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

**PUBLIC REPORT**

**Polymer in Accelerator 2950**

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/1589	Huntsman Advanced Materials (Australia) Pty Ltd	Polymer in Accelerator 2950	Yes	≤1 tonnes per annum	A component of industrial coatings

## CONCLUSIONS AND REGULATORY OBLIGATIONS

### Hazard classification

Based on the data provided, the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], with the following risk phrase:

R22 Harmful if swallowed

and

The classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2009) is presented below. The environmental classification under this system is not mandated in Australia and carries no legal status but is presented for information purposes.

	<i>Hazard category</i>	<i>Hazard statement</i>
Acute oral toxicity	4	Harmful if swallowed
Environment	Acute 3	Harmful to aquatic life
	Chronic 1	Very toxic to aquatic life with long lasting effects

### 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 reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

### Recommendations

#### REGULATORY CONTROLS

##### Hazard Classification and Labelling

- Safe Work Australia, should consider the following health hazard classification for the notified polymer:
  - Xn: R22 Harmful if swallowed
- Use the following risk phrases for products/mixtures containing the notified polymer:
  - Conc. ≥25%: Xn ; R22.

- Based on the ecotoxicity data, the notifier should consider their obligations under the Australian Dangerous Goods Code.

#### Health Surveillance

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

#### Material Safety Data Sheet

- The MSDS for products containing the notified polymer should reflect the hazards associated with the residual monomer, if appropriate based on the concentration.

#### CONTROL MEASURES

##### Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
  - Enclosed, automated processes, where possible
  - Spray application in ventilated environments
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid contact with skin and eyes
  - Avoid inhalation of spray during application
  - Avoid contact with uncured coatings or overspray
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced and in the final coating products:
  - Safety goggles
  - Impervious gloves
  - Coveralls
  - 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.
- MSDS for products containing the notified polymer should contain reference to Polymer in Accelerator 2950 in the list of ingredients, in order to provide a link for workers to the NICNAS assessment.
- Where not already contained in the MSDS for products containing the notified polymer, appropriate engineering controls, safe work practices and personal protective equipment to reduce exposure should be recommended on the product MSDS.
- 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 importation volume exceeds one tonne per annum notified polymer;
- or
- (2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of industrial coatings, or is likely to change 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 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.

## **ASSESSMENT DETAILS**

### **1. APPLICANT AND NOTIFICATION DETAILS**

#### APPLICANT(S)

Huntsman Advanced Materials (Australia) Pty Ltd (ABN: 93 091 627 879)  
Gate 3, 765 Ballarat Rd  
Deer Park, VIC 3023

#### NOTIFICATION CATEGORY

Limited-small volume: Synthetic polymer with Mn <1000 Da (1 tonne or less per year).

#### EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants and import volume.

#### VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: density, vapour pressure, hydrolysis as a function of pH, adsorption/desorption, flash point, dissociation constant, autoignition temperature, explosive properties and oxidising properties.

#### PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES  
USA, Korea and China.

## 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)  
Accelerator 2950 CH ( $\leq 70\%$  notified polymer)

MOLECULAR WEIGHT  
Mn <500 Da

ANALYTICAL DATA  
Reference IR and GPC spectra were provided.

## 3. COMPOSITION

DEGREE OF PURITY >90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

One hazardous impurity/residual monomer is present at a level above the concentration cut-off for classification. The impurity is present at a concentration of  $\geq 1\%$  and may result in sensitisation by skin contact (R43 classification).

## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellow liquid\*

Property	Value	Data Source/Justification
Freezing Point	-41.9 °C	Measured
Boiling Point	Decomposition at ~240 °C at 101.3 kPa	Measured
Density*	970 – 1,050 kg/m <sup>3</sup> at 20 °C	MSDS
Vapour Pressure*	1x10 <sup>-4</sup> kPa at 20 °C	MSDS
Water Solubility	$\geq 466.9$ g/L	Measured
Hydrolysis as a Function of pH	Not determined	No hydrolysable groups present.
Partition Coefficient (n-octanol/water)	log K <sub>ow</sub> = 0.99	Measured
Adsorption/Desorption	log K <sub>oc</sub> = 1.21 at 25 °C	Estimated for a representative low molecular weight oligomer using KOCWIN v2.00 (US EPA 2009). Expected to sorb to soil and sludge based on presence of cationic functionality.
Dissociation Constant	pK <sub>a</sub> ~10	Based on data from analogous compounds.
Flash Point*	>100 °C (closed cup)	MSDS
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions based on the flash point.
Explosive Properties	Not determined	There are no chemical groups within the structure that imply explosive properties.
Oxidising Properties	Not determined	There are no chemical groups within the structure that imply oxidative properties.

