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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Ebecryl® 3702 radiation curing resins

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 Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

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:

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1454	Cytec Australia Holdings Pty Ltd Prysmian Telecom Cables and Systems Australia Pty Ltd Australian Optical Fibre Agencies	Ebecryl® 3702 radiation curing resins	Yes	≤ 115 tonnes per annum	Component of industrial inks and coatings

*ND = not determined

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*
Skin Sensitisation (Category 1)	H317 – May cause an allergic skin reaction

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:
R43 May cause sensitisation by skin contact

Human health risk assessment
Provided that the recommended control measures are in place to minimise exposure to the notified polymer (or solutions containing 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 its assessed use pattern, the notified polymer is not expected to cause any unreasonable risk to the aquatic environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

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

- The following should be used for products/mixtures containing the notified polymer:
  - Conc. ≥ 1%: H317

Health Surveillance

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

CONTROL MEASURES
Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following 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

- 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

- 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

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

- 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, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequently 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(2) of the Act; if
- the function or use of the polymer has changed from a component of industrial inks and coatings, or is likely to change significantly;
- the amount of polymer being introduced has increased from 115 tonnes per annum, 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 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.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANTS
Cytec Australia Holdings Pty Ltd (ABN: 45 081 148 629)
Suite 1, Level 1 Norwest Quay, 21 Solent Circuit
Norwest Business Park
BAULKHAM HILLS NSW 2153

Prysmian Telecom Cables and Systems Australia Pty Ltd (ABN: 14 001 313 551)
4 Thew Parade
DEE WHY NSW 2099

Australian Optical Fibre Agencies (ABN: 88 891 187 886)
10 Woodview Court
WHEELERS HILL VIC 3150

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 and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: dissociation constant, particle size, flash point, acute inhalation toxicity, genotoxic damage in vivo.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Ebecryl® 3702 radiation curing resins
Ebecryl® EB 3702
Cablelite 6D4-xx color (products containing the notified polymer)

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear green to brown highly viscous liquid.

Property	Value	Data Source/Justification
Glass Transition Point	-9 °C	Measured
Boiling Point	Decomposition observed from 225 °C	Measured
Density	1.15 x 10^3 kg/m^3 at 20 °C	Measured
Vapour Pressure	< 6.5 x 10^{-11} kPa at 25 °C	Measured
Water Solubility	Not determined	Expected to have limited solubility based on its predominantly hydrophobic structure
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional groups. However, significant hydrolysis is not expected due to its limited water solubility.
Partition Coefficient (n-octanol/water)	log Pow = 3.0 at 35 °C (main component, 71%)	Measured
Adsorption/Desorption	log Koc = 3.52 at 35 °C (main component, 73%)	Measured
Dissociation Constant	Not determined	Not expected to be ionised under environmental conditions (pH 4-9) as the notified polymer does not contain readily dissociable functionalities
Flammability	Not highly flammable in contact with water or pyrophoric	Measured/Estimated based on chemical structure
Autoignition Temperature	465 °C at 101.77-104.04 kPa	Measured
Explosive Properties	Predicted negative	Estimated based on chemical structure
Oxidising Properties	Predicted negative	Estimated 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 contains acrylate groups which may undergo crosslinking when exposed to intense ultraviolet (UV) light or an electron beam (EB).

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 be imported at 100% concentration and also as a component (≤ 50%) of ink and

optical fibre cables coating formulations.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 25	≤ 25	≤ 25	≤ 115	≤ 115

PORT OF ENTRY
Sydney and Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Cytec Australia Holdings Pty Ltd
Prysmian Telecom Cables and Systems Australia Pty Ltd
Australian Optical Fibre Agencies

TRANSPORTATION AND PACKAGING
The notified polymer may be imported at 100% concentration in 205 L lined steel drums for local reformulation into ink products. Alternatively, the notified polymer may be imported as a component (≤ 50%) of finished inks in 5 kg bottles or 10 kg plastic buckets or as a component (< 18%) of coatings in 1 L glass bottles. The products containing the notified polymer will be transported from the port of entry by road to either the notifier's or the end-users' warehouse facilities.

USE
Component (≤ 50%) in UV/EB curable lithographic and flexographic printing inks (≤ 15 tonnes per annum of the proposed maximum introduction volume) and a component (< 18%) in UV curable coatings to be applied to fibre optic cables for the telecommunication industry (remainder of the proposed introduction volume).

OPERATION DESCRIPTION
For use as a component in UV/EB curable lithographic and flexographic printing inks:
At reformulation sites, metering pumps will be used to transfer the notified polymer (100% concentration) from the import containers into sealable mixing vessels. Therein, the notified polymer will be mixed with other ingredients. The sealed mixing vessels will be fitted with a high-speed mixer and local exhaust ventilation systems. The resulting ink containing the notified polymer (≤ 50%) will be filtered under exhaust ventilation prior to being dispensed into 5 kg bottles or 10 kg plastic buckets for supply to printing houses.

