum Value* | *Maximum Duration of Any Effect* | *Maximum Value at End of Observation Period* |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | | | |
| *Erythema/Eschar* | 1.67 | 1.67 | 1.67 | 2 | < 10 days | 0 |
| *Oedema* | 0 | 0 | 0 | 0 | - | 0 |

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal

| | |
|---|---|
| Remarks - Results | Well defined erythema was observed in all animals at 24 and 48 hours after treatment. This had reduced to very slight erythema by 72 hours after treatment, which persisted in one animal for up to 7 days after treatment. The authors of this study note that remnants of the test item were stuck onto the treatment site of all animals for up to 48 hours after treatment, despite cleaning of the application site immediately after treatment. |
| CONCLUSION | The notified polymer is slightly irritating to the skin. |
| TEST FACILITY | RCC (2004b) |

**B.4. Irritation – eye (*in vitro*)**

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 438 Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage (2013)<br>EC Council Regulation No 440/2008 B.48 Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants (2010) |
| Vehicle | None |
| Remarks - Method | No significant protocol deviations. Sodium chloride (9g/L saline) was used as a negative control and acetic acid (10%) was used as a positive control in the study. |

RESULTS

| *Test material* | *Mean max. corneal swelling up to 75 min post treatment (%)* | *Mean max. corneal swelling up to 240 min post treatment (%)* | *Mean corneal opacity* | *Mean fluorescein retention* | *Overall ICE Class* |
|---|---|---|---|---|---|
| *Negative control* | 3 | 3 | 0.5 | 0.0 | 3 × I |
| *Test substance* | 2 | 4 | 0.3 | 0.0 | 3 × I |
| *Positive control* | 23 | 27 | 4.0 | 0.3 | 1 × I<br>1× III<br>1 × IV |

ICE class = Isolated chicken eye class

| | |
|---|---|
| Remarks - Results | No additional effects were observed during the study. Positive and negative controls performed as expected, demonstrating the validity of the study. Based on the results of this study, the test item did not cause ocular corrosion or severe irritation in chicken eyes under an *in vitro* setting. The overall ICE score for the test item was 3 × I. As such, the test item is categorised as "no category" i.e. does not require GHS classification for eye irritation or serious eye damage |
| CONCLUSION | The notified polymer was considered to be non-irritating to the eye under the conditions of the test. |
| TEST FACILITY | Toxi-Coop (2016b). |

**B.5. Skin sensitisation – mouse local lymph node assay (LLNA)**

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 429 Skin Sensitisation: Local Lymph Node Assay (2010)<br>EC Council Regulation No 440/2008 B.42 Skin Sensitisation: Local Lymph Node Assay (2012) |
| Species/Strain | Mouse/CBA (Ca Ola Hsd) |
| Vehicle | Dimethylformamide |
| Preliminary study | Yes |
| Positive control | 25% α-Hexylcinnamaldehyde in acetone: olive oil mixture (4:1) |
| Remarks - Method | No deviation from the guideline was noted. A dose range finding test using the test substance at 25, 50 and 75% concentration was conducted to determine dose concentrations for the main study. Based on these results, 75% concentration was chosen as the high dose for the main study as it was expected not to induce any systemic toxic effects, 25% or more increase in ear thickness or moderate to severe erythema. |

RESULTS

| *Concentration (% w/w)* | *Number and sex of animals* | *Proliferative response (DPM/lymph node)* | *Stimulation Index (Test/Control Ratio)* |
|---|---|---|---|
| *Test Substance* | | | |
| 0 (vehicle control) | 4F | 499.1 | 1.0 |
| 10 | 4F | 1002.9 | 2.0 |
| 25 | 4F | 1069.1 | 2.1 |
| 50 | 4F | 2479.9 | 5.0 |
| 75 | 4F | 3061.6 | 6.1 |
| *Positive Control* | | | |
| 0 (vehicle control) | 4F | 804.4 | 1 |
| 25 | 4F | 10966.4 | 13.6 |

| | |
|---|---|
| EC3 | 32.8% |
| Remarks - Results | No mortalities and no signs of systemic toxicity were noted in the test or |

control animals during the study. No signs of irritation or any other local effect were observed in all animals. Positive and negative (vehicle) controls performed as expected, confirming the validity of the study.