\*For imported product containing  $\leq 70\%$  notified polymer.

DISCUSSION OF PROPERTIES

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

#### *Reactivity*

The notified polymer is expected to be stable under normal conditions of use. It is incompatible with strong acids, bases and oxidising agents.

#### *Dangerous Goods classification*

Based on the submitted physico-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 either as a component ( $\leq 70\%$ ) of Accelerator 2950 CH or as a component ( $\leq 15\%$ ) of finished coatings.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	<1	<1	<1	<1	<1

### PORT OF ENTRY

Melbourne and Sydney

### IDENTITY OF MANUFACTURER/RECIPIENTS

Huntsman Advanced Materials (Australia) Pty Ltd

### TRANSPORTATION AND PACKAGING

The imported product containing the notified polymer will be packaged in either 205 L steel drums or 2.8 L metal cans. The products will be transported by road from the wharf of entry to the notifier's warehousing facilities or to customer sites. Following reformulation, the end-use coatings will be packaged in 1.5 or 20 L containers.

### USE

The notified polymer will be used as an accelerator in the hardener component of two-part epoxy anticorrosion coating systems (e.g. for marine vessels).

### OPERATION DESCRIPTION

#### *Reformulation*

The imported product containing the notified polymer (at  $\leq 70\%$  concentration) will be transferred into open stainless steel floor pots (1000 L capacity) and blended with the other coating components using high speed dispersion and mixing. Local exhaust ventilation will be used during reformulation and the pots will be covered during dispersion. Following quality control analysis, the finished coatings containing the notified polymer (at  $\leq 15\%$ ) will be gravity fed into 1, 5 or 20 L containers via hoppers, under exhaust ventilation.

#### *Paint Application*

At end-use sites, the coatings containing the notified polymer (at  $\leq 15\%$ ) will be blended with other components and then applied by professional painters to boat hulls in industrial settings (mainly by airless spray but potentially also by brush or roller).

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1. Exposure Assessment

#### 6.1.1. Occupational Exposure

### CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage workers	1-2	20
Blending and filling workers	2-4	5-10
Quality Control Personnel	0.5	5-10
Spray painters	2-4	100-200

#### EXPOSURE DETAILS

##### *Transport and Storage*

Transport and storage workers may come into contact with the notified polymer (at  $\leq 70\%$ ) only in the event of an accident involving rupture of the containers.

##### *Reformulation*

Dermal, ocular and possibly inhalation exposure of the formulation workers to the notified polymer (at  $\leq 70\%$ ) may occur during reformulation processes (including transfer, sampling, cleaning and maintenance tasks). Local exhaust ventilation and bunding will be used in the reformulation area, and a ventilation extraction system will be in place for each filling line. In addition, personal protective equipment (PPE) such as chemical resistant gloves, goggles and appropriate industrial clothing will be used.

##### *Paint Application*

During paint application, spray painters may be exposed to the notified polymer (at  $\leq 15\%$ ) through the dermal, ocular and inhalation routes. The potential for exposure should be minimised through the use of PPE (respiratory protection, chemical goggles or face shield, appropriate clothing and impermeable gloves). Once dried, the notified polymer is not expected to be bioavailable and further dermal contact should not lead to exposure.

#### 6.1.2. Public Exposure

The products containing the notified polymer will only be used for industrial applications. The public may have dermal contact with ships/boats that have surface coatings containing the notified polymer at  $\leq 15\%$ . However, following application, the notified polymer will be cured within the paint film and will not be available for exposure.

#### 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.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 between 300-2000 mg/kg bw; harmful
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration	non genotoxic

##### *Toxicokinetics, metabolism and distribution.*

Given the relatively low molecular weight ( $< 500$  Da), high water solubility ( $\geq 466.9$  g/L) and low partition coefficient ( $\log K_{ow} = 0.99$ ) of the notified polymer, absorption across the gastrointestinal tract and dermal absorption of the notified polymer may occur. The notified polymer may also be absorbed across the respiratory tract.

