File No: STD/1483

January 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Interzone 954 Part B

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also 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(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1483	Akzo Nobel Pty Ltd	Polymer in Interzone 954 Part B	Yes	≤ 95 tonnes per annum	Component of industrial coatings for steel corrosion protection

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 for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Corrosive (Category 1)	H314 – Causes severe skin burns and eye damage
Skin sensitisation (Category 1)	H317 – May cause an allergic skin reaction

In Australia, additional non-GHS hazard statements apply (see *Guidance on the Classification of Hazardous Chemicals Under the WHS Regulations* for further information; SWA, 2012c). Based on the available information, the following additional (non-GHS) hazard statement is also recommended (if applicable):

AUH071 – Corrosive to the respiratory tract

Based on the available information, the notified polymer (at ≤ 83% concentration) is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R34: Causes burns
R43: May cause sensitisation by skin contact

The environmental hazard classification according to the *Globally Harmonised System for the 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.

Hazard classification	*Hazard statement*
Acute (Category 1)	H400 – Very toxic to aquatic life
Chronic (Category 1)	H410 – Very toxic to aquatic life with long lasting effects

Human health risk assessment
Provided that the recommended control measures are in place to minimise exposure to the notified polymer, the notified polymer is not considered to pose an unreasonable health risk to 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 assessed 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:
  - Corrosive (Category 1): H314 – Causes severe skin burns and eye damage
  - Skin Sensitisation (Category 1): H317 – May cause an allergic skin reaction
  - AUH071 – Corrosive to the respiratory tract

The above should be used for products/mixtures containing the notified polymer, if applicable, based on the concentration of the notified polymer present and the intended use/exposure scenario.

- Due to the corrosive properties of the notified polymer, the notifier should consider their obligations under the Australian Dangerous Goods Code.

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.

(Material) Safety Data Sheet

- The (M)SDS provided by the notifier should be amended as follows:
  - Skin Sensitisation (Category 1): H317 – May cause an allergic skin reaction

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, as introduced and/or in uncured form:
  - Enclosed, automated processes, where possible
  - Exhaust ventilation, where possible
  - Spray booths for spray application, where practicable.

- 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 as introduced and/or in uncured form:
  - Avoid contact with skin and eyes
  - Avoid inhalation
  - Avoid spills and splashing during use
  - Clean up spills promptly
  - Avoid contact with uncured coatings
  - Prevent leaks and spills
  - A shower and eyewash station or similar facilities should be available

- 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 as introduced and/or in uncured form:
  - Coveralls
  - Impervious gloves
  - Impervious footwear
  - Goggles and face shield
  - Appropriately fitted respiratory protection during spray application
  - Respiratory protection (if ventilation is inadequate and/or if inhalation exposure to the notified polymer is expected)

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, 2012a) 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 for the 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

- The notified polymer should be disposed of to landfill.

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, 2012b) 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 chemical 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(2) of the Act; if
- the function or use of the polymer has changed from a component of industrial coating for steel corrosion protection, 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.

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet
The (M)SDS of the notified polymer (and products containing the notified polymer) provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Akzo Nobel Pty Ltd (ABN: 59 000 119 424)
115 Hyde Road
YERONGA QLD 4104

NOTIFICATION CATEGORY
Standard: Synthetic polymer with Mn < 1000 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, manufacture/import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: acute inhalation study, acute dermal toxicity, acute eye irritation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
CEC/754, CEC/781, CER/40

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Interzone 954 Part B (product containing the notified polymer)

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference NMR, IR, GC, GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 80%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Pale, straw coloured viscous liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	0 °C	Measured
Boiling Point	295 °C at 100.6 kPa (partial boiling or decomposition)	Measured
Density	1020 kg/m^3 at 20.0 °C	Measured
Vapour Pressure	8.6 x 10^{-5} kPa at 25 °C	Measured
Water Solubility	≥ 119 g/L at 20.0 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains functionality that may hydrolyse slowly under environmental conditions (pH 4-9)
Partition Coefficient (n-octanol/water)	Log Pow = 0.408 at 24.0 °C	Measured. However, the notified polymer has surface activity and expected to partition to the interface between octanol

		and water.
Adsorption/Desorption	Not determined	Expected to partition to surfaces from water in the environment based on its surfactant properties and cationic functionalities.
Dissociation Constant	pKa = 8.4, 9.6 and 10.3	Estimated using SPARC, v4.6, 2011; The notified polymer contains basic functionalities and is expected to be ionised in the environment.
Flash Point	91 °C at 102.8 kPa	Measured
Autoignition Temperature	312 °C	Measured
Explosive Properties	Predicted to be negative	Estimated, based on the chemical structure of the test item.
Oxidising Properties	Predicted to be negative	Estimated, based on the chemical structure of the test item.
Surface tension	47.8 to 48.8 mN/m	Measured

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. It is intended to react in the curing of the two-part coating. Thermal decomposition occurs at temperatures > 250 °C.

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 for the 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 imported as a component of a curing agent containing the notified polymer at 55-65% concentration in 200L steel drums.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	80	80	85	90	95

PORT OF ENTRY
Brisbane and Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Akzo Nobel Pty Ltd

TRANSPORTATION AND PACKAGING
The product containing the notified polymer will be imported in 200 L steel drums and transported from the port to the notifier's facilities. It will then be dispensed into 4 L steel cans, which will be shipped to warehouses around Australia, as well as by ship to Tasmania and New Zealand.