The results demonstrate a significant dose response relationship ($p = 0.03$) between the test substance and measured proliferative response. As the test substance at 50% and 75% concentration elicited a simulation index > 3, an EC3 value could be derived. The EC3 value of the test substance is 32.8% and therefore categorised as a Category 1B skin sensitiser (EC3 > 2%).

CONCLUSION There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.

TEST FACILITY Toxi-Coop (2017a)

**B.6. Repeat dose toxicity**

TEST SUBSTANCE Notified polymer

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents (2008)
EC Council Regulation No 440/2008 B.7 Repeated Dose (28 Days) Toxicity (Oral) (2008)

| | |
|---|---|
| Species/Strain | Rat/Wistar (HanHsd) |
| Route of Administration | Oral – gavage |
| Exposure Information | Total exposure days: 28 days<br>Dose regimen: 7 days per week<br>Post-exposure observation period: 14 days |
| Vehicle | PEG 400 |
| Remarks - Method | No significant protocol deviations |

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw/day* | *Mortality* |
|---|---|---|---|
| control | 5M/5F | 0 | 0/10 |
| low dose | 5M/5F | 100 | 0/10 |
| mid dose | 5M/5F | 300 | 0/10 |
| high dose | 5M/5F | 1000 | 0/10 |
| control recovery | 5M/5F | 0 | 0/10 |
| high dose recovery | 5M/5F | 1000 | 0/10 |

*Mortality and Time to Death*
All animals survived the scheduled treatment or recovery periods.

*Clinical Observations*
Sensory reactivity, grip strength and motor activity were very similar in all treated groups compared with control animals.

Food consumption of treated animals was comparable to control animals. However, the mean body weight gain of females treated at 100 mg/kg bw/day was statistically significantly higher than control animals on week 2 of treatment. This lead to the mean body weights for these females being statistically significantly higher than controls on Days 21 and 27 of treatment. Male animals treated with 1000 mg/kg bw/day also displayed statistically significant changes in clinical observations throughout the study. As the significant effects seen in females were not observed at higher doses and the significant effects seen in males were minor (< 7% compared to controls), the authors of the study deemed these effects not to be of toxicological significance.

*Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis*

Haematology

At 300 mg/kg bw/day, males had a statistically significant higher white blood cell count and mean percentage of neutrophil granulocytes than controls. The mean percentages of lymphocytes and eosinophil granulocytes in these males were statistically significantly lower than controls. Females treated at 300 mg/kg bw/day showed a statistically significant increase in the mean percentage of monocytes. Males and females treated at 1000 mg/kg bw/day displayed numerous statistically significant haematological differences.

All statistically significant differences noted in the study were reported to be within historical control ranges and therefore not considered by the authors of this study to be toxicologically relevant.

Clinical Biochemistry

At 100 mg/kg bw/day, males had a lower mean cholesterol concentration and higher mean albumin: globulin ratio both statistically significant. Females treated at this dose displayed a statistically significant increase in mean potassium concentration.

At 300 mg/kg bw/day the following changes were reported with statistical significance: higher albumin: globulin ratio and mean aspartate aminotransferase activity, and lower mean concentrations of inorganic phosphorus, calcium and potassium in males; lower mean cholesterol concentration in females.

Males and females treated with 1000 mg/kg bw/day displayed many statistically significant changes in clinical biochemical parameters, including a statistically significant decrease in mean cholesterol concentration.

