File No: STD/1650

June 2018

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

GENOPOL BP-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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

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/1650	Cintox Australia Pty Ltd	GENOPOL BP-2	Yes	< 50 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 indirect 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 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) – 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 chemical present.

Health Surveillance

- As the notified 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 during reformulation:
  - 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 to the notified polymer during reformulation and use:
  - 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 during reformulation and use:
  - 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.

Storage

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

Emergency procedures

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

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;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a 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
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, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details 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(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME
GENOPOL BP-2

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) is < 1,000 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: Brown, pasty liquid

Property	Value	Data Source/Justification
Softening Point	-21.4 °C	Measured
Boiling Point	380 - 406 °C at 101.3 kPa	Measured
Density	1,200 kg/m^3 at 20 °C	Measured
Vapour Pressure	3.0×10^{-7} kPa at 20 °C 4.3×10^{-7} kPa at 25 °C 2.0×10^{-6} kPa at 50 °C	Measured
Water Solubility	< 4.1 x 10^{-4} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities but hydrolysis is not expected in environmental conditions due to very low solubility in water.
Partition Coefficient (n-octanol/water)	Polymer component 1: log P_{ow} = 2.4 at 20 °C	Measured

	Polymer component 2: log P_{ow} = 4.2 at 20 °C Polymer component 3: log P_{ow} = 5.9 at 20 °C	
Surface Tension	53.7 mN/m at 20 °C	Measured
Adsorption/Desorption	log K_{oc} = 2.58 - > 5.63 at 40 °C	Measured
Dissociation Constant	Not determined	No dissociable functionality
Thermal Stability	-290 J/g	Measured
Flash Point	242 °C at 101.3 kPa	Measured
Flammability	Not determined	Estimated. Predicted to be low based on high flash point
Autoignition Temperature	435 °C	Measured
Explosive Properties	Not explosive	Expert statement
Oxidising Properties	Not determined	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 CHEMICAL (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 (> 99% purity) as a pasty liquid.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 50	< 50	< 50	< 50	< 50

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The neat notified polymer will be imported in 200 L steel drums and will be transported by road from the port wharf to the notifier's warehouse and 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 metal 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

Reformulation
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 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 notified polymer at ≤ 100% concentration may occur during manually weighing, charging the blending vessels, sampling, quality control analysis 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. As stated by the notifier, exposure of workers to the notified polymer will be further reduced by the use of personal protective equipment (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 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 coating/ink matrix and will not be available for exposure.

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/ink is dried and cured, the notified polymer will be bound within the ink/coating 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*
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
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	evidence of sensitisation (EC3 = 64.3%)
Rat, repeat dose oral toxicity – 28 days.	NOAEL: 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vivo* mouse micronucleus test	non genotoxic

Toxicokinetics
Based on the low water solubility and high lipophilicity of the notified polymer, dermal absorption 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 studies conducted in rabbits, the notified polymer is slightly irritating to the skin and eyes.

In the skin irritation study, very slight erythema was noted in all animals at 24 hours after treatment and in 2/3 animals at 48 hours after treatment. All signs of irritation were resolved by the 72 hour time point. No oedema was noted during the study.

In the eye irritation study, very slight conjunctival irritation was noted up to 24 hours after treatment. By the 48 hour time point, all treated eyes appeared normal. No corneal or iridial effects were noted. However, corneal fluorescein retention indicative of corneal damage occurred across approximately 25% of the corneal area in 2 out of 3 treated eyes at the 24 hour observation, but not thereafter.

In a mouse local lymph node assay (LLNA), the notified polymer was determined to be a weak skin sensitiser with an estimated concentration required to produce a 3-fold increase in lymph node cell stimulation (EC3) of 64.3%.

Repeated dose toxicity
In a 28-day repeated dose oral (gavage) toxicity study with a 14 day recovery period, rats were treated with the notified polymer at 0, 100, 300 or 1000 mg/kg bw/day. Slightly elevated liver and kidney weights in male animals were noted in all dose groups; however, this was not considered by the study authors to be toxicologically relevant as there were no related clinical chemistry or histopathological findings.