USE
The notified polymer will be used as one component of a two-part system in industrial coatings for the preservation of steel. The notified polymer will be used in industrial settings only and will not be used in the DIY (do-it-yourself)market. Uses include steel pipework, cooling towers, sludge water tanks, splash zones, waste water facilities, wharf piles and ship loaders.

OPERATION DESCRIPTION

The imported curing agent containing the notified polymer at 55-65% concentration will be dispensed from 200 L steel drums into a 500 L steel pan/dispenser and mixed at low speed until uniform. The mixture will then be repackaged into 4 L steel cans under a nitrogen blanket, for distribution to end use sites.

At the end-use sites, Part B of the two-part system Interzone 954 (containing the notified substance at 55-65% concentration) will be homogenised, in some applications using a high speed power agitator, prior to the addition of Part B to a similarly homogenised Part A. The resulting mixture will then be applied to steel surfaces by professional painting contractors. The concentration in the coating mixture will be < 10%. Application will be mainly by spray, using a two-person application team – a sprayer and a potman. Where necessary, the sprayer will be lifted to the work area in a cherry picker. For smaller projects, the coating may be applied by brush or roller.

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)*
Paint Formulation	14	40
Quality control during formulation	1	40
End user – spray application	6	75
End user – pot-men	6	75

EXPOSURE DETAILS

Transportation and warehousing workers
Exposure of workers to the notified polymer during transport and storage is not expected except in the unlikely event of an accident involving a breach of the sealed cans.

Repackaging
Dermal, ocular and inhalation exposure of workers to the notified polymer at 55-65% concentration may occur during the transfer of the notified polymer from 200 L steel drums into a 500 L steel pan/dispenser and during the subsequent filling of 4 L steel cans. Exposure may also occur during quality control analysis. The use of personal protective equipment (PPE) such as respirators, impervious gloves, goggles and coveralls should minimise exposure. Exposure is also expected to be minimised by the use of local exhaust ventilation and/or enclosed systems.

Application of the two-part system
Dermal, ocular and inhalation exposure of workers to the notified polymer at 55-65% concentration may occur during the homogenisation of Part B of the two-part system Interzone 954. Dermal, ocular and inhalation exposure of workers to the notified polymer at < 10% concentration may occur during the handling of the product formed from the mixing of the two components, Part A and Part B of the two-part system. The resulting mixture will typically be applied to surfaces by spray. Spray applications will be conducted both indoors (20% of the total import volume) and outdoors (80% of the total import volume). In some applications, products containing the notified polymer may be applied by brush and/or roller. Workers applying the coatings may incur dermal, ocular and inhalation exposure. The use of personal protective equipment (PPE) such as respirators, impervious gloves, goggles and coveralls would limit exposure. Exposure may also be minimised during indoor application by the use of ventilated spray booths. Where application occurs outdoors from a cherry picker, in some cases exposure would be reduced by use of an enclosed cab.

After application and once cured, the notified polymer is not expected to be bioavailable, and further dermal contact should not lead to exposure.

6.1.2. Public Exposure
Coatings containing the notified polymer at 55-65% concentration are intended for industrial use only and will not be sold to the public. Members of the public may come into contact with steel structures coated with coatings

containing the notified polymer. However, once the coatings have cured, the notified polymer will be unavailable for exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer at > 80% concentration are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Skin irritation (in vitro)	corrosive
Mouse, skin sensitisation – Local lymph node assay	evidence of sensitisation
Rat, repeat dose oral toxicity – 56 days	NOEL = 100 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro gene mutation	non genotoxic
Genotoxicity – in vitro chromosome aberration	non genotoxic

Toxicokinetics, metabolism and distribution.
No toxicokinetic data on the notified polymer were submitted. Absorption across the skin, gastrointestinal tract and respiratory tract is expected based on the low molecular weight (<1000), the presence of significant levels of species with molecular weight <500 Da, and the partition coefficient (Log Pow = 0.408) and water solubility (≥ 119 g/L). This is supported by evidence of systemic toxicity observed in the repeat dose oral study in rats, and toxic effects after dermal administration in the LLNA.

Acute toxicity.
Acute studies were not carried out because of the corrosivity of the notified polymer. During a preliminary study for skin sensitisation mortality was seen in test animals treated dermally 2 or 3 times with the notified polymer at 50% concentration and 25% concentration. However, toxicity was not observed at 10% concentration. These results suggest that the polymer is acutely toxic; however the limited data available is not sufficient for classification.

Irritation and sensitisation.
The notified polymer was corrosive under the conditions of an *in vitro* membrane barrier test (Corrositex system). The study authors determined an R34 – "Causes burns" classification, based on the break through time.

Eye irritation studies were not carried out due to corrosivity.

The notified polymer is a skin sensitiser based on a positive result from an LLNA study in mice.