All statistically significant differences in clinical biochemistry parameters, except for those seen with cholesterol, were within historical values. Decreases in mean cholesterol concentrations showed no dose-response and study authors considered this to be of no biological relevance because no degenerative or necrotic changes associated with cholesterol loss were seen at necropsy.

*Effects in Organs*

Female controls presented slight hydrometra (1/5 animals) and female recovery controls displayed slight (2/5 animals) to moderate (2/5 animals) hydrometra.

At 100 mg/kg/ bw/day, one female animal displayed moderate hydrometra and another female displayed pale liver and moderate hydrometra. These females treated at this dose also had statistically significant lower mean brain weight, higher mean kidneys weight and statistically significant higher mean body weight, liver weight and kidneys weight relative to brain weight.

At 300 mg/kg bw/day, 4 out of 5 males presented with yellowish-grey epididymal foci and statistically significant higher brain, heart, seminal vesicles and adrenal gland weights. These males also displayed statistically significant higher epididymes weight (relative to body and brain weight) and focal dilation of the epididymal tubules (4/5 males). At this dose, one female displayed slight hydrometra whilst another female presented with slight hydrometra and pale liver. Females treated at 300 mg/kg bw/day also had significantly lower mean brain weight (relative to body weight), higher mean body weight (relative to brain weight) and minimal hepatic lipidosis.

All males treated with 1000 mg/kg bw/day presented with abnormalities in organs such as the liver, epididymal foci, testes, seminal vesicles and prostate. All abnormalities, excluding those in the liver, were present after the recovery period. These males also displayed statistically significant differences in brain, testes, heart, epididymes, seminal vesicles and adrenal glands weights. Females treated with 1000 mg/kg bw/day presented with abnormalities the liver and uterus, which were reversible after the recovery period.

The hydrometra observed throughout the treatment and recovery periods was deemed by the study authors as related to the normal female sexual cycle rather than the test item.

Remarks – Results

Test substance-related adverse effects observed at 1000 mg/kg bw/day included lower mean cholesterol concentrations, pale and nutmeg-like patterned liver, hepatic lipidosis, small testes, epididymes, seminal vesicle and prostate, yellowish-grey epididymal foci, reduced weights of testes, epididymes and seminal vesicle, decreased spermatogenesis, lack of spermatozoa, focal dilation of epididymal tubules and decreased amount of secretum in the seminal vesicle and prostate. Adverse effects in the testes and epididymes (including effects on

spermatozoa and spermatogenesis), persisted throughout the recovery period.

Test substance-related adverse effects observed at 300 mg/kg bw/day included statistically significant decreased mean cholesterol concentrations, pale liver and hepatic lipidosis in females, and yellowish-grey epididymal foci and focal dilation of epididymal tubules in males. Treatment-related effects at 100 mg/kg bw/day included statistically significant decreased cholesterol levels in males; however, there were no degenerative effects related to this.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 100 mg/kg bw/day by the study authors, based on effects in the liver and male reproductive organs observed at 300 mg/kg bw/day.

TEST FACILITY Toxi-Coop (2017b)

### B.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified polymer

METHOD OECD TG 471 Bacterial Reverse Mutation Test (1997)
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria (2000)
Plate incorporation procedure (preliminary test) and Pre incubation procedure (main test)

| | |
|---|---|
| Species/Strain | *S. typhimurium*: TA1535, TA1537, TA98, TA100<br>*E. coli*: WP2uvrA |
| Metabolic Activation System | S9 fraction from phenobarbital/β-napthoflavone induced rat liver. |
| Concentration Range in Main Test | a) With metabolic activation: 3 – 5000 µg/plate (preliminary test)<br>33 – 5000 µg/plate (main test)<br>b) Without metabolic activation: 3 – 5000 µg/plate (preliminary test)<br>33 – 5000 µg/plate (main test) |
| Vehicle | THF (> 99% purity) |
| Remarks - Method | Final concentration of S9 mix was reduced from 15% to 10% to align with revised SOP. A preliminary experiment was conducted to determine the dose range for the main test. |

