

File No: LTD/1603

May 2013

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

**PUBLIC REPORT**

**Polymer in Chroma-Chem Coatings**

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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	<a href="http://www.nicnas.gov.au">www.nicnas.gov.au</a>

**Director  
NICNAS**

## **TABLE OF CONTENTS**

SUMMARY .....	3
CONCLUSIONS AND REGULATORY OBLIGATIONS .....	3
ASSESSMENT DETAILS.....	5
1. APPLICANT AND NOTIFICATION DETAILS.....	5
2. IDENTITY OF CHEMICAL.....	5
3. COMPOSITION.....	5
4. PHYSICAL AND CHEMICAL PROPERTIES .....	5
5. INTRODUCTION AND USE INFORMATION.....	6
6. HUMAN HEALTH IMPLICATIONS .....	7
6.1. Exposure Assessment.....	7
6.1.1. Occupational Exposure.....	7
6.1.2. Public Exposure.....	7
6.2. Human Health Effects Assessment .....	8
6.3. Human Health Risk Characterisation .....	8
6.3.1. Occupational Health and Safety.....	8
6.3.2. Public Health.....	9
7. ENVIRONMENTAL IMPLICATIONS.....	9
7.1. Environmental Exposure & Fate Assessment .....	9
7.1.1. Environmental Exposure.....	9
7.1.2. Environmental Fate .....	9
7.1.3. Predicted Environmental Concentration (PEC).....	9
7.2. Environmental Effects Assessment.....	10
7.2.1. Predicted No-Effect Concentration.....	10
7.3. Environmental Risk Assessment.....	10
<u>APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES .....</u>	<u>11</u>
<u>APPENDIX B: TOXICOLOGICAL INVESTIGATIONS.....</u>	<u>12</u>
B.1. Acute toxicity – oral.....	12
B.2. Irritation – eye .....	12
<u>APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS .....</u>	<u>14</u>
C.1.1. Ready biodegradability .....	14
C.1. Ecotoxicological Investigations .....	14
C.2.1. Acute toxicity to fish .....	14
C.2.2. Acute toxicity to aquatic invertebrates.....	15
BIBLIOGRAPHY .....	17

## SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1603	Chromaflo Technologies Australia Pty Ltd	Polymer in Chroma-Chem Coatings	ND*	≤100 tonne/s per annum	Component of marine and industrial coatings

\*ND = not determined

## CONCLUSIONS AND REGULATORY OBLIGATIONS

### **Hazard classification**

Based on the limited toxicity data provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

### **Human health risk assessment**

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

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

### **Environmental risk assessment**

On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

### **Recommendations**

#### **CONTROL MEASURES**

##### **Occupational Health and Safety**

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced:
  - Local exhaust ventilation where available, if mists or aerosols are expected to be generated
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
  - Avoid contact with skin and eyes
  - Do not inhale vapours/mists
- A person conducting a business or undertaking at a workplace should implement the following personal protective equipment is used by workers to minimise occupational exposure during handling of the notified polymer as introduced:
  - Coveralls
  - Impervious gloves
  - Goggles
  - Respiratory protection if aerosols or mists are generated

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 Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012 or relevant State and Territory Codes of Practice).
- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

#### Disposal

- The notified polymer should be disposed of to landfill.

#### Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

### Regulatory Obligations

#### *Secondary Notification*

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified 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;or
- (2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from component of marine and industrial coatings, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 100 tonnes per annum, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

No additional secondary notification conditions are stipulated.

#### *(Material) Safety Data Sheet*

The (M)SDS of a product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

## **ASSESSMENT DETAILS**

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

**APPLICANT(S)**

Chromoflo Technologies Australia Pty Ltd (ABN:16 079 823 313 )  
30 Commerical Drive  
DANDENONG VIC 3175

**NOTIFICATION CATEGORY**

Limited: Synthetic polymer with Mn  $\geq$ 1000 Da.