The No Observed Adverse Effect Level (NOAEL) for the notified polymer was established as 1,000 mg/kg bw/day by the study authors, based on no treatment-related adverse effects at all dose levels.

Mutagenicity/Genotoxicity
The notified polymer tested negative in a bacterial reverse mutation assay and in an *in vivo* erythrocyte micronucleus assay in mice.

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 toxicological information provided, the notified polymer is a skin sensitiser and a slight eye and skin irritant.

Reformulation

During reformulation, workers may be at risk of skin sensitisation and slight skin and eye irritation effects when handling the notified polymer as introduced. 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, impervious gloves and eye protection) will also be used to limit worker exposure.

End-Use

Printing and coating workers may be at risk of skin 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, impervious 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 available for exposure.

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 available for exposure.

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 any 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 and coatings. 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 and coating 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 reused to the extent practicable or 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 be disposed of through an approved waste management facility.

RELEASE OF CHEMICAL FROM USE

The finished inks and coatings containing the notified polymer at ≤ 15% concentration will be applied to metal, paper or plastic substrates using standard 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 and the remaining polymer will be bound within the ink 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, which will either disposed of to landfill or enter recycling streams for substrate reclamation (namely metals or paper fibre). Residual notified polymer in empty end-use containers is expected to be cured into an inert solid matrix and be disposed of to landfill along with the empty containers.

7.1.2. Environmental Fate

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. 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, 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.

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. Additionally the amount of notified polymer reacted during ink curing or released from paper recycling has not been provided. Therefore for the worst case scenario 100% release from paper will be assumed. According to APC (2015) 60% of paper is recycled, leading to potential release to sewers. 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 or coatings is unknown, it is assumed that 100% is available for release.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	50,000	kg/year
Proportion expected to be released to sewer	60	%
Annual quantity of chemical released to sewer	30,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	115.38	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:	23.66	µg/L
PEC - Ocean:	2.37	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 23.65 µg/L may potentially result in a soil concentration of approximately 0.15 mg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 0.78 mg/kg and 1.57 mg/kg, respectively.

7.2. Environmental Effects Assessment

The results from the ecotoxicological investigation 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	96 h LC50 > 7.1 mg/L	Not harmful to fish up to its water solubility limit
Daphnia Toxicity	48 h EC50 > 1.9 mg/L	Not harmful to aquatic invertebrates up to its water solubility limit
Algal Toxicity	96 h EC50 > 1.9 mg/L	Not harmful to alga up to its water solubility limit
Inhibition of Bacterial Respiration	3 h EC50 > 1,000 mg/L	Not expected to inhibit bacterial respiration

Based on the above ecotoxicological data 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 toxicity (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 -21.4 °C

Method	OECD TG 102 Melting Point/Melting Range (1995) 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 the phase transformation of the test item is regarded as softening, rather than melting.
Test Facility	consilab (2017a)

Boiling Point 380 - 406 °C at 101.3 kPa

Method	OECD TG 103 Boiling Point (1995) EC Council Regulation No 440/2008 A.2 Boiling Temperature
Remarks	Boiling point measured using differential scanning calorimetry.
Test Facility	consilab (2017a)

Density 1,200 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids (1995) EC Council Regulation No 440/2008 A.3 Relative Density
Remarks	Gas comparison pycnometer method used at 20 °C.
Test Facility	consilab (2017b)

Vapour Pressure 3.0×10^{-7} kPa at 20 °C
4.3×10^{-7} kPa at 25 °C
2.0×10^{-6} kPa at 50 °C

Method	OECD TG 104 Vapour Pressure (2006) EC Council Regulation No 440/2008 A.4 Vapour Pressure
Remarks	Vapour pressure measured via effusion (vapour pressure balance) method at 68 to 118 °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 (2017c)