##### *Acute toxicity.*

The notified polymer was found to be harmful in an acute oral toxicity study in rats. All 3 animals that were treated at 2,000 mg/kg bw were killed *in extremis* 1 hour after dosing, with noted signs of toxicity including ventral recumbency, sedation, tachypnea and cyanosis. No mortalities were observed in animals dosed at 300 mg/kg bw/day.

##### *Irritation and Sensitisation.*

The notified polymer contains functional groups that have been associated with skin or respiratory sensitisation and corrosive effects. Based on the information available, the potential for these effects cannot be ruled out. In addition, the notified polymer contains a hazardous impurity/residual monomer that may result in sensitisation



by skin contact.

#### *Mutagenicity.*

The notified polymer was found to be non-mutagenic in a bacterial reverse mutation assay and was not clastogenic in an in vitro mammalian chromosome aberration test.

#### **Health hazard classification**

Based on the data provided, the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase:

R22 Harmful if swallowed

### **6.3. Human Health Risk Characterisation**

#### **6.3.1. Occupational Health and Safety**

The notified polymer will be handled by workers at  $\leq 70\%$  concentration as imported and  $\leq 15\%$  concentration in end-use products. Limited data was provided on the toxicological characteristics of the notified polymer. While the notified polymer is classified as harmful by the oral route, the potential acute toxicity effects via the dermal and inhalation routes have not been determined. In addition, skin sensitisation and/or corrosive effects following contact with the notified polymer cannot be excluded. Therefore, given the absence of supporting toxicity studies, steps should be taken to avoid exposure to the notified polymer.

Therefore, provided that control measure are in place to minimise worker exposure, including the use of ventilated environments, automated processes and PPE, the risk to the health of workers from use of the notified polymer is not considered to be unreasonable.

#### **6.3.2. Public Health**

As exposure to the notified polymer from articles containing the cured coating is not expected, the risk to the health of the public from the use of the notified polymer is not considered to be unreasonable.

## **7. ENVIRONMENTAL IMPLICATIONS**

### **7.1. Environmental Exposure & Fate Assessment**

#### **7.1.1. Environmental Exposure**

##### **RELEASE OF CHEMICAL AT SITE**

The release of the notified polymer to the environment during importation, storage and transport is expected to be due to accidental spills. At the coating manufacturing site, the notified polymer will be mixed with other solvents and ingredients in a mixer. Any accidental spill is expected to be collected using suitable absorbent material and disposed of to landfill, if not suitable for recycling back into the coating product. During the blending process, the notified polymer from container residues (0.25%), spills and leaks (0.25%) is expected to be collected and disposed of to landfill. Empty containers, mixing vessels and transfer lines will be cleaned with suitable solvent and the collected residues will be recycled where possible.

##### **RELEASE OF CHEMICAL FROM USE**

After mixing the two parts of the coating system, the majority of the coating will be applied using airless spraying or applied to small areas using brushes or roller. Losses through spray application are expected to be up to 20% from overspray and 2% from equipment cleaning. Releases from application using brushes and rollers are expected to be ( $<1\%$ ) from dripping and (5%) from cleaning. Overspray will be collected through the use of protective curtains and floor sheeting. Collected overspray is expected to be disposed of by licensed waste contractors. Residual paint mixture is likely to be washed from the equipment using recycled paint solvent, and the washings disposed of by solvent recyclers.

##### **RELEASE OF CHEMICAL FROM DISPOSAL**

The majority of the notified polymer will be cured into an inert matrix with other chemical substances as part of the coating process and hence will be immobilised within a polymeric film on coated articles. The polymer incorporated into the coating will be disposed of along with the coated articles, at the end of their useful life, and are expected to be disposed of to landfill. Coating containers containing notified polymer residues ( $<1\%$  of

the import volume of the notified polymer) are expected to be disposed of to landfill or subjected to recycling processes.

