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

**PUBLIC REPORT**

**Polymer in UVIVID FLEXO JD Ink Series**

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**

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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/1538	Fujifilm Australia Pty Ltd	Polymer in UVIVID FLEXO JD Ink Series	ND*	≤5 tonnes per annum	Component of ink for flexographic printing

\*ND = not determined

## CONCLUSIONS AND REGULATORY OBLIGATIONS

### **Hazard classification**

Based on the limited data provided, the notified polymer cannot be classified as hazardous, according to 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**

#### REGULATORY CONTROLS

#### CONTROL MEASURES

#### Occupational Health and Safety

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

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

- 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 chemical 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 a component of printing ink, or is likely to change significantly;
  - the amount of polymer being introduced has increased from five 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.

*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)**

Fujifilm Australia Pty Ltd (ABN 80 000 064 433)  
114 Old Pittwater Road  
BROOKVALE NSW 2100

**NOTIFICATION CATEGORY**

Limited: Synthetic polymer with  $M_n \geq 1000$  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, and import volume.

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

Variation to the schedule of data requirements is claimed as follows: Melting/Boiling Point, Vapour Pressure, Hydrolysis as a Function of pH, Partition Coefficient, Dissociation Constant, Adsorption/Desorption, Particle Size, Flash Point, Flammability Limits, Autoignition Temperature and Explosive Properties.

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

None

**NOTIFICATION IN OTHER COUNTRIES**

None

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

**MARKETING NAME(S)**

Polymer in UVIVID FLEXO JD

**MOLECULAR WEIGHT**

$M_n > 1,000$  Da

**ANALYTICAL DATA**

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

### **3. COMPOSITION**

DEGREE OF PURITY             $> 98\%$

**HAZARDOUS IMPURITIES/RESIDUAL MONOMERS**

None

**ADDITIVES/ADJUVANTS**

None

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

None

**DEGRADATION PRODUCTS**

None

#### 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Brown liquid

Property	Value	Data Source/Justification
Freezing Point	Not determined	Being a viscous liquid, expected to have a freezing point of <0°C.
Boiling Point	Not determined	Expected to decompose at high temperatures before boiling.
Density	1098 kg/m <sup>3</sup> at 25°C	Measured
Vapour Pressure	Not determined	The notified polymer has a high molecular weight and is therefore, expected to have very low vapour pressure.
Water Solubility	Test 1: < 3.8 × 10 <sup>-3</sup> g/L at 20°C Test 2: < 12 × 10 <sup>-3</sup> g/L at 20°C, pH 4, 7 and 9	Measured
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	The notified polymer is 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	Not determined	Vapour pressure anticipated to be too low for flash point determination.
Flammability	Not determined	Vapour pressure anticipated to be too low for flammability determination.
Autoignition Temperature	Not determined	Expected to decompose before auto-ignition occurs.
Explosive Properties	Not determined	Not expected to be explosive based on structure.

#### 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.

#### *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 in finished inks at a concentration of up to 10%.

## 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>	1-5	1-5	1-5	1-5	1-5

## PORT OF ENTRY

Melbourne and Sydney

## TRANSPORTATION AND PACKAGING

The notified polymer will be transported by road from the dockside to the notifier's warehouse and then redistributed by road to printing houses. The notified polymer will be imported in the original import containers i.e. 5 kg plastic tubs.

## USE

The notified polymer will be used as a component of UV-curable inks at concentrations up to 10% for flexographic printing on various substrate types including plastic, paper and metal foil. Some examples of printing applications include self-adhesive labels, sachets and pouches, unsupported films, low shrink sleeves, wrap-around and in-mould labels.

## OPERATION DESCRIPTION

The notified polymer will not be manufactured, reformulated or repackaged in Australia.

At the end use industrial printing companies, ink bottles will be manually connected to the printing machine via an inlet and attached to a flexible tube which supplies the ink head. The ink will be automatically injected from the bottles into the printing machine. Separate ink bottles will be provided for each of the required colours for printing.

While printers are running, printer operators will monitor their operation and keep the substrate (e.g., vinyl, paper, etc) feeders stocked and attend to substrate jams. Throughout the print run, quality control will be carried out by printer operators.

After printing, the notified polymer will be fixed (UV-cured) with other ink ingredients into the substrate matrix.