**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, import volume.

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

Variation to the schedule of data requirements is claimed as follows: Boiling point, melting point, vapour pressure, hydrolysis as a function of pH, partition coefficient, dissociation constant, adsorption/desorption, particle size, flash point, flammability limits, explosive and oxidising properties.

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

None

**NOTIFICATION IN OTHER COUNTRIES**

None

### **2. IDENTITY OF CHEMICAL**

**MARKETING NAME(S)**

Polymer in Chroma-Chem Coatings

**MOLECULAR WEIGHT**

>1,000 Da

**ANALYTICAL DATA**

Reference NMR, IR, GPC and UV spectra were provided.

### **3. COMPOSITION**

DEGREE OF PURITY >95%

**LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES**

The notified polymer is a liquid. Thus, the residual monomer content is available for release.

**DEGRADATION PRODUCTS**

Degradation products are not known

### **4. PHYSICAL AND CHEMICAL PROPERTIES**

APPEARANCE AT 20 °C AND 101.3 kPa: A viscous yellow to brown liquid

Property	Value	Data Source/Justification
Freezing Point	Not determined	Estimated to be <0 °C
Boiling Point	Not determined	Expected to decompose before boiling
Density	1098 kg/m <sup>3</sup>	(M)SDS
Vapour Pressure	Not determined	Expected to have low vapour pressure based on molecular weight
Water Solubility	Test 1: <3.8 ×10 <sup>-3</sup> g/L at 20 °C	Measured

	Test 2: $<12 \times 10^{-3}$ g/L at 20 °C, pH 4, 7 and 9	
Hydrolysis as a Function of pH	Not determined	Expected to slowly hydrolyse under ambient environmental conditions
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is an ionic emulsifier and will tend to accumulate at the phase interface of octanol and water and/or form emulsions
Adsorption/Desorption	Not determined	Expected to partition to surfaces from water in the environment based on its surface activity
Dissociation Constant	Not determined	The notified polymer will be ionised in the environmental pH range (4-9)
Flash Point	181 °C	(M)SDS
Flammability	Not determined	Not expected to form flammable mixtures in air, based on low vapour pressure.
Autoignition Temperature	Not determined	Expected to decompose before auto-ignition occurs.
Explosive Properties	Not determined	Does not contain explosives
Oxidising Properties	Not determined	Not expected to oxidise.

## 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. The notified polymer will react during end-use. The notified polymer should be stored away from strong acids, bases and oxidising agents.

**Physical hazard classification**

Based on the limited physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

**5. INTRODUCTION AND USE INFORMATION**

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

The notified polymer will be imported as part of a formulation ( $\leq 1\%$ ) in finished coatings and may be imported undiluted for local formulation.

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

Year	1	2	3	4	5
Tonnes	10-100	10-100	10-100	10-100	10-100

## PORT OF ENTRY

Sydney and Melbourne

## IDENTITY OF MANUFACTURER/RECIPIENTS

Chromaflo Technologies Australia

## TRANSPORTATION AND PACKAGING

The notified polymer will be imported as a component of finished coatings in 5 L cans, 205 L steel drums or 1000 L intermediate bulk containers (IBC). The notified polymer may be imported in 205 L steel drums for local formulation. Transportation within Australia will be by road.

## USE

The notified polymer will be used as a component of coatings applied to hulls of marine vessels and steel structures such as offshore oil and gas rigs. The coatings will not be used for anti-fouling applications.

## OPERATION DESCRIPTION

The notified polymer will not be manufactured but may be reformulated and packaged in Australia.

*Reformulation.* The notified polymer will be transferred from 205 L steel drums, using drum lifts, into open stainless steel blending tanks (10,000 L), which are under local exhaust ventilation. High speed dispersion and mixing is used to blend components which are then diluted to form the end-use coatings. Floor pots are covered during these operations.

