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June 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Toner Pearls

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

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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Director
NICNAS

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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/1447	Canon Australia Pty Ltd	Polymer in Toner Pearls	No	≤ 10,000 tonnes per annum	Component of printing ink

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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

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

Environmental risk assessment
On the basis of the assessed use pattern and the low toxicity up to the limit of water solubility, the notified polymer is not expected to pose an unacceptable risk to the aquatic environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

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.

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 polymer, 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 component of printing ink, 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 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)
Canon Australia Pty Ltd (ABN: 66 005 002 951)
Building A, The Park Estate
5 Talavera Road
MACQUARIE PARK NSW 2113.

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

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: skin irritation, eye irritation, skin sensitisation, acute daphnia toxicity and acute algae toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
USA (2008)
South Korea (2011)
China (2012)
EU

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Low melting polyester amide resin
Oce Toner Pearls (contains notified polymer at ≤ 50% concentration)

MOLECULAR WEIGHT
NAMW < 500 Da

ANALYTICAL DATA
Reference IR and HPLC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY 50-60%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellowish solid/off-white waxy powder

Property	Value	Data Source/Justification
Melting Point	11–15 °C	Measured
Boiling Point	> 225 °C at 101.3 kPa	Measured. Decomposes without boiling.
Density	1,177 kg/m^3 at 20 °C	Measured
Vapour Pressure	< 8.4 × 10^{-10} kPa at 20 °C	Measured
Water Solubility	≤ 0.2 × 10^{-3} g/L	Estimated (EPIWEB 4.1; US EPA, 2011)
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable functional groups. However, significant hydrolysis is not expected under

		environmental conditions based on its low solubility in water.
Partition Coefficient (n-octanol/water)	log P_{ow} ≥ 3.8 at 25 °C	Measured
Adsorption/Desorption	log K_{oc} ≥ 3.81 at 35 °C	Measured
Dissociation Constant	Not determined	No readily dissociable functionalities
Flammability	Not highly flammable	Measured
Flammability in Contact with Water	Not predicted to be flammable in contact with water	Estimated
Autoignition Temperature	425 °C	Measured
Explosive Properties	Not predicted to be explosive	Estimated
Oxidising Properties	Not predicted to be oxidising	Estimated

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System 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 or reformulated in Australia. The notified polymer will be imported as a component of a finished product, in closed ink cartridges at ≤ 50% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 5,000	< 5,000	< 5,000	< 5,000	< 10,000

PORT OF ENTRY
Sydney (by sea and air)

TRANSPORTATION AND PACKAGING
Finished products containing the notified polymer at ≤ 50% concentration will be imported as solid spheres (with a diameter of about 12 mm) contained in polystyrene cartridges in sealed styrene-butadiene packaging. Each cartridge will contain either 500 g or 900 g of finished ink. These cartridges will be packed in boxes. These will be packed in pallets and distributed within Australia by road.

USE
The notified polymer will be used as part of an ink for printing at ≤ 50% concentration. The finished products are only expected to be used in large format printers.

OPERATION DESCRIPTION
There will be no manufacture, reformulation or repackaging of the notified polymer in Australia.

End-use
The cartridges containing the finished inks will be taken out of the blister package and placed into the printers. During this process, engineering controls will ensure that no ink will fall out of the cartridges. During the printing process, the ink will pass a spindle and fall into the imaging device in a closed system. Inside the printer the ink will be printed onto the paper.

Most of the ink (> 98%) will be consumed during printing, with the remainder (< 2%) ending as waste in a waste box. From time to time, contamination on the printer heads will be rinsed away with ink, which will be

automatically collected in a waste box (capacity 300 g). The waste material is solid and no direct contact to the user is expected. The waste box will be disposed of to landfill.

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)*
Importation/waterside	< 8	10–50
Transport and storage workers	< 8	10–50
Office worker	Occasional	200
Service technician	1	52

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may be exposed to the notified polymer as a component of the finished ink products at ≤ 50% concentration, only in the event of an accidental rupture of containers.

End-use

Given the low vapour pressure (8.4×10^{-10} kPa at 20 °C) of the notified polymer and the particle size (12 mm) of the finished products, inhalation exposure to the notified polymer is not expected. As the finished products are contained within a sealed cartridge and the printing process is enclosed, the potential for dermal exposure will be limited during printing. However, service technicians and office workers may be dermally exposed to the notified polymer at ≤ 50% concentration on an infrequent basis when changing cartridges, removing waste boxes or during printer maintenance. Service technicians may wear gloves, though office workers are unlikely to do so.

Dermal exposure from contact with printed paper is not expected as the notified polymer will be bound to the paper matrix when printed.

