

File No: EX/222 (LTD/1933)

May 2019

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

PUBLIC REPORT

Polymer in ECOS® ND 15

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Energy.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director
NICNAS**

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This assessment report is for an extension of the original assessment certificate for Polymer in ECOS® ND 15 (LTD/1933). Based on the submission of new information by the extension notifier, the original assessment report has been modified. These modifications have been made under the heading 'Extension Application' in the respective sections.

SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
EX/222 (LTD/1933)	Flint CPS Inks Australia Pty Ltd	Polymer in ECOS® ND 15	ND	≤ 0.05 tonne per annum	Component of industrial paints and coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the characteristics of cobalt compounds, 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, only if the level of free cobalt ions is above the cut-off concentration for classification. Based on the available information, this situation is not expected to occur in formulations available for inhalation in the scenarios covered by this assessment. The recommended hazard classification, if the free cobalt ions reach this level, is presented in the following table.

<i>Hazard classification</i>	<i>Hazard statement</i>
Respiratory Sensitiser - Category 1	H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Specific organ toxicity (repeated exposure) – Category 1	H372 - Causes damage to organs through prolonged or repeated inhalation exposure
Carcinogenicity – Category 1B	H350i - May cause cancer
Reproductive toxicity – Category 1B	H360F - May damage fertility

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrases, only if the level of free cobalt ions is above the cut-off concentration for classification:

- R42: May cause sensitisation by inhalation
- R48/23: Danger of serious damage to health by prolonged exposure through inhalation
- R49: May cause cancer by inhalation
- R60: May impair fertility

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

<i>Hazard classification</i>	<i>Hazard statement</i>
Acute Category 3	H402 – Harmful to aquatic life

Human health risk assessment

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

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

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified polymer:
 - Enclosed processes where possible
 - Spray booths or exhaust ventilation for spray application of coatings, where possible.
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid inhalation during spray application
 - Avoid contact with skin and eyes
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Impervious gloves, goggles, coveralls
 - Respiratory protection, if inhalation exposure may occur

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.
- A copy of the (M)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 has a number-average molecular weight of less than 1000;
 - the polymer will be used in end-use products at > 1%
 - the polymer will be used in products available to the public.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of industrial paints and coatings, or is likely to change significantly;
 - the amount of polymer being introduced has increased, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

(Material) Safety Data Sheet

The (M)SDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

Current Extension Application:

The applicant for the extension application has provided a SDS for the notified chemical. The accuracy of the information on the SDS remains the responsibility of the extension applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Holder of original assessment certificate (LTD/1933)

Umicore Marketing Services Australia Pty Ltd (ABN: 71 116 948 764)
1/49 Calarco Drive
DERRIMUT VIC 3030

Applicant(s) for the current Extension of the Original Assessment Certificate

Flint CPS Inks Australia Pty Ltd (ABN: 82 079 823 279)
25-51 Berends Drive
DANDENONG SOUTH VIC 3 175

NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn \geq 1,000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, molecular and structural formulae, molecular weight, analytical data, polymer constituents, purity, residual monomers and impurities.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: boiling point, vapour pressure, flammability, auto-ignition temperature, explosive properties and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada (2014, USA (2015) and Philippines (2014)

2. IDENTITY OF CHEMICAL

MARKETING NAME

ECOS® ND 15 (imported product containing the notified polymer at ~80% concentration)

CAS NUMBER

Not assigned

OTHER NAME

Cobalt based polymer with fatty acids and polyol

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference GPC spectrum was provided

3. COMPOSITION

Degree of Purity

> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Purple gel

Property	Value	Data Source/Justification
Melting Point/Freezing Point	135-150 °C	Measured

Property	Value	Data Source/Justification
Boiling Point	Not determined	Decomposes after melting
Density	974 kg/m ³	Measured
Vapour Pressure	Not determined	Expected to be low based on high molecular weight
Water Solubility	8 × 10 ⁻⁴ g/L (cobalt solubility) at 30 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities; however, not expected to rapidly hydrolyse based on low water solubility
Partition Coefficient (n-octanol/water)	Not determined	Expected to be high based on low water solubility
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on high molecular weight and anionicity
Dissociation Constant	Not determined	Expected to be ionised under environmental conditions (pH 4-9)
Flash Point	106 °C (closed cup)	Measured
Flammability	Not determined	Not expected to be highly flammable based on measured flash point
Autoignition Temperature	Not determined	Not expected to autoignite
Explosive Properties	Not determined	Not expected to be explosive based on chemical structure
Oxidising Properties	Not determined	Not expected to be oxidising based on chemical structure

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 be introduced at ~80 % concentration in organic solvent.

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

Original Introduction Volume

Year	1	2	3	4	5
Tonnes	3-5	3-5	3-10	3-10	3-10

Current Extension Application Introduction Volume

Year	1	2	3	4	5
Tonnes	≤ 0.05	≤ 0.05	≤ 0.05	≤ 0.05	≤ 0.05

PORT OF ENTRY

Melbourne

TRANSPORTATION AND PACKAGING

The product will be sold in 200ltr drums in Australia.

