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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

NEJI-18 polymer in Epson Ink Cartridge

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 the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full 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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FULL PUBLIC REPORT

NEJI-18 polymer in Epson Ink Cartridge

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
EPSON Australia Pty. Ltd. (ABN 91 002 625 783)
3 Talavera Road, North Ryde, NSW 2113

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical names, CAS number, Molecular formula, Structural formula, Molecular weight, Spectral data, Purity, % Weight of impurities, Identity of manufacturer, Import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LVC/749

NOTIFICATION IN OTHER COUNTRIES
EU (2007) Switzerland (2007)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
NEJI-18

MOLECULAR WEIGHT
> 1000 Da

ANALYTICAL DATA
Reference IR, GPC, ^{1}H NMR and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY 93%

DEGRADATION PRODUCTS
The notified polymer is not expected to easily degrade.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None known

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: White crystalline

Property	Value	Data Source/Justification
Melting Point/Boiling Point	No melting/boiling temperature	Measured
Density	1170 kg/m^3 at 20°C	Measured

Vapour Pressure	< 1.10×10^{-8} kPa at 20°C	Measured
Water Solubility	< $5x10^{-4}$ g/L at 20°C and pH 7.9	Measured
Extractivity	< 5 mg/L at 20°C and pH 7.8	Measured
Hydrolysis as a Function of pH	Not determined	Poorly soluble in water.
Partition Coefficient (n-octanol/water)	Not determined	Poorly soluble in water and n-octanol.
Adsorption/Desorption	Not determined	Polymeric compound
Dissociation Constant	Not determined	Poorly soluble in water, no method available.
Particle Size	Inhalable fraction (< 100 μm): 1.79% Respirable fraction (< 10 μm): 0 % MMAD* = 668.516 μm	Measured
Flash Point	Not determined	NAMW > 1000
Flammability (solids)	Considered not highly flammable	Measured
Flammability (contact with water)	Not determined	Not expected to be highly flammable in contact with water or damp air
Surface Tensions	Not determined	Poorly soluble in water.
Pyrophoric Properties	Not determined	Not expected to be pyrophoric
Autoignition Temperature	Not self ignitable	Measured
Explosive Properties	Not determined	Not expected to be explosive

* MMAD = Mass Median Aerodynamic Diameter

DISCUSSION OF PROPERTIES

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

Reactivity

There are no chemical groups that would imply oxidising properties, therefore the result has been predicted negative.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as a component of inkjet printer inks (approximately 2.5%), contained within individually packaged inkjet printer cartridges.

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

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

PORT OF ENTRY

Sydney

IDENTITY OF RECIPIENTS

None known at this time. Potentially, the inkjet printer cartridges containing the notified polymer will be supplied to offices and retailers nationwide.

TRANSPORTATION AND PACKAGING

The notified polymer will be imported as a component of ready-to-use sealed plastic inkjet cartridges of 5-100 mL volumes. The cartridges are individually wrapped in plastic and cardboard packaging, and these will be imported in bulk in cardboard cartons. The cartridges will be transported by road.

USE

The notified polymer will be used in inkjet printer inks as a fixing agent at approximately 2.5%. The inks will be imported within inkjet printer cartridges, which will be used for office and general printing work by the public. Sealed ink cartridges containing the notified polymer will be used as necessary to replace spent cartridges in inkjet printers.

OPERATION DESCRIPTION

No reformulation or repackaging of the notified polymer will occur in Australia. The products containing the notified polymer will be delivered to the end-user in the same form that they will be imported. The cartridges will be distributed to a number of outlets, where the cardboard cartons will be opened and boxes containing individual cartridges will be stacked on shelves.

The cartridges will be transported and stored prior to national distribution where they will be used in office or home printing equipment. The cartridges will be installed or replaced into the inkjet printer by office workers, service technicians or consumers. Replacement of printer cartridges involves removal of the old printer cartridge from the printing machine and directly loading the new cartridge.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Importation/Waterside workers	10	4 hrs per day	70 days per year
Storage and transport	100	6 hrs per day	240 days per year
Office workers, service technicians, consumers	10,000	< 0.1 hrs per day	20 days per day

EXPOSURE DETAILS

Worker exposure to the notified polymer during the importation, transport and storage of the printer cartridges is not expected, except in the unlikely event of an accident where the cartridge and its packaging may be breached.

Both office workers and service technicians may be exposed to the notified polymer in ink (approximately 2.5% concentration) while replacing spent printer cartridges. Dermal exposure to small quantities of the notified polymer may occur if the print heads are touched while replacing the cartridges, but workers are expected to avoid direct contact with inks to avoid staining of their skin and/or clothing. In addition, dermal and possibly ocular exposure could occur when handling faulty or ruptured cartridges. However, the design of the cartridges is expected to be such that they can be easily replaced without dermal exposure to ink. Accidental contact is expected to be minimal.