### 7.1.2. Environmental Fate

One study submitted by the notifier indicates that the notified polymer is not readily biodegradable. The majority of notified polymer will be applied to marine structures including the hulls of ships, and hence there may be contact of the notified polymer with the marine environment. However, the notified polymer is expected to be cured into a solid polymer matrix as part of its normal use pattern and is therefore not expected to be mobile, bioavailable nor biodegradable in its cured form. Moreover, additional coatings may be applied onto the coatings containing the notified polymer and hence the exposure of the notified polymer to the marine environment is anticipated to be very low. The majority of the imported quantity of notified polymer is expected to be ultimately disposed of to landfill or thermally decomposed during recycling of metal structures to which it is applied. Bioaccumulation of the uncured polymer is unlikely due to its high molecular weight and limited potential for aquatic exposure. Notified polymer, both in the uncured and cured forms, that is disposed of to landfill is not expected to be mobile and will slowly degrade by abiotic and biotic processes to produce water and oxides of carbon and nitrogen.

### 7.1.3. Predicted Environmental Concentration (PEC)

A predicted environmental concentration (PEC) was not determined since, based on the reported use pattern, the notified polymer is not expected to be released to the aquatic environment.

## 7.2. Environmental Effects Assessment

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

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
<u>Acute Toxicity</u>		
Fish	96 h LC50 = 40 mg/L	Harmful to fish
Daphnia	48 h EC50 = 24 mg/L	Harmful to aquatic invertebrates
Algal	72 h ErC50 >0.22 mg/L	Potentially very toxic to algae
	72 h NOEC = 0.02 mg/L	Very toxic to algae with long lasting effects

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009) the notified polymer is harmful to fish and aquatic invertebrates. GHS classification for algae should be based on the ErC50 (effective median concentration for growth rate inhibition). Only in the cases whereby no ErC50 is recorded should classification be based on the lowest EC50 available, such as EbC50. As the 72 hr ErC50 from the submitted test presents only a lower limit of 0.22 mg/L, the possibility remains that the ErC50 is below 1 mg/L. Hence, under the GHS the notified polymer could potentially be classified as very toxic to aquatic organisms. However, in the absence of a defined endpoint for the algal 72 hr ErC50, there is insufficient information to formally classify the notified polymer on the algal endpoint. Therefore, at best, the notified polymer can be classified as 'Acute Category 3: harmful to aquatic life'. Further, on the basis of algal NOEC and the lack of rapid biodegradability, the notified polymer is classified as 'Chronic Category 1: very toxic to aquatic life with long lasting effects'.

### 7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as, based on its assessed use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

## 7.3. Environmental Risk Assessment

The risk quotient ( $Q = \text{PEC}/\text{PNEC}$ ) for the notified polymer has not been calculated as release to the aquatic environment in ecotoxicologically significant quantities is not expected based on its low import volume and assessed use pattern.

The majority of the notified polymer will ultimately be disposed of to landfill as cured polymer. In its cured state, the notified polymer will be irreversibly bound within an inert matrix, and is not expected to be bioavailable or mobile. The notified polymer is not readily biodegradable, but it is not expected to bioaccumulate. Based on the low import volume and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.



**APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES****Freezing Point** -41.9 °C

Method	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Determined by placing a test tube containing the test substance in a dry ice/acetone bath until solidification occurred.
Test Facility	RCC (2008a)

**Boiling Point** Decomposition from ~240 °C at 101.3 kPa

Method	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Determined by differential scanning calorimetry. The test substance decomposed prior to boiling.
Test Facility	RCC (2008a)

**Water Solubility** ≥466.9 g/L

Method	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Duplicate samples of ~5.2 g of the notified polymer were weighed, mixed with 5 mL of water and stirred at room temperature for about 24 hours. After filtration, the solution was diluted in a ratio of 1:1666.67 with water. The quantification was performed using HPLC with respect to calibration curve. The results of the test indicated that the water solubility of the notified polymer was 466.9 g/L (or above).
Test Facility	RCC (2008b)

**Partition Coefficient (n-octanol/water)** log Kow = 0.99

Method	OECD TG 107 Partition Coefficient (n-octanol/water). EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks	Determined using the flask shaking method according to the above guidelines. After shaking vessels containing water and n-octanol with volume ratios 1:1, 2:1 and 1:2 for 30 minutes at room temperature, the partition coefficient (log Kow) of the notified polymer was calculated to be 0.99. The quantification was performed using HPLC with respect to the calibration curve.
Test Facility	RCC (2008b)

## APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

### B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/HanRcc:WIST (SPF)
Vehicle	Purified water
Remarks - Method	No significant protocol deviations

#### RESULTS

Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
I	3 female	300	0/3
II	3 female	300	0/3
III	3 female	2000	3/3

LD50 Between 300 and 2000 mg/kg bw

Signs of Toxicity The Group III treated animals were killed *in extremis* 1 hour after dosing, with noted signs of toxicity including sedation, ventral recumbency, tachypnea and cyanosis.