USE

The notified polymer will be used as a component of industrial paints and coatings at $\leq 1\%$ concentration.

OPERATION DESCRIPTION

The notified polymer will not be manufactured in Australia.

After importation, the notified polymer (at $\sim 80\%$ concentration) will be reformulated into paints and coatings. At the reformulation sites the contents of the imported drums containing the notified polymer will be transferred to a feeder tanker or directly to a mixing vessel, typically using a pump, for blending with pigments and other ingredients to form the finished products. Following quality control analysis, the finished products (containing $\leq 1\%$ notified polymer) will be transferred using automated and metered processes to various containers for distribution to end-users.

The finished products containing the notified polymer may be applied by brush, roller or spray on a wide range of substrates (glass, metal, wood, plaster and brick substrates) by commercial /industrial users.

6. HUMAN HEALTH IMPLICATIONS**6.1. Exposure Assessment****6.1.1. Occupational Exposure****CATEGORY OF WORKERS**

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Reformulation workers	0.75	220

EXPOSURE DETAILS

Transport and storage workers are not expected to be exposed to the notified polymer (at $\sim 80\%$ concentration) except in the unlikely event of an accident.

Reformulation

Reformulation will be largely automated; however workers may be exposed (dermal and ocular) to the notified polymer at up to 80% concentration when transferring the contents of the imported containers to the mixing equipment and during quality control testing. Inhalation exposure will not occur as the concentrated polymer will not be aerosolised. Dermal and ocular exposure to workers should be mitigated through the stated use by the notifier of personal protective equipment (PPE) including coveralls, gloves and goggles.

End-use

Exposure to paints and coatings containing the notified polymer (at $\leq 1\%$ concentration) may occur during transfer, application and cleaning processes. The potential for exposure should be minimised through the stated use by the notifier of PPE (goggles, gloves and coveralls) by workers, including the use of respiratory protection during spray application. Inhalation exposure may be further mitigated through the use of exhaust ventilation and spray booths, where possible.

Workers may come into contact with substrates coated with the notified polymer after application. However, once the paints or coatings have dried, the notified polymer will be bound within a solid matrix and will not be available for exposure.

6.1.2. Public Exposure

The public may come into contact with substrates coated with the notified polymer after application. However, once the paints or coatings have dried, the notified polymer will be bound within a solid 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.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Skin irritation (<i>in vitro</i>)	non-irritating
Skin corrosion (<i>in vitro</i>)	non-corrosive
Eye irritation (<i>in vitro</i>)	non-irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation – Buehler Method	no evidence of sensitisation
Comet assay (<i>in vitro</i>)	inconclusive

Toxicokinetics

The number average molecular weight of the notified polymer is above 1,000 Da. Polymers of high molecular weight do not readily cross the skin or other biological membranes. However, the notified polymer contains a significant proportion of low molecular weight species (< 1,000 Da) that may be absorbed.

Release of cobalt from the notified polymer was investigated in artificial biological fluids (artificial gastric fluid and alveolar fluid). Bioelution into artificial gastric solution was approximately 5% after 2 h or 5 h. In artificial lung fluids the solubility varied from approximately 1 to 3% of total cobalt and was related to particle size of the polymer.

Acute toxicity

Based on studies conducted in rats, the notified polymer is of low acute oral and dermal toxicity.

Irritation and sensitisation

An *in vitro* study using a reconstituted human epidermis model indicated that the notified polymer is not expected to be irritating to the skin. The notified polymer was found to be non-irritating to the rabbit eyes and in an *in vitro* study (BCOP).

A skin sensitisation study conducted with the notified polymer (100% induction and challenge concentration; Buehler test) in guinea pigs showed no signs of sensitisation.

Genotoxicity

In an *in vitro* hOGG1-modified Comet assay using human lung epithelial cells (non-validated method), the notified polymer induced less DNA damage than the positive controls and negligible oxidative DNA-base lesions at concentrations up to 800 µg/mL. The cause of higher amounts of DNA damage at the highest concentration of 1600 µg/mL was not clear, and the effect may not have been cobalt-related as cytotoxicity was seen at this level. The overall results were not conclusive, and the potential for DNA damage cannot be ruled out. It is considered that effective protective processes exist *in vivo* to prevent genotoxicity of cobalt compounds in humans (NICNAS b).

Cobalt-related toxicity

The toxicological effects of cobalt and cobalt containing compounds arise from the bio-accessibility of cobalt ions in different biological fluids (e.g. gastric fluid, interstitial fluid and lysosomal fluid) (NICNAS a). Potential toxicity is most likely to occur through inhalation exposure. Based on the classifications applied to Cobalt salts of Organic Acids (NICNAS b), the notified polymer may have a range of health effects. These include sensitisation; repeated dose toxicity and carcinogenicity by the inhalation route; and reproductive toxicity. However, considering the data indicating limited bio-accessibility for the notified polymer, its toxicity potential is expected to be reduced compared to these compounds.