Water Solubility $< 4.1 \times 10^{-4}$ g/L at 20 °C

Method	OECD TG 105 Water Solubility (1995) EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks	Column Elution Method
Test Facility	consilab (2017d)

Partition Coefficient (n-octanol/water) Component 1 (9%): log P_{ow} = 2.4 at 20 °C
Component 2 (42%): log P_{ow}= 4.2 at 20 °C
Component 3 (49%): log P_{ow}= 5.9 at 20 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water) High Performance Liquid Chromatography (HPLC) Method (2004) EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks	HPLC Method
Test Facility	consilab (2017e)

Surface Tension 53.7 mN/m at 20 °C

Method	OECD TG 115 Surface Tension of Aqueous Solutions (1995) EC Council Regulation No 440/2008 A.5 Surface Tension
Remarks	Concentration: 1 g/L saturated solution. Based on the result of this study, the test item is regarded as surface active.
Test Facility	consilab (2017f)

Adsorption/Desorption log K_{oc} = 2.58 - > 5.63 at 40°C

Method	OECD TG 121 – Estimation of the Adsorption Coefficient (K_{OC} on Soil and Sewerage Sludge using High Performance Liquid Chromatography (HPLC)) (2001)
Remarks	None
Test Facility	EAG (2017a)

Thermal Stability -290 J/g

Method	OECD TG 113 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 500 °C.
Test Facility	consilab (2017a)

Flash Point 242 °C at 101.3 kPa

Method	EC Council Regulation No 440/2008 A.9 Flash Point
Remarks	Closed cup method
Test Facility	consilab (2017h)

Autoignition Temperature 435 °C

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases)
Test Facility	consilab (2017i)

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 (2017a)

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) EC Directive 2004/73/EC B.1 tris Acute Oral Toxicity – Acute Toxic Class Method (2004)
Species/Strain	Rat/HanRcc:WIST (SPF)
Vehicle	PEG 300
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	3F	2000	0/3
2	3F	2000	0/3

LD50	> 2000 mg/kg bw
Signs of Toxicity	None.
Effects in Organs	All animals in the first group displayed a reduced stomach size and an empty jejunum and ileum. The colon and duodenum of all these animals were distended with gas.
Remarks - Results	No mortality occurred. One animal presented a slight decrease in body weight (1.8%) between test day 8 and 15 of the observation period. The remaining 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 (2006a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test (1987) 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	Semi-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 used 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	Very slight erythema was noted in one female on Day 1.
Signs of Toxicity - Systemic	None observed during the study.
Effects in Organs	No findings related to the test item were noted.
Remarks - Results	No impairment in body weight development was seen during the study.
CONCLUSION	The notified polymer is of low acute toxicity via the dermal route.

TEST FACILITY Toxi-Coop (2017a)

B.3. Irritation – skin

TEST SUBSTANCE Notified polymer

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion (2002)
EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation) (2004)

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None
Observation Period	7 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	0.67	0.33	0.67	1	< 3 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 Very slight erythema was noted in all animals at 24 hours after treatment and in 2/3 animals at 48 hours after treatment. All signs of irritation were resolved by the 72 hour time point.

CONCLUSION The notified polymer is slightly irritating to the skin.

TEST FACILITY RCC (2006b)

B.4. Irritation – eye

TEST SUBSTANCE Notified polymer

METHOD OECD TG 405 Acute Eye Irritation/Corrosion (2012)

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None
Observation Period	3 days
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			
Conjunctiva: redness	0	0.33	0	1	< 2 days	0
Conjunctiva: chemosis	0.33	0	0	1	< 2 days	0
Conjunctiva: discharge	0.33	0.33	0	1	< 2 days	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results Very slight conjunctival irritation was observed in all treated eyes up to the 24 hour observation. All signs of irritation were resolved at the 48 hour observation.

Fluorescein retention was observed in 2/3 animals at the 24 hour

observation only. The retention area accounted for less than a quarter of the cornea. Negative controls performed as expected.