At end-use sites, the ink bottles will be manually connected to the printing machines via an inlet and attached to a flexible tube which will supply the ink heads. The inks will be automatically injected into printing machines. After printing, the notified polymer will be fixed (UV or EB-cured) with other ink ingredients onto the substrate (e.g. vinyl) matrix. Exhaust ventilation will be fitted to the commercial printing machines.

For use as a component in UV curable coatings to be applied to fibre optic cables:
At end-use sites, a closed pressure hose system will be used to transfer the coatings containing the notified polymer (< 18%) to a specialised machine equipped with vacuum and exhaust functions and with sealed dies. Therein, glass fibre cables will be run through the system and will be sequentially coated with a formulation containing the notified polymer and exposed to a UV light source that will cure and in so doing harden the coating. During the automated operation process, the coating system will be fully closed. At the completion of the process, the coating die will be cleaned using solvents.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS
It is anticipated that transport and warehouse/stores personnel would only be exposed to the notified polymer in the event of an accident.

For use as a component in UV/EB curable lithographic and flexographic printing inks:
Dermal and ocular exposure to the notified polymer at concentrations of ≤ 100% is possible during the

reformulation processes (e.g. during transfer processes, quality control analysis and cleaning and maintenance tasks). Exposure is expected to be limited by the use of enclosed/automated systems and the use of personal protective equipment (PPE), including gloves, protective clothing and safety glasses. Inhalation exposure to the notified polymer is not expected, as the notified polymer has a low vapour pressure (< 6.5 x 10^{-11} kPa at 25 °C) and both the mixing vessel and filtration equipment will be fitted with exhaust lines.

Dermal and ocular exposure to the notified polymer at concentrations of ≤ 50% is possible at end-use sites (e.g. during transfer processes and cleaning and maintenance tasks). Exposure is expected to be limited by the use of largely automated/enclosed systems and the use of PPE, including gloves, protective clothing and safety glasses.

Workers may be exposed to materials that have been printed with products containing the notified polymer, however, after curing the notified polymer will be bound within a polymer matrix and will not be bioavailable.

For use as a component in UV curable coatings to be applied to fibre optic cables:
Dermal and ocular exposure to the imported products containing the notified polymer at concentrations of < 18% is possible during the connection and disconnection of hoses and during cleaning/maintenance tasks. Exposure is expected to be limited by the use of enclosed/automated processes and the use of PPE, including gloves, protective clothing and safety glasses. Inhalation exposure to the notified polymer is not expected as the notified polymer has a low vapour pressure and the coating machine will be fitted with exhaust lines.

Workers may be exposed to cables that have been coated with products containing the notified polymer, however, after curing the notified polymer will be bound within a polymer matrix and will not be bioavailable.

6.1.2. Public Exposure

The notified polymer is intended for industrial use only, and will not be available to the public. Direct exposure would therefore not be expected.

Members of the public are unlikely to experience dermal exposure to cables coated with products containing the notified polymer, but may be exposed to printed materials containing the notified polymer. However, in such products, the notified polymer will be bound within a polymer matrix and will not be bioavailable.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL 300 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test	non genotoxic

Toxicokinetics, metabolism and distribution.
While passive diffusion of the notified polymer across the gastrointestinal tract and dermal absorption may occur, the extent of absorption may be limited by the molecular weight of the notified polymer (> 500 Da). The expected absorption is supported by the observations of adverse effects that were noted in animal studies following oral and dermal exposure to the notified chemical.

Acute toxicity.
The notified polymer was found to be of low acute toxicity via the oral and dermal routes based on tests conducted in rats.

No acute inhalation toxicity data were provided for the notified polymer.

Irritation and sensitisation.
The notified polymer was found to be slightly irritating to the skin and eyes of rabbits. However, the effects did not warrant classification of the chemical as a skin irritant (slight erythema of the skin noted < 24 hours after patch removal and slight conjunctival effects noted at observations < 48 hours post-instillation of the test substance).

In an LLNA study in mice, there was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer (stimulation indices of 4.2, 7.2 and 15.0 at 10, 25 and 50%, respectively).

Repeated Dose Toxicity.
The notified polymer was administered orally (gavage) to rats for a period of 28 consecutive days at dose levels of 1000, 300 and 100 mg/kg bw/day. Effects were observed in animals treated at 300 mg/kg bw/day and above, with the combination of effects (e.g. higher bile acids levels) observed at 1000 mg/kg bw/day considered by the study authors to be adverse in nature. Therefore, the No Observed Adverse Effect Level (NOAEL) was established by the study authors as 300 mg/kg bw/day.

