File No: LTD/1597

June 2012

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

# PUBLIC REPORT

## Polymer in Intersleek 970

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

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

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


| | |
|---|---|
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**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 SUBSTANCE | INTRODUCTION VOLUME | USE |
|---|---|---|---|---|---|
| LTD/1597 | Akzo Nobel Pty Ltd | Polymer in Intersleek 970 | No | ≤ 1 tonne per annum | Component of coatings at < 10%. |

# CONCLUSIONS AND REGULATORY OBLIGATIONS

**Hazard classification**
Based on the available data, the notified polymer is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(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, the notified polymer is not considered to pose an unreasonable risk to the environment.

**Recommendations**

CONTROL MEASURES
OCCUPATIONAL HEALTH AND SAFETY

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer, as introduced:
  - Adequate ventilation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid inhalation of aerosols during spray application

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Respiratory protection during spray applications

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

- Spray applications should be carried out in accordance with the Safe Work Australia *National Guidance Material for Spray Painting* [NOHSC (1999)] or relevant State and Territory Codes of Practice.

- 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 polymer is listed on the Australian Inventory of Chemical Substances (AICS).

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

(1) Under Section 64(1) of the Act; if
- the polymer has a number-average molecular weight of less than 1000;
- the percentage of low molecular weight species < 1000 Da exceeds 1%;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of finished surface coating products at < 10%, or is likely to change significantly;
- the amount of polymer being introduced has increased from 1 tonne per annum, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

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

# ASSESSMENT DETAILS

## 1. APPLICANT AND NOTIFICATION DETAILS

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

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 name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, identity of manufacturer, use details and thermal degradation products.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: water solubility, hydrolysis as a function of pH, partition coefficient, absorption/desorption, flash point, flammability limits, autoignition temperature and explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA, Canada, Korea, New Zealand, Taiwan.

## 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Fluorolink E10H, 5147X (neat notified polymer)
Intersleek 970 (coating product containing the notified polymer at < 10%)

OTHER NAMES
Tetrafluoroethylene, oxidized, oligomers, reduced, methyl esters, reduced, reaction product, with ethylene oxide
Fomblin ZDOL TX 2000

MOLECULAR WEIGHT
Mn > 1,000 Da.

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

## 3. COMPOSITION

DEGREE OF PURITY > 99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless liquid

| Property | Value | Data Source/Justification |
|---|---|---|
| Pour Point | -39°C | Measured |
| Boiling Point | > 250°C at 101.3 kPa | Measured. Notified polymer decomposes prior to boiling. |
| Density | 1680 kg/m$^3$ at 20 °C | Measured |

| | | |
|---|---|---|
| Vapour Pressure | < $1x10^{-7}$ kPa at 23 ºC | Measured |
| Water Solubility | 4.48 $1x10^{-4}$ g/L | Measured |
| Hydrolysis as a Function of pH | Not determined | No hydrolysis as function of pH is predicted on structural grounds of the notified polymer. |
| Partition Coefficient (n-octanol/water) | Not determined | Physical nature of the notified polymer and its molecular weight distribution make the analysis extremely difficult to perform and interpret. |
| Adsorption/Desorption | Not determined | The low water solubility of the notified polymer makes the analysis of the concentration in the aqueous phase extremely difficult to perform and interpret. |
| Dissociation Constant | Not determined | Dissociation of the notified polymer in water is not expected due to the lack of acid or base groups. |
| Flash Point | Not determined | The notified polymer has a low volatility and is therefore not expected to have a low flash point. |
| Flammability | Not determined | Not expected to be flammable based on structure. |
| Autoignition Temperature | Not determined | Not expected to autoignite based on structure. |
| Explosive Properties | Not determined | Not expected to be explosive based on structure. |
| Oxidising Properties | Not determined | Not expected to be oxidising based on structure. |
| Viscosity | 105 $mm^2/s$ at 20°C | Measured |

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

*Reactivity*
Stable under normal conditions of use. Thermal decomposition occurs at temperatures >250ºC.

*Dangerous Goods classification*
Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

## 5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported at < 10% in a finished coating product Intersleek 970.

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
Brisbane, Melbourne, Sydney, Fremantle.

IDENTITY OF RECIPIENTS
Akzo Nobel Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer (at < 10%) will be imported as a component of finished coating products in 10 L cylindrical lined open top pails.

USE
The notified polymer will be used as a component (< 10%) of a finished coating product for use in marine applications.