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY Safety Evaluation Center (2018)

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)
EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay) (2012)

Species/Strain	Mouse/CBA (Ca Ola Hsd)
Vehicle	Dimethylformamide (DMF)
Preliminary study	Yes
Positive control	25% α-Hexylcinnamaldehyde in acetone:olive oil mixture (4:1).
Remarks - Method	No significant deviations from the study guideline were 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% was chosen as the high dose for the main study as it was not expected to induce any systemic toxicity, a 25% or more increase in ear thickness or moderate to severe erythema.

RESULTS

Concentration (% w/w)	*Number and sex of animals*	*Proliferative response (DPM/mouse)*	*Stimulation Index (Test/Control Ratio)*
Test Substance			
0 (vehicle control)	4F	281.9	1.0
10	4F	303.4	1.1
25	4F	304.4	1.1
50	4F	619.1	2.2
75	4F	1012.9	3.6
Positive Control			
0 (vehicle control)	4F	185.9	1.0
25	4F	3712.9	20.0

EC3	64.3%
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 were observed in any treatment group. Between days 2 – 6 of treatment, all animals treated at 75% concentration presented hair loss on the top of the head. A very similar result was noted in all animals treated at 75% concentration during the dose range finding test. This was considered by the study authors as a local effect with no contribution to the increased lymphoproliferation. The positive control performed as expected confirming the validity of the study.

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

TEST FACILITY Toxi-Coop (2017b)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents (2008) EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral) (2008)
Species/Strain	Rat/Wistar (Han Hsd)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	PEG 400
Remarks - Method	No significant protocol deviations. Dose levels were selected based on the results of a dose-range finding study performed previously (Toxi-Coop Study 673-400-2983).

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
No unscheduled mortality occurred during the study period.

Clinical Observations
No toxicologically relevant test substance-related effects on locomotor activity, food consumption, body weight or body weight gains were observed.

Laboratory Findings – Haematology, Clinical Chemistry
No toxicologically relevant test substance-related effects were noted for these parameters.

Effects in Organs
In male animals of the low, mid and high dose group, slightly higher mean weights of liver and kidneys (absolute or relative to body or brain weights) were noted. Liver weight relative to body weight was 10%, 22% and 27% higher in low, mid and high dose male animals compared with male control animals. Liver weight relative to brain weight was 11%, 21% and 25% higher for low, mid and high dose male animals compared to male control animals. Kidney weight relative to body weight for low, mid and high dose male animals was 11%, 17% and 12% higher than in male control animals. Kidney weight relative to brain weight for low, mid and high dose male animals was 12%, 15% and 10% higher than in male control animals. In male animals of the high dose recovery group, the liver weights (absolute and relative to body and brain weights) remained higher than the control. Liver weight relative to body weight was 18% higher for the high dose recovery male animals as compared to male control recovery animals. Liver weight relative to brain weight was 19% higher for the high dose recovery male animals as compared to male control recovery animals.

No test-substance related effects on macroscopic findings or histopathological findings were noted.

Remarks – Results
The slightly elevated liver weight in male animals was not accompanied by biochemical or histological changes and was thus considered an adaptive response and of no toxicological relevance by the study authors.

Slight changes in the kidney weight relative to bodyweight in male animals was also not considered of toxicological relevance by the study authors as there was no dose response relationship and there were no related biochemical or histological changes.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day in this study based on an absence of treatment-related adverse effects at all dose levels.

TEST FACILITY Toxi-Coop (2018)

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 (Test 1)and pre incubation (Test 2) procedure

Species/Strain	*Salmonella typhimurium*: TA1535, TA1537, TA98, TA100 *Escherichia coli*: WP2uvrA
Metabolic Activation System	S9 fraction from phenobarbital/β-napthoflavone-induced rat liver
Concentration Range in Preliminary Test	a) With metabolic activation: 3 - 5000 µg/plate b) Without metabolic activation: 3 - 5000 µg/plate
Concentration Range in Main Test	a) With metabolic activation: 33 – 5000 µg/plate b) Without metabolic activation: 33 – 5000 µg/plate
Vehicle	Tetrahydrofuran (THF)
Remarks - Method	No significant protocol deviations. The preliminary test was used as the main test (Test 1).