Service technicians may also experience skin contact with the notified polymer (approximately 2.5% in the ink) during maintenance of inkjet printers. The exposure of these workers is likely to be limited to contact of inks with their fingertips during the handling and cleaning of printer components.

Dermal exposure of office workers to the notified polymer from dried inks on printed paper is expected to be minimal, as the dye will be largely bound to the paper within the matrix of the dried ink.

6.1.2. Public exposure

The exposure of the public to the notified polymer through the use of inkjet printer inks is expected to be identical to that experienced by office workers during the changing of cartridges, printing onto paper and other media, and handling dried, printed pages. Members of the public may be expected to change inkjet printer cartridges less frequently than would office workers, as domestic applications are often smaller.

Public exposure through importation, transportation or storage is expected to be negligible. Such exposure could only occur in the extremely unlikely event of an accident where crates, boxes, packaging and cartridges were ruptured, liberating inks containing the notified polymer.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in 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	non-irritating
Rabbit, eye irritation	slightly irritating

Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* chromosome aberration	non genotoxic

Toxicokinetics, metabolism and distribution
The notified polymer is not expected to be absorbed through the skin, gastrointestinal wall and lungs due to its high molecular weight (>1000 Da). However, the notified polymer contains < 5% low molecular weight species < 1000 Da and some impurities which would have greater potential for absorption.

Acute toxicity
The notified polymer was of low acute oral toxicity in a study on rats. According to the OECD test guideline the LD50 cut-off value was considered to exceed 5000 mg/kg bw. The notified polymer was of low acute dermal toxicity in a study on rats, where LD50 was estimated to be > 2000 mg/kg.

Irritation
Based on the studies provided, the notified polymer was considered to be non-irritating to skin and slightly irritating to eyes.

Sensitisation
There was no evidence of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer in a mouse LLNA, with concentrations tested up to 50%.

Repeated Dose Toxicity
The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day on the basis that no toxicologically significant changes were noted in any of the parameters examined/determined in the study presented.

Mutagenicity
The notified polymer was not mutagenic in bacteria reverse mutation and not genotoxic in *in vitro* chromosomal aberrations in human lymphocytes.

Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Based on the available toxicological data, the notified polymer was of low oral and dermal toxicity, was non-irritating to skin and slightly irritating to eyes, was not sensitising, and was negative in two in vitro genotoxicity studies. The NOAEL was established as 1000 mg/kg bw/day on the basis that no toxicologically significant changes were noted in any of the parameters examined/determined in the repeat dose toxicity study presented.

Due to the enclosed nature of the packaging containing the notified polymer, both in transport and during use, oral and inhalation exposure to workers is expected to be low. Some dermal exposure to technicians and office workers may occur during changing of cartridge containing approximately 2.5% of the notified polymer. As the polymer has molecular weight > 1000 Da, dermal absorption would be reduced.

The exposure of workers to the notified polymer on dried, printed paper is expected to be very low, as the dye containing the notified polymer should remain bound to the paper or the cured print matrix.

Overall the risk to workers is expected to be low, based on the low exposure and the low toxicity in available studies.

6.3.2. Public health
The exposure and hazard of the notified polymer to the members of the public during the use of inkjet printers are expected to be identical or similar to that experienced by office workers. Therefore, the risk of the notified polymer to the health of the public is assessed to be low. The unlikely but potential public exposure through accidents during importation, transportation or storage is assessed as negligible.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Printer ink will be imported in ready-to-use cartridges (containing < 5% notified polymer). No release is expected as manufacturing and reformulation of the ink containing the notified polymer will not take place in Australia. Environmental release of the notified polymer is unlikely during importation, storage and transportation, and spillage during a transport accident is the most likely reason for environmental release. Individual container capacity, container and packaging specifications would limit the extent of release.

RELEASE OF CHEMICAL FROM USE

The ink cartridges are designed to prevent leakage and will not open during transport, use, installation or replacement. Therefore, release of ink containing the notified polymer to the environment is not expected under normal conditions of use. If ink is released from the cartridges during installation and replacement it will be contained with absorbent material and disposed of in landfill. Cartridges are contained within the printer until the contents are used then they are removed and sent to a recycling and disposal centre.