6.1.2. Public Exposure

Finished ink products are expected to be used by industrial and office workers only in large format printers. Hence, public exposure is not expected during printing processes. The public may come into contact with the finished product containing the notified polymer at ≤ 50% concentration. However, the notified polymer is not expected to be bioavailable as the polymer will be bound to the paper matrix when printed.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer (purity 50-60%) and finished products containing the notified polymer are summarised in the following table. The impurities contained in the notified polymer have similar functionality and are therefore expected to have similar toxicological properties to the notified polymer. Thus the results obtained from toxicological studies conducted on the notified polymer with purity of 50-60% are expected to represent the toxicological profile of the notified polymer. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating*
Rabbit, eye irritation	slightly irritating*
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation*
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation[#]
Rat, repeat dose oral toxicity – 28 days.	NOAEL > 1,000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vivo* mouse micronucleus test	non genotoxic

*Tests performed on finished product 1 containing the notified polymer at ≤ 50% concentration

[#]Test performed on finished product 2 containing the notified polymer at ≤ 50% concentration

Toxicokinetics.
Whilst absorption of the notified polymer may occur (MW < 500 Da), the extent of absorption through the skin or gastrointestinal tract is expected to be limited, based on its low water solubility (< 0.1 mg/mL at 20 °C) and relatively high log Pow (≥ 3.8 at 25 °C).

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

No acute inhalation toxicity data were provided for the notified polymer. Inhalation exposure to the notified polymer is not expected due to the low vapour pressure (< 8.4×10^{-10} kPa at 20°C). In addition, the size of the finished product excludes the possibility of exposure to dust.

Irritation and sensitisation.
No irritation or sensitisation studies were provided for the notified polymer. However studies were provided for representative finished products containing the notified polymer that will be introduced into Australia.

A finished ink product containing the notified polymer at ≤ 50% concentration was found to be non-irritating to the skin and slightly irritating to the eyes of rabbits. Instillation of the test substance resulted in slight irritation of the conjunctivae, which was seen as redness and discharge. The irritation had resolved within 24 hours for all animals. There were no other signs of eye irritation or damage reported.

Two finished ink products containing the notified polymer at ≤ 50% concentration were found to be non-sensitising in separate LLNA studies when tested up to 25% and 50% concentration, respectively.

Based on the results of these studies conducted on finished products and absence of structural alerts for irritation or sensitisation, the notified polymer is not expected to be irritating or sensitising.

Repeated Dose Toxicity.
In a 28-day repeated dose oral toxicity study in rats the NOAEL was established as 1,000 mg/kg bw/day based on no adverse toxicological effects attributed to the notified polymer being observed at the highest dose tested.

Mutagenicity/Genotoxicity.
The notified polymer was not mutagenic in a bacterial reverse mutation study and was not genotoxic in an *in vivo* mouse micronucleus test.

Health hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
There will be no reformulation or repackaging of the notified polymer in Australia. As such, only printer service technicians and office workers will be potentially exposed to the notified polymer at ≤ 50% concentration in finished products on an infrequent basis when changing cartridges, removing waste boxes or during printer maintenance. Gloves may be worn by service technicians if performing regular printer maintenance operations. Based on the toxicity studies provided, exposure to the notified polymer under the proposed use scenario is not expected to result in adverse health effects.

Therefore, based on the information available, the risk to workers associated with use of the notified polymer at ≤ 50% concentration in finished ink products is not considered to be unreasonable.

6.3.2. Public Health
Exposure of members of the public to the notified polymer during printing processes is not expected as the finished ink products containing the notified polymer are intended for use in printers in dedicated print rooms. Following printing onto paper (or other substrates), the notified polymer is not expected to be bioavailable. Therefore, under the proposed use conditions, 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

Finished products containing the notified polymer will be imported into Australia in closed cartridges. Environmental release of the notified polymer is unlikely to occur during importation, storage and transportation as cartridges are designed to minimise release.

RELEASE OF CHEMICAL FROM USE

When used as an ink ingredient, the majority of the ink containing the notified polymer is expected to be applied to paper and fixed on the surface of the substrates. During printing, it is estimated < 2% of the total import volume of the notified polymer may be released to the environment as a result of ink waste. Collected waste ink residues are expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Following its use, most of the notified polymer is anticipated to share the fate of printed articles and be disposed of to landfill or subjected to paper recycling processes. Approximately half of the amount of used paper is expected to be recycled. The notified polymer may partition to waste waters during paper recycling processes and be released to sewage treatment plants (STPs). Limited amounts of the notified polymer contained in empty cartridges are expected to be disposed of to landfill.

7.1.2. Environmental Fate

The notified polymer, when used as an ink ingredient, is expected to remain fixed to paper for its useful life. The notified polymer is expected to be disposed of to landfill along with used paper or potentially released to sewer in recycling wastewaters when used paper is recycled. During paper recycling processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches to improve the detachment of ink from the fibres. The notified polymer has low water solubility and high adsorption coefficient ($\log K_{oc} \geq 3.81$). Therefore the majority of the notified polymer is expected to partition to sludge during paper recycling and waste water treatment processes. The sludge is expected to be disposed of to landfill or applied to agricultural soils. A proportion of the notified polymer may partition to the water column in STPs effluent and be released to the aquatic compartment.