Mutagenicity/Genotoxicity.
The notified polymer was not mutagenic in a bacterial reverse mutation test, and was not clastogenic to human peripheral lymphocytes *in vitro*.

Health 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 following table.

Hazard classification	***Hazard statement***
Skin Sensitisation (Category 1)	H317 – May cause an allergic skin reaction

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:

R43 May cause sensitisation by skin contact

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Dermal and ocular exposure to the notified polymer, at concentrations ≤100%, by workers may occur during reformulation and end-use processes. As the notified chemical may cause sensitisation by skin contact, caution should be exercised when handling the notified polymer or solutions containing the notified polymer.

In all uses, after articles printed or coated with formulations containing the notified polymer have been cured, the notified polymer will be bound within a polymer matrix and will not be bioavailable.

Therefore, provided that control measures are in place to minimise worker exposure to the notified polymer (or solutions containing the notified polymer), including the use of automated processes and PPE, the use of the notified polymer is not considered to pose an unreasonable health risk to workers.

6.3.2. Public Health
The notified polymer is intended to be used in industrial settings only. Articles upon which the notified polymer has been printed/coated may be available to the public. However, the notified polymer will be bound within a polymer matrix and will not be bioavailable. Therefore, under the proposed use scenario, 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 may be imported for local reformulation into ink products or as a component of finished inks/coatings. An estimated 2% of the annual import volume of notified polymer may be lost as result of accidental spills from damaged import containers and during reformulation into ink products. The spillages are expected to be collected using suitable materials and disposed of to landfill. Notified polymer contained in residues (1%) in empty import containers is expected to be disposed of to landfill or treated properly in the drum recycling processes.

RELEASE OF CHEMICAL FROM USE

For use as a component in UV/EB curable lithographic and flexographic printing inks (≤ 15 tonnes):

The majority of notified polymer will be UV-cured and the resultant polymers are expected to be stable within an inert matrix on the printed substrates. Release of the notified polymer to the environment may come from ink spills and wash-downs of printing equipment. Any spills of the notified polymer are expected to be contained, collected with inert material and disposed of in accordance with local regulations. A maximum of 3% of ink was estimated by the notifier to be released to sewer from equipment cleaning.

For use as a component in UV curable coatings to be applied to fibre optic cables(≤ 100 tonnes):

At the industry coating sites, the coating products containing the notified polymer will be transferred to a specialised machine via a closed pressure hose. The coating will be pushed via an enclosed system to a pressurised applicator through which glass fibre cable runs and be sequentially coated. The coated glass fibre cable will pass through a UV light source where the coating is cured. Release of the notified polymer to the environment will be negligible as the coating system will be fully enclosed and the operation automated. Waste from accidental spills during the cleaning and shutdown production process, and from the cleaning of the application equipment, is expected to be contained, collected and disposed of according to the local regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer is expected to be irreversibly incorporated into the inert polymeric matrix adhering to printed substrates (vinyl, canvas, plastic packaging and paper) or coated substrates (fibre optic cable). At the end of their useful life, these articles are expected to be disposed of to landfill. Up to 20% of the ink products is expected to be printed onto paper. It is assumed that half of the used paper will be disposed of to landfill and half will undergo paper recycling processes. Remaining residues of the notified polymer in empty containers are expected to account for 1% of the total import volume and are expected to be disposed of to landfill.

7.1.2. Environmental Fate

The majority of the notified polymer is expected to be disposed of to landfill along with the printed or coated articles. Notified polymer applied to these articles will be UV/EB cured and in this form is not expected to be bioavailable. Approximately half of the paper to which the ink containing the notified polymer is applied to will be recycled. During recycling processes, waste paper will be repulped using a variety of chemical agents, which, amongst other things, will enhance detachment of inks from the fibres. However, the notified polymer will be UV/EB cured into the ink matrix and is unlikely to be released into the supernatant waters during recycling processes. The majority of the cured notified polymer is anticipated to adsorb to sludge and sediment. Uncured notified polymer released to sewer from equipment cleaning processes is expected to predominately adsorb to sludge due to its non-ionic properties. Sludge containing notified polymer residues may be disposed of to landfill or applied to agricultural soil. The notified polymer is not readily biodegradable (0% biodegradability over 28 days). However, significant bioaccumulation is unlikely based on its use pattern (limited release to aquatic environment) and low n-octanol/water partition coefficient (log Pow = 3 (main component, 71% of the notified polymer)). The notified polymer will eventually degrade in landfill or soil to form water and oxides of carbon. For the details of the environmental fate studies please refer to Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)