Most of the notified polymer (> 98%) will be bound to the printed paper, which will be disposed of to landfill, recycled or incinerated. Recycling of treated paper may result in the release of a proportion of the notified polymer to the aquatic compartment. Waste paper is repulped using a variety of chemical treatments, which result in fibre separation and ink detachment from the fibres. The waste is expected to go to trade waste sewers. Approximately 50% of the ink printed on paper will enter paper recycling of which a proportion of the ink is expected to be recovered during recycling. Most will partition to sludge and due to the low percentage of the notified polymer in these inks and the widespread use, release to the aquatic compartment from any given recycling plant will still be low based on worst case assumptions. Any chemical absorbed to sludge during recycling process will be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The total import volume of the notified polymer will ultimately be disposed as normal office/domestic waste that will end up in either landfill or be incinerated. Some waste paper printed with the ink may be disposed of directly to landfill with the notified polymer bound to the paper. Some will enter the paper recycling process. Used cartridges may be sent to recycling and disposal centres. The cartridges will be broken down into component parts for recycling. Residual ink (< 2% of the notified polymer) left in the empty cartridges will be separated from the cartridges and incinerated during the recycling of the cartridges.

Notified polymer that is incinerated is expected to thermally decompose to form predominantly simple organic compounds and various salts. Similarly, notified polymer that is disposed of to landfill should eventually degrade.

7.1.2 Environmental fate

A single biodegradability test report was submitted which indicates that the notified polymer is not ready biodegradable. For the details of the environmental fate study please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

Manufacture, reformulation and packaging into end-use containers occurs overseas, and release is not expected. After use, printed-paper may be disposed of by incineration, to landfill or be recycled. Notified polymer disposed of to landfill, may be mobile, however, the low proposed annual import volume, and diffuse release throughout Australia will mitigate any potential exposure while the notified polymer slowly degrades.

In Australia, approximately 50% of printed-paper is recycled. The following Predicted Environmental Concentration calculation assumes this 50% recycling, and given the limited solubility in water, 10% release to sewer and as a worst case scenario assumes no recovery within STPs.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	50	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	0.14	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.03	µg/L
PEC - Ocean:	0.00	µg/L

STP effluent reuse 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 1300 kg/m^3). Using these assumptions, irrigation with a concentration of 0.032 mg/L may potentially result in a soil concentration of approximately 3.240 X 10^{-4} mg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 1.620 X 10^{-3} mg/kg and 3.240 X 10^{-3} mg/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 >100 mg/L* (WAF)	Not toxic to limit of water solubility.
Daphnia Toxicity	E_iC50 >100 mg/L* (WAF)	Not toxic to limit of water solubility.
Algal Toxicity	E_iC50 >100 mg/L* (WAF)	Not toxic to limit of water solubility.
Inhibition of Bacterial Respiration	E_iC50 >100 mg/L* (WAF)	Not Harmful

*Water solubility < 0.5 mg/L

7.2.1 Predicted No-Effect Concentration

Aquatic ecotoxicity data were provided for three trophic levels. The following Predicted No-Effect Concentration has been calculated using an assessment factor of 100 and the water solubility endpoint.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Invertebrates).	0.50	mg/L
Assessment Factor	100.00	
PNEC:	5.00	µg/L

7.3. Environmental risk assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated.

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	0.03	5	0.006
Q - Ocean:	0.00	5	0.001

This indicates that the current import volume and use pattern is not expected to pose an unacceptable risk to the aquatic environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

and

As a comparison only, the classification of notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Acute toxicity	Category 5	May be harmful in contact with skin (dermal)

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

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio:

The notified polymer is not considered to pose a risk to the environment based on its reported use pattern.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Specific engineering controls, work practices or personal protective equipment required for safe use should be selected on the basis of all ingredients in the formulation.

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

- Service personnel should wear cotton or disposable gloves and ensure adequate ventilation is present when removing spent printer cartridges containing the notified polymer and during routine maintenance and repairs.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must 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 chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from used in inkjet printer inks as a fixing agent at approximately 2.5%, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 1 tonne per annum, or is likely to increase, significantly;
  - if the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical 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 MSDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Boiling point No melting/boiling temperature

Method	OECD TG 102 Melting Point/Melting Range. OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Evaporation of a part of the test substance combined with a glass transition was observed at 25-150 ºC. Reaction and/or decomposition of the test substance were observed above approximately 175 ºC.
Test Facility	NOTOX B.V. (2007b)

Density 1170 kg/m^3 at 20ºC

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	An air comparison pycnometer was used.
Test Facility	NOTOX B.V. (2007b)

Vapour Pressure $< 1.10 \times 10^{-8}$ kPa at 20ºC

Method	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Isothermal thermogravimetric diffusion method was used from 100 – 160°C.
Test Facility	NOTOX B.V. (2007b)

Water Solubility $< 5x10^{-4}$ g/L at 20ºC and pH 7.9

Method	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Column Elution Method was used. The water solubility was below the limit of quantification of the applied SEC-UV analytical method.
Test Facility	NOTOX B.V. (2007b)

Hydrolysis as a Function of pH Not determined.