Repeated dose toxicity.
In a combined repeat dose gavage study with a reproductive/developmental screening test, rats were administered the notified polymer at 10, 30 or 100 mg/kg bw/day for up to 56 days. At these doses there were some minor effects, but these were mostly considered to be incidental and unrelated to treatment. In a preliminary 14-day range-finding study, toxicity causing mortalities was seen at 300 mg/kg bw/day. The No Observed Effect Level (NOEL) for the main study was established as 100 mg/kg bw/day based on a lack of toxicologically significant findings for both systemic toxicity and reproductive toxicity at this dosage.

Mutagenicity/Genotoxicity.
The notified polymer was not mutagenic in a bacterial reverse mutation test. It was not mutagenic to mouse lymphoma cells treated *in vitro* in a gene mutation test, nor was it clastogenic to human lymphocytes in an *in vitro* chromosome aberration test.

Toxicity for reproduction.
In a repeat dose gavage study with reproduction/developmental screening test with dosing up to 56 days, no toxicologically significant findings were reported.

Impurities
The notified polymer contains a hazardous impurity that is corrosive and acutely harmful by all routes.

Health hazard classification

Based on the available information, the notified polymer as introduced at 55-65% recommended for hazard classification according to the *Globally Harmonised System for the 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*
Corrosive (Category 1)	H314 – Causes severe skin burns and eye damage
Skin sensitisation (Category 1)	H317 – May cause an allergic skin reaction

In Australia, additional non-GHS hazard statements apply (see *Guidance on the Classification of Hazardous Chemicals Under the WHS Regulations* for further information; SWA, 2012c). Based on the available information, the following additional (non-GHS) hazard statement is also recommended:

AUH071 – Corrosive to the respiratory tract

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 phrase(s):

R34 Causes burns
R43 May cause sensitisation by skin contact

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymer is corrosive and a skin sensitiser. Workers may be exposed to the polymer at 55-65% in the imported product during repackaging and during handling at the end-use sites. Pot-men and workers applying the coatings may also be exposed to the polymer at <10% after it is mixed with the second part of the coating product, during application by spray, brush or roller. Exposure of workers may be dermal, ocular and via inhalation.

Engineering controls such as enclosed processes or spray booths are expected to be used during repackaging and during indoors applications. These controls would minimise worker exposure, especially during spray application.

The risk to workers is considered to be highest where inhalation exposure to the notified polymer is not controlled by engineering controls, e.g. during spray applications outside. During these processes, PPE is required to minimise worker exposure and risk.

Provided that sufficient control measures are in place to minimise worker exposure to the notified polymer, including engineering controls whenever possible, safe work practices and PPE, the risk to workers is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer is intended for use in industrial applications by qualified operators. The public may come into contact with manufactured products containing the cured coating; however, the notified polymer will be reacted into the coating matrix and not bioavailable. Therefore, when used in the proposed manner, the risk to public health from the notified polymer 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 not be manufactured in Australia. The imported curing agent containing the notified polymer will be repackaged for distribution to end-use sites. Spills from repackaging and residues remaining in the empty containers are expected to be collected and disposed of to landfill. No significant release of the notified polymer to the aquatic environment is expected from these activities.

RELEASE OF CHEMICAL FROM USE

The notified polymer will be used as one component of a two-part system in industrial coatings for the preservation of steel. At the end-use sites, the two-part mixture containing the notified polymer will be mixed to form an inert polymerised coating after curing. The resulting coating is expected to be applied to steel surfaces mainly by spray for both indoors (20% of the total import volume) and outdoors (80% of the total import volume) applications. In some applications, products containing the notified polymer may be applied by brush and/or roller. The transfer efficiency is expected to be high when coatings are applied to substrates using brush and/or roller. Therefore, the main release of the notified polymer to the environment may come from overspray.

The indoor application is expected to occur in professional spray yards or spray booths. In spray yards or booths, the overspray is expected to be collected and disposed of in accordance with local regulations. When application is undertaken in outdoor areas, the overspray is expected to be cured as inert polymer on the ground and may potentially be washed into aquatic systems over time. However, cured notified polymer is not expected to be bioavailable. It is estimated by the notifier that up to 1% of the total import volume of the notified polymer may be released to the environment from equipment cleaning. The washings from cleaning and spills from the spray application are expected to be collected and disposed of. Solid wastes are expected to be disposed of to landfill and liquid wastes are expected to be disposed of by licensed authorities.

The notified polymer is expected to be used in industrial applications only and not be used commercially or domestically. Therefore, significant quantities of the notified polymer are not expected to be released to the aquatic environment.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the notified polymer is expected to share the fate of the articles to which it has been applied and either be thermally decomposed during metal reclamation processes or disposed of to landfill. Residual notified polymer remaining in used containers (up to 0.1%) is expected to be disposed to landfill, as cured film, or be collected and disposed of by a licensed authority, as uncured liquids.

7.1.2. Environmental Fate

The notified polymer was determined not to readily biodegrade in the environment (16% biodegradability over 28 days). For the details of the environmental fate study please refer to Appendix C.

Used as one component of a two-part system for industrial coating of steel, the majority of the notified polymer is expected to cross-link to form an inert polymer film after its application. The notified polymer will share the fate of the coated articles, which are expected to be eventually disposed of to landfill or be subjected to metal reclamation. In its cured form, the notified polymer is not expected to be bioavailable or mobile in the environment. Bioaccumulation of the uncured polymer is unlikely due to the limited bioavailability and surface activity of the notified polymer. The notified polymer will eventually degrade in landfill via biotic or abiotic pathways, or by thermal decomposition during metal reclamation processes, to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer is not expected to be present at significant concentrations in the aquatic environment because of the very low potential for direct release to surface waters when used in steel coating for industrial applications. A predicted environmental concentration (PEC) has therefore not been calculated.