RESULTS

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

Remarks - Results No substantial increase in revertant colony numbers of any of the five tester strains was observed following treatment with the test substance at any concentration, 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 (2006)

B.8. Genotoxicity – *in vivo* mouse micronucleus test

TEST SUBSTANCE Notified polymer

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test (1997)

Species/Strain	Mouse/NMRI
Route of Administration	Oral – gavage
Vehicle	PEG400

Remarks - Method

No significant protocol deviations.

A preliminary acute toxicity study was carried out using 2 male and 2 female mice dosed with the test substance at 2000 mg/kg bw. No clinical signs of toxicity were noted for up to 2 days after dosing.

An additional study was conducted to confirm the bioavailability of the test substance in the absence of clinical signs of toxicity. Six male mice were dosed with the test substance at 2000 mg/kg bw. The blood of 3 males was collected 1 hour after treatment and the blood of the remaining 3 males was collected 4 hours after treatment. The samples were then analysed using LC-MS. The test substance was detected in the plasma of all treated mice, but not in untreated controls.

On the bases of these studies, 2000 mg/kg bw was determined to be a suitable limit dose for the main study.

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Sacrifice Time (hours)*
I (vehicle control)	7M	0	24
II (low dose)	7M	500	24
III (mid dose)	7M	1000	24
IV (high dose)	7M	2000	24
	7M	2000	48
V (positive control, CP or M)	7M	40	24

CP = cyclophosphamide dissolved in sterile water.

RESULTS

Doses Producing Toxicity: No clinical signs of toxicity were noted.

Genotoxic Effects: The test substance induced no statistically significant or biologically relevant increases in micronucleated, polychromatic erythrocytes (PCEs) at any of the doses or sacrifice times.

Remarks - Results: The mean number of PCEs was not substantially decreased after treatment with the test item in comparison with untreated control mice, indicating that the test item was not cytotoxic to bone marrow.

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

CONCLUSION

The notified polymer was not clastogenic under the conditions of this *in vivo* mouse micronucleus test.

TEST FACILITY

Harlan CCR (2015)

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: CO_2 Evolution Test (1992)

Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical carbon dioxide production ($THCO_2$)
Remarks - Method	Conducted in accordance with the test guidelines above, and in compliance with GLP standards and principles. The test substance (45.2 mg) was directly added to 3L inoculum before diluted with test medium to achieve a nominal concentration of 10.2 mg C/L.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	1.8	7	62.3
14	5.2	14	84.1
21	7.9	21	90.7
29	10.7	29	95.4

Remarks - Results: The validity criteria for the test were met.

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 chemical attained 10.7% degradation after 29 days and, therefore, cannot be considered as readily biodegradable under the conditions of OECD Guideline 301B.

CONCLUSION: The notified polymer is not readily biodegradable.

TEST FACILITY: CTI (2017a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 203 Fish, Acute Toxicity Test – Semi Static (1992)

Species	Rare minnow (*Gobiocypris rarus*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	160 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	A preliminary test was conducted, but not detailed. On the basis of this preliminary test a limit test was conducted on seven fish (3.03 ± 0.21 cm) at a test concentration of 100 mg/L and a control, with no replicates. The

test substance was weighed directly into the test water, stirred for 6 hours and filtered (0.45 µm). Test solutions were renewed daily and both old and new solutions were analysed.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*
Nominal	*Actual*		*96 h*
0 (Control)	< LOD*	7	0
100	7.1†	7	0

*Limit of Detection
†Geometric mean of measured concentrations

LC50	> 7.1 mg/L at 96 hours
NOEC	> 7.1 mg/L at 96 hours
Remarks – Results	All validity criteria were satisfied. No notable observations on the test solutions made. No abnormal symptoms observed in any fish. Recovery and precision testing of the analytical method conducted on 3 mg/L solutions. The relative standard deviation after precision testing was 2.7% and the mean recovery of samples was 107.2 - 113.4%. The dissolved oxygen was 62.7- 93.6% air saturation value. The initial measured concentration of the notified polymer was 7.6 mg/L, but subsequent measured concentrations were 79.8 - 106.3% of this value. Therefore geometric mean of all samples (old and new) was used to define the LC50.