It is reported by the notifier that up to 15 tonnes of notified polymer may be used for ink products and 3% of ink containing the notified polymer is estimated to be released to sewer from the cleaning of printing equipment. The following predicted environmental concentrations (PEC) for ocean and river waters have been calculated assuming that 3% of the notified polymer will reach the aquatic compartment from the cleaning of equipment. For a worst case scenario, it was assumed that the release of the notified polymer occurred over 260 days per annum, corresponding to release only on working days, with no removal of the notified polymer in the sewage treatment plants (STPs).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	≤ 15000	kg/year
Proportion expected to be released to sewer	3%	
Annual quantity of chemical released to sewer	450	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1.73	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	≤ 0.38	µg/L
PEC - Ocean:	≤ 0.04	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.383 µg/L may potentially result in a soil concentration of approximately 2.55 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer the applied soil in 5 and 10 years may be approximately 12.76 µg/kg and 25.51 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.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) > 0.11 mg/L	Not harmful to fish up to the limit of its water solubility
Daphnia Toxicity	EC50 (48 h) > 0.16 mg/L	Not harmful to aquatic invertebrates up to the limit of its water solubility
Algal Toxicity	ErC50 (72 h) > 6.8 mg/L	Not harmful to algae up to the limit of its water solubility

Classification should only be based on toxic responses observed in the soluble range and, therefore, the notified polymer cannot be formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

A predicted no-effect of concentration (PNEC) for the aquatic compartment has not been calculated, as the notified polymer is not harmful up to the limit of its solubility in water and the potential for release to the aquatic environment is low.

7.3. Environmental Risk Assessment

The risk quotient (RQ = PEC/PNEC) has not been calculated, since the notified polymer is not harmful up to the limit of its water solubility and therefore the PNEC value is not attainable. The majority of the notified polymer will eventually be disposed to landfill following its use in industrial coatings and inks. In its cured state, the notified polymer will be irreversibly bound into an inert matrix and is unlikely to leach or be bioavailable. Based on its assessed use pattern and the absence of any significant acute toxicity effects to

species from 3 aquatic trophic levels, the notified polymer is not expected to cause an unreasonable risk to the aquatic environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Glass Transition Point -9 °C

Method	OECD TG 102 Melting Point/Melting Range.
Remarks	Determined using differential scanning calorimetry (DSC).
Test Facility	NOTOX (2012a)

Boiling Point Decomposition observed from 225 °C

Method	OECD TG 103 Boiling Point.
Remarks	Determined using DSC. From 225 °C, a strong exothermic effect was noted, which the study authors noted to be due to decomposition and/or reaction of the test substance.
Test Facility	NOTOX (2012a)

Density 1.15×10^3 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids.
Remarks	Determined using a gas comparison pycnometer.
Test Facility	NOTOX (2012a)

Vapour Pressure $< 6.5 \times 10^{-11}$ kPa at 25 °C

Method	OECD TG 104 Vapour Pressure.
Remarks	Determined using the isothermal thermogravimetric effusion method.
Test Facility	NOTOX (2012a)

Partition Coefficient (n-octanol/water) log Pow = 3.0 - 6.2 at 35 ± 1.0 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	HPLC Method. Test substance was dissolved in methanol followed by ultrasonication for 5 minutes to prepare the stock solution. One major peak (71% of the test substance) with log Pow = 3.0 was observed in the chromatogram. Approximately 22% was observed to have log Pow values of ≥ 4.1, which was reported to be derived from the impurities in the test substance.
Test Facility	NOTOX (2012a)

Adsorption/Desorption – screening test log K_{oc} = 3.52 - 5.54 at 35 ± 1.0 °C

Method	OECD TG 121 Adsorption - Desorption estimation using high performance liquid chromatography (HPLC) method.
Remarks	HPLC Method. Test substance was dissolved in methanol followed with ultrasonication for 5 minutes to prepare the stock solution. One major peak (73% of the test substance) with log Koc = 3.52 was observed in the chromatogram. Additional peaks with log Koc ≤ 2.63 (10%) and log Koc ≥ 4 (17%) were observed in the chromatogram, which were reported to be derived from the impurities in the test substance.
Test Facility	NOTOX (2012a)

Flammability Not highly flammable in contact with water or pyrophoric

Method	EC Council Regulation No 440/2008 A.12 Flammability (Contact with Water).
Remarks	The study authors note that during handling, the test substance was not found to ignite spontaneously in contact with water or with air, and on the basis of structural considerations, was considered not highly flammable in contact with water or to have pyrophoric properties.
Test Facility	NOTOX (2012a)

Autoignition Temperature 465 °C at 101.77-104.04 kPa

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks	Determined using a commercially available auto-ignition temperature apparatus.
Test Facility	NOTOX (2012a)

Explosive Properties Predicted negative

Method	EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks	The structure of the notified polymer does not contain chemical groups that are associated with explosive properties.
Test Facility	NOTOX (2012a)

Oxidizing Properties Predicted negative

Method	EC Council Regulation No 440/2008 A.21 Oxidizing Properties (Liquids).
Remarks	The structure of the notified polymer does not contain chemical groups that are associated with oxidising properties.
Test Facility	NOTOX (2012a)

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/Wistar Crl;WI (Han) (outbred, SPF-Quality)
- Vehicle: Polyethylene glycol 400
- Remarks - Method: No significant protocol deviations.