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.

Endpoint	*Result (mg/L)*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) = 28 NOEC (96 h) = 3.2	Harmful to fish
Daphnia Toxicity	EC50 (48 h) = 0.90 NOEC (48 h) = 0.32	Very toxic to aquatic invertebrates
Algal Toxicity	E_rC50 (72 h) = 0.029 NOE_rC (72 h) = 0.0023	Very toxic to algae
Inhibition of Bacterial Respiration	EC50 (3 h) = 200 NOEC (3 h) = 10	May be inhibitory to bacterial respiration

Based on the endpoints of algal toxicity, the notified polymer is considered to be very toxic to aquatic organisms on an acute basis, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009). Therefore, the notified polymer is formally classified as "Acute Category 1; Very toxic to aquatic life" under the GHS. Based on the acute toxicity and potential for the notified polymer to persist in the environment, the chronic hazard of the notified polymer has been formally classified as "Chronic Category 1; Very toxic to aquatic life with long lasting effects" under the GHS.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) for the notified polymer has been calculated and is presented in the table below. The PNEC is calculated based on the endpoint of the most sensitive species (algae, E_rC50 = 0.029 mg/L). An assessment factor of 100 has been used as acute toxicity endpoints for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Invertebrates)	0.029	mg/L
Assessment Factor	100	
PNEC:	0.29	µg/L

7.3. Environmental Risk Assessment

A Risk Quotient is unable to be quantified as a PEC was not calculated. There is no significant aquatic release of the notified polymer anticipated based on its reported use pattern. Moreover, after curing, the majority of the imported quantity of the notified polymer will be irreversibly incorporated into an inert matrix and it is not expected to be mobile, bioavailable or bioaccumulative. Uncured polymer waste is not expected to bioaccumulate in biota either based on the notified polymer's surface activity. On the basis of the assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Pour Point 0 ± 3 °C

Method	OECD TG 102 Melting Point/Melting Range.
Remarks	Test performed on the notified polymer, containing the notified polymer at 50-100%.
Test Facility	Harlan (2012a)

Boiling Point 295 °C at 101.3 kPa

Method	OECD TG 103 Boiling Point.
Remarks	Test performed on the notified polymer, containing the notified polymer at 50-100%. DSC method. The notified polymer underwent partial boiling and/or decomposition from approximately 295 °C.
Test Facility	Harlan (2012a)

Density 1020 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids.
Remarks	Test performed on the notified polymer, containing the notified polymer at 50-100%. The density was determined using a pycnometer.
Test Facility	Harlan (2012a)

Vapour Pressure 8.6 x 10^{-5} kPa at 25 °C

Method	EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks	Test performed on the notified polymer, containing the notified polymer at 50-100%. A vapour pressure balance was used to determine the vapour pressure at various temperatures and a linear regression analysis employed to calculate the vapour pressure at 25 °C.
Test Facility	Harlan (2012b)

Water Solubility ≥ 119 g/L at 20.0 °C

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method. The notified polymer has surface activity and is expected to disperse in water. No definitive test was performed given a saturation concentration could not be determined as is required by the test guidelines. The overall conclusion has been taken as a limit value of the highest observed solubility obtained during the preliminary test. The pH of the test sample was measured to be 11.2-11.9.
Test Facility	Harlan (2012a)

Partition Coefficient (n-octanol/water) Log Pow = 0.408 at 24.0 °C

Method	OECD TG 107 Partition Coefficient (n-octanol/water).
Remarks	Flask Method. Water and n-octanol were pre-saturated with their respective opposite phases prior to use. The pH of n-octanol saturated water was adjusted to pH 12 to ensure the test substance was partitioned essentially in its non-ionized form. Phase separation was completed by centrifugation. Aliquots from each phase were taken for analysis. The concentration of the test substance in the each phase was determined by HPLC. However, the notified polymer has surface activity and it is expected to partition to phases boundaries. Its partition coefficient may not be accurately determined.
Test Facility	Harlan (2012a)

Surface Tension 47.8-48.8 mN/m at 20 °C

Method	OECD TG 115 Surface Tension of Aqueous Solutions.
Remarks	Test performed on the notified polymer, containing the notified polymer at 50-100%. The concentration used was 1.02-1.03 g/L.

A ring method involving a tensiometer, designed to be compatible with the OECD method, was used.
The notified polymer was considered to be surface-active.