CONCLUSION The notified chemical is not toxic to its limit of water solubility.

TEST FACILITY CTI (2017b)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD OECD TG 202 *Daphnia sp*. Acute Immobilisation Test and Reproduction Test (1984)

Species	*Daphnia magna*
Exposure Period	48 hours *[acute study]*
Auxiliary Solvent	0.1 mL/L Dimethylformamide (DMF)
Water Hardness	144 mg $CaCO_3$/L (moderately hard)
Analytical Monitoring	LC/MS/MS
Remarks - Method	A range finding test was conducted, but not detailed. Based on the findings, a primary stock solution of nominal concentration of 20 g/L was prepared from the notified chemical in DMF. Secondary stocks (nominal concentrations of 1.3, 2.5, 5.0 and 10 g/L) were prepared from the primary stock. Aliquots of the secondary stock were added to test water to obtain the nominal concentrations (below). Four replicates of five daphnids were exposed to the test concentrations, a solvent control and a negative control.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h [acute]*	*48 h [acute]*
Negative control	< LOQ*	20	0	0
Solvent control	< LOQ*	20	0	0
0.13	0.12	20	0	0
0.25	0.23	20	0	0
0.50	0.49	20	0	0
1.0	0.94	20	0	0
2.0	1.9	20	0	0

* Limit of Quantitation: 0.05 mg/L

LC50	> 1.9 mg/L at 48 hours (measured)
NOEC (or LOEC)	1.9 mg/L at 48 hours (measured)
Remarks - Results	Dissolved oxygen concentrations remained ≥ 8.6 mg/L (≥ 95% of saturation) throughout the test. All validity criteria were met. The measured concentrations were between 91 and 93% of the nominal amounts. Recovery and precision testing of the analytical method were conducted on 0.05 and 2.5 mg/L solutions. The relative standard deviation was 3.05% and average recovery 99.7%. Test solutions appeared clear and colourless, with no evidence of precipitation observed. Daphnids in the highest concentration showed signs of lethargy. This observation is the basis for the determination of the No Observed Effect Concentration (NOEC).
CONCLUSION	The notified chemical is not toxic to its limit of water solubility.
TEST FACILITY	EAG (2017b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test (2011)
Species	Freshwater alga (*Raphidocelis subcapitata*)
Exposure Period	96 hours
Concentration Range	Nominal: 0.13 – 0.20 mg/L Actual: 0.057 – 0.22 mg/L
Auxiliary Solvent	N,N-dimethylformamide (DMF) 1 mL/L
Water Hardness	140 - 144 mg $CaCO_3$/L
Analytical Monitoring	LC/MS/MS
Remarks - Method	A preliminary study using test concentrations of 0.02, 0.2 and 2.0 mg/L was conducted. No inhibition of algal growth was observed. Based on these findings, the maihn test was conducted by exposing four replicates of freshwater alga (1×10^4 cells/mL) to the test substance (0.13, 0.25, 0.50, 1.0, and 2.0 µg/L), a solvent control and a positive control. The test solutions were prepared by 1000-fold dilution in algal medium of secondary stock solutions containing 0.13, 0.25, 0.50, 1.0, and 2.0 mg/L of the test substance dissolved in (DMF). Duplicate samples of test solution were taken for chemical analysis at test initiation and termination.