Any residual ink within printing equipment will be wiped clean using rags and solvents. These rags and dirty solvents are expected to be disposed of by the printing company through licensed waste disposal contractors.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1. Exposure Assessment

#### 6.1.1. Occupational Exposure

## NUMBER AND 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	10-20	4-8	50
Quality control/chemists and technical service	6	0.5 - 6	25
Printer operators	> 1000	1-2	25
Service technicians	200	8	200

## EXPOSURE DETAILS

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

Although printing processes are largely automated, workers can be exposed to ink products containing the notified polymer (up to 10%) during certain tasks of the printing process. Mainly dermal and accidental ocular exposure are expected. These tasks include manually connecting the ink bottles to the printing machine via an inlet and during manual replacement of ink bottles and the clearing of substrate jams.

Exposure is also possible for short durations during ink handling procedures. Such exposure will be minimised by the use of local exhaust ventilation and also by wearing gloves and goggles. Inhalation exposure may occur to aerosols of the notified polymer during the operation of the printers. However, this is expected to be minimised by the employment of local exhaust ventilation in areas surrounding printing machines.

Dermal and ocular exposure is also possible to chemists from testing of liquid ink products (containing up to 10% of notified polymer) and also to service technicians involved in maintaining the printing machines such as removing any residual ink within printing equipment using rags and solvents and during the removal of filters. Exposure will be limited due to the use of PPE such as overalls, gloves and goggles by workers.

After printing, the notified polymer will be fixed (UV-cured) along with other ink ingredients onto the substrate matrix and there is very limited potential for the release or bioavailability of the notified polymer. Therefore, the potential for any dermal exposure to the notified polymer from contact with the dried ink is expected to be low.

### 6.1.2. Public Exposure

The notified polymer is intended for industrial use only and will not be sold to the general public. The general public may come in contact with the printed substrates containing the notified polymer. The notified polymer, once released onto the substrate, will be cured onto it and is expected to remain bound to the substrate print matrix. Thus, exposure to the general public, when handling products printed with 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 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 >2000 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 (>1000 Da.) salt with a low proportion of low molecular weight species (<5% with molecular weight <1000Da.) and limited water solubility (<5 mg/L). Based on these characteristics, it is not expected to be absorbed following oral, dermal or inhalation exposure.

### *Acute toxicity*

The notified polymer was found to be of low acute oral toxicity 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 been evaluated by the US National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods and the Interagency Coordinating Committee on the Validation of Alternative Methods (NICEATM-ICCVAM). ICCVAM concluded that the HET-CAM test method:

- is not recommended as a screening test to distinguish substances labelled as irritants from all other hazard categories when results are to be used specifically for hazard classification and labelling purposes;
- is not recommended to identify moderate and mild ocular irritants;
- is not recommended for screening and identifying ocular corrosives and severe irritants in a tiered-testing strategy as part of a weight-of-evidence approach (ICCVAM, 2010).

In addition, ICCVAM made several recommendations to improve the usefulness of the HET-CAM test method.

Given the above 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.



The notified polymer was not tested for its potential to illicit skin sensitisation. It does not contain any known structural alerts for skin sensitisation (Barratt et al. 1994) and is therefore not expected to be a skin sensitiser.

#### ***Health hazard classification***

Based on the limited data provided, the notified polymer cannot be classified as hazardous, according to *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

### **6.3. Human health risk characterisation**

#### **6.3.1. Occupational health and safety**

Based on limited toxicological data provided and other characteristics of the notified polymer such as high molecular weight (>1000 Da), low proportion of low molecular weight species (<5% with molecular weight <1000Da.) and limited water solubility (<5 mg/L), the notified polymer is unlikely to represent a significant health hazard.

Printer operators and service technicians may encounter dermal and possibly inhalation exposure to ink formulations containing the notified polymer at up to 10% during replacement of ink bottles, printer maintenance and cleaning. These workers are expected to wear PPE such as overalls, gloves and goggles to minimise dermal exposure. Furthermore, exposure is not anticipated for workers handling printed substrates as the notified polymer will be bound within a print matrix and is not expected to be bioavailable.

Given the relatively low concentration (up to 10%) of the notified polymer in ink formulations, the use of PPE and engineering controls to further minimise exposure and the lack of bioavailability of the notified polymer in the printed material, the risk posed to occupational health and safety of workers is not considered to be unreasonable.

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

The ink products containing the notified polymer will not be sold to the public. No exposure is expected from the dried printed materials as the notified polymer will not be in bioavailable form. Therefore, as exposure to the general public is not expected, the notified polymer does not pose an unreasonable risk to the public.

## **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 a final product in 5 kg plastic bottles. No manufacturing and reformulation of the notified polymer will take place in Australia. Environmental release of the notified polymer is unlikely to occur during importation, storage and transportation.

