File No: LTD/1604

March 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Suncure Starluxe & Suncure Lazer Inks

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 CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1604	DIC Australia Pty Ltd	Polymer in Suncure Starluxe & Suncure Lazer Inks	ND*	≤10 tonne/s per annum	Component of ink for lithographic printing

*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 PEC/PNEC ratio and 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 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:
  - Coveralls
  - Impervious gloves
  - Goggles

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

- 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 ink for lithographic printing or is likely to change significantly;
  - the amount of polymer being introduced has increased from 10 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 (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)
DIC Australia Pty Ltd (ABN: 12 000 079 550)
42 Sunmore Close
HEATHERTON VIC 3202

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, 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, autoignition temperature, explosive and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Suncure Starluxe & Suncure Lazer Inks (products containing the notified polymer)

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, any residual monomer content is available for release

DEGRADATION PRODUCTS
Degradation products are not known. Expected to form oxides of carbon, phosphorus and nitrogen after combustion.

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^3	(M)SDS
Vapour Pressure	Not determined	Expected to have low vapour pressure based on molecular weight

Water Solubility	Test 1: <3.8 $\times 10^{-3}$ g/L at 20 ºC Test 2: <12 $\times 10^{-3}$ g/L at 20 ºC, 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	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 explosophores
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 able to be 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 a formulation (≤10% concentration) in finished inks.

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

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

PORT OF ENTRY
Sydney and Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
DIC Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be transported by road. The notified polymer will be transported in the original import containers (3 or 10 kg plastic tubs).

USE
The notified polymer will be used in a UV-curable ink formulation which will be used in UV lithographic offset printing applications for printing on various substrate types, including plastic, paper and cardboard. Examples include labels and (non-food contact) packaging. Printing on recyclable paper substrates is expected to account for approximately 50% of the import volume.

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

Although printing processes are essentially automated, some parts of the printing processes require manual operation. At the end-use industrial printing companies, ink tubs will be manually poured into ink reservoirs of the printing machines. 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. Exhaust ventilation is fitted to commercial machines to remove solvent and airborne ink components.

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

Any residual ink within printing equipment will be wiped clean using rags and solvents. The 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

CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
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 event of an accident where packaging may be breached.

Although printing processes are largely automated, workers can be exposed to ink products containing the notified polymer (≤10% concentration) during certain tasks of the printing process and during cleaning processes. Dermal and accidental ocular exposures are expected. Exposure is possible for short durations during ink handling procedures. Such exposure will be minimised by the use of safe work practices and wearing personal protective equipment (PPE) including impervious gloves and goggles. Inhalation exposure may occur from aerosols of the notified polymer during the operation of the lithographic 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 possible to chemists from testing of liquid ink products (containing ≤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 to the notified polymer will be minimised from the use of PPE such as coveralls, impervious gloves and goggles by workers.

After printing, the notified polymer will be incorporated in the UV-cured print matrix along with other ink ingredients. 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 ink is expected to be low.

6.1.2. Public Exposure

The products containing the notified polymer (≤10% concentration) are intended for use in industrial situations and will not be sold to the public. The public may come into contact with the printed products containing the notified polymer after application to substrates. However, once the ink is cured and dried, the notified polymer is expected to remain bound within the polymer matrix and not be bioavailable. Public exposure to 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.

Endpoint	*Result and Assessment Conclusion*
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 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 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).

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.

Printer operators and service technicians may encounter dermal, ocular and possibly inhalation exposure to ink formulations containing the notified polymer at ≤10% during replacement of ink bottles, printer maintenance and cleaning. Dermal and ocular exposure of workers to the notified polymer will be minimised through the use of PPE such as coveralls, impervious gloves and goggles and inhalation exposure through engineering controls such as local exhaust ventilation. Dermal exposure is not expected for workers handling printed substrates as the notified polymer will be bound within a print matrix and is not expected to be bioavailable.

The risk to workers is not considered to be unreasonable if such 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 materials. 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 into Australia as a component of a final product. 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 tubs 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. Waste ink due to equipment cleaning or spillage (1% of the annual import volume) 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 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 notified polymer applied to paper, half of this amount is expected to be recycled. During recycling processes, waste paper is 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)

For the worst case scenario, it is assumed that 100% of total annual imported volume of the notified polymer will be printed on paper. A Predicted Environmental Concentration (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 waste recycling water containing the notified polymer will be discharged to sewers national 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	10,000	kg/year
Proportion expected to be released to sewer	50 %	
Annual quantity of chemical released to sewer	5,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	19.23	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	4.25	µg/L
PEC - Ocean:	0.43	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 4.25 µg/L may potentially result in a soil concentration of approximately 28.35 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 142 µg/kg and 284 µg/kg, respectively.

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.

Endpoint	*Result*	*Assessment Conclusion*
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

As assessment factor of 1000 has been used to derive a Predicted No-Effect Concentration (PNEC) as acute toxicity endpoints are available for the effects of the notified polymer on aquatic species from only two trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment	
EC50 (Fish)	100 mg/L
Assessment Factor	1,000
PNEC:	100 µg/L

7.3. Environmental Risk Assessment

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	4.25	100	0.043
Q - Ocean:	0.43	100	0.004

The Risk Quotients (Q = PEC/PNEC) for the worst case discharge scenario have been calculated to be <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^3 at 25 ºC

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^{-3} g/L at 20 ºC

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 deutero-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^{-3} g/L at 20 ºC

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 deutero-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

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
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).
Species/Strain: SPAFAS chicken eggs

Remarks - Method: 6 eggs were fertilised and incubated for the test substance, negative and positive controls readings taken at 0.5, 2 and 5 mins. The eggs were incubated at 37.5 ± 0.5°C and a relative humidity of 62.5% (±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 µL, 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.

	Scores at time (min):		
Effect	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

Test Solution	*Average Irritation score*
Tap water	0.00
Notified polymer	0.5
5% Texapon ASV (sodium magnesium lauryl-myristy1-6-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. 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 ºC. 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

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation**
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 by >60% by the 10th 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.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 (*Danio rerio*, Hamilton Buchanan)
Exposure Period	96 hours
Auxiliary Solvent	None reported
Water Hardness	70-90 mg $CaCO_3$/L
Analytical Monitoring	^{1}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	>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 $CaCO_3$/L
Analytical Monitoring	^{1}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 D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h [acute]*	*48 h [acute]*
0	0	5	0	0
100 (WAF)	<5	25	0	0

EL50	>100 mg/L (WAF) at 48 hours (based on loading rate)
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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