RESULTS

Biomass		*Growth*	
EbC50 *mg/L at 96 h*	*NOEC* *mg/L*	*ErC50* *mg/L at 96 h*	*NOEC* *mg/L*
> 0.22	≥ 0.22	> 0.22	≥ 0.22

Remarks - Results	The pH in the test solutions and control rose from 7.3-7.4 to 9.2-9.5. The measured concentrations were below the recommended recovery range of 70-110% and so the geometric mean of the measured concentrations was used. Recovery and precision testing of the analytical method were conducted on 0.05 and 2.5 mg/L solutions. The relative standard deviation was 2.75% and average recovery 100%. The mean cell density increased by a factor of 168 after three days in the control. The coefficient of variation of average specific growth rates in the negative control and the mean percent coefficient of variation for section-by-section specific growth rates and mean growth rate between replicates in the negative control replicates were 26.1% and 4.4%, respectively. All validity criteria were met.

CONCLUSION	The notified chemical is not toxic to its limit of water solubility.
TEST FACILITY	EAG (2017c)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test (2010)
Inoculum	Activated sludge from STP treated (predominately) domestic waste.
Exposure Period	3 hours
Concentration Range	Nominal: 10 - 1000 mg/L Actual: Not determined
Remarks – Method	The inoculum was exposed to three concentrations of notified chemical, with the highest concentration performed in triplicate. A blank control, an abiotic control and reference substance (3,5 dichlorophenol) were also run.
RESULTS	
IC50	> 1000 mg/L
NOEC	≥ 1000 mg/L
Remarks – Results	The reference substance had an EC50 of 14.6 mg/L, which is within the accepted range. There was no significant respiration in the abiotic control.
CONCLUSION	The notified chemical is not inhibitory to activated sludge microorganisms
TEST FACILITY	EAG (2017d)

BIBLIOGRAPHY

consilab (2017a) [Notified Polymer] Determination of physico-chemical properties Melting Point (EC A.1. and OECD 102) and Boiling Point (EC A.2. and OECD 103) and Thermal Stability (OECD 113) and Explosive Properties (UN Class 1) (Study No. CSL-17-0946.01, October, 2017). Frankfurt, Germany, consilab Gesellschaft für Anlagensicherheit mbH (Unpublished report submitted by the notifier).

consilab (2017b) [Notified Polymer] Determination of physico-chemical properties Relative Density (EC A.3. and OECD 109) (Study No. CSL-17-0946.02, October, 2017). Frankfurt, Germany, consilab Gesellschaft für Anlagensicherheit mbH (Unpublished report submitted by the notifier).

consilab (2017c) [Notified Polymer] Determination of physico-chemical properties Vapour Pressure (EC A.4. and OECD 104) (Study No. CSL-17-0946.03, October, 2017). Frankfurt, Germany, consilab Gesellschaft für Anlagensicherheit mbH (Unpublished report submitted by the notifier).

consilab (2017d) [Notified Polymer] Determination of physico-chemical properties Water Solubility (EC A.6. and OECD 105) (Study No. CSL-17-0946.05, October, 2017). Frankfurt, Germany, consilab Gesellschaft für Anlagensicherheit mbH (Unpublished report submitted by the notifier).

consilab (2017e) Determination of physico-chemical properties Partition Coefficient (Study No. CSL-17-0946.06, October, 2017). Frankfurt, Germany, consilab Gesellschaft für Anlagensicherheit mbH (Unpublished report submitted by the notifier).

consilab (2017f) [Notified Polymer] Determination of physico-chemical properties Surface Tension (EC A.5. and OECD 115) (Study No. CSL-17-0946.04, October, 2017). Frankfurt, Germany, consilab Gesellschaft für Anlagensicherheit mbH (Unpublished report submitted by the notifier).

consilab (2017h) [Notified Polymer] Determination of physico-chemical properties Flash Point (EC A.9.) (Study No. CSL-17-0946.07, October, 2017). Frankfurt, Germany, consilab Gesellschaft für Anlagensicherheit mbH (Unpublished report submitted by the notifier).

consilab (2017i) [Notified Polymer] Determination of physico-chemical properties Auto-Ignition Temperature (Liquids and Gases) (EC A.15.) (Study No. CSL-17-0946.08, October, 2017). Frankfurt, Germany, consilab Gesellschaft für Anlagensicherheit mbH (Unpublished report submitted by the notifier).