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

The plastic ink bottles will be designed to prevent leakage and will not be opened during transport, use, installation or replacement. Therefore, release of ink containing the notified polymer to the environment is not expected under normal conditions of use. If leakage or spillage does occur, the ink will be physically contained with absorbent material and disposed of to landfill. The ink bottles will be contained within the printer until the contents are consumed and then they will be removed and sent for recycling or disposed of to landfill. Approximately 0.1% of the ink containing the notified polymer will remain in spent ink bottles.

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

The majority of the notified polymer is expected to be disposed of to landfill and is expected to remain associated with the substrates (e.g. plastic and paper) to which it has been applied. Of the 2% notified polymer applied to paper, half of this amount is expected to be recycled. During recycling processes, waste paper will be repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres.

#### **7.1.2. Environmental Fate**

The majority of the notified polymer will end up in landfill where it is expected to slowly decompose by abiotic and biotic processes to form water and oxides of carbon, nitrogen and phosphorus.

A small fraction of the notified polymer is expected to be released to the sewerage system due to the recycling of paper to which the product containing the notified polymer will be applied. In the waste water treatment processes in sewage treatment plants, most of the notified polymer is expected to partition to sludge or to suspended solids due to its low water solubility and surface activity, where it will be removed for disposal to landfill or used on land for soil remediation (Painter, 1992). Moreover, the notified polymer is expected to be efficiently removed from waste water in waste water treatment plants through adsorption to sludge or by flocculation due to the cationic component of the polymer (Boethling and Nabholz, 1997).

In surface waters, the notified polymer will partition to suspended solids and organic matter. It is not readily biodegradable but is expected to slowly hydrolyse. Based on its relatively high molecular weight and surface activity the notified polymer is not expected to bioaccumulate.

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

### 7.1.3. Predicted Environmental Concentration (PEC)

A PEC for discharge of the notified polymer to surface waters has been calculated assuming that half of the paper to which the ink containing the notified polymer is applied will be recycled and will be discharged to sewers nation wide with no removal in sewage treatment plants. The details of this worst case scenario are as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	5,000	kg/year
Proportion expected to be released to sewer	1.00%	
Annual quantity of chemical released to sewer	50.00	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	0.19	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.05	µg/L
PEC - Ocean:	0.00	µg/L

## 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.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	LC50 (96 h) > 100 mg/L	Not harmful
Daphnia Toxicity	EC50 (48 h) > 100 mg/L	Not harmful

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 poorly water soluble and 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

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Fish LC50	> 100	mg/L
Assessment Factor	1000	
PNEC:	>100	µg/L

An assessment factor of 1000 has been used to derive a PNEC, as acute toxicity endpoints are available for the effects of the notified polymer on aquatic species from only two trophic levels.

### 7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.05	>100	<b>0.00</b>
Q - Ocean	0.00	>100	<b>0.00</b>

The Risk Quotients ( $Q = \text{PEC}/\text{PNEC}$ ) for the worst case discharge scenario have been calculated to be  $\ll 1$  for both river and ocean compartments. This indicates the notified polymer is not expected to pose an unacceptable risk to the aquatic environment based on its reported use pattern.

**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 Directive 92/69/EEC 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 author's 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 observed
Effects in Organs	None observed
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/polymer is of low toxicity via the oral route.

TEST FACILITY Stockhausen GmbH (2004a)

## B.2. Irritation – eye The Hen's Egg Test – Utilizing the Chorioallantoic Membrane (HET-CAM)

TEST SUBSTANCE Notified polymer

METHOD Hen's Egg Test (HET) - Chorioallantoic Membrane (CAM) Test. Modification of that described by Kemper and Luepke (1986).

Species SPAFAS chicken eggs

Number of eggs 6 fertilised and incubated for the test substance, negative and positive controls

Observation period Readings taken at 0.5, 2 and 5 mins

Treatment 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 sack 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 CAM's similarly tested.

Remarks - Method 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              Under the conditions of this test, the notified polymer is predicted to be non-irritating to the eye.

TEST FACILITY            Stockhausen GmbH (2004b)

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

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

#### **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.
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CONCLUSION	The notified polymer cannot be classed as readily biodegradable
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TEST FACILITY	Stockhausen GmbH (2005a)
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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 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

LC50	> 100 mg/L at 96 hours (based on loading rate)
NOEC (or LOEC)	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.
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TEST FACILITY	Stockhausen GmbH (2006a)
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**C.2.2. Acute toxicity to aquatic invertebrates**

TEST SUBSTANCE	Notified polymer
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METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test – Static test
Species	<i>Daphnia magna</i>
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

EC50	> 100 mg/L (WAF) at 48 hours (based on loading rate)
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NOEL	> 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)

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