RESULTS

| *Metabolic Activation* | *Test Substance Concentration (µg/plate) Resulting in:* | | | | | |
|---|---|---|---|---|---|---|
| | *Cytotoxicity in Prelim. Test* | *Cytotoxicity in Main Test* | *Precipitation in Prelim. Test* | *Precipitation in Main Test* | *Genotoxic Effect in Prelim. Test* | *Genotoxic Effect in Main Test* |
| *Absent* | | | | | | |
| Test 1 | > 5000 | - | > 5000 | - | Negative | - |
| Test 2 | - | ≥ 1000 | - | ≥ 2500 | - | Negative |
| *Present* | | | | | | |
| Test 1 | > 5000 | - | ≥ 2500 | - | Negative | - |
| Test 2 | - | > 5000 | - | ≥ 1000 | - | Negative |

Remarks - Results The preliminary test was considered by the study authors as a main test since no relevant toxic effects were observed. No substantial increase in revertant colony numbers of any of the five tester strains was observed following treatment with the test substance at any dose level, in the presence or absence of metabolic activation. Positive controls performed as expected, confirming the validity of the test system.

CONCLUSION The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY RCC-CCR (2006a)

### B.8. Genotoxicity – *in vitro* mammalian chromosome aberration

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test (1997)<br>EC Directive 2000/32/EC B.10 Mutagenicity - *In vitro* Mammalian Chromosome Aberration Test (2000) |
| Species/Strain | Chinese hamster |
| Cell Type/Cell Line | Lung/V79 |
| Metabolic Activation System | S9 fraction from phenobarbital/β-napthoflavone induced rat liver. |
| Vehicle | THF (> 99% purity) |
| Remarks - Method | No significant protocol deviations. A preliminary experiment was conducted to determine the dose range for the main test. |

| *Metabolic Activation* | *Test Substance Concentration (µg/mL)* | *Exposure Period* | *Harvest Time* |
|---|---|---|---|
| *Absent* | | | |
| Test 1 | 0, 2.4, 4.9, 9.8*, 19.5*, 39.1*, 78.1, 156.3 | 4 h | 18 h |
| Test 2 | - | - | - |
| *Present* | | | |
| Test 1 | 0, 9.8, 19.5, 39.1*, 78.1*, 156.3*, 312.5*, 625.0 | 4 h | 18 h |
| Test 2 | - | - | - |

*Cultures selected for metaphase analysis.

RESULTS

| *Metabolic Activation* | *Test Substance Concentration (µg/mL) Resulting in:* | | | |
|---|---|---|---|---|
| | *Cytotoxicity in Preliminary Test* | *Cytotoxicity in Main Test* | *Precipitation* | *Genotoxic Effect* |
| *Absent* | | | | |
| Test 1 (4h exposure) | ≥ 78.1 | ≥ 78.1 | ≥ 19.5 | Negative |
| Test 2 (24 h exposure) | ≥ 39.1 | - | - | - |
| *Present* | | | | |
| Test 1 (4h exposure) | ≥ 312.5 | ≥ 312.5 | ≥ 78.1 | Negative |
| Test 2 | - | - | - | - |

Remarks - Results

In the presence and absence of metabolic activation, there were no biologically relevant increases in polyploid or endomitotic cells after treatment with the test item.

In the absence of metabolic activation, there was no biologically relevant increase in cells carrying structural chromosome aberrations. In the presence of metabolic activation, a statistically significant increase in cells carrying structural chromosome aberrations was observed at the highest evaluated test substance concentration (i.e. 312.5 µg/mL). However given the high cytotoxicity (63%) at this concentration and negative results at lower less cytotoxic concentrations, the response is not considered a positive result.

The positive controls performed as expected, confirming the validity of the test system.

CONCLUSION

The notified polymer was not clastogenic to Chinese hamster lung cells treated *in vitro* under the conditions of the test.