The notified polymer is not readily biodegradable (biodegradability ≤ 10% over 28 days) but significant bioaccumulation is unlikely based on the low measured bioconcentration factor (BCF ≤ 54). In landfill, soils and water, the notified polymer is expected to eventually degrade through biotic and abiotic processes to form water, oxides of carbon and nitrogen. For the details of the environmental fate studies please refer to Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)

Considering the low water solubility of the notified polymer, and based on OECD Emission Scenario Documents on Pulp, Paper and Board Industry (ENV/JM/MONO(2009)25) for one individual paper recycling mill, the daily release of the notified polymer to waste water (E_{deink_water}) before any treatment plant, whether on-site or off-site, was calculated as follows:

$$E_{deink\_water} = C_{wastewater} \times Flow_{wastewater} \times Q_r$$
$$\leq 0.2 \text{ mg/L} \times 12 \text{ m}^3\text{/t} \times 266 \text{ t/day}$$
$$\leq 0.638 \text{ kg/day}$$

E_{deink_water} (kg/day): Emission per day to waste water from de-inking or washing process during paper recycling; (OECD, ENV/JM/MONO(2009)25).

$C_{wastewater}$ (mg/L): Concentration of the notified polymer in waste water from paper recycling processes; ≤ 0.2 mg/L (i.e. the maximum predicted water solubility).

$Flow_{wastewater}$ (m^3/t recycled paper): Waste water generated from the whole plant; defaulted 12 m^3/day.

Q_r (t/day): Quantity of paper recycled at one site per day; defaulted 266 t/day.

Waste water from paper recycling processes is expected to be treated on-site before released to public sewer. Therefore, the daily release of the notified polymer to sewer ($E_{primary\_water}$) from one individual paper recycling mill was calculated as following:

$$E_{primary\_water} = E_{deink\_water} \times F_{primary\_water}$$
$$\leq 0.638 \text{ kg/day} \times 0.1$$
$$\leq 0.0638 \text{ kg/day}$$

$E_{primary\_water}$ (kg/day): Emission to waste water after primary treatment of effluent;

$F_{primary\_water}$: Fraction of notified polymer remaining in waste water after primary treatment (0.1 for substance with water solubility of <1 mg/L).

The waste water containing the notified polymer released to sewer is expected to be further treated at the public sewage treatment plant (STP). It was estimated by SimpleTreat (EC, 2003) that up to 79% of the notified polymer will remain in the water column in the STP with 21% removed in sludge. Therefore, the daily release of the notified polymer to surface water (E_{STP_water}) from an individual STP was calculated as following:

$$E_{STP\_water} = E_{primary\_water} \times F_{STP\_water}$$
$$\leq 0.0638 \text{ kg/day} \times 0.79$$
$$\leq 0.05 \text{ kg/day}$$

E_{STP_water} (kg/day): Emission to surface water from STP effluent;
F_{STP_water}: Fraction of notified polymer remaining in water after STP treatment.

For a conservative scenario, it is assumed that waste water will be released to a moderately-sized STP and be diluted by the daily average water flow at the STP. The resultant Predicted Environmental Concentration (PEC) in river was calculated as following:

$$PEC_{river} = E_{STP\_water} \div W_{daily\_individual\ STP\_flow}$$
$$\leq 0.05 \text{ kg/day} \div 115 \text{ ML/day}$$
$$\leq 0.43 \text{ µg/L}$$

$F_{daily\text{-}individual\ STP\_flow}$ (ML): Individual STP daily average water flow (115ML, Brisbane water, QSL)

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations are summarised in the table below. The fish toxicity study was conducted on the notified polymer. The daphnia toxicity study was conducted in the water accommodation fractions (WAFs) of a finished ink product containing the notified polymer at ≤ 50% concentration. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 hours) > 5 mg/L*	Not harmful to fish
Daphnia Toxicity	EL50 (48 hours) > 30 mg/L (WAFs)	Not harmful to aquatic invertebrates

***** Ecotoxicity endpoint is above the predicted water solubility of the notified polymer.

Ecotoxicity was also estimated for representative low and high molecular weight components using Ecological Structure-Activity Relationships (ECOSAR; US EPA, 2011) under the consideration of the predicted values for water solubility and water/octanol partition coefficients. The conservative predicted ecotoxicological endpoints for the notified polymer are reported below. ECOSAR predictions for higher molecular weight components of the notified polymer indicated that they were not expected to be toxic up to the limit of their water solubility.