Health hazard classification

Based on the characteristics of cobalt compounds, 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, only if the level of free cobalt ions is above the cut-off concentration for classification. Based on the available information, this situation is not expected to occur in formulations available for inhalation in the scenarios covered by this assessment. The recommended hazard classification, if the free cobalt ions reach this level, is presented in the following table.

<i>Hazard classification</i>	<i>Hazard statement</i>
Respiratory Sensitiser - Category 1	H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Specific organ toxicity (repeated exposure) – Category 1	H372 - Causes damage to organs through prolonged or repeated inhalation exposure
Carcinogenicity – Category 1B	H350i - May cause cancer
Reproductive toxicity – Category 1B	H360F - May damage fertility

Based on the characteristics of cobalt compounds, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrases, only if the level of free cobalt ions is above the cut-off concentration for classification:

- R42: May cause sensitisation by inhalation
- R48/23: Danger of serious damage to health by prolonged exposure through inhalation
- R49: May cause cancer by inhalation
- R60: May impair fertility

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the toxicological studies provided, the notified polymer is of low acute oral and dermal toxicity; non-irritating to the skin and eyes; and not a skin sensitiser. The potential for systemic toxicity that may be associated with cobalt compounds is expected to be reduced given the low solubility and high molecular weight of the notified polymer.

Workers may be exposed to the notified polymer at ~80% concentration during reformulation processes, although not by inhalation. Workers may also be exposed to the notified polymer at $\leq 1\%$ concentration during application of coating products, including via spray application. Exposure during these processes is expected to be limited by the use of engineering controls and appropriate PPE, with additional controls where spray application occurs.

Once the surface coatings have dried, the notified polymer will be bound within an inert matrix and will not be bioavailable.

Several factors reduce the expected hazard and risk to workers, through reducing the potential for exposure to free cobalt. The concentration of the polymer in end-use products is $< 1\%$; the level of available cobalt in the polymer is low; the measured bioavailability in biological fluids is low; and the matrix of both the imported polymer at 80% and the final paint products is expected to further reduce bioavailability. Given these factors and controls in place to limit exposure, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The paints containing the notified polymer will not be used by the public. The public may come into contact with surfaces coated with products containing the notified polymer. In this form the notified polymer will be bound within an inert matrix and will not be bioavailable. Therefore the risk to the public is not considered to be unreasonable.

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 as a component of a product for reformulation into finished paints and coatings. There is unlikely to be any significant release to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the product containing the notified polymer is expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

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

waste management services. Empty import containers are expected to be recycled or disposed of through licensed waste management services.

RELEASE OF CHEMICAL FROM USE

Paints and coatings containing the notified polymer will be used by both professional and Do-It-Yourself (DIY) users. During use, paints and coatings containing the notified polymer are expected to be applied by brush, roller and spray techniques. It is expected that some of the coating product will be in the form of overspray during spraying operations, and will typically entail disposal to landfill after being collected with adsorbents.

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

RELEASE OF CHEMICAL FROM DISPOSAL

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

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

7.1.2. Environmental Fate

The majority of the notified polymer is expected to be cured within an inert coating matrix, and is expected to share the fate of the articles to which it has been applied. These will involve eventual disposal to landfill. Once cured, the notified polymer is not expected to be bioavailable or bioaccumulative. The notified polymer is also expected to enter landfill as collected wastes and residues. The notified polymer is not readily biodegradable (27.41% in 28 days). For details of the environmental fate study, please refer to Appendix C. Bioaccumulation of uncured notified polymer is unlikely, based on its high molecular weight. The notified polymer is not expected to be mobile in the environment, due to its limited water solubility and potential to adsorb to soil and sediment based on its anionic properties. Therefore, a significant portion of the notified polymer (> 50%) is expected to partition to sludge and sediment (Boethling and Nabholz, 1997) during wastewater treatment processes in sewage treatment plants (STPs). In surface waters and in landfill, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and cobalt.

7.1.3. Predicted Environmental Concentration (PEC)

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

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	500	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	1.37	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.303	µg/L
PEC - Ocean:	0.030	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 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 1,500 kg/m³). Using these assumptions, irrigation with a concentration of 0.30 µg/L may potentially result in a soil concentration of approximately 2.02 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 10.10 µg/kg and 20.19 µg/kg, respectively.