TEST FACILITY

RCC-CCR (2006b)

### B.9. Genotoxicity – *in vitro* mammalian cell gene mutation

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 476 *In vitro* Mammalian Cell Gene Mutation Test (1998)<br>EC Directive 2000/32/EC B.17 Mutagenicity - *In vitro* Mammalian Cell Gene Mutation Test (2000) |
| Species/Strain | Mouse |
| Cell Type/Cell Line | Lymphoma/L5178Y $TK^{(+/-)}$ |
| Metabolic Activation System | S9 fraction from phenobarbital/β-napthoflavone induced rat liver. |
| Vehicle | THF (> 99% purity) |
| Remarks - Method | No deviations from the study plan were noted. The mouse lymphoma cells were tested with the test substance for potential to induce mutations at the thymidine kinase (TK) locus. Preliminary experiments were conducted to determine the dose range for the main study. Each test consisted of two cultures run in duplicate. |

| *Metabolic Activation* | *Test Substance Concentration (µg/mL)* | *Exposure Period* | *Expression Time* | *Selection Time* |
|---|---|---|---|---|
| *Absent* | | | | |
| Test 1 | 5*, 10*, 20*, 40*, 60, 80* | 4 h | 48 h | 10 – 15 days |
| Test 2 | 5, 10*, 20*, 40*, 60*, 80* | 24 h | 72 h | 10 – 15 days |
| *Present* | | | | |
| Test 1 | 10, 20*, 40*, 60, 80*, 160*, 320* | 4 h | 48 h | 10 – 15 days |
| Test 2 | 20, 40*, 80*, 160*, 240*, 320* | 4 h | 48 h | 10 – 15 days |
| Test 3 | 240*, 320*, 360*, 400*, 440* | 4 h | 48 h | 10 – 15 days |

*Cultures selected for metaphase analysis.

| *Metabolic Activation* | *Test Substance Concentration (µg/mL) Resulting in:* | | | |
|---|---|---|---|---|
| | *Cytotoxicity in Preliminary Test* | *Cytotoxicity in Main Test* | *Precipitation* | *Genotoxic Effect* |
| *Absent* | | | | |
| Test 1 | ≥ 39.1 | > 80.0 | ≥ 40 | Negative |
| Test 2 | ≥ 78.1 | ≥ 80.0 | ≥ 60 | Negative |
| *Present* | | | | |
| Test 1 | ≥ 312.5 | ≥ 320.0 | > 320 | Negative |
| Test 2 | - | > 320.0 | > 320 | Negative |
| Test 3 | - | ≥ 240.0 | ≥ 320 | Negative |

| | |
|---|---|
| Remarks - Results | In Tests 1 and 3 with metabolic activation and Test 2 with and without metabolic activation, the test substance induced statistically significant dose-dependent increases in mutant frequency within some cultures. However, all mutation frequencies (with the exception of one isolated reading) remained within historical negative and solvent control values. As such, the authors of this study do not consider these significant dose-dependent increases of biological relevance with respect to the test substance. |
| CONCLUSION | The notified polymer was not clastogenic to the TK locus in the L5178 $TK^{(+/-)}$ mouse lymphoma cells treated *in vitro* under the conditions of the test. |
| TEST FACILITY | RCC-CCR (2006c) |

# APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

## C.1. Environmental Fate

### C.1.1. Ready biodegradability

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 301 B Ready Biodegradability: CO2 Evolution Test<br>EC Directive 92/69/EEC C.4-C Ready Biodegradability |
| Inoculum | Activated sludge from a local STP |
| Exposure Period | 28 days |
| Auxiliary Solvent | None |
| Analytical Monitoring | $CO_2$ using a Shimadzum TOC-VCSH carbon analyzer. |
| Remarks - Method | No significant deviation from the test guidelines was reported. The test substance (0.04769 g) was directly added into 3L culture chambers before dilution water was added to achieve a nominal concentration of 10 mgC/L. A toxicity control was run. |