In order to achieve sample homogeneity, the test substance and test substance solutions were heated in a water bath. The test substance was heated at a maximum temperature of 40 °C (maximum 1 hour and 55 minutes) and the test substance solutions were heated at a maximum temperature of 55.8 °C (maximum 18 minutes). The solutions were allowed to cool to a maximum temperature of 38 °C before dosing.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3F	2000	0/3
II	3F	2000	0/3

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: There were no mortalities during the study. All animals exhibited a hunched posture on day 1. In addition, a single animal showed piloerection on day 1.
- Effects in Organs: No macroscopic abnormalities were recorded.
- Remarks - Results: All animals gained weight over the course of the study.

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

TEST FACILITY: NOTOX (2011a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 402 Acute Dermal Toxicity.
- Species/Strain: Rat/Wistar Crl;WI (Han) (outbred, SPF-Quality)
- Vehicle: Polyethylene glycol 400
- Type of dressing: Occlusive.
- Remarks - Method: No significant protocol deviations.

In order to achieve sample homogeneity, the test substance solution was heated in a water bath. The test substance was heated at a maximum temperature of 55.8 °C (maximum 21 minutes). The solutions were allowed to cool to a maximum temperature of 25.3 °C before dosing.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5F/5M	2000	0/10

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: Chromodacryorrhoea was noted in 2 males and 1 female on day 1 only. In addition, yellow discolouration of the back, scabs on the treated skin

	and/or scales on the back and/or treated skin were noted in 4 male animals throughout the observation period.
Effects in Organs	A single male animal was found to have a diaphragmatic hernia (median lobe of the liver).
Remarks - Results	The diaphragmatic hernia was considered by the study authors to be of no toxicological significance. Body weight loss or the absence of weight gain was noted in 3 female animals on day 8 following treatment. However, all animals were noted to have gained weight by the end of the observation period.
CONCLUSION	The notified polymer is of low toxicity via the dermal route.
TEST FACILITY	NOTOX (2011b)

B.3. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3M
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. A single animal was initially treated, with the remaining 2 animals treated 7 days later.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	1	< 24 hours	0
Oedema	0	0	0	0	-	0

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

Remarks - Results	Very slight erythema was observed in each animal 1 hour following removal of the dressing and test substance (using water). No other reactions were recorded for any animal at any other time. Sticky remnants of the test substance were noted to have been present up to and including the 24 hour observation.
CONCLUSION	The notified polymer is slightly irritating to the skin.
TEST FACILITY	WIL Research Europe (2012)

B.4. Irritation – eye

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

A single animal was initially treated, with the remaining 2 animals treated 7 days later.

The test substance was heated in a water bath at a maximum temperature of 37 °C (maximum 82 minutes) prior to instillation.

Following the 24-hour observation, a 2% aqueous fluorescein solution was instilled into both eyes of each animal.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.3	0.3	0.3	1	< 48 hours	0
Conjunctiva: chemosis	0	0	0	0	0	0
Conjunctiva: discharge	0.3	0	0	1	< 48 hours	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results

At the 1 and 24 hour observation periods, slight conjunctival redness was observed in all tested animals. Discharge was noted in the eyes of 2 animals 1 hour after instillation of the test substance and in one animal 24 hours after instillation.

All signs of irritation were resolved by the 48-hour observation period.

Remnants of the test substance were noted to have been present on the outside of the eyelids up to and/or including the 48 hour observation.

CONCLUSION

The notified polymer is slightly irritating to the eye.

TEST FACILITY

NOTOX (2011c)

B.5. 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/J strain

Vehicle

Dimethyl formamide

Remarks - Method

No significant protocol deviations.

Concentrations were chosen on the basis of a preliminary screening test (maximum concentration tested was 50%).

In order to achieve sample homogeneity, the test substance solutions were heated in a water bath. The solutions were heated at a maximum temperature of 39.5 °C (maximum 2.5 hours).

No concurrent positive control group was included in the study. However, a positive control study had previously been conducted by the testing facility using the same methods, animal strain and supplier with α-hexylcinnamaldehyde in acetone:olive oil (4:1).