Test Facility Harlan (2012a)

Flash Point 91 °C at 101.3 kPa

Method EC Council Regulation No 440/2008 A.9 Flash Point.
Remarks Test performed on the notified polymer, containing the notified polymer at 50-100%. A closed cup equilibrium method was used. The flash point temperature was determined at a pressure of 102.8 kPa and this temperature was corrected to a pressure of 101.3 kPa.
Test Facility Harlan (2012b)

Autoignition Temperature 312 ± 5 °C

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks Test performed on the notified polymer, containing the notified polymer at 50-100%. The test determined the lowest temperature at which the notified polymer underwent ignition in a heated flask.
Test Facility Harlan (2012b)

Explosive Properties Predicted to be negative

Method EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks The notified polymer was assessed for chemical groups that imply explosive properties according to Bretherick's Handbook on Reactive Chemical Hazards, 7th Edition, Academic Press, 2007.
Test Facility Harlan (2012b)

Oxidizing Properties Predicted to be negative

Method EC Council Regulation No 440/2008 A.21 Oxidizing Properties (Liquids).
Remarks The notified polymer was assessed for chemical groups that imply oxidising properties according to Bretherick's Handbook on Reactive Chemical Hazards, 7th Edition, Academic Press, 2007.
Test Facility Harlan (2012b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – skin (in vitro)

TEST SUBSTANCE	Notified Polymer
METHOD	OECD TG 435 In Vitro Membrane Barrier Test Method for Skin Corrosion
Remarks - Method	Sulphuric acid (95-98%) was used as the positive control and citric acid (10%) was used as the negative control. The notified polymer was tested concurrently with the formulated product containing the polymer, using the Corrositex system. There were no significant protocol deviations.
RESULTS	
Remarks - Results	The test substance produced an immediate colour change in the compatibility test and is therefore appropriate for use in the test system. The test substance was classified in Category 1, for the purpose of determining which breakthrough timescale should be used for determining corrosivity. In the membrane barrier test, a colour change was observed after an average of 119 minutes in four replicates, thus the test substance is considered corrosive and can be assigned an EU Risk Phrase R34.
CONCLUSION	The notified polymer is corrosive under the conditions of the membrane barrier test.
TEST FACILITY	Harlan (2011c)

B.2. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified Polymer
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/ CBA/Ca, female
Vehicle	Acetone:olive oil (4:1)
Remarks - Method	No significant protocol deviations. The concentrations used in the main study were chosen on the basis of a preliminary test. Toxicity was evident in animals treated with 50% and 25% of the notified polymer. At 10% there was no increase in ear thickness ≥25% that would indicate systemic toxicity or irritation. Thus this concentration was selected as the highest concentration for the main study. The positive control was tested concurrently.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Positive Control (α-Hexylcinnamaldehyde)		
21 (85% x 25%)	14446	8.40
Test Substance		
0 (vehicle control)	1720	-
2.5	4622	2.69
5	11451	6.66
10	35607	20.70

Remarks - Results	In the main study, no signs of systemic toxicity were observed at any concentration, however mild redness on the ears was noted in the animals treated at 10%.

	The stimulation index was >3 in the 5% and 10% test groups, indicating a sensitising response. The stimulation index (EC_3) was calculated to be 2.7%. The positive control behaved as expected, confirming the validity of the test system.
CONCLUSION	There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.
TEST FACILITY	Harlan (2012c)

B.3. Repeat dose toxicity

TEST SUBSTANCE	Notified Polymer
METHOD	OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test.
Species/Strain	Rat/Wistar Han:HsdRccHan:WIST
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: Up to 56 days Dose regimen: 7 days per week
Vehicle	Polyethylene glycol 400
Remarks - Method	The doses for the main study were determined from a fourteen day repeated dose oral (gavage) range-finding toxicity study using doses of 30, 100, and 300 mg/kg bw/day. Significant toxicity was seen in the animals treated at 300 mg/kg bw/day. Within the 100 mg/kg bw/day dosage group, one male and one female each exhibited noisy respiration on Day 2 and Day 1 respectively, whilst increased salivation post dosing was observed in all test animals on Day 12 and in all males on Day 14. Males in the 100 mg/kg bw/day dosage group also exhibited lower body weight gains and lower food conversion efficiencies. In the main study, functional observations were performed on five selected males from each dose group after the completion of the pairing phase, and for five selected parental females from each dose group on Day 4 post partum. Haematology and blood chemistry were evaluated prior to termination on five selected males and females from each dose group.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	10M + 10F	0	0/20
low dose	10M + 10F	10	0/20
mid dose	10M + 10F	30	0/20
high dose	10M + 10F	100	0/20

Mortality and Time to Death

No mortalities were reported.

Clinical Observations

Salivation was observed post-dosing in the 30 mg/kg bw/day and 100 mg/kg bw/day groups.

Noisy respiration was observed following doses at 100 mg/kg bw/day in one male and one female on Day 4 and Day 36 respectively.

Generalised fur loss was observed in one female from Day 27 onwards.

No treatment-related findings were seen in the test animals compared to controls in weekly open field arena observations, functional tests or sensory reactivity.

Bodyweights, Food Consumption and Water Consumption

Statistically significant decreases in body weight gains in males dosed at 100 mg/kg bw/day were observed during Week 1. However, the subsequent gain in weight of these test animals was equal to or slightly greater than control animals.
There were no statistically significant changes in food efficiency (ratio of bodyweight gain to absolute consumption) or significant intergroup differences in water consumption.

Reproductive Performance – Mating, Fertility, Gestation Length
Treatment at any dose did not affect mating performance as assessed by pre-coital interval and mating evidence at the times of conception.
One mated female dosed at 30 mg/kg bw/day failed to achieve pregnancy. Otherwise, fertility was not affected at any dose.
Gestation length was unaffected by treatment at any dose.