Signs of toxicity noted in the Group I and II treated animals included slightly ruffled fur and slight sedation (which persisted up to 5 hours post-treatment).

Effects in Organs With the exception of a liquid contents in the stomachs of the animals of the high dose group, no abnormalities were noted at necropsy.

CONCLUSION The notified polymer is harmful via the oral route.

TEST FACILITY RCC (2008c)

### B.2. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	Similar to OECD TG 471 Bacterial Reverse Mutation Test.
Species/Strain	Plate incorporation procedure/Pre incubation procedure <i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA
Metabolic Activation System	S9 fraction: phenobarbital/naphthoflavone induced rat liver
Concentration Range in	a) With metabolic activation: 33-5000 µg/plate
Main Test	b) Without metabolic activation: 33-5000 µg/plate
Vehicle	Dimethyl sulphoxide
Remarks - Method	A preliminary toxicity test (all strains; plate incorporation procedure; 3-5000 µg/plate) was performed to determine the toxicity of the test material. The results are reported as Test 1. Test 2 was conducted using the pre-incubation procedure.
	Vehicle and positive controls were used in parallel with the test material. Positive controls: i) without S9: sodium azide (TA1535, TA100), 4-nitro-o-phenylene-diamine (TA1537, TA98) and methyl methane sulfonate (WP2uvrA); ii) with S9: 2-aminoanthracene (TA1535, TA1537, TA98, TA100 and WP2uvrA).

#### RESULTS

Metabolic	Test Substance Concentration (µg/plate) Resulting in:
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<i>Activation</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>			
Test 1	>5000	>5000	Negative
Test 2	≥5000	>5000	Negative
<i>Present</i>			
Test 1	>5000	>5000	Negative
Test 2	>5000	>5000	Negative

Remarks - Results	<p>In Test 2, the test substance caused a visible reduction in the growth of the bacterial background lawn to all strains at 5000 µg/plate, without metabolic activation.</p> <p>No significant increases in the frequency of revertant colonies were noted for any of the bacterial strains, up to and including the maximum dose, either with or without metabolic activation.</p> <p>All positive controls induced expected increases in the frequencies of revertant colonies, confirming the validity of the test system.</p>
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	RCC (2008d)

### B.3. Genotoxicity – in vitro

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Chinese hamster
Cell Type/Cell Line	V79 cells
Metabolic Activation System	S9 fraction: Phenobarbital/naphthoflavone induced rat liver
Vehicle	Dimethyl sulphoxide
Remarks - Method	No significant protocol deviations.
	<p>A preliminary toxicity test (39.1-5000 µg/mL) was performed to determine the toxicity of the test material (4 hour exposure period with and without activation and 24 hour exposure period without activation).</p> <p>Vehicle and positive controls (ethylmethane sulfonate without S9 and cyclophosphamide with S9) were used in parallel with the test material.</p>

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL)</i>	<i>Exposure Period</i>	<i>Harvest Time</i>
<i>Absent</i>			
Test 1	156.3, 312.5, 625.0, 1250.0*, 2500.0*, 5000.0*	4 h	18 h
Test 2	78.1*, 156.3*, 312.5*, 625.0, 1250.0, 2500.0	18 h	18 h
<i>Present</i>			
Test 1	156.3, 312.5*, 625.9*, 1250.0*, 2500.0, 5000.0	4 h	18 h
Test 2	78.1, 156.3, 312.5*, 625.0*, 1250.0*, 2500.0	4 h	18 h

\*Cultures selected for metaphase analysis.

### RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	>5000	>5000.0	>5000	Negative
Test 2	≥1250	>312.5	>2500	Negative

<i>Present</i>				
Test 1	>5000	≥1250.0	>5000	Negative
Test 2		>1250.0	>2500	Negative
Remarks - Results	<p>In the preliminary toxicity test (24 h exposure; without metabolic activation), the toxicity of the notified polymer was determined through the observation of reduced cell numbers. In Test 1 (with metabolic activation), the toxicity of the notified polymer was determined through the observation of a reduced mitotic index. In Test 2 (with and without metabolic activation), the study authors note that concentrations showing clear cytotoxicity were not scorable for cytogenetic damage.</p> <p>In both tests, in the presence and absence of metabolic activation, no biologically relevant increase in the number of cells with chromosomal aberrations was noted. There was a significant increase in the number of aberrant cells (4%) in Test 2 with metabolic activation (at 312.5 µg/mL), however, this was reported by the study authors to be within the historical control range and was therefore not considered to be biologically significant.</p> <p>The positive controls gave satisfactory responses, confirming the validity of the test system.</p>			
CONCLUSION	The notified polymer was not clastogenic to Chinese Hamster V79 Cells treated in vitro under the conditions of the test.			
TEST FACILITY	RCC (2008e)			

## **APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS**

### **C.1. Environmental Fate**

#### **C.1.1. Ready biodegradability**

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 A Ready Biodegradability: DOC Die-Away Test. EC Directive 92/69/EEC C.4-A DOC Die-Away Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Filtrate from each sample analysed for DOC using a TOC Analyser equipped with automatic sampler (Shimadzu TOC-5000A). This uses a combustion/non-dispersive infrared gas analysis method.
Remarks - Method	According to the OECD guidelines above, a ready biodegradability test was carried out using the test substance, activated sludge (30 mg/L) incubated under darkness for 28 days in a temperature controlled room (20 – 24 °C). A reference control and toxicity control were run in parallel.

#### **RESULTS**

<i>Test substance</i>		<i>Sodium benzoate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
0	0	0	0
4	-1	4	98
7	1	7	100
10	1	-	-
14	-7	14	99
21	1	-	-
28	3	28	99

Remarks - Results	<p>The mean concentrations of dissolved organic carbon (DOC) were not significantly different after 28 days with inoculum and notified polymer as compared to initial DOC concentrations. Therefore, the test substance was not biodegradable under the test conditions.</p> <p>The reference material sodium benzoate showed the expected biodegradation (&gt;90%) in the system within 7 days, validating the experiment.</p> <p>In the toxicity control, containing the notified polymer, the reference item sodium benzoate and activated sludge, the initial DOC decreased by 45% within 14 days of exposure. This indicates that the notified polymer was not inhibitory to activated sludge when tested with reference material in the system.</p>
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CONCLUSION	The notified polymer is not ready biodegradable.
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TEST FACILITY	RCC (2008f)
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### **C.2. Ecotoxicological Investigations**



**C.2.1. Acute toxicity to fish**

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – Static
Species	Zebra fish ( <i>Brachydanio rerio</i> )
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	125 mg CaCO <sub>3</sub> /L
Analytical Monitoring	HPLC and UV/VIS-detection
Remarks – Method	Conducted in accordance with the guidelines above. Six nominal concentrations were tested: 0, 4.6, 10, 22, 46 and 100 mg/L. Seven fish per test solution were observed for mortality and visible abnormalities after 2, 24, 48, 72 and 96 hours test duration. Test conditions were: 21-22 °C, pH 7.4-7.9, 8.3-8.6 mg O <sub>2</sub> /L, 8 hours dark and 16 hours light period. The LC50 and the 95% confidence interval were calculated as far as possible by moving average interpolation. The NOEC was determined directly from raw data.

**RESULTS**

Concentration mg/L		Number of Fish	Mortality				
Nominal	Actual (4 d)		2 h	24 h	48 h	72 h	96 h
Control	0	7	0	0	0	0	0
4.6	<LOQ*	7	0	0	0	0	0
10	9.78	7	0	0	0	0	0
22	21.4	7	0	0	0	2	3
46	46.1	7	0	0	1	1	2
100	103	7	0	0	3	6	7

\* LOQ = Limit of quantification for the test item = 5.01 mg/L.

LC50	40 mg/L at 96 hours (95% CI: 22-71)
NOEC	10 mg/L at 96 hours.
Remarks – Results	The test substance was stable for 96 hours in this static non-renewal test. No mortality was recorded in the control and at the test concentration of up to 10 mg/L. Validity criteria for the test were satisfied with no significant deviation from the guidelines.

CONCLUSION The notified polymer is harmful to fish.