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/animal)*	*Stimulation Index (Test/Control Ratio)*

Test Substance		
0 (vehicle control)	390 (± 50)	1.0
10	1655 (± 147)	4.2
25	2814 (± 376)	7.2
50	5850 (± 1454)	15.0

Remarks - Results

There were no mortalities and no clinical signs of toxicity were observed.

Very slight erythema was noted in animals treated with 25% test substance on days 3-4 and in animals treated with 50% test substance on days 2-4. All auricular lymph nodes of animals treated with a concentration of 25% or 50% test substance were noted to have appeared larger in size compared to the nodes of the control animals. No macroscopic abnormalities of the surrounding area were noted in any of the animals.

The stimulation index for all three test groups dosed with the tested substance was > 3. Based on these results, the EC3 of the test substance was < 10%.

CONCLUSION

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

TEST FACILITY

NOTOX (2011d)

B.6. Repeat dose toxicity

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

Species/Strain: Rat/Crl:WI(Han)

Route of Administration: Oral – gavage

Exposure Information: Total exposure days: 28 days
Dose regimen: 7 days per week
Post-exposure observation period: none

Vehicle: Polyethylene glycol 400

Remarks - Method: No significant protocol deviations.

Doses were chosen based on the results of a 5-day range-finding study.

In order to achieve sample homogeneity, the test substance and test substance solutions were heated in a water bath. The test substance was heated at a maximum temperature of 39.6 °C (maximum 4 hours and 10 minutes) and the test substance solutions were heated at a maximum temperature of 59.6-61.2 °C (maximum 19-32 minutes). The solutions were allowed to cool to a maximum temperature of 39.6 °C before dosing.

RESULTS

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

Mortality and Time to Death

There were no unscheduled deaths during the study.

Clinical Observations

Hunched posture was noted in all female animals in the high dose group starting from day 19. Increased salivation was noted in female animals in the low dose group (from day 13) and all animals in the higher dose groups (from day 9).

There were no toxicologically significant changes in the functional performance parameters measured.

There were no significant differences in the bodyweight gain and food consumption between the control and treated groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

A prolonged prothrombin time was observed for males treated at 1000 mg/kg bw/day.

Statistically significantly increased relative monocyte counts in males and lower haemoglobin and haematocrit levels in females were observed, but the levels were reported by the study authors to be within the range considered normal for rats of the age and strain used. A statistically significant reduction in neutrophil counts in females treated at 100 mg/kg bw/day and lower red blood cell counts in females treated at 300 mg/kg bw/day were considered by the study authors to be of no toxicological significance as they remained within the range considered normal for rats of the age and strain used and/or occurred in the absence of a dose-response relationship.

Statistically significantly higher mean total bilirubin and cholesterol levels were observed in male and female animals treated at 1000 mg/kg bw/day. Higher cholesterol levels were also observed in males treated at 300 mg/kg bw/day. In addition, higher bile acids levels were observed in females treated at 1000 mg/kg bw/day (statistically significant) and in males treated at 300 and 1000 mg/kg bw/day. Other statistically significant changes in the clinical biochemistry parameters that occurred in animals treated at 100 and/or 300 mg/kg bw/day were considered by the study authors to be of no toxicological significance, as they remained within the range considered normal for rats of the age and strain used and/or occurred in the absence of a dose-response relationship.

Effects in Organs

The following macroscopic findings in treated animals were considered by the study authors to be of no toxicological significance as they were within the background range of findings that are encountered among rats of this age and strain and did not show a dose-related incidence trend:

- Reduction in the size of the right seminal vesicle in both a control male and in a male dosed at 1000 mg/kg bw/day.
- Foci on the thymus of 1 control female, 1 male dosed at 100 mg/kg bw/day and 1 female dosed at 300 mg/kg bw/day.
- Diaphragmatic hernia of the right medial lobe of the liver in 1 male dosed at 300 mg/kg bw/day.
- A yellowish, hard nodule in the body of the left epididymis of 1male dosed at 300 mg/kg bw/day.
- Pelvic dilation of the right kidney in 2 males dosed at 1000 mg/kg bw/day.
- The presence of fluid in the uterus in 1 or 2 females of all groups.
- Dark red discolouration of the left mandibular lymph node in 1 female dosed at 100 mg/kg bw/day.
- Tan foci on the right side of the clitoral gland of 1 female dosed at 300 mg/kg bw/day and of 1 female dosed at 1000 mg/kg bw/day.
- Enlargement of the left mandibular lymph node in 1 female dosed at 1000 mg/kg bw/day.

No toxicological significant changes were noted in the absolute and relative organ weights. Higher relative kidney weights in males and females treated at 1000 mg/kg bw/day were not considered by the study authors to be toxicologically significant as they were not accompanied by findings in clinical laboratory investigations or microscopic examination that suggested organ dysfunction.