OPERATION DESCRIPTION
The notified polymer will be imported in finished coating products which will be transported to various industrial sites for application to marine structures. Spray application is expected to be the most common method of application. A potman will connect a hose from the import container to the spray equipment and continue to feed in coating product as required. The sprayer will spray the coating product onto marine structures. Small amounts may also be applied by roller and brush. After application, equipment will be cleaned and rinsed with solvents.

## 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)* |
|---|---|---|
| Transport and Warehousing | 0 | 60 |
| Potmen | 6 | 75 |
| Sprayers | 6 | 75 |

EXPOSURE DETAILS
Exposure during transport and storage is not expected except in the case of an accident involving a breach of the containers.

Potmen may experience dermal and ocular exposure to spills and splashes of coating products containing the notified polymer at < 10% concentration during opening of product containers, connecting them to a hose, replacing empty containers and cleaning of equipment. However, personal protective equipment (PPE) such as gloves, goggles and coveralls should minimise exposure.

Sprayers may come into contact with the notified polymer (< 10%) through inhalation during spray application, as well as dermal and ocular routes during application, cleaning and maintenance of equipment. The use of PPE such as organic vapour respirators, gloves, goggles and coveralls should minimise exposure.

After application and once cured and dried, the notified polymer will be reacted into the polymer matrix and will not be bioavailable.

#### 6.1.2. Public Exposure
Coatings containing the notified polymer at < 10% are intended for industrial use only and will not be sold to the public. Members of the public may come into contact with marine structures coated with coatings containing the notified polymer. However, once the coatings have cured and dried, the notified polymer will be reacted into the polymer matrix and will not be bioavailable.

### 6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

| *Endpoint* | *Result and Assessment Conclusion* |
|---|---|
| Rat, acute oral toxicity | LD50 > 5000 mg/kg bw; low toxicity |
| Rat, acute dermal toxicity | LD50 > 5000 mg/kg bw; low toxicity |
| Rabbit, skin irritation | non-irritating |

| | |
|---|---|
| Rabbit, eye irritation | non-irritating |
| Guinea pig, skin sensitisation – non-adjuvant test. | no evidence of sensitisation |
| Mutagenicity – bacterial reverse mutation | non mutagenic |

*Toxicokinetics*
The notified polymer has a high number average molecular weight (> 1,000 Da), low percentage (< 1%) of low molecular weight species < 1000 Da and predicted low water solubility, and therefore, is not expected to be readily absorbed via dermal, oral or inhalation routes. This is supported by the results of the acute oral and dermal toxicity studies.

*Acute toxicity*
The notified polymer was found to be of low acute oral and dermal toxicity (LD50 > 5000 mg/kg bw). The notified polymer was not tested for its toxicity via the inhalation route.

*Irritation and Sensitisation*
The notified polymer was found to be non-irritating to the skin and eye of rabbits and not sensitising to guinea pigs in a Buehler test.

*Mutagenicity*
The notified polymer was found not to be mutagenic in a bacterial reverse mutation assay.

***Health hazard classification***
Based on the data provided, the notified polymer is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

### 6.3. Human Health Risk Characterisation

#### 6.3.1. Occupational Health and Safety
The notified polymer is not expected to be hazardous based on the high molecular weight, low percentage of low molecular weight species (< 1000 Da) and the results of toxicity studies.

Any dermal and ocular exposure experienced by transport workers and potmen to the notified polymer at < 10% in coatings should not pose an unreasonable risk especially when appropriate PPE is used.

Spray painters may encounter inhalation exposure to the notified polymer at < 10%, in addition to dermal and ocular exposure. Spray application is not considered to result in an unreasonable risk provided that there is adequate ventilation (e.g. spraying occurs in a ventilated spray booth or in a well-ventilated area) and respiratory protection is worn.

#### 6.3.2. Public Health
Products containing the notified polymer at < 10% are not intended for use by the public. The public may come into contact with surfaces coated with products containing the notified polymer, however once the coatings are dried and cured, the notified polymer is not bioavailable. Therefore, based on the proposed use, the risk to public health is not considered unreasonable.

## 7. ENVIRONMENTAL IMPLICATIONS

### 7.1. Environmental Exposure & Fate Assessment

#### 7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will be imported into Australia as a component of finished paint product for use in marine applications. No further reformulation in Australia is required. Only a negligible amount of the notified polymer may be released from storage and transportation of the products containing the notified polymer.