TEST FACILITY Harlan Laboratories Ltd (2008a)

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

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 <i>Daphnia</i> sp. Acute Immobilisation Test – Static EC Directive 92/69/EEC C.2 Acute Toxicity for <i>Daphnia</i> – Static
Species	<i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg CaCO <sub>3</sub> /L
Analytical Monitoring	HPLC and UV/VIS-detection
Remarks - Method	Conducted in accordance with the guidelines above. Six nominal concentrations were tested: 0, 1.0, 3.2, 10, 32 and 100 mg/L. Twenty daphnids per test solution were used in four replicates of five daphnids. The immobility of daphnids were observed after 24 and 48 hours test duration. Test conditions were: 20 °C, pH 7.8-8.1, 8.4 mg O <sub>2</sub> /L, 8 hours dark and 16 hours light period. The 24 h and 48 h EC50 and 95%

confidence limits were calculated by Probit Analysis. The NOEC was determined directly from raw data.

## RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual (2 d)		24 h	48 h
Control	-	20	0	0
1.0	-	20	0	0
3.2	-	20	0	0
10	8.99	20	0	0
32	30.7	20	0	15
100	97.6	20	17	20

EC50 61 mg/L at 24 hours (95% CI: 26-188 mg/L)  
 24 mg/L at 48 hours (95% CI: 19-30 mg/L)

NOEC 10 mg/L at 48 hours

Remarks - Results The actual concentration of the nominal concentrations of 1.0 and 3.2 mg/L were not analysed as the concentration were below the 48 h NOEC determined in this test. The test media concentrations were stable for the 48 hours of the test. No precipitation of the test substance was reported. Validity criteria for the test were satisfied with no significant deviation from the guidelines.

CONCLUSION The notified polymer is harmful to *Daphnia magna*.

TEST FACILITY Harlan Laboratories Ltd (2008b)

## C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified polymer

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

Species *Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*)

Exposure Period 72 hours

Concentration Range Nominal: Control, 5.0, 15.8, 50, 158, 500 µg/L  
 Actual: Control, -, 22.2, 30.8, 77, 219 µg/L (-, 141, 62, 49, 44%, of nominal). Lowest dose of 5.0 µg/L was not analysed as this concentration was below the NOEC determined in the test. Measured concentrations were between 56 and 92% of nominal at start of test, and between 21 and 219% of nominal values at the end of the test. Mean measured concentrations were between 44 and 141% of nominal values.

Auxiliary Solvent None

Water Hardness 24 mg CaCO<sub>3</sub>/L

Analytical Monitoring HPLC with UV/VIS detection.

Remarks - Method Conducted in accordance with the guidelines above. Six nominal concentrations were tested. The test design included three replicates per test concentration and six replicates of the control. Initial algal cell density was 1000 cells/mL. Test conditions were: 23-24°C, pH 8.7-9.4, light intensity 6850-7960 Lux. The 72 h EC50 values and confidence intervals were calculated as far as possible by Probit Analysis. The NOEC was determined by comparison to the control by Dunnett's tests.

## RESULTS

Growth Rate		Yield	
EC50*	NOEC	EC50*	NOEC
µg/L at 72 h	µg/L at 72 h	µg/L at 72 h	µg/L at 72 h

Test solutions	>219	22.2	141	22.2
*95% confidence intervals could not be determined, however reasoning was not provided as to why not.				
Remarks - Results	<p>The report defined the growth rate as the logarithmic increase in biomass (fluorescence) during the exposure period. The yield was defined as the biomass increase during the study (fluorescence of sample at end of exposure minus that at beginning of exposure). In the control, the biomass increased by a factor of 170 over 72 hours. Thus the validity criterion of increase of biomass by at least a factor of 16 within three days was fulfilled. The coefficient of variation of the average specific growth rates in the replicates of the control after 72 hours was 0.9%. According to the OECD guidelines, the coefficient of variation must not be higher than 7%. Thus, the validity criterion was fulfilled. The concentration-effect relationship of average growth rates after 72 h indicated that the ErC50 would fall below 1 mg/L. However, due to poor recovery rates of the test substance in spiked water samples and treatment samples, and the fit of the curve to the data points, the use of the dose curve to extrapolate the 72 h EC50 should be treated with caution. However, in the absence of a defined 72 h ErC50 endpoint, the data infer that the test substance may be potentially very toxic to algae.</p>			
CONCLUSION	The notified polymer is potentially very toxic to algae.			
TEST FACILITY	Harlan Laboratories Ltd (2009)			

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