Sampling of the products containing the notified polymer and coating formulations will occur by manual collection of material from open floor pots into steel cans (500 mL) and analysis in a laboratory environment. The formulated product containing <1% notified polymer is filled from floor pots by gravity feed into 5 L steel cans, 205 L steel drums or 1000 L IBC. Blending operators operate and clean the automated guarded filling equipment in the presence of local exhaust ventilation.

*End-Use.* Spray painters will mix and apply the coatings containing the notified polymer at <1% to marine vessels (hulls) and steel structures (e.g. offshore gas and oil rigs) in dry dock using airless spraying. Overspray will be collected and disposed of by licensed waste contractors. Residual paint mixture will be washed from equipment manually using recycled solvent, and disposed of by solvent recyclers.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1. Exposure Assessment

#### 6.1.1. Occupational Exposure

## CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	2-4	1-2	20
Quality control	1	2-4	5-10
Blending operators	1-2	0.5	5-10
Spray Painter	20-50	2-4	100-200

## EXPOSURE DETAILS

Worker exposure to the notified polymer (in neat form or as part of a formulation) during the importation, transport and storage of the coatings is not expected, except in the event of an accident where packaging may be breached.

Dermal, ocular and inhalation exposure is possible to blending operators during transfer of the notified polymer from containers and formulation of the notified polymer into end-use products. Exposure to the notified polymer will be minimised from the use of local exhaust ventilation around blending equipment (in a bunded area) and PPE such as respiratory protection, impervious gloves, goggles and coveralls by workers.

Dermal and ocular exposure is possible to quality control workers during the reformulation process and QC sampling and testing. Exposure to the notified polymer will be minimised from the use of PPE such as laboratory coats, impervious gloves and goggles by workers.

Dermal, ocular and inhalation exposure is possible to spray painters during application to surfaces of products containing <1% of the notified polymer. Exposure to the notified polymer will be minimised from the use of PPE such as respiratory protection, impervious gloves, goggles and coveralls by workers.

After spray coating, the notified polymer will be incorporated along with other ingredients into the substrate matrix. There is limited potential for the release or bioavailability of the notified polymer after curing. Therefore, the potential for any dermal exposure to the notified polymer from contact with the dried coating is expected to be low.

#### 6.1.2. Public Exposure

The products containing the notified polymer (<1% concentration) are intended for use in industrial situations and will not be sold to the public. The public may come into contact with the products containing the notified polymer after application to substrates. However, once the coatings are cured and dried, the notified polymer will be bound within the polymer matrix and is not expected to be bioavailable. Public exposure the notified polymer is expected to be negligible.

## 6.2. Human Health Effects Assessment

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

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Hen's Egg Test – Chorio-allantoic membrane (HET-CAM)	Non-irritating

### *Toxicokinetics*

The notified polymer is a high molecular weight salt (>1000 Da) with a low proportion of low molecular weight species (<5% with molecular weight <1000 Da) and limited water solubility (<5 mg/L). These characteristics are expected to limit absorption in the gastrointestinal tract, or following dermal or inhalation exposure.

### *Acute toxicity*

The notified polymer was found to be of low acute oral toxicity in rats with a LD50 > 2000 mg/kg bw. No mortalities or signs of systemic toxicity were observed. The treated animals displayed expected weight gains during the study.

### *Irritation and Sensitisation*

The notified polymer was predicted to be non-irritating to the eye in a HET-CAM test. The HET-CAM assay has not yet been validated as a replacement test for the *in vivo* Draize test, and is not to be used for regulatory hazard classification purposes, based on a lack of adequate data (ICCVAM, 2009). Given the ICCVAM conclusions, it is uncertain whether the minimal response in the HET-CAM assay for the notified polymer indicated non-irritancy potential for the notified polymer.

No toxicological data were available for other endpoints. The notified polymer contains a functional group of concern for irritation/corrosion, and these effects cannot be ruled out.