CTI (2017a) Ready Biodegradability Test of [Notified Polymer] (CO_2 Evolution Test) (Study No. G17301015A, November, 2017). Suzhou, China, CTI-Safety Evaluation Technical Service Co., Ltd (Unpublished report submitted by the notifier).

CTI (2017b) [Notified Polymer]: Fish (Rare Minnow) Acute Toxicity Test (Study No. G17203019A, December, 2017). Suzhou, China, CTI-Safety Evaluation Technical Service Co., Ltd (Unpublished report submitted by the notifier).

EAG (2017a) Estimation of Adsorption Coefficient Using High Performance Liquid Chromatography (HPLC) (Study No. 837K-101, September, 2017). Maryland, USA, EAG Laboratories Inc. (Unpublished report submitted by the notifier).

EAG (2017b) [Notified Polymer]: A 48-Hour Static Acute Toxicity Test with the Cladoceran (*Daphnia magna*) (Study No. 837A-105, November, 2017). Maryland, USA, EAG Laboratories Inc. (Unpublished report submitted by the notifier).

EAG (2017c) [Notified Polymer]: A 96-Hour Toxicity Test with the Freshwater Alga (*Raphidocelis subcapitata*) (Study No. 837P-105, November, 2017). Maryland, USA, EAG Laboratories Inc. (Unpublished report submitted by the notifier).

EAG (2017d) [Notified Polymer]: An Activated Sludge, Respiration Inhibition Test (Study No. 837E-103, December, 2017). Maryland, USA, EAG Laboratories Inc. (Unpublished report submitted by the notifier).

Harlan CCR (2015) [Notified Polymer]: Micronucleus Assay in Bone Marrow Cells of the Mouse (Study No. 1660501, August, 2015). Rossdorf, Germany, Harlan Cytotest Cell Research GmbH (Unpublished report submitted by the notifier).

RCC (2006a) [Notified Polymer] Acute Oral Toxicity Study in Rats (Study No. A44515, January, 2006). Füllinsdorf, Switzerland, RCC Ltd (Unpublished report submitted by the notifier).

RCC (2006b) [Notified Polymer] Primary Skin Irritation Study in Rabbits (4-Hour Semi-Occlusive Application) (Study No. A44548, January, 2006). Füllinsdorf, Switzerland, RCC Ltd (Unpublished report submitted by the notifier).

RCC-CCR (2006) *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay with [Notified Polymer] (Study No. 925001, February, 2006). Rossdorf, Germany, RCC Cytotest Cell Research GmbH (Unpublished report submitted by the notifier).

Safety Evaluation Center (2018) Acute Eye Irritation/Corrosion Study of [Notified Polymer] in Rabbits (Study No. G1754D0060, January, 2018). Shenyang, China, Safety Evaluation Center of Shenyang Research Institute of Chemical Industry Ltd (Unpublished report submitted by the notifier).

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, https://www.safeworkaustralia.gov.au/doc/model-code-practice-managing-risks-hazardous-chemicals-workplace

Toxi-Coop (2017a) Acute Dermal Toxicity Study of [Notified Polymer] in Rats (Study No. 673-402-2982, September, 2017). Budapest, Hungary, Toxi-Coop Zrt. (Unpublished study submitted by the notifier).

Toxi-Coop (2017b) Skin Sensitisation Study: Local Lymph Node Assay of [Notified Polymer] in Mice (Pooled Treatment Group Approach) (Study No. 673-429-2985, September, 2017). Budapest, Hungary, Toxi-Coop Zrt. (Unpublished study submitted by the notifier).

Toxi-Coop (2018) 28-Day Repeated Dose Oral Toxicity Study of [Notified Polymer] in Rats (Study No. 673-407-2984, February, 2018). Budapest, Hungary, Toxi-Coop Zrt. (Unpublished study submitted by the notifier).

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 >