Litter Responses – Offspring Litter Size, Sex Ration and Viability, Offspring Growth and Development
One female dosed at 30 mg/kg bw/day did not conceive. The remaining dosage groups achieved 10 litters from the 10 females of each group.
There were no effects at any doses on corpora lutea and implantation counts, post-natal litter size, offspring survival or sex ratio.
There were no obvious effects from maternal treatment at any dose on mean offspring body weight or litter weight on Day 1 or Day 4. Surface righting ability of the offspring on Day 1 was unaffected by treatment at any dose. Treatment at any dose did not lead to any clinical signs of adverse effects on offspring development.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
There was no obvious effect of treatment on haematology parameters for either sex at any dose.
At 10 mg/kg bw/day dose, males were found to have statistically significant lower lymphocyte counts compared with control, but the study authors considered this finding to be incidental and unrelated to treatment.
There were no obvious effects of treatment on blood chemistry parameters for males at any dose.
For males at all dosages, there were statistically significant lower bile acid levels reported. However there was no dose-response for these symptoms. For males at 10 mg/kg bw/day, statistically higher lower albumin and higher glucose levels were reported. The study authors concluded that these finding were incidental and unrelated to treatment due to the absence of a dose-response for these symptoms.
For females at 30 and 100 mg/kg bw/day, statistically significant higher chlorine levels were reported. The study authors concluded that these finding were incidental and unrelated to treatment due to the absence of a dose-response for these symptoms.

Effects in Organs
The study authors reported that in the necropsy findings, there were no treatment related effects on offspring.
In the adult test animals, one male dosed at 10 mg/kg bw/day was found to have reddened lungs. This finding was considered by the test authors to be incidental and unrelated to treatment.
There were no statistically significant differences from the controls for organ weights at any dose.
There were no microscopic changes observed that were considered to be related to the treatment.
The kidneys of one female treated at 100 mg/kg bw/day were reported to have tubular necrosis. However, this was an isolated case and was considered by the study authors to be incidental and unrelated to the treatment with the test item.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 100 mg/kg bw/day in this study, based on an absence of toxicologically significant findings for both systemic toxicity and reproductive toxicity.

TEST FACILITY Harlan (2013)

B.4. Genotoxicity – bacteria

TEST SUBSTANCE	Notified Polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test Plate incorporation and Pre-incubation procedures
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver

Concentration Range in Main Test	Test 1: Plate incorporation method with and without metabolic activation: – All salmonella strains: 0.5, 1.5, 5, 15, 50, 150, 500 µg/plate – E.coli strain WP2uvrA: 1.5, 5, 15, 50, 150, 500, 1500 µg/plate Test 2: Pre-incubation method with and without metabolic activation: – All bacterial strains: 0.5, 1.5, 5, 15, 50, 150, 500 µg/plate
Vehicle	Dimethyl sulphoxide
Remarks - Method	A preliminary toxicity study was conducted with strains TA100 and WP2uvrA. A range-finding study (Test 1) was conducted by the plate incorporation method in the presence and absence of metabolic activation using 0.5-500 µg/plate. The main study (Test 2) was conducted using the pre-incubation method.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 150	-	>1500	negative
Test 2	-	≥ 500	>1500	negative
Present				
Test 1	≥ 150	-	>1500	negative
Test 2	-	≥ 500	>1500	negative

Remarks - Results	There were no statistically significant increases in the mutation frequency of treated plates over concurrent controls. The positive controls produced satisfactory responses, thus confirming the sensitivity of the study.

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

TEST FACILITY Harlan (2012e)

B.5. Genotoxicity – in vitro

TEST SUBSTANCE Notified Polymer

METHOD OECD TG 476 In Vitro Mammalian Cell Gene Mutation Test

Species/Strain	
Cell Type/Cell Line	Mouse lymphoma/L5178Y
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver
Vehicle	Dimethyl sulphoxide
Remarks - Method	A range-finding study was conducted in the presence and absence of metabolic activation at concentrations of up to 1000 µg/mL, as the maximum dose level was limited by the effects on pH caused by the polymer. Positive controls: ethyl methanesulfonate (without metabolic activation), cyclophosphamide (with metabolic activation). No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 12.5, 25, 50, 100, 200, 300, 400, 500	4 hours	48 hours
Test 2	0, 3.75, 7.5, 15, 30, 45, 60, 80, 100	24 hours	48 hours
Present			
Test 1	0, 50, 100, 200, 300, 400, 500, 600, 700	4 hours	48 hours
Test 2	0, 50, 100, 200, 300, 400, 500, 600, 700	4 hours	48 hours

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test*	*Cytotoxicity* in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 500	> 500	none observed	negative
Test 2	≥ 125	≥ 100	none observed	negative
Present				
Test 1	≥ 750	≥ 700	none observed	negative
Test 2	≥ 750	≥ 700	none observed	negative

* ≤10% relative survival

Remarks – Results: There were no statistically significant increases in mutant frequency in the plates treated with the test substance. The positive controls produced a positive response, thus confirming the sensitivity of the test.

CONCLUSION: The notified polymer was not mutagenic to mouse lymphoma cells treated *in vitro* under the conditions of the test.