Remarks	According to the guideline, the concentration of test samples should not exceed half the water solubility of the test substance or 0.01M, whichever is lower. The water solubility of the test substance is < 0.5 mg/L. No analytical method was available to support the hydrolysis test at this low concentration level. The test on the hydrolysis of the test substance was therefore not performed. While the notified polymer contains hydrolysable functionality, this is not expected to occur within the environmental pH range of 4 – 9.
Test Facility	NOTOX B.V. (2007b)

Partition Coefficient (n-octanol/water) Not determined

Remarks	With the information on the water solubility ($< 5x10^{-4}$ g/L) and n-octanol solubility ($< 2x10^{-3}$ g/L) it was not possible to determine an accurate value on the partition coefficient of the test substance due to its limited solubility in water and n-octanol.
Test Facility	NOTOX B.V. (2007b)

Adsorption/Desorption Not determined

Remarks	The test substance is a polymeric compound. Therefore, it is not possible to apply the HPLC method for the determination of the adsorption coefficient (K_{OC}) of the test substance. The K_{OC} value could also not be calculated using a Quantitative Structure Activity Relationship (QSAR) since no accurate value on the partition coefficient (P_{OW}) of the test substance could be obtained. According to this, no value on the K_{OC} for the test

substance was obtained.
Test Facility NOTOX B.V. (2007b)

Dissociation Constant Not determined, expected to have typical carboxylic acidity

Remarks According to the guideline, OECD TG 112 Dissociation Constants in Water, the concentration of test samples should not exceed half the water solubility of the test substance or 0.01M, whichever is lower. The water solubility of the test substance is < 0.5 mg/L. The titration method or spectrophotometric method cannot be performed at this low concentration level. The test on the determination of the dissociation constants of the test substance was therefore not performed. In addition, the calculation method could also not be applied since the test substance is a polymeric compound with a relatively complex molecular structure.
Test Facility NOTOX B.V. (2007b)

Particle Size Inhalable fraction (< 100 μm): 1.79%
Respirable fraction (< 10 μm): 0 %
MMAD= 668.516 μm

Method Internal method
Remarks This analysis is conducted initially using a visual microscope (100× and 400× magnification) and is then undertaken more formally using a Laser Diffraction Particle Size Analyser.
Test Facility Chilworth Technology (2007)

Flammability Considered not highly flammable

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks No burning with flame or smouldering over 200 mm within 4 minutes was observed.
Test Facility NOTOX B.V. (2007a)

Flammability Not highly flammable in contact with water or damp air

Method EC Directive 92/69/EEC A.12 Flammability (Contact with Water).
Remarks The structure of the notified polymer does not contain groups that might lead to the evolution of a dangerous amount of flammable gas when coming into contact with water or damp air. No metals, transition metals, boron or silicon are present. The impurities, present for ≤ 2% in the test substance, were not taken into account but it is not to be expected that these have any influence.
Test Facility NOTOX B.V. (2007a)

Pyrophoric Properties Not pyrophoric

Method EC Directive 92/69/EEC A.13 Pyrophoric Properties of Solids and Liquids.
Remarks The structure of the notified polymer does not contain any chemical groups that might lead to spontaneous ignition a short time after coming into contact with air.
Test Facility NOTOX B.V. (2007a)

Autoignition Temperature Not ignitable

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The test substance is not self-ignitable from 20 ºC to 400 ºC.
Test Facility NOTOX B.V. (2007b)

Explosive Properties Not explosive

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks The molecular structure of the test substance does not contain any chemically unstable or highly energetic groups that might lead to an explosion.
Calculation of the oxygen balance of the test substance was not possible since the

compound is a polymeric product with a molecular weight distribution.

Test Facility NOTOX B.V. (2007b)

Surface Tension Not performed

Method OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.

Remarks The water solubility of the test substance is < 0.5 mg/L. According to the guidelines, substances with a water solubility < 1 mg/L need not to be tested.

Test Facility NOTOX B.V. (2007b)

Oxidizing Properties Not oxidising

Method EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).

Remarks The test substance does not contain any group that might act as an oxidising agent. The oxygen atoms that are present in the test substance are all bonded to carbon, which indicates that the molecule is oxygen-deficient.

Extractivity < 5 mg/L at 20ºC and pH 7.8

Method OECD 120: Solution/extraction behaviour of polymers in water.