Of the animals dosed at 300 mg/kg bw/day, 4 of 5 males and 2 of 5 females had minimal (barely noticeable) vacuolation of Kupffer cells in the liver, whilst all animals dosed at 1000 mg/kg bw/day had minimal vacuolation of Kupffer cells. All other microscopic findings were reported to be within the range of background pathology encountered in Wistar rats of the age and strain used and occurred at similar incidences and severity in both control and treated rats.

Remarks – Results

The combination of effects in animals observed at 1000 mg/kg bw/day was considered by the study authors to

be adverse in nature.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established by the study authors as 300 mg/kg bw/day, based on the observation of adverse effects in animals treated at 1000 mg/kg bw/day.

TEST FACILITY NOTOX (2012b)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified polymer

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure.

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction from phenobarbital/ß-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 33 – 3330 µg/plate b) Without metabolic activation: 33 – 3330 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	A range-finding study was conducted using 8 concentrations of the test substance, assayed in triplicate against strains TA100 and WP2uvrA (3-5000 µg/plate). This formed part of Test 1. Precipitation was observed in tester strain TA100 at ≥ 3330 µg/plate and in the tester strain WP2uvrA at ≥ 333 µg/plate. The negative control was dimethyl sulfoxide and positive controls were sodium azide (TA1535), ICR-191 (TA1537), 2-nitrofluorene (TA98), methyl methane sulfonate (TA100) and 4-nitroquinoline N-oxide (WP2uvrA) without metabolic activation, and 2-aminoanthracene (all strains) in the presence of metabolic activation.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	≥ 1000	≥ 333	negative
Test 2	> 3330	≥ 333	negative
Present			
Test 1	> 3330	≥ 333	negative
Test 2	≥ 3330	≥ 333	negative

Remarks - Results

In both experiments, precipitation was observed at ≥ 333 µg/plate during testing with *E. Coli*. In experiment 1, during testing of plates containing *S. typhimurium*, precipitation was observed at ≥ 3330 µg/plate, but in experiment 2, precipitation was observed at ≥ 1000 µg/plate.

In experiment 1, toxicity was reported to have been observed in the absence of metabolic activation (strain TA98 only) at a dose of ≥ 1000 µg/plate. In experiment 2, toxicity was reported to have been observed in the presence of metabolic activation (strain TA100 only) at a dose of 3330 µg/plate.

No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains up to and including the maximum dose, either with or without metabolic activation.

The positive controls gave satisfactory responses, confirming the validity of the test system.

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

TEST FACILITY NOTOX (2012c)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE Notified polymer

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain Human
Cell Type/Cell Line Peripheral lymphocytes
Metabolic Activation System S9 fraction from phenobarbital/β-napthoflavone induced rat liver
Vehicle Dimethyl sulfoxide
Remarks - Method A preliminary toxicity study was performed (3 hour exposure, with and without activation and 24 and 48 hour exposure without activation) at concentrations 10-1000 µg/mL.

Vehicle and positive controls (Mitomycin C without metabolic activation and cyclophosphamide with metabolic activation) were used in parallel with the test material.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	1*, 3, 10, 20, 30*, 40*	3	24
Test 2	1, 3*, 10*, 30, 40*, 45	24	24
Test 2A	1, 10*, 30, 40*, 45*, 50	48	48
Present			
Test 1	10*, 30, 80*, 100*, 150, 200	3	24
Test 2	10*, 30*, 80, 100*, 150, 200	3	48

*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	≥ 33	> 40	> 40	Negative
Test 2	≥ 33	≥ 40	> 45	Negative
Test 2A	≥ 33	≥ 50	> 50	Negative
Present				
Test 1	≥ 100	≥ 100	≥ 150	Negative
Test 2		≥ 100	≥ 150	Negative

Remarks - Results No significant increases in the number of cells with aberrations were noted, with or without metabolic activation.

The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.

CONCLUSION The notified polymer was not clastogenic to human peripheral lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY NOTOX (2012d)

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 (modified sturm test).
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	TOC-V_{CPH} total organic carbon analyser; Chemical titration
Remarks - Method	No significant protocol deviations The test substance was not sufficiently soluble to prepare a stock aqueous solution at a concentration of 1 g/L. The weighed test substance was added to the test bottles directly.