Endpoint	*Result*		*Assessment Conclusion*
Acute	MW=764[a]	MW=446[a]	
Fish Toxicity	LC50 (96 h) = 0.039 mg/L[b]	LC50 (96 h) = 0.565 mg/L[b]	Not harmful to fish
Daphnia Toxicity	LC50 (48 h) = 0.096 mg/L[b]	LC50 (48 h) = 0.764 mg/L[b]	Not harmful to aquatic invertebrates
Algal Toxicity	EC50 (96 h) = 0.106 mg/L[b]	EC50 (96 h) = 0.192 mg/L	Not harmful to algae
Chronic			
Fish Toxicity	ChV = 0.00023 mg/L[b,c]	ChV = 0.003 mg/L[c]	Not harmful to fish with long lasting effects
Daphnia Toxicity	ChV = 0.0013 mg/L[b,c]	ChV = 0.01 mg/L[c]	Not harmful to aquatic invertebrates with long lasting effects
Algal Toxicity	ChV = 0.116 mg/L[b,c]	ChV = 0.594 mg/L[b,c]	Not harmful to algae with long lasting effects

a Water solubility is 0.2 $\times 10^{-3}$ g/L ($logP_{OW}$ = 4.54) and 5×10^{-8} g/L ($logP_{OW}$ = 6.31) for the low molecular weight and high molecular weight component, respectively.
b Not expected to be harmful up to the limit of water solubility.
c ChV = Chronic value = $(NOEC \times LOEC)^{1/2}$

Both the experimental data and ECOSAR results demonstrate that the notified polymer is not harmful to aquatic organisms up to the limit of its water solubility on an acute basis. The predicted acute endpoint for alga is at a comparable level to the water solubility. Since the chronic endpoint is significantly higher than the water solubility, the notified polymer is therefore considered not harmful to alga on acute and long lasting basis, up to the limit of water solubility. Based on the measured toxicity endpoint for fish and daphnia, the notified polymer is not formally classified under the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

ECOSAR results demonstrate that only the low molecular weight component of notified polymer is predicted to have potential chronic toxicity to aquatic organisms. Therefore, these endpoints are not entirely representative of the chronic toxicity of the whole notified polymer. Thus they are not considered sufficient to formally classify the long term hazard of the notified polymer to aquatic life under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has not been calculated since the notified polymer is considered to be not harmful to aquatic organisms up to the limit of its water solubility.

7.3. Environmental Risk Assessment

The Risk Quotient (RQ, PEC/PNEC) has not been calculated since no PNEC is available.

Based on the expected low toxicity to the aquatic organisms and the assessed use pattern, the notified polymer is not expected to pose an unacceptable risk to the environment from the proposed use as a component of ink.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point 11–15 °C

Method	OECD TG 102 Melting Point/Melting Range. EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks	Determined using differential scanning calorimetry. A melting point could not be determined. Instead a glass transition temperature was recorded.
Test Facility	NOTOX (2009a)

Boiling Point Decomposes without boiling at > 225 °C at 101.3 kPa

Method	OECD TG 103 Boiling Point. EC Council Regulation No 440/2008 A.2 Boiling Temperature.
Remarks	Determined using differential scanning calorimetry.
Test Facility	NOTOX (2009a)

Density 1,177 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids. EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	Determined using the pycnometer method.
Test Facility	NOTOX (2009a)

Vapour Pressure < 8.4×10^{-10} kPa at 20 °C

Method	OECD TG 104 Vapour Pressure. EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks	Determined using isothermal thermogravimetric effusion.
Test Facility	NOTOX (2009a)

Water Solubility ≤ 0.2×10^{-3} g/L

Method OECD TG 105 Water Solubility and QSAR calculation.

Remarks

Column Elution Method was used in the laboratory test. The test substance contains different compounds depending on the polymerisation level. Four main chromatography peaks were observed in the main study. Based on peaks 2 - 4, water solubility of the test substance was determined to be < 0.1×10^{-3} g/L. Based on peak 1, water solubility was determined to be 8.2×10^{-3} g/L (NOTOX, 2009).

As indicated in the Pow test below, the notified polymer contains many components of different P_{OW}, indicating different water solubilities. It is believed that the tested water solubility is for the components of the notified polymer with low molecular weights and hence these components have corresponding higher water solubilities. Therefore, this limit is not considered to be representative of the actual water solubility for the notified polymer.

Quantitative structure–activity relationship **(**QSAR) calculation was used to estimate the water solubility of oligomers of the notified polymer oligomer with two expected molecular weights (445.52 and 764.9). The calculations indicate that the water solubility is 0.2×10^{-3} g/L for the chemical oligomer of the lower molecular weight 445.52 Da, and 5×10^{-8} g/L for the chemical oligomer of the higher molecular weight 764.9 Da (EPIWEB 4.1; US EPA, 2011).

Therefore, based on the above considerations, the water solubility is expected to be ≤ 0.2×10^{-3} g/L.

Partition Coefficient (n-octanol/water) log Pow ≥ 3.8 at 25 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	HPLC Method. A large number of peaks were observed in the chromatograms of the test substances as the notified polymer is of variable composition. The log Pow values were

determined to be 3.8, 5.2, 5.6 and > 6.5 for the four main components of the test structure, respectively.

Test Facility NOTOX (2009)

Adsorption/Desorption log K_{oc} ≥ 3.81 at 35 °C

Method OECD TG 121 Estimation of the Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC).