Test Facility NOTOX B.V. (2007b)

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 Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar strain Crl:WI
Vehicle	Propylene glycol
Remarks - Method	There were no deviations from the protocol.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity	Hunched posture was noted in all animals on day 1 and/or 2.
Effects in Organs	No abnormalities were found at macroscopic post mortem examination of the animals.
Remarks - Results	The body weight gain shown by the animals over the study period was considered to be normal.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	NOTOX B.V. (2007c)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/Wistar strain Crl:WI
Vehicle	Propylene glycol
Type of dressing	Occlusive.
Remarks - Method	There were no deviations from the protocol.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 M	2000	2
2	5 F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Lethargy, flat and/or hunched posture, laboured and/or shallow respiration, piloerection, ptosis, hypothermia, clonic spasms, uncoordinated movements and/or moribund appearance were noted in the males on Days 1 and 2. The females showed restless behavior and/or flat posture on Day 1. Scales were seen in the treated skin-area of the majority of females during the observation period.
Signs of Toxicity - Systemic	The changes noted in body weight gain in surviving males and females

	were within the range expected for rats used in this type of study and were therefore considered not indicative of toxicity.
Effects in Organs	No abnormalities were found at macroscopic post mortem examination of the animals.

CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	NOTOX B.V. (2007d)

B.3. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Albino Rabbit/New Zealand White
Number of Animals	3 M
Vehicle	Moistened with water ethanol (50% v/v)
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	There were no deviations from standard operating procedures that affected the integrity of the study.

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	0	-	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	No skin irritation or corrosion was caused by 4 hour exposure. No staining of the treated skin by the test substance was observed and no test substance remnants were seen. No symptoms of systemic toxicity were observed in the animals during the test period and no mortality occurred.
CONCLUSION	The notified chemical is non-irritating to the skin.
TEST FACILITY	NOTOX B.V. (2007e)

B.4. Irritation – eye

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Albino Rabbit/New Zealand White
Number of Animals	3 M
Observation Period	72 hours
Remarks - Method	There were no deviations from the protocol.

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	1	0.3	2	< 72 hours	0
Conjunctiva: chemosis	0	0	0	2	< 24 hours	0

Conjunctiva: discharge	0.3	0	0	1	< 48 hours	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	1	< 24 hours	0

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

Remarks - Results

Instillation of approximately 46 mg of notified polymer (a volume of approximately 0.1 ml) into one eye of each of three rabbits resulted in effects on the iris and conjunctivae.
Iridial irritation grade 1 was observed in two animals and had resolved within 24 hours. The other animals did not show iridial irritation.
The irritation of the conjunctivae had completely resolved within 48 hours in two animals and within 72 hours in the other animal.
No corneal opacity was observed, and the treatment of the eyes with 2% fluorescein, 24 hours after test substance instillation revealed no corneal epithelial damage.
There was no evidence of ocular corrosion.
Remnants of test substance were present in the eye on Day 1.
No staining of (peri) ocular tissues by the test substance was observed.
No symptoms of systemic toxicity were observed in the animals during the test period and no mortality occurred.

CONCLUSION

The notified chemical is slightly irritating to the eye.

TEST FACILITY

NOTOX B.V. (2007f)

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

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 429 Local Lymph Node Assay.
EC Directive 67/548/EEC B.42 Skin sensitisation – mouse local lymph node assay.

Species/Strain

Mouse/CBA strain, inbred, SPF-Quality

Vehicle

Propylene glycol

Remarks - Method

In the preliminary irritation study (25% and 50%), no irritation was observed in any of the animals examined. Based on the results, the highest test substance concentration selected for the main study was a 50% concentration.
There were no deviations from standard operating procedures that affected the integrity of the study.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	264 ± 49	1.0
10%	350 ± 69	1.3 ± 0.4
25%	352 ± 89	1.3 ± 0.4
50%	243 ± 32	0.9 ± 0.2
Positive Control (Alpha-Hexylcinnamaldehyde)		
0	357 ± 61	1.0 ± 0.2
5%	474 ± 85	1.3 ± 0.3
10%	547 ± 48	1.5 ± 0.3
25%	1980 ± 315	5.5 ± 1.3

Remarks - Results

No skin reactions were observed in any of the animals examined.
The majority of nodes were considered normal in size, except for one

extremely enlarged node of one animal in the 25% group.
No macroscopic abnormalities of the surrounding area were noted.
Body weights and body weight gain of experimental animals remained in the same range as controls over the study period.
The DPM value of one animal in the 25% group was rejected and not used for interpretation, since it was considered to be outside the range of this study.
No mortality occurred and no symptoms of systemic toxicity were observed in the animals of the main study.

The stimulation index was significantly < 3 and no dose response was seen.
The six monthly reliability check with Hexylcinnamaldehyde confirmed the validity of the test system.