RELEASE OF CHEMICAL FROM USE
The application process is the stage where the notified polymer undergoes a polymerisation reaction and forms part of an inert dried film. Once the product is applied, the notified polymer will be trapped in an inert film in a drying/curing process.

The application will be carried out by professional painting contractors only, normally by spray. At the end of the spraying operation the spray equipment will be cleaned using solvent. This cleaning solvent will be used several times and is expected to be sent to a solvent recovery contractor for recovery. The waste solids containing the notified polymer are expected to be collected and sent to landfill.

Some smaller jobs may be carried out by individuals using brush and/or roller. In some cases, the paint may be applied directly from a can, paint kettle or roller tray. After application, the equipment will be cleaned and the waste generated will be treated in the same way as for the spray equipment. Any unused paint will be returned to the original container. At the end of their life, brushes and rollers will be allowed to dry and disposed of as solid waste.

Based on the above information, no significant release of the notified polymer to sewer is expected from use.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer associated to substrates after painting application will share the fate of the substrates. At the end of their life, the notified polymer may be disposed of to landfill with the substrates, or thermally decomposed during recycling processes to form water, hydrofluoric acid, and oxides of carbon.

Any residues in the empty containers will be dried, forming inert solids, and be disposed of to landfill with the containers.

### 7.1.2. Environmental Fate

The provided study on the inherent biodegradability showed that the notified polymer is not inherently biodegradable. For the details of the environmental fate studies please refer to Appendix C. Given the high molecular weight of > 1000 Da, the notified polymer is not considered to be bioaccumulative in organisms.
Any releases of the notified polymer from use or container residues are expected to be sent to landfill. The notified polymer associated to substrates after coating application will share the fate of the substrates: either sent to landfill at the end of their useful life or thermally decomposed during the substrates' recycling to form water, hydrofluoric acid, and oxides of carbon. In landfill, the notified polymer is not expected to leach and will eventually undergo slow biotic and abiotic degradation processes, forming water, hydrofluoric acid, and oxides of carbon.

### 7.1.3. Predicted Environmental Concentration (PEC)

Based on above assumption for the use pattern of the notified polymer, no significant release to aquatic environment is expected. Therefore, the Predicted Environmental Concentration (PEC) was not calculated.

## 7.2. Environmental Effects Assessment

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

| *Endpoint* | *Result* | *Assessment Conclusion* |
|---|---|---|
| Fish Toxicity | EC50 > 100 mg/L | Not harmful |
| Daphnia Toxicity | EC50 > 100 mg/L | Not harmful |
| Algal Toxicity | EC50 > 100 mg/L | Not harmful up to the limit of water solubility |

The notified polymer is considered to be not harmful to aquatic life as indicated by the above summarised toxicity endpoints.

The determined ecotoxicological endpoints were utilised to determine the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) rating below.

Under the GHS the notified polymer is considered to be not harmful to fish, aquatic invertebrates and algae. Therefore, the notified polymer is not formally classified under the GHS for acute toxicity. No chronic toxicity data is available, and the notified polymer is not considered to have potential for bioaccumulation, although it is not inherently biodegradable, due to the molecular weight of > 1000 Da. Therefore, the notified polymer is not classified under the GHS for chronic toxicity.

### 7.2.1. Predicted No-Effect Concentration

Since no significant release of the notified polymer to aquatic environment is predicted from the proposed use pattern, the Predicted No-Effect Concentration (PNEC) was not calculated.

### 7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) was not calculated since no significant release of the notified polymer to aquatic environment is predicted from the reported use pattern.

The notified polymer is not expected to pose any unreasonable risk to aquatic environment based on the assessed use pattern.

For PBT consideration, the notified polymer may be persistent according to the study on inherent biodegradability properties. It is not considered to meet the criterion for bioaccumulation given the high molecular weight of > 1000 Da. It is not considered to meet the criterion for toxicity since it is determined not harmful to aquatic life based on the provided studies on toxicity to fish, daphnids and alga.

## APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

**Pour Point** -39ºC

| | |
|---|---|
| Method | OECD TG 102 Melting Point/Melting Range.<br>EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature. |
| Test Facility | Solvay Solexis S.p.A. (2011) |

**Density** 1680 kg/$m^3$ at 20ºC

| | |
|---|---|
| Method | OECD TG 109 Density of Liquids and Solids.<br>EC Council Regulation No 440/2008 A.3 Relative Density. |
| Remarks | Hydrometer method |
| Test Facility | Solvay Solexis S.p.A. (2011) |

**Vapour Pressure** < $1x10^{-7}$ kPa at 23ºC

| | |
|---|---|
| Method | EPA Product Properties Test Guidelines, OPPTS 830.7950, Vapor Pressure (1996). |
| Remarks | An in-house method (Cottrell's method) was used to estimate vapour pressure.<br>A reference perfluorotributylamine was used and a whole set of 20 data points (temperature and pressure) were obtained and analysed using Antoine's equations. Based on these data, vapour pressure for the notified polymer was calculated from an experiment that was carried out by measuring the weight loss during a heating scan in air. The vapour pressure for the notified polymer was determined as $1x10^{-7}$ kPa at 23ºC. |
| Test Facility | Solvay Solexis S.p.A. (2011a) |

**Water Solubility** 4.48 x $10^{-4}$ g/L

| | |
|---|---|
| Method | In-house method based on Liquid chromatography-mass spectroscopy (APCI-POS). |
| Remarks | Saturated aqueous solution was prepared by mixing 1 g of the notified polymer in 500 g of milliQ water. After C18 solid phase extraction, the notified polymer in the dried column was recovered with 2-propanol/HFE7100 (80/20) for LC-MS analysis. The solubility of the notified polymer in water was determined to be 0.488 µg/g (equivalent to 4.48 $1x10^{-4}$ g/L). Test temperature was not provided. |
| Test Facility | Solvay Solexis S.p.A. (2011a) |

**Viscosity** 105 $mm^2$/s at 20ºC

| | |
|---|---|
| Method | OECD TG 114 Viscosity of Liquids. |
| Test Facility | Solvay Solexis S.p.A. (2011) |

# APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

## B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified polymer

METHOD: Not stated
- Species/Strain: Rat/Sprague-Dawley
- Vehicle: None
- Remarks - Method: The test substance was administered in 5000 mg/kg bw single dose by gavage in a method similar to OECD TG 401 Acute Oral Toxicity.

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Mortality* |
|---|---|---|---|
| I | 6 M | 5000 | 0/6 |
| II | 6 F | 5000 | 0/6 |

- LD50: > 5000 mg/kg bw
- Signs of Toxicity: none
- Effects in Organs: none
- Remarks - Results: No mortalities or abnormalities were reported during observation. No treatment related effects were observed at necropsy.

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

TEST FACILITY: University of Milan (1988)

## 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/Sprague-Dawley
- Vehicle: None
- Type of dressing: Occlusive
- Remarks - Method: No significant protocol deviations.

RESULTS

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

- LD50: > 2000mg/kg bw
- Signs of Toxicity - Local: None
- Signs of Toxicity - Systemic: No clinical signs were observed.
- Effects in Organs: No significant abnormalities were found at necropsy.
- Remarks - Results: There were no mortalities and all animals continued to gain weight over the 14-day observation period.

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

TEST FACILITY: RTC (2007a)

**B.3. Irritation – skin**

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | Not stated |
| Species/Strain | Rabbit/Albino Hy/Cr |
| Number of Animals | 3 |
| Vehicle | None |
| Observation Period | 72 hours |
| Type of Dressing | Occlusive |
| Remarks - Method | Similar to OECD TG 404. Test not conducted according to GLP. |

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 | 0 |
| *Oedema* | 0 | 0 | 0 | 0 | 0 | 0 |

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

| | |
|---|---|
| CONCLUSION | The notified polymer is non-irritating to the skin. |
| TEST FACILITY | University of Milan (1988) |

**B.4. Irritation – eye**

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | Not stated |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 |
| Observation Period | 7 days |
| Remarks - Method | Similar to OECD TG 405. Test not conducted according to GLP. |

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 | 0 | 0 |
| *Conjunctiva: chemosis* | 0 | 0 | 0 | 0 | 0 | 0 |
| *Conjunctiva: discharge* | 0 | 0 | 0 | 0 | 0 | 0 |
| *Corneal opacity* | 0 | 0 | 0 | 0 | 0 | 0 |
| *Iridial inflammation* | 0 | 0 | 0 | 0 | 0 | 0 |

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

| | |
|---|---|
| CONCLUSION | The notified polymer is non-irritating to the eye. |
| TEST FACILITY | University of Milan (1988) |