TEST FACILITY: Harlan (2012f)

B.6. Genotoxicity – in vitro

TEST SUBSTANCE: Notified Polymer

METHOD: OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Species/Strain: Human

Cell Type/Cell Line: Lymphocytes

Metabolic Activation System: S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver (2% in preliminary test and Test 1, 1% in Test 2)

Vehicle: Dimethyl sulphoxide

Remarks - Method: A range-finding study was conducted at concentrations of up to 2000 µg/mL only, as significant changes in pH were seen at higher concentrations. The results of this study were used to determine the dosages for the main study.
The positive controls used were Mitomycin C (without metabolic activation) and Cyclophosphamide (with metabolic activation).
No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 62.5, 125, 250*, 500*, 750*, 1000*	4	20
Test 2	0*, 15.63, 31.25*, 62.5*, 125*, 250*, 500	24	24
Present			
Test 1	0*, 125, 250*, 500*, 750*, 1000*, 1500	4	20
Test 2	0*, 125*, 250*, 500*, 750*, 1000, 1500	4	20

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 1000	≥ 250	none observed	negative
Test 2	≥ 500	≥ 250	none observed	negative
Present				
Test 1	≥ 1000	≥ 500	none observed	negative

Test 2	≥ 500	≥ 250	none observed	negative

Remarks - Results	In the preliminary test haemolysis was observed for different test conditions at ≥ 500 µg/mL and ≥ 1000 µg/mL, and marked toxicity was noted in all groups. Haemolysis was observed during Test 1 at the end of the exposure period at concentrations ≥ 250 µg/mL in the 4(20)-hour exposure group in the absence of metabolic activation and at concentrations ≥ 500 µg/mL in the presence of metabolic activation. Haemolysis was observed during Test 2 at the end of the exposure period at concentrations ≥ 250 µg/mL in both exposure groups in the absence and presence of metabolic activation. The test item did not induce any statistically significant increases in the frequency of cells with aberrations, either in the presence or absence of metabolic activation. Statistically significant increases in aberrations were seen in the positive control groups.
CONCLUSION	The notified polymer was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	Harlan (2012f)

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 sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Carbon dioxide and total organic carbon analysis
Remarks - Method	The test substance was exposed to activated sewage sludge in sealed culture vessels in the dark at approximately 21°C. The degradation of the test item was assessed by the determination of carbon dioxide produced. The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	0	2	49
8	0	8	88
14	0	14	100
21	10	21	96
28	19	28	98
29*	16	29	94

* Day 29 values corrected to include any carry-over of CO_2 detected in the replicate

Remarks - Results	All validity criteria for the test were satisfied. The toxicity control attained 37% degradation after 14 days and 46% after 28 days, indicating the test substance was not toxic to the micro-organisms in the sewage treatment sludge used in the test.
CONCLUSION	The notified polymer is not considered to be readily biodegradable
TEST FACILITY	Harlan (2012g)

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.
Species	Rainbow Trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	140 mg $CaCO_3$/L
Analytical Monitoring	High performance liquid chromatography mass spectrometry (HPLC-MS-MS)
Remarks – Method	Following a preliminary range-finding test, a group of 7 fish was exposed to an aqueous solution of test substance at 14 °C under semi-static conditions. The test media were renewed daily. The number of mortalities and any

sub-lethal effects of exposure in each test and control were monitored 3 hours after the start of exposure and then daily throughout the test.

The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	< LOQ*	7	0	0	0	0	0
1.0	-	7	0	0	0	0	0
3.2	2.92	7	0	0	0	0	0
10	10.0	7	0	0	14	14	14
32	28.7	7	0	0	29	29	43
100	102	7	0	29	86	86	100

*: LOQ = Limit of quantitation (0.093 mg/L)

LC50	28 mg/Lat 96 hours (95% confidence limit: 15-56 mg/L).
NOEC	3.2 mg/L at 96 hours.
Remarks – Results	All validity criteria for the test were satisfied.

The measured concentrations for the test substance at 0, 24 and 96 hours ranged from 86% to 102% of nominal test concentrations. Therefore, it was considered justifiable to calculate the EC50 values in terms of the nominal concentrations.

After 24 hours exposure, a single fish was observed with severe loss of equilibrium. Due to the approach of a substantial severity limit, the fish was killed and considered as the mortality for the 48-hour time point. After 72 hours exposure, a single fish was observed with severe loss of equilibrium. The fish was killed and considered as the mortality for the 96-hour time point.

CONCLUSION The notified polymer is harmful to fish

TEST FACILITY Harlan (2012g)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified Polymer

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test and Reproduction Test – Static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	High performance liquid chromatography mass spectrometry (HPLC-MS-MS)
Remarks - Method	Following a preliminary range-finding test, two groups of daphnia (10 daphnids per replicate) were exposed to an aqueous solution of test substance at 20 °C under static conditions.

The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.

RESULTS

Concentration mg/L	*Number of D. magna*	*Number Immobilised*

Nominal	*Actual*		*24 h*	*48 h*
Control	< LOQ*	20	0	0
0.10	-	20	0	0
0.32	0.305	20	0	0
1.0	0.957	20	0	16
3.2	3.28	20	4	17
10	11.2	20	17	20
32	31.3	20	20	20
100	102	20	20	20

*: LOQ = Limit of quantitation (0.047 mg/L)

LC50	0.90 mg/L at 48 hours (95% confidence limit: 0.65-1.3 mg/L)
NOEC	0.32 mg/L at 48 hours
Remarks - Results	All validity criteria for the test were satisfied. The measured concentrations for the test substance at 0 and 48 hours ranged from 88% to 112% of nominal test concentrations. Therefore, the results were based on nominal concentrations.