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

TEST FACILITY — NOTOX B.V. (2007g)

B.6. Repeat dose toxicity

TEST SUBSTANCE — Notified polymer

METHOD — OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain	Rat: Wistar Crl:(WI) BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: none
Vehicle	Propylene glycol
Remarks - Method	There were no deviations from standard operating procedures that affected the integrity of the study. Preliminary dose range finding study was performed with 3 female animals and 5 day regime dosing with 500 and 1000 mg/kg bw/day. No significant toxicity was observed and doses for the main test were determined as outlined below.

RESULTS

Dose mg/kg bw/day	*Number and Sex of Animals*	*Mortality*
0	5/sex	None
50	5/sex	None
150	5/sex	1 M
1000	5/sex	None

Mortality and Time to Death

No mortality occurred during the study period that was considered to be related to treatment with the test substance.
One male at 150 mg/kg/day was found dead after dosing on day 4. Prior to death, this animal showed lethargy, flat posture and laboured respiration. Necropsy revealed perforation of the oesophagus and reddish fluid in the thoracic cavity. Histopathological examination showed evidence of oesophageal rupture which along which the macroscopic abnormalities indicated gavage trauma as the cause of demise. No further mortality occurred during the study period.

Clinical Observations

There were no clinical signs of toxicity noted over the 28-day observation period.

Incidental findings that were noted included salivation, alopecia and rales. These findings are commonly noted in rats of this age and strain which are housed and treated under the conditions in this study. At the incidence observed, these were considered signs of no toxicological significance. No clinical signs were noted among control males, and animals at 50 mg/kg/day.
Hearing ability, papillary reflex, static righting reflex and grip strength were normal in all animals.
The variation in motor activity did not indicate a relation with treatment.
Body weights and body weight gain of treated animals remained in the same range as controls over the 4-week study period.
Food consumption before or after allowance for body weight was similar between treated and control animals.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No toxicologically relevant changes occurred in haematological parameters of treated rats. Higher neutrophil counts with concurrently reduced lymphocyte counts were noted in males at 100 mg/kg/day and in females at 150 mg/kg/day. This shift in type of white blood cells was considered to be secondary non-specific response to stress and to be of no toxicological significance.
No toxicologically relevant changes occurred in clinical biochemistry parameters of treated rats.

Effects in Organs
Necropsy did not reveal any toxicologically relevant alterations.
Statistically significant higher thymus weight and thymus to body weight ratio were noted in females at 150 and 1000 mg/kg/day. As they were of a very minor nature and not associated with dose related macroscopic or microscopic changes, these were considered not to be a sign of toxicity. In the macroscopic and microscopic examination, agonal haemorrhage was seen in one female control animal and one female in the 1000 mg/kg bw/day group but this was also not considered substance related.
There were no microscopic findings recorded which could be attributed to treatment with the test substance.

Remarks – Results
No toxicologically significant changes were noted in any of the parameters examined/determined in this study (i.e. clinical appearance, functional observations, body weight, food consumption, clinical laboratory investigations, macroscopic examination, organ weights, and microscopic examination).

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on the results presented.

TEST FACILITY	NOTOX B.V. (2007h)

B.7. 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
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA)
Metabolic Activation System	Rat liver S9-mix induced by a combination of phenobarbital and β–naphthoflavone (used 5% in Test 1 and 10% in Test 2).
Concentration Range in Main Test	a) With metabolic activation: 100, 333, 1000, 3330, 5000 µg/plate b) Without metabolic activation: 100, 333, 1000, 3330, 5000 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	There were no deviations from standard operating procedures that affected the integrity of the study.

RESULTS

Metabolic	*Test Substance Concentration (µg/plate) Resulting in:*

Activation	*Cytotoxicity in Preliminary Test*	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000 µg/plate	> 5000 µg/plate	> 5000 µg/plate	negative
Test 2	> 5000 µg/plate	> 5000 µg/plate	> 5000 µg/plate	negative
Present				
Test 1	> 5000 µg/plate	> 5000 µg/plate	> 5000 µg/plate	negative
Test 2	> 5000 µg/plate	> 5000 µg/plate	> 5000 µg/plate	negative

Remarks - Results: All bacterial strains showed negative responses over the entire dose range, i.e. no significant dose-related increase in the number of revertants in two independently repeated experiments.
The negative and strain-specific positive control values were within the laboratory historical control data ranges indicating that the test conditions were adequate and that the metabolic activation system functioned properly.

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

TEST FACILITY: NOTOX B.V. (2007i)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - *In vitro* Mammalian Chromosome Aberration Test.