**B.5. Skin sensitisation**

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 406 Skin Sensitisation - Buehler test.<br>EC Directive 96/54/EC B.6 Skin Sensitisation - Buehler test. |
| Species/Strain | Guinea pig/Dunkin-Hartley strain |
| PRELIMINARY STUDY | Maximum Non-irritating Concentration:<br>topical: undiluted test item (> 99%) |

MAIN STUDY

| | | |
|---|---|---|
| Number of Animals | Test Group: 20 | Control Group: 10 |
| INDUCTION PHASE | Induction Concentration: | |
| | topical: undiluted test item (> 99%) | |
| Signs of Irritation | None | |
| CHALLENGE PHASE | | |
| 1st challenge | topical: undiluted test item (> 99%) | |
| Remarks - Method | No significant protocol deviations | |

RESULTS

| *Animal* | *Challenge Concentration* | *Number of Animals Showing Skin Reactions after: 1st challenge* | |
|---|---|---|---|
| | | *24 h* | *48 h* |
| *Test Group* | > 99% | 0/20 | 0/20 |
| *Control Group* | Vehicle (80% ethanol/water) | 0/10 | 0/10 |

| | |
|---|---|
| Remarks - Results | No signs of irritation were observed following any of the exposures during induction.<br>No response was observed to the undiluted test item in either test or control group animals 24 and 48 hours following 6 hours topical exposure at challenge. |
| CONCLUSION | There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test. |
| TEST FACILITY | RTC (2007b) |

### B.6. Genotoxicity – bacteria

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 471 Bacterial Reverse Mutation Test – Pre-incubation method. |
| Species/Strain | *S. typhimurium*: TA1535, TA1537, TA1538, TA98, TA100 |
| Metabolic Activation System | S9 fraction from Aroclor 1254 induced rat liver. |
| Concentration Range in Main Test | a) With metabolic activation: 0-5000 µg/plate<br>b) Without metabolic activation: 0-5000 µg/plate |
| Vehicle | Dimethyl sulfoxide (DMSO) |
| Remarks - Method | No significant protocol deviations. |

RESULTS

| *Metabolic Activation* | *Test Substance Concentration (µg/plate) Resulting in:* | | | |
|---|---|---|---|---|
| | *Cytotoxicity in Preliminary Test* | *Cytotoxicity in Main Test* | *Precipitation* | *Genotoxic Effect* |
| *Absent* | | | | |
| Test 1 | None | None | None | Negative |
| Test 2 | None | None | None | Negative |
| *Present* | | | | |
| Test 1 | None | None | None | Negative |
| Test 2 | None | None | None | Negative |

| | |
|---|---|
| Remarks - Results | No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains up to and including the maximum dose, either with or without metabolic activation.<br>The positive controls gave satisfactory responses, confirming the validity of the test system. |
| CONCLUSION | The notified polymer was not mutagenic to bacteria under the conditions |

| | |
|---|---|
| | of the test. |
| TEST FACILITY | Huntingdon Research Centre Ltd (1989) |

# APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

## C.1. Environmental Fate

### C.1.1. Bioaccumulation

CONCLUSION

No study on the bioaccumulative properties of the notified polymer has been conducted. Based on the high molecular weight of > 1000 and the property of not being biodegradable (indicated by the following inherent biodegradation study), the notified polymer is not considered to have potential for bioaccumulation.

### C.1.2. Inherent biodegradability

TEST SUBSTANCE

Notified polymer

METHOD

OECD Guideline for Testing of Chemicals, No. 302 C, Inherent Biodegradability: Modified MITI-Test (II), 1981. With the following modifications were made:
- Activated sludge from only one source was used.
- The activated sludge was not fed during the holding period.
- The holding period was maximum seven days.
- The test water according to OECD Guideline for Testing of Chemicals No. 301 F, Ready Biodegradability: Manometric Respirometry Test, 1992 was used.
- The test was run at 22 °C.
- Only the biological oxygen demand (BOD) was monitored, no test item specific analysis was performed.