7.2. Environmental Effects Assessment

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

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	96 h LL50 = 95.78 mg/L (WAF*)	Harmful to fish (acute)
	33 d NOEL > 100 mg/L (WAF*)	Not harmful to fish up to the water solubility limit (chronic)
Daphnia Toxicity	48 h EL50 > 100 mg/L (WAF*)	Not harmful to aquatic invertebrates up to the water solubility limit (acute)
	21 d NOEL = 6.25 mg/L (WAF*)	May cause long lasting harmful effects to aquatic invertebrates (chronic)
Algal Toxicity	72 h EL50 = 16.2 mg/L (WAF*)	Harmful to algae
	72 h NOEL = 6.25 mg/L (WAF*)	May cause long lasting harmful effects to algae

* Water accommodated fraction

Based on the above ecotoxicological endpoints for the notified polymer, it is expected to be harmful to fish and algae, but is not expected to be harmful to aquatic invertebrates up to the limit of its solubility in water. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified polymer is formally classified as 'Acute Category 3; Harmful to aquatic life'. Based on the above chronic endpoints, the notified polymer is not formally classified under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for aquatic invertebrates. A safety factor of 10 was applied given acute and chronic endpoints are available for aquatic species representing three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
NOEL (<i>Daphnia</i> , 21 d)	6.25	mg/L
Assessment Factor	10	
Mitigation Factor	1.00	
PNEC:	625	µg/L

7.3. Environmental Risk Assessment

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

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q – River	0.303	625	0.0005
Q – Ocean	0.030	625	< 0.0001

The risk quotient for discharge of treated effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. The notified polymer is not considered readily biodegradable; however it is not expected to be bioaccumulative based on its high molecular weight. On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in paints and coatings, the notified polymer is not expected to pose an unreasonable risk to the environment.

8. RISK ASSESSMENT FOR EXTENSION APPLICATION

Current Extension Application

There are no changes under the proposed extension to the use, or the occupational and public exposure. The proposed introduction volume is a small fraction of the volume proposed under the previous assessment. Therefore, the circumstances in the extension are not expected to impact on the original human health and environment risk assessment and recommendations.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Melting Point/Freezing Point** 135-150 °C

Method Method followed not stated
Remarks Study summary only provided. Determined using differential scanning calorimetry (DSC). The sample was stated to be in the form of a gel-like material hence the melting point is essentially a transition from gel to liquid phase, not a solid-liquid transition. After melting, the DSC indicated the test substance degraded.
Test Facility Umicore (2016)

Density 974 kg/m³

Method ISO 2811
Remarks Study summary only provided
Test Facility Umicore (2016)

Water Solubility 8×10^{-4} g/L (cobalt solubility) at 30 °C

Method In-house method
Remarks 1 g of test substance was added to ultrapure water and shaken at 30 °C for 24 h, then allowed to settle for 24 h at room temperature. Any undissolved material was filtered and the cobalt content in solution was measured using Atomic Absorption Spectrometry.
Test Facility Umicore (2014a)

Flash Point 106 °C (closed cup)

Method ASTM D93-72
Remarks Study summary only provided
Test Facility Umicore (2016)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Acute toxicity – oral**

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method
Species/Strain	Rat/White Wistar, HsdCpb: WU
Vehicle	Sesame oil
Remarks - Method	Due to the significantly large volume of the highest dose, it was split into two equal portions and administered within 4 hours of each other.

RESULTS

<i>Groups</i>	<i>Number and Sex of Animals</i>	<i>Dose (mg/kg bw)</i>	<i>Mortality</i>
1	6F	50	0
2	6F	300	0
3	6F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	No signs of toxicity were observed
Effects in Organs	No macroscopic findings were observed at necropsy
Remarks - Results	The mean body weight increase of all dose groups was in the normal range 14 days post-application. However, single animals of the 2000 mg/kg dose group showed body weight losses 7 or 14 days post-application.

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

TEST FACILITY Evonik (2011a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test
Species/Strain	Rat/CR:(WI)
Vehicle	Water and a small amount of olive oil
Type of dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5/sex	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Black discolouration on the skin and fur around the site of application which fully reversed after 10 days
Signs of Toxicity - Systemic	No signs of toxicity were observed
Effects in Organs	No macroscopic findings were observed at necropsy
Remarks - Results	There were no effects on bodyweight in any animal during the study

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

TEST FACILITY CiToxLAB (2012a)

B.3. Irritation – skin (*in vitro*)

TEST SUBSTANCE Notified polymer

METHOD	OECD TG 439 In vitro Skin Irritation: Reconstructed Human <i>Epidermis</i> Test Method
Vehicle	None
Remarks - Method	EpiDerm™ (EPI-200-SIT) was used as the test system. Standard MTT assay was used to determine cell viability.
	The test substance (23.8 mg) was topically applied on top of the stratum corneum in triplicate. The tissues were incubated for 42 hours at 37 °C following an exposure period of 60 minutes.
	Positive and negative controls were run in parallel with the test substance:
	- Negative control: Ultra-pure water
	- Positive control: Sodium dodecyl sulfate (5 % aqueous solution)

RESULTS

<i>Test material</i>	<i>Mean OD₅₇₀ of triplicate tissues</i>	<i>Relative mean Viability (%)</i>	<i>SD of relative mean viability</i>
<i>Negative control</i>	1.86	100	1.2
<i>Test substance</i>	1.76	94.8	4.4
<i>Positive control</i>	0.145	7.8	1.3