Remarks The test substance contains different compounds as the notified polymer is of variable composition. A large number of peaks were observed in the chromatograms of the test substance. The log K_{oc} values were calculated to be ≥ 3.81 for the four main components of the test structure.

Test Facility NOTOX (2009)

Flammability Not highly flammable

Method EC Council Regulation No 440/2008 A.10 Flammability (Solids).

Remarks The test substance could not be ignited under the conditions of the test. The test substance melted in contact with the ignition source.

Test Facility NOTOX (2009a)

Flammability in Contact with Water Not predicted to be flammable

Method EC Council Regulation No 440/2008 A.12 Flammability (Contact with Water).

Remarks A statement provided by the testing laboratory indicates that the notified polymer does not contain chemical groups likely to lead to spontaneous combustion in contact with air at room temperature.

Test Facility NOTOX (2009a)

Autoignition Temperature 425 °C

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

Remarks The auto-ignition temperature was determined using a commercially available auto-ignition temperature apparatus (Chilworth Technology, Southhampton, UK).

Test Facility NOTOX (2009a)

Explosive Properties Not predicted to be explosive

Method EC Council Regulation No 440/2008 A.14 Explosive Properties.

Remarks The calculated oxygen balance for the notified polymer is -200 to -213%. This value is outside the region where there may be potential for an explosion. The molecular structure does not contain any chemical groups that might lead to explosion.

Test Facility NOTOX (2009a)

Oxidizing Properties Not predicted to be oxidising

Method EC Council Regulation No 440/2008 A.17 Oxidizing Properties (Solids).

Remarks A statement provided by the testing laboratory indicates that the notified polymer does not contain chemical groups that are expected to result in oxidising properties.

Test Facility NOTOX (2009a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar strain Crl:WI (Han) (outbred, SPF-Quality)
Vehicle	Polyethylene glycol
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 F	2,000	0/3
II	3 F	2,000	0/3

LD50	>2,000 mg/kg bw
Signs of Toxicity	Hunched posture observed in all animals with recovery within 2 to 4 hours post dosing.
Effects in Organs	No treatment related effects on organs were observed at the macroscopic level.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	NOTOX (2009b)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Council Regulation No 440/2008 B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/Wistar strain, Crl:WI (Han) (outbred, SPF-Quality)
Vehicle	Polyethylene glycol 400
Type of dressing	Semi-occlusive.
Remarks - Method	The test substance was administered to rats by a single dermal application at 2,000 mg/kg boy weight for 24 hours. Animals were subjected to daily observations and weekly determination of body weight. Macroscopic examination was performed after terminal sacrifice at day 15.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 M, 5 F	2,000	0

LD50	>2,000 mg/kg bw
Signs of Toxicity - Local	None
Signs of Toxicity - Systemic	None
Effects in Organs	None
Remarks - Results	No mortality seen. Clinical investigation showed chromodacryorrhea for one female on day 1. No abnormalities were found at macroscopic post mortem examination of the animals. The change in body weights of the animals was within the normal range.
CONCLUSION	The notified polymer is of low toxicity via the dermal route.

TEST FACILITY WIL Research (2013a)

B.3. Irritation – skin

TEST SUBSTANCE Finished product 1 containing the notified polymer at ≤ 50% concentration

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 67/548/EEC B.4 Acute Toxicity: Dermal irritation/ Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

Remarks - Results No skin irritation or signs of systemic toxicity were reported for any animal at any time point.

CONCLUSION The test substance is non-irritating to the skin.

TEST FACILITY NOTOX (2005)

B.4. Irritation – eye

TEST SUBSTANCE Finished product 1 containing the notified polymer at ≤ 50% concentration

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 2004/73/EC B.5 Acute Toxicity: Eye Irritation/corrosion

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	No significant protocol deviation.

Following the 24-hour observation, a 2% 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	0	0	0	< 1 h	0
Conjunctiva: chemosis	0	0	0	0	-	0
Conjunctiva: discharge	0	0	0	0	< 1 h	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results Instillation of the test substance resulted in slight irritation of the conjunctivae, which was seen as redness and discharge. The irritation had resolved within 24 hours for all animals. No other signs of eye irritation or damage were reported.

CONCLUSION The test substance is slightly irritating to the eye.