### *Health hazard classification*

Based on the limited toxicity information available, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

## 6.3. Human Health Risk Characterisation

### 6.3.1. Occupational Health and Safety

Limited toxicological data was available on the notified polymer. It contains a structural alert for irritation/corrosion, and such effects cannot be ruled out.

Workers with exposure to products containing the notified polymer (at <1% concentration) include blenders, spray painters, QC Chemists and Transport and Storage workers. If the polymer is reformulated in Australia in future, workers may also be exposed to the polymer at high concentrations during formulation processes. Exposure is most likely to occur via the dermal route, although ocular and inhalation exposure to the notified polymer may occur. Dermal and ocular exposure of workers to the notified polymer would be minimised through safe work practices and the use of PPE such as overalls, impervious gloves and goggles. Inhalation exposure may occur during spray painting but would be minimised through the use of PPE such as respirators.

Once the marine structures are coated and dried, the polymer will be bound in the paint matrix and is not expected to be bioavailable.

The risk to workers is not considered unreasonable if the above controls are in place.



### 6.3.2. Public Health

The products containing the notified polymer will not be sold to the public. The public may have contact with the cured coated substrates. However, once cured, the notified polymer will be bound within a polymer matrix and is not expected to be bioavailable. Hence, public exposure to the notified polymer is not expected, and the risk to health of the public is not considered to be unreasonable.

## 7. ENVIRONMENTAL IMPLICATIONS

### 7.1. Environmental Exposure & Fate Assessment

#### 7.1.1. Environmental Exposure

##### RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported as a formulation in finished coatings or may be imported as raw material for local reformulation in the future. During reformulation processes, release of the notified polymer to the environment may occur from residues in import containers (0.25% of total annual import volume of the notified polymer), spills and leaks (0.25%) and from equipment cleaning processes. These wastes are expected to be collected and recycled where possible or disposed of to landfill.

##### RELEASE OF CHEMICAL FROM USE

The coating products containing the notified polymer will be applied to hulls of marine vessels and steel structures (e.g. offshore oil and gas rigs) in dry dock by using spray application, or with some small area applied by using brushes or rollers. During application by spray, it is estimated by the notifier that up to 20% of the notified polymer will be released as overspray. When coatings are applied by using brushes or rollers, less than 1% of the notified polymer is estimated to be released as drips. Overspray and drips are expected to be collected and disposed of to landfill. Equipment used to apply the coating formulations may be rinsed with solvent. It is estimated that up to 7% of the total annual import volume of the notified polymer from cleaning of equipment will be collected, treated and disposed of by a licensed waste contractor.

##### 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 in the coating will be disposed of along with the coated articles, at the end of their useful life, and will either go to metal recyclers or be disposed of to landfill. Residues in empty containers, estimated to account for less than 1% of the total annual import volume of the notified polymer, will be either disposed of through drums recyclers or disposed of to landfill along with empty containers.

#### 7.1.2. Environmental Fate

The majority of the notified polymer will be applied to hulls of marine vessels or steel structures for offshore applications, and hence there will 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, the coatings will not be used for anti-fouling applications and the coatings containing notified polymer will be overcoated with additional coatings. Therefore, 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. The notified polymer is not readily biodegradable (15% of biodegradability over 28 days) but is expected to slowly hydrolyse. However, bioaccumulation of the notified polymer is unlikely due to the relatively high molecular weight and surface activity. 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, nitrogen and phosphorus.

For the details of the environmental fate study refer to Appendix C.

#### 7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer is not expected to be present at significant concentrations in the aquatic environment because of the very low potential for direct release to surface waters when used in surface coatings. A predicted environmental concentration (PEC) has therefore not been calculated.

## 7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on water accommodation fractions (WAFs) of 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>
Fish Toxicity	LL50 (96 h) > 100 mg/L (WAFs)	Not harmful to fish
Daphnia Toxicity	EL50 (48 h) > 100 mg/L (WAFs)	Not harmful to aquatic invertebrates

The notified polymer is not harmful to fish and aquatic invertebrates up to its limit of solubility in water. The notified polymer is therefore not classified for acute aquatic hazard. Although the notified polymer is not readily biodegradable, it is not expected to bioaccumulate and therefore is not classified for long-term aquatic hazards under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009).