CONCLUSION The notified polymer is very toxic to aquatic invertebrates

TEST FACILITY Harlan (2012i)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified Polymer

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: Control, 0.0032, 0.01, 0.032, 0.1 and 0.32 mg/L Actual: < LOQ (Limit of quantitation, 0.0034 mg/L), < LOQ, 0.0029, 0.013, 0.093 and 0.30 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	High performance liquid chromatography mass spectrometry (HPLC-MS-MS)
Remarks - Method	Following a preliminary range-finding test and an initial experiment, *Pseudokirchneriella subcapitata* was exposed to an aqueous solution of test substance at 24 ± 1 °C under constant illumination and shaking. The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.

RESULTS

Biomass		*Growth*	
E_bC50	*NOE_bC*	*E_rC50*	*NOE_rC*
mg/L at 72 h	*mg/L at 72 h*	*mg/L at 72 h*	*mg/L at 72 h*
0.007	0.0017	0.029	0.0023
95% confidence limit: 0.006-0.008		95% confidence limit: 0.023-0.035	

Remarks - Results	All validity criteria for the test were satisfied. Analysis of the test preparations at 72 hours showed a slight decline in the measured test concentrations. The measured concentrations were in the range of less than LOQ to 0.25 mg/L for the nominal concentrations of 0.0032 mg/L to 0.32 mg/L. Due to this decline in measured test concentration, the results were reported based on the geometric mean measured test concentrations.

CONCLUSION	The notified polymer is very toxic to algae
TEST FACILITY	Harlan (2012j)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified Polymer
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: Control, 10, 32, 100, 320 and 1000 mg/L Actual: Not determined
Remarks – Method	Following a preliminary range-finding test, activated sludge was exposed to an aqueous dispersion of test substance at 20 ± 2 °C for 3 hours. The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.
RESULTS	
EC50	200 mg/L at 3 hours (95% confidence limit: 170-240 mg/L)
NOEC	10 mg/L at 3 hours
Remarks – Results	In some instances, the initial and final dissolved oxygen concentrations were below those recommended in the test guideline. This was considered to have no adverse effect on the results of the study given that in all cases the oxygen consumption rate was determined over the linear portion of the oxygen consumption trace. Variation in respiration rates of controls was ± 4.3%, within 15% range. The EC50 (3 hour contact) for 3,5-dichlorophenol, the reference test material, was determined to be 12 mg/L which is within the range of 5-30 mg/L. Therefore, the results for the study are considered valid.
CONCLUSION	The notified polymer may be inhibitory to bacterial respiration.
TEST FACILITY	Harlan (2012k)

BIBLIOGRAPHY

Harlan (2012a) [The Notified Polymer]: Determination of General Physico-Chemical Properties (Study No. 41102269, September, 2012). Derbyshire, U.K., Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2012b) [The Notified Polymer]: Determination of Hazardous Physico-Chemical Properties (Study No. 41102270, May, 2012). Derbyshire, U.K., Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2012c) [The Notified Polymer]: Local Lymph Node Assay in the Mouse (Study No. 41102277, April, 2012). Derbyshire, UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2011c) [The Notified Polymer]: Corrositex Assay (Study No. 41100684, March, 2011). Derbyshire, UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2013) [The Notified Polymer]: Oral (Gavage) Combined Repeat Dose Toxicity Study with Reproduction/Developmental Toxicity Screening Test in the Rat (OECD 422) (Study No. 41102279, September, 2013). Derbyshire, UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2012d) [The Notified Polymer]: Reverse Mutation Assay "Ames Test" Using Salmonella Typhimurium and Escherichia Coli (Study No. 41102280, April, 2012). Derbyshire, UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2012e) [The Notified Polymer]: L5178 TK +/- Mouse Lymphoma Assay (Study No. 41102918, May, 2012). Derbyshire, UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2012f) [The Notified Polymer]: Chromosome Aberration Test in Human Lymphocytes *In Vitro* (Study No. 41102281, June, 2012). Derbyshire, UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2012g) [The Notified Polymer]: Assessment of Ready Biodegradability; CO_2 Evolution Test (Study No. 41102286, September, 2012). Derbyshire, UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2012h) [The Notified Polymer]: Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) (Study No. 41102917, September, 2012). Derbyshire, UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2012i) [The Notified Polymer]: Acute Toxicity to *Daphnia Magna* (Study No. 41102284, September, 2012). Derbyshire, UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2012j) [The Notified Polymer]: Algal Growth Inhibition Test (Study No. 41102285, September, 2012). Derbyshire, UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2012k) [The Notified Polymer]: Toxicity to Activated Sludge in a Respiration Inhibition Test (Study No. 41102287, May, 2012). Derbyshire, UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia

SWA (2012a) Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/spray-painting-and-powder-coating.

SWA (2012b) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.

SWA (2012c) Guidance on the Classification of Hazardous Substances under the WHS Regulations, Safe Work Australia http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/guidance-classification-whs-regulations

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 >.