TEST FACILITY NOTOX (2006a)

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

TEST SUBSTANCE	Finished product 1 containing the notified polymer at ≤ 50% concentration
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)
Species/Strain	Mouse/CBA strain, inbred, SPF-Quality
Vehicle	Acetone/Olive oil (4:1 v/v)
Remarks - Method	Test substance concentrations selected for the main study were based on the results of preliminary study. A 25% test substance concentration was considered the highest concentration that could be prepared homogeneously to a visible acceptable level. No significant protocol deviations were made. Topical application was made to the dorsal surface of the ear. A concurrent positive control study was not run, but a previously conducted positive control data from the test facility was provided. α-Hexylcinnamic aldehyde was used as a positive control and vehicle was used as a negative control

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	319	1.0
5	355	1.1
10	150	0.5
25	273	0.9
Positive Control		
0	262	1.0
5	551	2.1
10	952	3.6
25	1969	7.5

Remarks - Results	No mortality occurred and no symptoms of systemic toxicity were observed in the study. Body weight and body weight gain of experimental animals remained in normal range. No skin irritation was observed in any of the animals examined. No scoring of erythema was possible in the experimental groups due to pink test substance remnants on the ear. The majority of the lymph nodes were considered normal in size, except for the node of one animal treated at 25%, which was reduced in size. No macroscopic abnormalities of the surrounding area were noted.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the test substance.
TEST FACILITY	NOTOX (2006b)

B.6. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Finished product 2 containing the notified polymer at ≤ 50% concentration
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)
Species/Strain	Mouse/CBA strain, inbred, SPF-Quality
Vehicle	Acetone/Olive oil (4:1 v/v)

Remarks - Method: Test substance concentrations selected for the main study were based on the results of preliminary study. No significant protocol deviations were made. Topical application was made to the dorsal surface of the ear. A concurrent positive control study was not run, but a previously conducted positive control data from the test facility was provided. α-Hexylcinnamic aldehyde was used as a positive control and vehicle was used as a negative control

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	176	1.0
5	305	1.7
25	298	1.7
50	224	1.3
Positive Control		
0 (vehicle control)	413	1.0
5	618	1.5
10	1184	2.9
25	2529	6.1

Remarks - Results: No mortality occurred and no symptoms of systemic toxicity were observed in the study.
A slight body weight loss was noted in some animals. This was consider not toxicologically significant.
One animal from 25% test group showed irritation of the ears but was considered not to have a toxicologically significant effect on the activity of the lymph nodes.

CONCLUSION: There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the test substance.

TEST FACILITY: NOTOX (2006c)

B.7. 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) (outbred, SPF-Quality)
Route of Administration: Oral – gavage
Exposure Information: Total exposure days: 28 days
Dose regimen: 7 days per week
Vehicle: Polyethylene glycol 400
Remarks - Method: No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5M/5F	0	0
low dose	5M/5F	100	0
mid dose	5M/5F	300	0
high dose	5M/5F	1,000	0

Mortality and Time to Death
No mortality occurred during the test period

Clinical Observations
No clinical signs of toxicity were noted during the observation period.

Salivation seen after dosing among all animals of the 100, 300 and 1,000 mg/kg dose group during the treatment period was considered to be a physiological response rather than a sign of systemic toxicity considering the nature and minor severity of the effect and its time of occurrence (i.e. after dosing). This sign may be related to taste of the test substance.

A broken tail apex of one male at 300 mg/kg and salivation noted for some control animals on day 6 and 7 occurred within the range of findings considered normal for rats of this age and strain.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Males exposed to 300 mg/kg of the test substance showed statistically significantly higher relative lymphocyte counts and female rats exposed to 1,000 mg/kg showed higher white blood cell counts. The counts remained well within the range considered normal for rats of this age and strain and/or showed no dose-related trend. These changes were therefore considered not to be of toxicological relevance.

Male rats exposed to the test substance at concentrations 100, 300 and 1,000 mg/kg showed significantly higher levels of blood glucose and females at 1,000 mg/kg showed significantly higher levels of bile acid. The findings also remained well within the range considered normal for rats of this age and strain. The data showed no clear dose-related trend and had no morphological correlates.

These changes were not considered to be toxicologically significant by the study authors as they were well within the range considered normal at the test age and in the strain of rats used for the study.

Effects in Organs
The incidence of necropsy findings among control and treated animals occurred within the background range of findings that are encountered among rats of this age and strain, did not show a dose-related incidence trend, and occurred in the absence of any treatment-related histopathological changes. These necropsy findings were therefore considered to be of no toxicological relevance.

Females in 1,000 mg/kg dose group showed significantly higher liver weight which remained within the range considered normal for rats of this age and strain and no corroborative histopathological or clinical biochemistry findings were noted. Liver weight was similar to control levels when corrected for body weights.

Male rats in 100 mg/kg dose group showed significantly higher heart to body weight ratio. This trend was not dose dependent and the mean remained within the range considered normal for rats of this age and strain. No toxicological relevance was therefore ascribed to these changes.

All microscopic findings were within the range of background pathology encountered in Wistar rats of this age and strain and occurred at similar indices and severity in both control and treated rats.

These changes were not considered to be toxicologically significant by the study authors as they were well within the range considered normal at the test age and in the strain of rats used for the study.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established as > 1,000 mg/kg bw/day in this study, based on the no toxicologically significant effects seen at 1,000 mg/kg bw/day.