OD = optical density; SD = standard deviation

Remarks - Results	The test substance did not show any chemically reducing properties of the MTT. The relative mean tissue viability after 1 hour of exposure and 42 hours post incubation was > 50%.
CONCLUSION	The notified polymer was non-irritating to the skin under the conditions of the test.
TEST FACILITY	Evonik (2011b)

B.4. Corrosion – skin (*in vitro*)

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 431 In vitro Skin Corrosion: Reconstructed Human <i>Epidermis</i> Test Method
Vehicle	None
Remarks - Method	EpiDerm™ (EPI-200-SIT) was used as the test system. Standard MTT assay was used to determine cell viability.
	The test substance was topically applied on top of the stratum corneum in triplicate. The tissues exposed to the chemical for 3 minutes and 1 hour and then washed with PBS.
	Positive and negative controls were run in parallel with the test substance:
	- Negative control: Ultra-pure water
	- Positive control: 8N Potassium hydroxide (KOH)

RESULTS

<i>Test material</i>	<i>Mean OD₅₇₀ of triplicate tissues</i>		<i>Relative mean Viability (%)</i>		<i>SD of relative mean viability</i>	
	3 min	1 h	3 min	1 h	3 min	1 h
<i>Negative control</i>	1.6678	1.4722	100	100	11.6	9.3
<i>Test substance</i>	1.8893	1.4548	113.3	98.8	6	8.6
<i>Positive control</i>	0.1204	0.0908	7.2	6.2	0.3	0.2

Remarks - Results	The test substance did not show any chemically reducing properties of the MTT. The relative mean tissue viability after 1 hour of exposure was > 50%.
CONCLUSION	The notified polymer was non-corrosive to the skin under the conditions of the test.
TEST FACILITY	Evonik (2011c)

B.5. Irritation – eye (*in vitro*)

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants
Vehicle	Saline (0.9 % w/v NaCl in deionised water)
Remarks – Method	The test substance at 20 % and the positive and negative controls were applied to the cornea and incubated for 240 minutes at 32 ± 1 °C. The positive and negative controls were rinsed off after incubation. Fluorescein solution (1 mL) was applied for 90 min in horizontal position. Liquid was measured spectrophotometrically.
	Positive control: 10 % (w/v) Benzalkonium chloride in saline
	Negative control: saline

RESULTS

<i>Test material</i>	<i>Mean opacities of triplicate tissues</i>	<i>Mean permeabilities of triplicate tissues</i>	<i>IVIS</i>
<i>Vehicle control</i>	-1.00	0.059	0.00
<i>Test substance*</i>	2.33	- 0.003	2.30
<i>Positive control*</i>	250.00	0.315	254.73

IVIS = in vitro irritancy score

*Corrected for background values

Remarks - Results	The test substance did not cause any increase of the corneal opacity or permeability. The calculated IVIS score was 2.3 and therefore under the test guidelines, the test substance is considered a non-irritant.
CONCLUSION	The notified polymer was non-irritating to the eye under the conditions of the test.
TEST FACILITY	Harlan (2011)

B.6. Irritation – eye

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	No significant protocol deviations

RESULTS

After 1 hour of application, conjunctival redness (score 1) was observed in one animal. No further signs of irritation were observed in any test animal during the study period.

CONCLUSION The notified polymer is non-irritating to the eye.

TEST FACILITY CiToxLAB (2012c)

B.7. Skin sensitisation

TEST SUBSTANCE Notified polymer

METHOD OECD TG 406 Skin Sensitisation - Buehler Method

Species/Strain Guinea pig/albino (LAL/HA/BR)

PRELIMINARY STUDY Maximum Non-irritating Concentration: 100%

MAIN STUDY

Number of Animals Test Group: 20 Control Group: 10

Vehicle Skin moistened with olive oil prior to application

Positive control 2-Mercaptobenzothiazole. The positive control was not run concurrently with the test.

INDUCTION PHASE Induction Concentration: 100 %

Signs of Irritation Very slight erythema was detected in animals treated with the test substance. No signs of irritation were observed in the Control group (olive oil only).

CHALLENGE PHASE

1st challenge Topical: no positive reactions were reported.

Remarks – Method

The neat substance was too viscous to apply directly. It was applied to the skin as a 2.5 x 2.5 cm layer of test material with an olive oil layer to ensure good contact. Approximately 24 hours prior to the preliminary test, the animal's backs were shaved. The skin was moistened with olive oil prior to application of the test substance. A gauze patch was applied over the skin and covered with adhesive hypoallergenic plaster for 6 h.

The neat substance was topically administered to the skin for 6 h, once per week for 3 weeks as an induction. Fourteen days following the last topical induction, animals were challenged with a single dose of the substance at 100 %. Control animals were treated with olive oil (0.5 mL).

For the challenge exposure, the test substance was applied to the left flank and olive oil on the right flank for 6 h.