Cell Type/Cell Line: Cultured peripheral human lymphocytes
Metabolic Activation System: Rat liver S9-mix induced by a combination of phenobarbital and β–naphthoflavone.
Vehicle: Dimethyl sulfoxide (soluble at ≤ 333 µg/mL)
Remarks - Method: There were no deviations from standard operating procedures that affected the integrity of the study. Dosages were determined in a range finding test.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 33*, 100*, 333*	3 h	24 h
Test 2a	0*, 33*, 100*, 333, 1000*	24 h	24 h
Test 2b	0*, 33*, 100*, 333, 1000*	48 h	48 h
Present			
Test 1	0*, 33*, 100*, 333*	3 h	24 h
Test 2	0*, 33*, 100*, 333*	3 h	48 h

*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	> 1000			
Test 1		> 333	≥ 333	negative
Test 2a		> 1000	≥ 333	negative
Test 2b		> 1000	≥ 333	negative
Present	> 333			
Test 1		> 333	≥ 333	negative
Test 2		> 333	≥ 333	negative

Remarks - Results	Positive control chemicals, mitomycin C and cyclophosphamide, both produced a statistically significant increase in the incidence of cells with chromosome aberrations, indicating that the test conditions were adequate and the metabolic activation system (S9-mix) functioned properly. Both in the absence and presence of S9-mix the notified polymer did not induce a statistically significant or biologically relevant increase in the number of cells with chromosome aberrations in two independent experiments. Slight increase of aberrations was noted in all doses compared to controls in Test 2 48 h exposure without metabolic activation but this is not statistically significant. No effects of the notified polymer on the polyploid cells and cells with endoreduplicated chromosomes were observed both in the absence and presence of S9-mix. Therefore it can be concluded that the notified polymer does not disturb mitotic processes and cell cycle progression and does not induce numerical chromosome aberrations under the conditions of the test.
CONCLUSION	The notified polymer was not clastogenic to human lymphocytes treated *in vitro* under the conditions of the test.
TEST FACILITY	NOTOX B.V. (2007j)

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. EC Directive 92/69/EEC C.4-C Biodegradation: Determination of the " Ready" Biodegradability: Carbon Dioxide Evolution Test
Inoculum	Activated sludge
Exposure Period	29 days
Auxiliary Solvent	None
Analytical Monitoring	CO_2
Remarks – Method	There were no deviations from the protocol. Since the test substance was poorly soluble in water, weighed amounts were added to the test bottles containing medium with microbial organisms and mineral components. The test solutions were continuously stirred during the test to ensure optimal contact between the test substance and the test organisms.

RESULTS

Test substance		*<Sodium acetate>*	
Day	*% degradation*	*Day*	*% degradation*
2	0	2	11
5	2	5	37
7	2	7	51
9	2	9	58
14	2	14	64
19	2	19	67
23	3	23	68
27	3	27	69
29	3	29	69

Remarks – Results	10% degradation was not achieved after 12 days. In addition, 60% degradation was not reached after 29 days incubation. In the toxicity control, the test substance was found not to inhibit microbial activity. Since all criteria for acceptability of the test were met, this study was considered to be valid.
CONCLUSION	The notified polymer cannot be classified as ready biodegradable.
TEST FACILITY	NOTOX B.V. (2007k)

C.1.2. Bioaccumulation

REMARKS	Based on its very low solubility in water and n-octanol, the notified polymer is not expected to bioaccumulate.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer

METHOD	OECD TG 203 Fish, Acute Toxicity Test – limit test/static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – limit test/static.
Species	*Cyprinus carpio* (Carp)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	180 mg $CaCO_3$/L
Analytical Monitoring	Water sample was taken at the beginning of the test. Because of the low water solubility of the notified polymer, it was decided to analyse the residue of the filter that was used during preparation of the nominal 100 mg/L test solution. An aliquot of the residue was transferred into a 5 mL volumetric flask. The flask was filled up to the mark with dichloromethane and subsequently diluted by a factor of 500.
Remarks – Method	There were no deviations from the protocol. A limit test was performed exposing seven fish to a blank-control and a 0.45 µm filtered test substance solution prepared at a loading rate of 100 mg/L by ultrasonification for 5 minutes followed by stirring for 24 hours subsequent to filtration.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	< detection limit	7	0	0	0	0	0
100	< detection limit	7	0	0	0	0	0

LC50	> water solubility at 96 hours.
NOEC	water solubility at 96 hours.
Remarks – Results	Analysis of the samples taken from the filtrate at the start of the test showed that measured concentrations were below the limit of quantification (1 mg/L). Analyses of the filter material indicated that this was test substance. No further analysis was performed. The notified polymer induced no visible or lethal effects in carps when exposed to the maximum soluble concentration in water (< 0.5 mg/L) generated by exposure of test media to a loading rate of 100 mg/L (NOEC). Hence, the 96-LC_{50} of the notified polymer for *Cyprinus carpio* (carp) was above the level of solubility in water. The study met the acceptability criteria prescribed by the protocol and was considered valid.
CONCLUSION	The notified polymer is not toxic to *Cyprinus carpio* up to the level of its solubility in water.
TEST FACILITY	NOTOX B.V. (2007l)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	180 mg $CaCO_3$/L
Analytical Monitoring	Water sample was taken at the beginning of the test. Because of the low water solubility of the notified polymer, it was decided to analyse the residue of the filter that was used during

preparation of the nominal 100 mg/L test solution. An aliquot of the residue was transferred into a 5 mL volumetric flask. The flask was filled op to the mark with dichloromethane and subsequently diluted by a factor of 500.