TEST FACILITY WIL Research (2014)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure/Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100,

	E. coli: WP2uvrA
Metabolic Activation System	S9 fraction from Aroclor-1254 induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 10–1,000 µg/plate b) Without metabolic activation: 10–1,000 µg/plate
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks - Method	No significant protocol deviations

A preliminary test was performed from 3–5,000 µg/plate with and without metabolic activation (strains TA100 and WP2uvrA). There was no significant increase in the number of revertant colonies with or without metabolic activation or any bacterial growth inhibition evident. Precipitation was observed in all strains at 1,000 µg/plate and above. The results of the preliminary test formed part of the main test (Test 1).

The negative control was DMSO and positive controls were sodium azide, 9-aminoacridine, methylmethanesulfonate, and 4-nitroquinoline-*N*-oxide in the absence of metabolic activation and 2-aminoanthracene in the presence of metabolic activation.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	> 1,000	≥ 1,000	Negative
Test 2		> 1,000	≥ 1,000	Negative
Present				
Test 1	> 5,000	> 1,000	≥ 1,000	Negative
Test 2		> 1,000	≥ 1,000	Negative

Remarks - Results

The test substance was tested up to the maximum dose level of 1,000 µg/plate. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation.

All the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION

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

TEST FACILITY

NOTOX (2004)

B.9. Genotoxicity – in vivo

TEST SUBSTANCE

Notified polymer

METHOD

Species/Strain	Mice/NMRI BR (SPF)
Route of Administration	Repeated intraperitoneal injection
Vehicle	Corn oil
Remarks - Method	The animals received the doses as two injections 1 to 2 hours apart. Due to calculation error the animals were dose up to 4,000 mg/kg instead of 2,000 mg/kg as required in the guidelines.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5M/5F	0	24
II (low dose)	5M/5F	1,000	24
III (mid dose)	5M/5F	2,000	24
IV (high dose)	5M/5F	4,000	24
V (high dose)	5M/5F	4,000	48
VI (positive control, CP)	5M/5F	40	48

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity	No toxicity seen at 4,000 mg/kg
Genotoxic Effects	None
Remarks - Results	Mice exposed to 4,000 mg/kg of the test substance showed the following clinical observations 20 hours following administration of the notified polymer; one male had a rough coat and one male showed wet fur on the ventral side of the body. One female died within 1 hour after the second treatment due to a technical error during dosing. Within 44 hours after dosing all animals recovered from the treatment. Although a significant increase in micronucleated polychromatic erythrocytes was observed in female animals treated with 4,000 and 1,000 mg/kg bw (48 hour and 24 hour sampling time respectively) compared to the vehicle treated animals, this increase was caused by the low incidence of micronuclei in the vehicle control group. Since all observed values in these groups were within the historical control data range the author of the study considered the increase to be biologically not relevant.

CONCLUSION The notified polymer was not clastogenic under the conditions of this in vivo Mammalian Erythrocyte Micronucleus Test.

TEST FACILITY WIL Research (2013b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	New chemical substances test methods as required by the chemical substances control law of Japan, Biodegradability Test of Chemical Substances by Microorganisms (latest revision, November 2006)
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Measurement of biochemical oxygen demand (BOD) HPLC
Remarks - Method	The test substance was exposed to activated sludge in a closed–system oxygen consumption measuring apparatus. The biochemical oxygen demand (BOD) was measured every 7 days over a 28-day period. The residual amount of the test substance was measured at the end of the test. Test was conducted according the test guideline above without significant deviation from the protocol reported.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation (BOD)*	*Day*	*% Degradation (BOD)*
7	1.5	7	1.2
14	2.5	14	64
21	2.8	21	67
28	3.6	28	68

Remarks - Results	The biodegradability was determined to be 4% and 10% based on the BOD and the residual amount of the test substance, respectively. All the validity criteria were met. New peaks were observed on the HPLC chromatogram during the test of residual amount of the test substance at day 28, implying that part of the test substance was transformed. Further analysis was performed by LC/MS to characterise the transformation products. Some of the transformed products were judged to be readily biodegradable based on Japan's chemicals collaborative knowledge database. Therefore, it was considered that the transformed products had been mineralised and BOD was detected.
CONCLUSION	The notified polymer is not readily biodegradable
TEST FACILITY	MCMC (2010)

C.1.2. Bioaccumulation

TEST SUBSTANCE	Notified polymer
METHOD	New chemical substances test methods as required by the chemical substances control law of Japan, Bioconcentration Test of Chemical Substances in Fish and Shellfish, (latest revision, November 2006). -Flow through.
Species	Carp (*Cyprinus carpio*)
Exposure Period	Exposure: 29 days Depuration: 0 days
Auxiliary Solvent	Dimethyl sulfoxide 25 ppm (v/v)
Concentration Range	Nominal: 0.01 and 0.001 mg/L

	Actual: 0.00859–0.0091 and 0.000763–0.000913 mg/L
Analytical Monitoring	Liquid Chromatography- Mass Spectrometry (LC-MS)
Remarks - Method	The test substance is a multi-component substance. Two components (component A and B) with their molecular weight < 1,000 were analysed quantitatively and their bioaccumulation potential was evaluated. The other two components (component C and D) were only monitored with their related ions since quantitative evaluation was difficult. In addition to a control (16 fish), two groups of fish (18 fish for each group) were exposed to the test substance at difference concentrations levels (0.01 and 0.001 mg/L). During the exposure period, the concentration of the test substance in water and fish was measured periodically. There was no depuration period. The bioconcentration factor (BCF) was determined by comparing the concentration of the test substance in the fish to the mean concentration of test substance in the test water. Test conditions were: 24 ± 2 °C, pH 7.3–7.7 and 7.7–8.4 mg O_2/L.