RESULTS

Animal	Challenge Concentration	Number of Animals Showing Skin Reactions after:			
		1 st challenge		2 nd challenge	
		24 h	48 h	24 h	48 h
Test Group	100 %	0	0	N/A	N/A
Control Group	100 %	0	0	N/A	N/A

Remarks - Results No signs of irritation were observed in the Test or Control groups.

CONCLUSION There no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

TEST FACILITY CiToxLAB (2012b)

B.8. Genotoxicity – *in vitro*

TEST SUBSTANCE Cobalt octoate (17 % Co content; MW: 345.34 Da) and notified polymer at 80%

METHOD	<i>In vitro</i> single cell gel (SCG)/Comet assay using the hOGG1-modification (Tice et al. 2000, Smith et al. 2006)
Species/Strain	Human
Cell Type/Cell Line	A549 lung epithelial cells
Metabolic Activation	N/A
System	
Vehicle	N/A
Remarks – Method	<p>The study was used to compare clastogenicity, induction of oxidative DNA-base lesions and cytotoxicity. Tail intensity was used as a measure of DNA damage. Soluble and particle fractions were tested. Chemicals were incubated with and without human 8-oxo-guanine DNA glycosylase (hOGG1).</p> <p>The soluble contents of the test substances were extracted in artificial physiological fluids at pH 7.4 (Artificial interstitial fluid – Gamble’s and artificial alveolar fluid - AAF) for 48 h. The preparations were then fractioned into pre-filtered (particle) fraction and filtered (soluble) fraction. The test substances were further diluted with HBSS before used to treat the cells. Pre-cultured cells were treated with the fractioned test substances for 4 h. In two additional experiments, the soluble contents of the test items were extracted in AAF only.</p> <p>Positive controls: cobalt sulphate heptahydrate (CoSO₄); ethyl methanesulfonate (EMS) Negative controls: Aluminium oxide, fused (Al₂O₃); Hank’s salt solution (HBSS), without phenol red, potassium bromate (KBrO₃)</p>
Remarks - Results	<p>Cobalt octoate exhibited similar solubility, clastogenic activity, induction of oxidative DNA-base lesions and cytotoxicity to one of the positive controls, CoSO₄. The notified polymer induced less DNA-damage and negligible oxidative DNA-base lesions at concentrations up to 800 µg/mL. It is thought that these lower results may be attributed to lower cobalt content and/or lower solubility.</p> <p>Higher amounts of DNA damage were seen for the notified polymer at the highest concentration of 1600 µg/mL. The study authors considered that non-cobalt mechanisms might be responsible.</p>
Conclusion	The extent of DNA damage induced by the notified polymer is likely to be related to its bioavailability.
Test Facility	Fraunhofer (2011)

B.9. Bio-elution in gastric fluid – *In vitro*

TEST SUBSTANCE	Notified polymer – 80%
METHOD	
System	Artificial gastric solution
Positive control	CoCl ₂
Negative control	Co ₃ O ₄
Remarks - Method	The study summary only was provided. A bio-elution test was performed on ECOS ND 15, CoCl ₂ and Co ₃ O ₄ to estimate the metal release. Cobalt release was measured after 2 and 5 hours of incubation at a loading rate of 2 g/L.

RESULTS

Sample	Metal	Solubility after 2 h (%)	Solubility after 5 h (%)
ECOS ND 15	Co	5.26 ± 0.74	5.7 ± 1.65

<i>Sample</i>	<i>Metal</i>	<i>Solubility after 2 h (%)</i>	<i>Solubility after 5 h (%)</i>
CoCl ₂	Co	103.07 ± 0.92	105.02 ± 1.02
Co ₃ O ₄	Co	0.04 ± 0.001	0.05 ± 0.002

Remarks – Results
CONCLUSION
TEST FACILITY

The notified polymer is only partially soluble in artificial gastric fluid.
The product containing the notified polymer is expected to have limited bio-accessibility in gastric fluid.
Umicore (2014b)

B.10. Bio-accessibility in lung fluid – *In vitro*

TEST SUBSTANCE
METHOD
System
Positive control
Remarks - Method

Notified polymer – 80 %
In-house method
Artificial alveolar fluid (AAF)
CoSO₄
A solubility test was performed on ECOS ND 15 and CoSO₄ to estimate the metal release in artificial lung fluid.