| | |
|---|---|
| Inoculum | Aerobic activated sludge from a wastewater treatment plant (ARA Ergolz II, Füllinsdorf, Switzerland) treating predominantly domestic wastewater |
| Exposure Period | 28 days |
| Auxiliary Solvent | None |
| Analytical Monitoring | Biochemical oxygen demand (BOD) was measured for determination of biodegradation degree (percentage of theoretical oxygen demand, ThOD). Analysis of the test item concentrations at test end was performed for the two test item samples by the Sponsor (non-GLP). |
| Remarks – Method | The study was performed with aerobic activated sludge in darkness at 22°C and pH 7.3 – 7.6. The final concentration of the activated sludge was 100 mg dry material/L. The test for the notified polymer was set up at 200 mg/L (ThOD 64 mg $O_2$/L) in duplicate. A blank control (contained activated sludge only) and a reference control (contained reference item sodium benzoate at 100 mg/L and activated sludge) were also set up in duplicate. A toxicity control (contained 200 mg/L notified polymer and 100 mg/L reference item (ThOD 167 mg $O_2$/L)) was set up in one replicate. |

RESULTS

| *Test substance* | | *sodium benzoate* | |
|---|---|---|---|
| *Day* | *% Degradation*[1] | *Day* | *% Degradation*[1] |
| 0 | 0 | 0 | 0 |
| 7 | 2 | 3 | 61 |
| 14 | -4[2] | 14 | 84 |
| 28 | -6[2] | 28 | 88 |

1 Corrected for the mean oxygen uptake of the inoculum controls.
2 Negative values due to higher oxygen consumption in the inoculum controls than in the test flasks with test item.

| | |
|---|---|
| Remarks – Results | In the toxicity control, containing both the notified polymer and the reference item sodium benzoate, the notified polymer had no inhibitory |

effect on the activity of activated sludge microorganisms at the tested concentration of 200 mg/L.

The biochemical oxygen demand (BOD) of the notified polymer in the test media was in the normal range found for the inoculum controls, indicating a very low degradation of the notified polymer at less than 1% in the test media. NMR analysis of the concentration at test end by the notifier also indicated a degradation of < 1%. Consequently, the notified polymer is considered not inherently biodegradable under the test conditions within 28 days.

The modifications to the test guideline were not considered to affect the outcome of the study due to the negligible biodegradation detected.

CONCLUSION The notified polymer is not inherently biodegradable.

TEST FACILITY RCC (2008a)

## C.2. Ecotoxicological Investigations

### C.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified polymer

METHOD OECD TG 203 Fish, Acute Toxicity Test (1992) - Semi-static test.
EU Commission Directive 92/69/EEC, Part C.1: Acute Toxicity for Fish (1992) - Semi- static test.

Species Zebra fish (*Brachydanio rerio*)
Exposure Period 96 hours
Auxiliary Solvent Ethanol at 100 ml/L, which is acceptable according to the test guideline requirement.
Water Hardness 125 mg $CaCO_3$/L
Analytical Monitoring The prepared solution concentrations were confirmed by the notifier using NMR method.

Remarks – Method A limit test was performed by exposing 10 fish to a test solution at a concentration of 100 mg/L. An organic solvent ethanol was used for preparation of the test solutions. Therefore, a blank control and a solvent control were performed in parallel. All the test and controls were performed at pH 7.4 – 7.5, a temperature of 21°C, and oxygen levels between 8.3 – 8.7 mg/L. All the test and control solutions were clear throughout the test period.

RESULTS

| *Concentration mg/L* | | *Number of Fish* | *Mortality* | | | | |
|---|---|---|---|---|---|---|---|
| *Nominal* | *Actual* | | *1 h* | *24 h* | *48 h* | *72 h* | *96 h* |
| Blank control | | 10 | 0 | 0 | 0 | 0 | 0 |
| Solvent control | | 10 | 0 | 0 | 0 | 0 | 0 |
| 100 | 100 | 10 | 0 | 0 | 0 | 0 | 0 |

LC50 >100 mg/L at 96 hours.

NOEC NOEC =100mg/L at 96 hours

Remarks – Results All test validity criteria were met.

No remarkable observations were recorded concerning the appearance of the test medium. The test medium appeared clear throughout the whole test duration.

Analysis of solutions at nominal concentration of 538 g/L using NMR showed a maximum error of 2% to the nominal concentration. Therefore, the actual test concentration of the notified polymer is the same as the

nominal concentration of 100 mg/L.

In the control and in the test medium of the nominal test item concentration of 100 mg/L all fish survived the 96-hour exposure period and no visible abnormalities were observed. Therefore, the NOEC is determined to be 100 mg/L.

The notified polymer is considered to be not acutely harmful to fish.

CONCLUSION The notified polymer is not acutely harmful to fish.