RESULTS

Bioconcentration Factor	BCF ≤ 54
CT50	Not determined
Remarks - Results	All the test validity criteria were met. As the test substance is a mixture, several peaks were detected in LC/MS chromatograms. Two quantifiable components (peaks A and B) were measured in the determination of BCF. For peak A and B, the variations of mean BCF determined at the three consecutive measurements did not fall within 20%. However, all of the BCF values during the exposure period were less than 100 and it is therefore considered to reach the steady state. The BCFs at the steady-state of component A was determined to be ≤ 18 for high concentration level and ≤ 49 for low concentration level. The BCFs of component B was determined to be ≤ 29 for high concentration level and ≤ 54 for low concentration level. The BCFs of component C was calculated to be < 3 at the high concentration level and < 25 at the low concentration. The BCFs for component D was calculated to be ≤ 30 at the high concentration level and < 25 at the low concentration level. The lipid content of the fish ranged from 4.3 % (n = 3, 3.1–5.9%) at the beginning of the test to 3.5 % (n = 3, 3.4–3.6%) at the end of the test. During the exposure period of 29 days, no mortality or abnormality in appearance, swimming or feeding behaviour of the fish was observed at all the concentration levels and control The test is considered reliable.

CONCLUSION	The notified polymer has a low potential to bioaccumulate in fish
TEST FACILITY	MCMC (2011)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer

METHOD

Species	Medaka (*Oryzias latipes*)
Exposure Period	96 hours
Auxiliary Solvent	100 mg/L HCO-40; 395 ppm (v/v) dimethyl sulfoxide.
Water Hardness	N/A

Analytical Monitoring	N/A
Remarks – Method	A limited test was conducted with 7 fish exposure to the test media at a nominal concentration of 5 mg/L for the test substance. The test media were renewed every 24 hours. No significant deviation from the protocol was reported.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
0	N/A	7	0	0	0	0
5	N/A	7	0	0	0	0

LC50	> 5 mg/L at 96 hours
NOEC	5 mg/L at 96 hours
Remarks – Results	All validity criteria for the test were satisfied. The concentration of the test substance was not measured and LC50 was evaluated based on the nominal concentration. Considering no effects were observed at the top test level of 5 mg/L, and the expected low water solubility of ≤ 0.2 mg/L, the notified polymer is considered not harmful to fish up to the limit of the water solubility.

CONCLUSION The notified polymer is not harmful to fish

TEST FACILITY MCMC (2011)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Finished product 3 containing the notified polymer at ≤ 50% concentration

METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Semi-static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	180 mg $CaCO_3$/L
Analytical Monitoring	Liquid chromatography
Remarks - Method	Weighed amount of liquid test substance (melted at 125 °C) was transferred to test media followed with stirring for 2 days and stabilisation for 1.5 hours. Water accommodation fraction (WAF) test solutions were prepared from the undiluted stock solution by use of siphoning through an inert tube. The final test solutions were clear and colourless. Limit tests in duplicate were conducted by exposure of 20 daphnids (5 daphnid × 4 groups) to a control and a WAF prepared at a loading rate of 100 mg/L. The test solutions were renewed daily.

RESULTS

Concentration mg/L	*Number of D. magna*	*Number Immobilised*	
Nominal (WAF)		*24 h*	*48 h*
0	20	0	0
100	20	0	0

EL50	> 30 mg/L (WAF) at 48 hours
Remarks - Results	Due to the very low solubility of test substance in test medium, concentration levels that caused 50% immobility in daphnids could not be reached. The EL50 was concluded to be greater than the concentration obtained in a WAF prepared at a loading rate of 100 mg/L. No effects were observed for the product (contains up to 50% the notified polymer)

	at the top test level of 100 mg/L. As the test substance contains the notified polymer at up to 50%, the endpoint for the notified polymer has been adjusted to account for the purity of the notified polymer (EL50 > 30 mg/L). Considering the expected low predicted water solubility of ≤ 0.2 mg/L and no effects were observed at up to 100 mg/L of the test substance, the notified polymer is considered not harmful to *Daphnia* up to the limit of the water solubility.
CONCLUSION	The test substance is not expected to be harmful to aquatic invertebrates up to the limit of its water solubility
TEST FACILITY	NOTOX (2008)

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