### 7.2.1. Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) was not calculated as there will be very low potential for aquatic exposure.

## 7.3. Environmental Risk Assessment

A Risk Quotient ( $Q = \text{PEC}/\text{PNEC}$ ) was not quantified as a PEC and PNEC were not calculated. The reported use pattern of the notified polymer indicates that there is no significant anticipated aquatic release. Moreover, after curing, the majority of the imported quantity of notified polymer will be incorporated into an inert matrix with other chemicals and is not expected to be mobile, bioavailable or biodegradable. Hence, the environmental exposure is expected to be minimal. On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

**APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES****Density** 1098 kg/m<sup>3</sup> at 25 °C

Method OECD TG 109 Density of Liquids and Solids.  
EC Council Regulation No 440/2008 A.3 Relative Density.  
Remarks Test Report not provided

**Water Solubility (Test 1)** <3.8 × 10<sup>-3</sup> g/L at 20 °C

Method Following the general procedure of OCED TG 105, approximately 1 g of notified polymer was added to 500 mL of water and stirred at 48 h at room temperature. After stirring the sample was kept undisturbed for 24 hours allowing separation of excess polymer from the water phase. The water phase appeared slightly turbid indicating that non-dissolved material remained in the water phase. From the centre volume ('water phase') of each solution, 100 mL of sample was carefully pipetted, avoiding uptake of larger droplets of notified polymer. This was labelled Sample 1. Another sample was prepared as above and centrifuged at 2575 × g to separate small droplets and part of the upper layer was removed by pipette and was labelled Sample 2. Sample 2 was clearer than Sample 1 but was still opaque, indicating an emulsion was present. Both samples were extracted twice with 70 mL of chloroform. The solvent was removed by a rotary evaporator and a known quantity of heptachloro-propane was added as an internal quantification standard for NMR measurement. The extract in heptachloro-propane was re-dissolved in ~5 mL of deuterio-chloroform and a 1 mL aliquot of each sample was transferred to NMR tubes and analysed. The measured concentration of the notified polymer extracted to the water phase was 9.9 mg/L in Sample 1 and 3.8 mg/L in Sample 2.

Remarks A water solubility test could not be conducted exactly according to OECD TG 105 due to the tendency of the notified polymer to form emulsions. These results should be treated with caution as an emulsion was present in the samples. Therefore, the water solubility of the notified polymer is expected to be much lower than 3.8 mg/L.

Test Facility Goldschmidt Analytical Laboratory (2004)

**Water Solubility (Test 2)** <12 × 10<sup>-3</sup> g/L at 20 °C

Method Following the general procedure of OCED TG 105, three tests were conducted at pH 4, 7 and 9, and approximately 1 g of notified polymer was added to 500 mL of water and stirred at 48 h at room temperature. After stirring the samples were kept undisturbed for 24 hours allowing separation of excess polymer from the water phase. In all three tests the water phase appeared turbid indicating that non-dissolved material remained in the water phase. From the centre volume ('water phase') of each solution, 100 mL of sample was carefully pipetted, avoiding uptake of larger droplets of notified polymer. These samples were centrifuged at 2575 × g to separate small droplets and part of the upper layer was removed by pipette. The samples were slightly opaque in the tests indicating an emulsion was present. Each sample was extracted twice with 70 mL of chloroform. The solvent was removed by a rotary evaporator and a known quantity of heptachloro-propane was added as an internal quantification standard for NMR measurement. The extract in heptachloro-propane was re-dissolved in ~5 mL of deuterio-chloroform and a 1 mL aliquot was transferred to an NMR tube and analysed. The measured concentration of the notified polymer extracted to the water phase was not strongly pH dependent (12 mg/L at pH 4 and 11 mg/L at pH 7 and 9).