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	0	2	3
5	0	5	30
7	0	7	50
9	0	9	59
14	0	14	60
28	0		

Remarks - Results	The theoretical CO_2 production was determined based on the total carbon content of test substance present in the test media, as the theoretical calculation of the CO_2 production was not possible. Biodegradation was calculated from the cumulative CO_2 production relative to the total expected CO_2 production. The degradation of toxicity control was 35% over 28 days, implying that the test substance was not inhibitory to microbial activity. All validity criteria for the test were satisfied.
CONCLUSION	The notified polymer is not readily biodegradable
TEST FACILITY	NOTOX (2011e)

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	Carp (*Cyprinus carpio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	180 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	The test substance was not completely soluble in test medium at the loading rate initially prepared. The stock solutions of the test substance

were prepared at the loading rates of 1.0, 10 and 100 mg/L individually. The solutions were stirred for 1 hour followed with 30 minutes settlement. The clear and colourless water accommodation fractions (WAFs) were subsequently siphoned and used as test solutions.

A combined limit/range-finding test was performed according to the guideline without significant deviation from the protocol.

RESULTS

Concentration		*Number of Fish*	*Mortality (%)*				
Nominal (mg/L of WAFs)	*Actual (mg/L)*		*2 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	N/A	7	0	0	0	0	0
1.0	N/A	3	0	0	0	0	0
10	N/A	3	0	0	0	0	0
100	0.11*	7	0	0	0	0	0

*Average concentration during the test

LC50	> 0.11 mg/L at 96 hours.
NOEC	0.11 mg/L at 96 hours.
Remarks – Results	The actual concentration in the sample take from WAFs prepared at 100 mg/L was determined to be 0.155 mg/L at the start of the test and dropped to 0.079 mg/L at 96 hours. The average exposure concentration was calculated to be 0.11 mg/L. Due to the low solubility of test substance, concentration levels that might be toxic to fish could not be reached. Three fish were exposed to WAFs prepared at loading rates of 1.0 and 10 mg/L in the range-finding test, deviating from the protocol whereby at least 7 fish must be used for each test concentration. However, this deviation was not considered to affect the results interpretation, as no mortality was observed at any test loading rate during the test period.
CONCLUSION	The notified polymer is not harmful to fish up to the limit of its solubility.
TEST FACILITY	NOTOX (2012e)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 *Daphnia sp*. Acute Immobilisation Test – Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	180 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	The test substance was not completely soluble in test medium at the loading rate initially prepared. The stock solutions of the test substance were prepared at the loading rates of 1.0, 10 and 100 mg/L individually. The solutions were stirred for 1 hour followed with 30 minutes settlement. The clear and colourless water accommodation fractions (WAFs) were subsequently siphoned and used as test solutions. A combined limit/range-finding test was performed according to the guideline without significant deviation from the protocol.

RESULTS

Concentration	*Number of D. magna*	*Number Immobilised*

Nominal (mg/L of WAF)	*Actual (mg/L)**		*24 h*	*48 h*
Control	N/A	20	0	2
1.0	0.0022	10	0	6
10	0.015	10	0	0
100	0.16	20	0	2

* Concentration determined for the test medium at the start of the test

EC50	> 0.16 mg/L at 48 hours
NOEC	Not reported
Remarks - Results	6 daphnids were observed to be immobilised when exposed to the test medium at the loading rate of 1.0 mg/L WAFs in the range-finding test. This was considered to be due to other physical elements rather than chemical toxicity of the test substance, since no immobilisation and less than 10% of the test daphnids were observed at the loading rate of 10 mg/L and 100 mg/L WAFs, respectively.
CONCLUSION	The notified polymer is not harmful to aquatic invertebrates up to the limit of its water solubility.
TEST FACILITY	NOTOX (2012f)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test - Static
Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 0, 1.0, 10 and 100 mg/L Actual: N/A, N/A, N/A and 6.8 mg/L (time weight average concentration)
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	The test substance was not completely soluble in the test medium at the loading rate initially prepared. The stock solutions of the test substance were prepared at the loading rates of 1.0, 10 and 100 mg/L individually. The test solutions were stirred for 1 hour followed with 30 minutes settlement. The clear and colourless water accommodation fractions (WAFs) were subsequently siphoned and used as test solutions. A combined limit/range-finding test was performed according to the guideline without significant deviation from the protocol.

RESULTS

Biomass		*Growth*	
E_bC50	*NOE_bC*	*ErC50*	*NOErC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
> 6.8*	Not reported	> 6.8*	6.8

* Time weight average concentration during the test

Remarks - Results	The actual concentration in the sample taken from WAFs prepared at 100 mg/L was determined to be 11 mg/L at the start of the test and dropped to 60% and further to 50% of the initial after 24 and 72 hours of exposure, respectively. The time weight average concentration was calculated to be 6.8 mg/L. Due to the low solubility of test substance, concentration levels that might be toxic to algae could not be reached.
CONCLUSION	The notified polymer is not harmful to algae up to the limit of its water solubility.

TEST FACILITY NOTOX (2012g)

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