RESULTS

<i>Sample</i>	<i>Metal</i>	<i>Mean cobalt solubility (%)</i>
ECOS ND 15	Co	2.71 ± 1.53
CoSO ₄	Co	70.8 ± 1.23

Remarks – Results
CONCLUSION
TEST FACILITY

The product containing the notified polymer is only partially soluble in in artificial lung fluid
The product containing the notified polymer is expected to have limited bio-accessibility.
Fraunhofer (2011)

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.
Inoculum	Activated sewage sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Carbon Dioxide (ThCO ₂)
Remarks - Method	Due to low water solubility, the appropriate volumes of the test substance were weighed and directly added to individual test vials. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

<i>Test substance</i>		<i>Toxicity control</i>		<i>Sodium benzoate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
6	4.86	6	24.6	6	59.36
15	15.09	15	33.07	15	77.86
22	21.62	22	Not determined	22	Not determined
28	27.41	28	Not determined	28	82.41

Remarks - Results

The carbon content could not be measured on days 2 and 3 of the test as the plastic vial stoppers were not fully closed. However, this was not deemed to have significantly impacted the integrity or validity of the study. The initial amount of carbon in test samples was 34 mg/L due to calculation error, which exceeded the recommended 20 mg/L. Higher starting carbon content increases the bioavailability of the test substance to the inoculum and may enhance biodegradation. However, as abiotic degradation is expected to be the predominant degradation pathway for the test substance, this was not deemed to have significantly impacted the integrity or validity of the study. All other validity criteria for the test were satisfied.

The percentage degradation of the reference compound surpassed the threshold level of 60% by 10 days (70.3%). Therefore, the tests indicate the suitability of the inoculum. The percentage degradation of the toxicity control surpassed the threshold level of 25% by 10 days (28.73%; 32.95% in 17 days), showing that toxicity was not a factor inhibiting the biodegradability of the test substance.

The degree of degradation of the test substance after 28 days was 27.41%. Therefore, the test substance is not considered to be readily biodegradable according to the OECD (301 B) guideline.

CONCLUSION The notified polymer is not readily biodegradable.

TEST FACILITY VITO (2012a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified polymer

METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static.
Species	<i>Danio rerio</i> (zebrafish)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	249.2 mg CaCO ₃ /L
Analytical Monitoring	Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES)
Remarks – Method	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. A stock solution with a nominal loading rate of 1,000 mg/L was prepared by stirring the test substance in water for 7 d, and any undissolved material was removed by filtration. The definitive test was conducted at the nominal loading rates of 31.25, 62.5, 125, 250, 500, and 1,000 mg/L of the test substance. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Concentration mg/L			Number of Fish	Mortality (%)			
Nominal	Actual	Cobalt		24 h	48 h	72 h	96 h
Control	Control	Control	7	0	0	0	0
31.25	35.36	0.186	7	0	0	0	0
62.5	66.75	0.146	7	0	0	0	0
125	124.82	0.417	7	57.1	100	100	100
250	251.77	0.485	7	85.7	100	100	100
500	498.41	0.907	7	100	100	100	100
1,000	994.08	2.527	7	100	100	100	100

LL50	95.78 mg/L (WAF) at 96 hours
NOEL	66.75 mg/L (WAF) at 96 hours
Remarks – Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 96 h test period. The actual concentrations of cobalt in the test substance were measured every 24 hours during the 96 h test period. The 96 h LL50 and NOEL for fish were determined to be 95.78 mg/L (WAF) and 66.75 mg/L (WAF) respectively, based on measured concentrations.

CONCLUSION The notified polymer is considered to be harmful to fish.

TEST FACILITY VITO (2012b)

C.2.2. Chronic toxicity to fish

Test Substance	Notified polymer
Method	OECD TG 210 Fish, Early-life Stage Toxicity Test – Continuous Flow-through.
Species	<i>Danio rerio</i> (zebrafish)
Exposure Period	33 days (30 days post-hatch)
Auxiliary Solvent	None
Water Hardness	108-116 mg CaCO ₃ /L
Analytical Monitoring	Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES)
Remarks – Method	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. A stock solution with a nominal loading rate of 1,000 mg/L was prepared by stirring the test substance in water for 7 d, and any undissolved material was removed by filtration. The definitive test was conducted at the nominal loading rates of 62.5, 125, 250, 500, and 1,000 mg/L of the test substance. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

Results

Nominal	Concentration mg/L		Number of Eggs	Mortality post-hatch day 30 (%)
	Nominal Cobalt	Actual Cobalt		
Control	0	0.0005	100	17
62.5	0.1032	0.1298	100	8
125	0.2063	0.2420	100	29
250	0.4125	0.4376	100	32
500	0.8250	0.8512	100	90
1,000	1.650	1.748	100	100

NOEL	> 100 mg/L (WAF; 0.4376 mg/L Co) at 33 days
Remarks – Results	All validity criteria for the test were satisfied. The actual concentrations of cobalt in the test substance were measured every 2-5 days during the 33 d test period. As measured concentrations were based on the cobalt content of the test substance, the nominal concentrations were used. The 33 d NOEL for fish was determined to be > 100 mg/L (WAF; 0.4376 mg/L cobalt), based on nominal concentrations.
Conclusion	The notified chemical is not considered to be harmful to fish on a chronic basis up to the limit of its water solubility.
Test Facility	Oregon State University (2015a)