RESULTS

| *Test substance* | | *Sodium Benzoate* | |
|---|---|---|---|
| *Day* | *% Degradation* | *Day* | *% Degradation* |
| 28 | - 5 | 28 | 86 |

| | |
|---|---|
| Remarks - Results | All validity criteria for the test were satisfied. The percentage degradation of the reference compound, sodium benzoate surpassed the threshold level of 60% within 14 days indicating the suitability of the inoculums. The toxicity control exceeded 25% biodegradation after 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The notified polymer did not degrade over 28 days. |
| CONCLUSION | The notified polymer is not readily degradable. |
| TEST FACILITY | EAG laboratories (2017b) |

## C.2. Ecotoxicological Investigations

### C.2.1. Acute toxicity to fish

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 203 Fish, Acute Toxicity Test – Static Renewal<br>U.S. EPA OCSPP 850.1075 Acute Toxicity for Fish – Static Renewal<br>ASTMA Standard E 729-96: Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertabrates and Amphibians. |
| Species | *Pimephales promelas* |
| Exposure Period | 96 hours |
| Auxiliary Solvent | Dimethylformamide (DMF) |
| Water Hardness | 144 mg $CaCO_3$/L |
| Analytical Monitoring | Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) |
| Remarks – Method | No significant deviations from the test guidelines were reported. A primary stock concentration of 20 mg/mL of the test substance was prepared in DMF with no visible particulates. The secondary stocks at nominal test concentrations were prepared by diluting the clear primary stock solution with dilution water. The test solution was renewed daily. The test concentrations were measured at the beginning of the test, prior to renewal, after renewal and at the end of the test. The mean concentration of these measurements is presented in the table below. The highest test |

concentration of 1.9 mg/L is higher than the test substance's water solubility limit.

RESULTS

| *Concentration mg/L* | | *Number of Fish* | *Mortality* | | | |
|---|---|---|---|---|---|---|
| *Nominal* | *Mean Measured* | | *24 h* | *48 h* | *72 h* | *96 h* |
| Negative Control | < LOQ[a] | 10 | 0 | 0 | 0 | 0 |
| Solvent Control | < LOQ[a] | 10 | 0 | 0 | 0 | 0 |
| 0.13 | 0.10 | 10 | 0 | 0 | 0 | 0 |
| 0.25 | 0.20 | 10 | 0 | 0 | 0 | 0 |
| 0.50 | 0.44 | 10 | 0 | 0 | 0 | 0 |
| 1.0 | 0.85 | 10 | 0 | 0 | 0 | 0 |
| 2.0 | 1.9 | 10 | 0 | 0 | 0 | 0 |

[a]LOQ: Limit of Quantitation of 0.080 mg/L

| | |
|---|---|
| LC50 | > 1.9 mg/L at 96 hours |
| Remarks – Results | All validity criteria for the test were satisfied. |

CONCLUSION The notified polymer is not harmful to fish up to its water solubility limit.

TEST FACILITY EAG laboratories (2017c)

**C.2.2. Acute toxicity to aquatic invertebrates**

TEST SUBSTANCE Notified polymer

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static Renewal
U.S. EPA OCSPP 850.1010 Acute Toxicity for Daphnia – Static Renewal
ASTMA Standard E 729-96: Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertabrates and Amphibians.

| | |
|---|---|
| Species | *Daphnia magna* |
| Exposure Period | 48 hours |
| Auxiliary Solvent | Dimethylformamide (DMF) |
| Water Hardness | 156 mg $CaCO_3$/L |
| Analytical Monitoring | Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) |
| Remarks - Method | No significant deviations from the test guidelines were reported. A primary stock concentration of 20 mg/mL of the test substance was prepared in DMF with no visible particulates. The secondary stocks at nominal test concentrations were prepared by diluting the clear primary stock solution with dilution water. The test solution was renewed daily. The test concentrations were measured at the beginning of the test, prior to renewal, after renewal and at the end of the test. The mean concentration of these measurements is presented in the table below. The highest test concentration of 2.1 mg/L is higher than the test substance's water solubility limit. |