Remarks A water solubility test could not be conducted according to OECD TG 105 due to the tendency of the notified polymer to form emulsions. These results should be treated with caution as an emulsion was present in the samples. Therefore, the water solubility of the notified polymer is expected to be much lower than 12 mg/L.

Test Facility Goldschmidt Analytical Laboratory (2006)

## 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/ White Wistar
Vehicle	None
Remarks - Method	The expiry date on the feed given to the animals had been slightly exceeded. The study authors noted that the food storage conditions were cool and dark and they did not expect any adverse effects as a result. This was confirmed by the feed supplier. No other significant protocol deviations.

#### RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	6 females	2000	None

LD50	>2000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
Remarks - Results	No mortalities or adverse effects were observed following dosing with the test substance. The animals displayed expected body weight gains during the study.

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

TEST FACILITY Stockhausen GmbH (2004a)

### B.2. Irritation – eye

TEST SUBSTANCE	Notified Polymer
METHOD	The Hen's Egg Test – Utilizing the Chorioallantoic Membrane (HET-CAM) Test. Modification of that described by Kemper and Luepke (1986). SPAFAS chicken eggs
Species/Strain	
Remarks - Method	Six eggs were fertilised and incubated for the test substance, negative and positive controls taken at 0.5, 2 and 5 mins. The eggs were incubated at $37.5 \pm 0.5^{\circ}\text{C}$ and a relative humidity of 62.5% ( $\pm 7.5\%$ ) in an automatic, rotating incubator for 9 days. After 9 days, the shell over the air sac of each egg was removed, wetted with physiological saline at room temperature for approximately 1 minute and the CAM was removed with forceps. A 200 $\mu\text{L}$ , solution of the test substance (undiluted) was applied to each CAM and effects of hyperemia, haemorrhage (including minimal haemorrhage) and coagulation were observed over a period of 5 mins and scored according to the maximum scores shown in the following table.

<i>Effect</i>	<i>Scores at time (min):</i>		
	0.5	2	5
Vascular injection	5	3	1
Haemorrhage	7	5	3
Coagulation	9	7	5

Each reaction type can be recorded only once for each CAM, therefore the maximum score per CAM is 21. The mean score was determined for all

CAMs similarly tested.

The duration of application with the test substance was not reported. The positive control used in the test was Texapon ASV (sodium magnesium lauryl myristyl-6-ethoxy-sulfate) diluted to 5% with tap water. The negative control used in the test was tap water.

#### RESULTS

	<i>Test Solution</i>	<i>Average Irritation score</i>
	Tap water	0.00
	Notified polymer	0.5
	5% Texapon ASV (sodium magnesium lauryl-myristyl-6-ethoxy-sulfate)	9.7

#### Remarks - Results

Haemorrhage of the CAM 5 minutes following treatment with the notified polymer was observed in one egg. This resulted in an irritation score of 0.5 out of a possible 21. In comparison, a score of 9.7 was reported for the positive control Texapon ASV at 5% concentration which is known to be slightly *irritating in vivo*. Therefore, a score of 0.5 for the notified polymer is predicted to be practically non-irritating.

#### CONCLUSION

The notified polymer is non-irritating to the eye.

#### TEST FACILITY

Stockhausen GmbH (2004b)

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

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

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I)
Inoculum	Aerobic activated sludge comprising samples from a lake, the effluent of a municipal sewage treatment plant and an extract of surface soil
Exposure Period	28 days
Auxiliary Solvent	None reported
Analytical Monitoring	Pressure decrease measured by Sensomat
Remarks - Method	The inoculum deviated from the OECD Guideline (samples should be collected from no fewer than 10 sites) but was not expected to produce a false positive result. The test substance was directly weighed into test vessels and made up to a final concentration of 100 mg/L in inoculated mineral medium. An abiotic control was made up in the same way except the inoculum was excluded and mercury chloride was added at a concentration of 1% (w/v). Test vessels were incubated in the dark at 25 °C. Since there was no reliable Theoretical Oxygen Demand (ThOD) calculation for the test substance available, the ThOD was measured as the Chemical Oxygen Demand in a separate study (Stockhausen GmbH (2005b)). This study was determined in accordance with the "German Standard Procedure" H 41, DIN 38 409, part 41 (December 1980), and was assessed as a reliable study.