C.2.3. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static.
Species	<i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg CaCO ₃ /L
Analytical Monitoring	Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES)
Remarks - Method	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. A stock solution with a nominal loading rate of 100 mg/L was prepared by stirring the test substance in water for 7 d, and any undissolved material was removed by filtration. The definitive test was conducted at the nominal loading rates of 50 and 100 mg/L of the test substance. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Nominal	Concentration mg/L		Number of <i>D. magna</i>	Cumulative Immobilised (%)	
	Nominal Cobalt	Cobalt		24 h	48 h
Control	Control	Control	30	0	0
50	0.394-0.420	0.394-0.420	20	0	0
100	0.730-0.739	0.730-0.739	20	0	0

EL50	> 100 mg/L (WAF) at 48 hours
NOEL	100 mg/L (WAF) at 48 hours
Remarks - Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 48 h test period. The actual concentrations of cobalt in the test substance were measured every 24 hours during the 48 h test period. As measured concentrations were based on the cobalt content of the test substance, the nominal concentrations were used. The 48 h EL50

and NOEL for daphnids were determined to be > 100 mg/L (WAF) and 100 mg/L (WAF), respectively, based on nominal concentrations.

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

TEST FACILITY VITO (2011)

C.2.4. Chronic toxicity to aquatic invertebrates

Test Substance Notified polymer

Method OECD TG 211 *Daphnia magna* Reproduction Test – Static.

Species *Daphnia magna*.

Exposure Period 21 days.

Auxiliary Solvent None

Water Hardness 135 mg CaCO₃/L

Analytical Monitoring Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES)

Remarks - Method The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. A stock solution with a nominal loading rate of 1,000 mg/L was prepared by stirring the test substance in water for 7 d, and any undissolved material was removed by filtration. The definitive test was conducted at the nominal loading rates of 3.13, 6.25, 12.5, 25, and 50 mg/L of the test substance (corresponding to nominal loading concentrations of 0.0275, 0.055, 0.11, 0.22, and 0.44 mg/L cobalt). The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

Results

	<i>Test Concentration (nominal; mg/L)</i>					
	<i>Control</i>	<i>3.13</i>	<i>6.25</i>	<i>12.5</i>	<i>25</i>	<i>50</i>
Total No. of Offspring Released by Survived <i>Daphnia</i>	135.6 ± 25.0	138.1 ± 11.9	120.2 ± 14.9	21.5 ± 29.8	0	0
Survival (%)	100	97.3	84.6	33.3	0	0

NOEL 6.25 mg/L (WAF; 0.05 mg/L Co) at 21 days

Remarks - Results All validity criteria for the test were satisfied. The test solutions were not renewed during the 21 d test period. The actual concentrations of cobalt in the test substance were measured every 2-5 days during the 21 d test period. All measured cobalt concentrations were within 15% difference of the nominal cobalt concentrations. As measured concentrations were based on the cobalt content of the test substance, the nominal concentrations were used. The 21 d NOEL for daphnids was determined to be 6.25 mg/L (WAF; 0.05 mg/L cobalt), based on nominal concentrations.

Conclusion The notified chemical is considered to be harmful to aquatic invertebrates on a chronic basis.

Test Facility Oregon State University (2015b)

C.2.5. Algal growth inhibition test

TEST SUBSTANCE Notified polymer

METHOD OECD TG 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test.

Species *Pseudokirchneriella subcapitata* (green alga)

Exposure Period	72 hours
Concentration Range	Nominal: 3.12-50 mg/L Actual: 0.02-0.155 mg/L cobalt
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES)
Remarks - Method	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. A stock solution with a nominal loading rate of 100 mg/L was prepared by stirring the test substance in water for 7 d, and any undissolved material was removed by filtration. The definitive test was conducted at the nominal loading rates of 3.12, 6.25, 12.5, 25, and 50 mg/L of the test substance. The test medium used contained 0.08 mg/L FeCl ₃ (instead of 0.06 mg/L) and 7.4 mg/L MgSO ₄ ·7H ₂ O (instead of 15 mg/L), which differs from the recommended concentrations in the OECD TG 201 guideline. However, this was not deemed to significantly impact the integrity or validity of the study. The test was conducted in accordance with the test guideline above, with no other significant deviation in protocol reported.

RESULTS

<i>Biomass</i>		<i>Growth</i>	
<i>EL50</i> <i>mg/L at 72 h</i>	<i>NOEL</i> <i>mg/L</i>	<i>EL50</i> <i>mg/L at 72 h</i>	<i>NOEL</i> <i>mg/L</i>
Not determined	Not determined	16.2	6.25

Remarks - Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 72 h test period. The actual concentrations of cobalt in the test substance were measured at the start and end of the 72 h test period. As measured concentrations were based on the cobalt content of the test substance, the nominal concentrations were used. The 72 h EL50 and NOEL for algae were determined to be 16.2 mg/L (WAF) and 6.25 mg/L (WAF), respectively, based on nominal concentrations.
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CONCLUSION The notified polymer is considered to be harmful to algae.

TEST FACILITY VITO (2013)

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