RESULTS

| *Concentration mg/L* | | *Number of D. magna* | *Number Immobilised* | |
|---|---|---|---|---|
| *Nominal* | *Mean Measured* | | *24 h* | *48 h* |
| Negative Control | < LOQ[a] | 20 | 0 | 0 |
| Solvent Control | < LOQ[a] | 20 | 0 | 0 |
| 0.13 | 0.13 | 20 | 0 | 0 |
| 0.25 | 0.25 | 20 | 0 | 0 |
| 0.50 | 0.50 | 20 | 0 | 0 |
| 1.0 | 1.0 | 20 | 0 | 0 |
| 2.0 | 2.1 | 20 | 0 | 0 |

LOQ[a]: Limit of Quantitation of 0.080 mg/L

| | |
|---|---|
| LC50 | > 2.1 mg/L at 48 hours |
| Remarks - Results | All validity criteria for the test were satisfied. |

CONCLUSION The notified polymer is not harmful to aquatic invertebrates up to its water solubility limit.

TEST FACILITY EAG laboratories (2017d)

**C.2.3. Algal growth inhibition test**

TEST SUBSTANCE Notified polymer

METHOD OECD TG 201 Alga, Growth Inhibition Test
EC Council Regulation No 440/2008 C.3 Algal Inhibition Test
U.S. EPA OCSPP 850.4500 Algal Inhibition Test

| | |
|---|---|
| Species | *Raphlidocelis subcapitata* |
| Exposure Period | 96 hours |
| Concentration Range | Nominal: 0.13, 0.25, 0.50, 1.0, 2.0 mg/L<br>Actual: 0.081, 0.17, 0.40, 0.78, 1.9 mg/L |
| Auxiliary Solvent | Dimethylformamide (DMF) |
| Water Hardness | Not determined |
| Analytical Monitoring | Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) |
| Remarks - Method | No significant deviations from the test guidelines were reported. A primary stock concentration of 20 mg/mL of the test substance was prepared in DMF with no visible particulates. The secondary stocks at nominal test concentrations were prepared by diluting the clear primary stock solution with dilution water. The concentration of the notified polymer was determined at study initiation (0 h) and termination (96 h). The highest test concentration of 1.9 mg/L, based on the mean measured concentration is higher than the test substance's water solubility limit. |

RESULTS

| *Biomass* | | *Growth* | |
|---|---|---|---|
| *EC50*<br>*mg/L at 96 h* | *NOEC*<br>*mg/L* | *EC50*<br>*mg/L at 96 h* | *NOEC*<br>*mg/L* |
| > 1.9 | > 1.9 | > 1.9 | > 1.9 |

Remarks - Results All validity criteria for the test were satisfied.

CONCLUSION The notified polymer is not harmful to alga up to its water solubility limit.

TEST FACILITY EAG laboratories (2017e)

**C.2.4. Inhibition of microbial activity**

TEST SUBSTANCE Notified polymer

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test

| | |
|---|---|
| Inoculum | Activated sludge from a local STP |
| Exposure Period | 3 hours |
| Concentration Range | Nominal: 10, 100, 1,000 mg/L |
| Remarks – Method | No significant deviations from the test guidelines were reported. The test substance was added directly to the test chambers. The test concentrations are above the test substance's water solubility. |

RESULTS

| | |
|---|---|
| IC50 | > 1,000 mg/L |

| | |
|---|---|
| Remarks – Results | All validity criteria for the test were satisfied. |
| CONCLUSION | The notified polymer does not inhibit microbial activity at STPs |
| TEST FACILITY | EAG laboratories (2017f) |

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