#### **RESULTS**

<i>Test substance</i>		<i>Sodium benzoate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation*</i>
5	6	5	75
15	12	15	87
28	15	28	88

\*Average of three replicates

Remarks - Results	All validity criteria for the test were satisfied except that at the end of the test, the difference between the two most extreme replicates in degradation of the test substance was greater than 20% (30%), however this would not have affected the reliability and final outcome of the test. The reference substance was degraded >60% by the 10 <sup>th</sup> day, indicating a suitable aerobic activated sludge inoculum was used. The test substance did not reach the pass level of 60% degradation for this test and therefore cannot be classified as readily biodegradable.
-------------------	--

CONCLUSION	The notified polymer is not considered to be readily biodegradable
------------	--

TEST FACILITY	Stockhausen GmbH (2005a)
---------------	--------------------------

### **C.1. Ecotoxicological Investigations**

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

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static Test
Species	Zebra Fish ( <i>Danio rerio</i> , Hamilton Buchanan)
Exposure Period	96 hours
Auxiliary Solvent	None reported
Water Hardness	70 – 90 mg CaCO <sub>3</sub> /L
Analytical Monitoring	<sup>1</sup> H NMR

## Remarks – Method

A Water Accommodated Fraction (WAF) was prepared by adding 1500 mg notified polymer to 15 L water and stirring for 24 h by magnetic stirrer at room temperature. The solution was allowed to stand for 2 hours to let undissolved polymer settle out and 10 L of the WAF was transferred to the test aquarium. Similarly treated dilution water served as the control.

## RESULTS

Concentration mg/L		Number of Fish	Mortality			
Nominal	Actual		24 h	48 h	72 h	96 h
0	0	10	0	0	0	0
100 (WAF)	< 4	10	0	0	0	0

LL50

&gt;100 mg/L at 96 hours (based on loading rate)

NOEL

100 mg/L at 96 hours (based on loading rate).

## Remarks – Results

Regarding the measured concentrations (NMR), the study author reported there was a “different signal form” between the integrated signal (4.0-4.2 ppm) in the pure test substance and the integrated signals (4.0-4.2 ppm) in all the samples. A lack of specificity is indicated and hence the analytical monitoring procedure has not been satisfactorily validated. Therefore the nominal (loading rates) will be considered. All validity criteria for the fish test were satisfied. There were no signs of toxicity or mortality observed in any of the fish over the course of the test

## CONCLUSION

The notified polymer is not harmful to fish up to the limit of its solubility in water.

## TEST FACILITY

Stockhausen GmbH (2006a)

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

## TEST SUBSTANCE

Notified polymer

## METHOD

OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Static test

Species

*Daphnia magna*

Exposure Period

48 hours

Auxiliary Solvent

None reported

Water Hardness

70-90 mg CaCO<sub>3</sub>/L

Analytical Monitoring

<sup>1</sup>H NMR

Remarks - Method

A Water Accommodated Fraction (WAF) was prepared by adding notified polymer to water to make up a concentration of 100 mg polymer / L and stirring for 24 h by magnetic stirrer at room temperature. The solution was allowed to stand for 2 hours to let undissolved polymer settle out. For each test run, approximately 30 mL of the WAF was removed by pipette from approximately 3 cm below the surface of the liquid and transferred into a 50 mL beaker, into which 5 daphnia were added.

## RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h [acute]	48 h [acute]
0	0	5	0	0
100 (WAF)	<5	25	0	0

EL50

&gt;100 mg/L (WAF) at 48 hours (based on loading rate)

NOEL

&gt;100 mg/L (WAF) at 48 hours (based on loading rate)

## Remarks - Results

Regarding the measured concentrations (NMR), the study author reported there was a “different signal form” between the integrated signal

(4.0-4.2 ppm) in the pure test substance and the integrated signals (4.0-4.2 ppm) in all the samples. A lack of specificity is indicated and hence the analytical monitoring procedure has not been satisfactorily validated. Therefore the nominal (loading rates) will be considered. The toxic response of daphnia to the reference compound  $K_2Cr_2O_7$  gave an EC50 (24 h) of 1.3 mg/L which was considered adequate. All validity criteria of the test were satisfied. No effects on the swimming ability of exposed daphnia were observed over the course of the test.

**CONCLUSION**

The notified polymer is not harmful to aquatic invertebrates up to the limit of solubility in water

**TEST FACILITY**

Stockhausen GmbH (2006b)



## **BIBLIOGRAPHY**

- Goldschmidt Analytical Laboratory (2004) Report on the Determination of Water Solubility. Project Report No.: 04094704. Essen, Germany. 11 November 2004 (Unpublished report provided by notifier)
- Goldschmidt Analytical Laboratory (2006) Report on the Determination of Water Solubility at Various pH. Project Report No.: 06031081. Essen, Germany. 15 May 2006 (Unpublished report provided by notifier)
- ICCVAM (2010). ICCVAM Test Method Evaluation Report: Current Validation Status of *In Vitro* Test Methods Proposed for Identifying Eye Injury Hazard Potential of Chemicals and Products. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Accessed online [12 December 2012]: <http://iccvam.niehs.nih.gov/methods/ocutox/MildMod-TMER.htm>
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3<sup>rd</sup> edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia
- Painter HA (1992) *Anionic Surfactants*. In: de Oude NT ed. *The Handbook of Environmental Chemistry*, Volume 3, Part F, *Anthropogenic Compounds, Detergents*, Springer-Verlag, Berlin, 1992 pp 1-88.
- Stockhausen GmbH (2004a) Notified chemical: Acute Oral Toxicity: Acute – Toxic – Class – Method on Rats. Final Report No. 477/2004. Study No. 16281. December 2004. Stockhausen GmbH, Krefeld, Germany (Unpublished report provided by notifier).
- Stockhausen GmbH (2004b) Notified chemical: Hen's Egg Test on the Chorioallantoic Membrane (HET-CAM). Final Report No. 455/2004. Study No. 16283. November 2004. Stockhausen GmbH, Krefeld, Germany (Unpublished report provided by notifier).
- Stockhausen GmbH (2005a) Notified chemical: Ready Biodegradability Modified MITI Test (I). Final Report No. 510/2004. Study No. 16298. 14 January 2005. Stockhausen GmbH, Krefeld, Germany (Unpublished report provided by notifier).
- Stockhausen GmbH (2005b) Notified chemical: Chemical Oxygen Demand. Final Report No. 508/2004. Study No. 16297. January 2005. Stockhausen GmbH, Krefeld, Germany (Unpublished report provided by notifier).
- Stockhausen GmbH (2006a) Notified chemical: Acute Fish Toxicity. Final Report No. 72/2006. Study No. 16574. March 2006. Stockhausen GmbH, Krefeld, Germany (Unpublished report provided by notifier).
- Stockhausen GmbH (2006b) Notified chemical: Acute Daphnia Toxicity *Daphnia sp.*, Acute Immobilisation Test. Final Report No. 71/2006. Study No. 16573. March 2006. Stockhausen GmbH, Krefeld, Germany (Unpublished report provided by notifier).
- United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3<sup>rd</sup> revised edition. United Nations Economic Commission for Europe (UN/ECE), <[http://www.unece.org/trans/danger/publi/ghs/ghs\\_rev03/03files\\_e.html](http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html)>.