TEST FACILITY RCC (2008b)

**C.2.2. Acute toxicity to aquatic invertebrates**

TEST SUBSTANCE Notified polymer

METHOD OECD Guideline for Testing of Chemicals, No. 202, *Daphnia sp.*, Acute Immobilisation Test, 2004.
EU Commission Directive 92/69/EEC, C.2, Acute Toxicity for Daphnia, 1992.

Species *Daphnia magna*
Exposure Period 48 hours
Auxiliary Solvent Ethanol at 100 ml/L, which is acceptable according to the test guideline requirement.
Water Hardness 250 mg $CaCO_3$/L
Analytical Monitoring The prepared solution concentrations were confirmed by the notifier using NMR method.

Remarks - Method A limit test was performed by exposing 20 daphnids to a test solution at a concentration of 100 mg/L. An organic solvent ethanol was used for preparation of the test solutions. Therefore, a blank control and a solvent control were performed in parallel. All the test and controls were performed at a pH of 7.8, a temperature between 20 – 21°C, and oxygen levels between 8.7 – 8.8 mg/L.

RESULTS

| *Concentration mg/L* | | *Number of D. magna* | *Number Immobilised* |
|---|---|---|---|
| *Nominal* | *Actual* | | *48 h* |
| Blank control | | 20 | 0 |
| Solvent control | | 20 | 0 |
| 100 | 100 | 20 | 0 |

LC50 >100 mg/L at 48 hours

NOEC (or LOEC) NOEC = 100 mg/L at 48 hours

Remarks - Results

All test validity criteria were met.

No remarkable observations were recorded concerning the appearance of the test medium. The test medium appeared clear throughout the whole test duration.

Analysis of solutions at nominal concentration of 538 g/L using NMR showed a maximum error of 2% to the nominal concentration. Therefore, the actual test concentration of the notified polymer is the same as the nominal concentration of 100 mg/L.
In the control and at the test item concentration of 100 mg/L, no immobilized daphnids were observed during the test period of 48 hours.

Therefore, the NOEC is determined to be 100 mg/L.
The notified polymer is considered to be not acutely harmful to daphnids.

CONCLUSION The notified polymer is not acutely harmful to *Daphnia magna*.

TEST FACILITY RCC (2008c)

**C.2.3. Algal growth inhibition test**

TEST SUBSTANCE Notified polymer

METHOD

OECD Guidelines for the Testing of Chemicals, No. 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test, 2006.
EU Commission Directive 92/69/EEC, C.3: Algal Inhibition Test, 1992.

| | |
|---|---|
| Species | *Desmodesmus subspicatus (Scenedesmus subspicatus)* |
| Exposure Period | 72 hours |
| Concentration Range | Nominal: 100 mg/L |
| Auxiliary Solvent | None |
| Water Hardness | 24 mg $CaCO_3$/L |
| Analytical Monitoring | The confirmation of test concentration of the notified polymer was not performed. |
| Remarks - Method | A limit test at 100 mg/L nominal was performed based on the results of a range-finding test. For the preparation of the test solution, the amount of 30.4 mg of the notified polymer was mixed into 304 mL of test water using ultrasonic treatment and intense stirring at room temperature.<br>The test was started (0 hours) by inoculation of 5,000 algal cells per mL of test medium. The flasks were covered with glass dishes. The incubation vessel was maintained at pH 7.9 – 8.0 and 22 – 24°C, and continuously illuminated at a light intensity range of 7100 to 8300 lux. |

RESULTS

| *Biomass* | | *Growth* | |
|---|---|---|---|
| *$E_bC50$ mg/L at 72 h* | *NOEC mg/L* | *$E_rC50$ mg/L at 72 h* | *NOEC mg/L* |
| > 100 (nominal) | 100 (nominal) | > 100 (nominal) | 100 nominal |

Remarks - Results

All test validity criteria were met.

No remarkable observations were recorded concerning the appearance of the test medium. The test medium appeared clear throughout the whole test duration.

The notified polymer had no inhibitory effect on the growth of *Desmodesmus subspicatus* after the test period of 72 hours at the test concentration of 100 mg/L. Considering the low water solubility (0.448 mg/L), the notified polymer is not acutely harmful to alga up to the limit of water solubility.

CONCLUSION The notified polymer is not acutely harmful to alga up to the limit of water solubility.

TEST FACILITY RCC (2008d)

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