Remarks – Method: A combined limit/range-finding test was performed. Twenty *Daphnia* were exposed to a blank-control and a 0.45 µm filtered solution prepared as above at a loading rate of 100 mg/L. In the combined range-finding test ten *Daphnia* were exposed to 0.45 µm filtrates prepared at loading rates of 1.0 and 10 mg/L. In addition a tend-fold dilution of the filtrate prepared at 1.0 mg/L was tested. Samples for confirmation of actual exposure concentrations were taken at the start of the test.

There were no deviations from the protocol.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	< detection limit	20	0	2 (10%)
0.1	< detection limit	20	0	0
1	< detection limit	20	0	0
10	< detection limit	20	0	0
100	< detection limit	20	0	0

LC50: > water solubility at 48 hours

NOEC: water solubility at 48 hours

Remarks – Results: Analysis of the samples taken from the filtrates at the start of the test showed that measured concentrations were below the limit of quantification (1 mg/L). Analyses of the filter residue indicated that this was test substance. No further analysis was performed.

The study met the acceptability criteria prescribed by the protocol and was considered valid.

CONCLUSION: The notified polymer is not toxic to *Daphnia magna* up to the level of its solubility in water.

TEST FACILITY: NOTOX B.V. (2007m)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species: *Pseudokirchneriella subcapitata*, strain: NIVA CHL 1

Exposure Period: 72 hours

Concentration Range Nominal: 1.0, 10.0 and 100 mg/L

Concentration Range Actual: All prepared solutions were below the detection limit.

Auxiliary Solvent: None

Water Hardness: 24 mg $CaCO_3$/L

Analytical Monitoring: Because of the low water solubility of the notified polymer, it was decided to analyse the residue of the filter that was used during preparation of the nominal 100 mg/L test solution. An aliquot of the residue was transferred into a 5 mL volumetric flask. The flask was filled op to the mark with dichloromethane and subsequently diluted by a factor of 500.

Remarks – Method

A combined limit/range-finding test was performed with exponentially growing algal cultures exposed to a blank-control and 0.45 µm filtered solutions prepared as above at loading rates of 1.0, 10, and 100 mg/L. The total test period was 72 hours and the initial algal cell density was 10^4 cells/mL. Samples for analytical confirmation of actual exposure concentrations were taken at the start of the test.

Analyses of the samples taken from the filtrated prepared at 100 mg/L at the start of the test showed that the measured concentration was below the limit of quantification (1 mg/L). Analyses of the filter residue indicated that this was the test substance. No further analysis was performed.

There were no deviations from the protocol.

RESULTS

Biomass		*Growth*	
E_bC50	*NOE_bC*	*E_rC50*	*NOE_rC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
> water solubility	water solubility	> water solubility	water solubility

Remarks – Results

No reduction of growth rate or inhibition of yield was recorded when exposing algae to the maximum soluble concentration in water (< 0.5 mg/L) generated by exposure of test media to a loading rate of 100 mg/L (NOEC). Instead, algal growth was stimulated in the notified polymer treated solutions. This stimulation increased with the logarithm of the loading rate.

The study met the acceptability criteria prescribed by the protocol and was considered valid.

CONCLUSION

The notified polymer is not toxic to *Pseudokirchneriella subcapitata* up to the level of its solubility in water.

TEST FACILITY

NOTOX B.V. (2007n)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.

Inoculum: Aerated activated sludge
Exposure Period: 3 hours
Concentration Range Nominal: 0, 100 mg/L
Remarks – Method: There were no deviations from the protocol.

RESULTS

IC50: > 100 mg/L
NOEC: ≥ 100 mg/L
Remarks – Results: No significant inhibition of the respiration rate of the sludge was recorded at 100 mg/L notified polymer. The duplicate measurement confirmed the result of the first measurement (values 2 and 7% inhibition only was recorded). Therefore, no further testing was needed. Hence, the EC_{50} of notified polymer exceeded 100 mg/L (based on nominal concentration).

CONCLUSION	Under the circumstances of the present test, the notified polymer was not toxic to waste water (activated sludge) bacteria at a loading rate of 100 mg/L, the regulatory limit concentration.
TEST FACILITY	NOTOX B.V. (2007k)

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