File No: LTD/1697

November 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

SC-506

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 conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

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/1697	Ricoh Australia Pty Ltd	SC-506	Yes	≤ 5 tonnes per annum	Component of paper treatment products

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is 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. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Acute toxicity (Category 4)	H302 - Harmful if swallowed
Skin sensitisation (Category 1)	H317 – May cause an allergic skin reaction

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:
R22: Harmful if swallowed
R43: May cause sensitisation by skin contact

The environmental hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute Category 1	H400 - Very toxic to aquatic life
Chronic Category 1	H410 - Very toxic to aquatic life with long lasting effects

Human health risk assessment
Provided that the recommended occupational health and safety control measures are being adhered to, under 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

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - Acute toxicity (Category 4): H302 – Harmful if swallowed
  - Skin sensitisation (Category 1): H317 – May cause an allergic skin reaction

Classification of products/mixtures containing the notified polymer should be considered based on the concentration of the notified polymer present.

Health Surveillance

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

(Material) Safety Data Sheet

- The (M)SDS for the notified polymer and products containing the notified polymer should reflect the hazards associated with the notified polymer, as noted above.

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:
  - Automated and enclosed processes, where possible
  - Adequate ventilation

- 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:
  - Avoid contact with skin and eyes

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Imperative gloves
  - Coveralls
  - 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.

Storage

- The handling and storage of the notified polymer should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

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(2) of the Act; if
- the function or use of the polymer has changed from a component of paper treatment products, or is likely to change significantly;
- the amount of polymer being introduced has increased, 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 the products (SC-506 and Pre-Coat) containing the notified polymer provided by the notifier were 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)
Ricoh Australia Pty Ltd (ABN: 30 000 593 171)
8 Rodborough Road
FRENCHS FOREST NSW 2086

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, additives/adjuvants, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints (excluding hydrolysis as a function of pH and partition coefficient).

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Permit No. 805

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
SC-506 (contains 60% notified polymer)
Pre-Coat (contains ≤ 50% notified polymer)

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Pale yellow liquid

Property	Value	Data Source/Justification
Freezing Point	Approximately 0 °C	Introduced as an aqueous solution
Boiling Point	Approximately 100 °C at 101.3 kPa	Introduced as an aqueous solution
Density	1110 kg/m^3 at 25 °C	(M)SDS
Vapour Pressure	Not determined	Expected to be low based on the high molecular weight of the notified polymer
Water Solubility	Not determined	Expected to be water soluble based on its predominately hydrophilic structure, MSDS and use pattern in water

Hydrolysis as a Function of pH	$t_{1/2}$ > 1 year at 25 °C, pH 4 - 9	Measured*
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is not expected to significantly partition to the octanol phase from water given it is expected to be readily soluble in water
Adsorption/Desorption	Not determined	A high value for K_{oc} is expected due to the cationic nature of the notified polymer. The notified polymer is expected to sorb strongly to soil, sediment and sludge
Dissociation Constant	Not determined	The notified polymer is a salt and will be ionised under environmental conditions (pH 4-9)
Flash Point	Not determined	Expected to be high based on the structure of the notified polymer
Flammability	Not determined	Not expected to be flammable. Introduced as an aqueous solution
Autoignition Temperature	Not determined	Not expected to undergo autoignition
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties

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.

Physical hazard classification
Based on the submitted 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 into Australia as a component of a finished product at ≤ 50% concentration in an aqueous solution.

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

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

PORT OF ENTRY
Sydney

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in finished aqueous products in a purpose designed 10 L "cartridge" (plastic bag/bladder inside a cardboard box) fitted with a valve for connection to printer intake port. The products containing the notified polymer will be transported by road from the dockside to the notifier's warehousing facility for storage prior to being distributed to the end–users' facilities.

USE
The notified polymer will be used as a component of paper treatment products for printing applications at ≤ 50% concentration.

OPERATION DESCRIPTION
The notified polymer will be imported as a component of paper treatment products at ≤ 50% concentration, which will be sold to end-users in the same form in which they are imported.

The operators at the end use site will unscrew the valve opening and insert a tube into the cartridge. The solution will be pumped directly from the cartridge into the printer. The solution will be deposited on the print head prior to deposition of ink onto the paper surface and will be air-dried prior to the paper leaving the printer. The product will only be used for commercial scale printing and will not be available to the public.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	0.5-1	12
End-use printing operators	8	200
End-use service technicians	1	200

EXPOSURE DETAILS
Transport and storage workers may come into contact with the notified polymer (≤ 50% concentration) only in the event of accidental rupture of containers.

The printing process at the end-use site will be largely enclosed and automated; however, workers (printing operators and service technicians) may be exposed (dermal and ocular) to the notified polymer at up to 50% concentration during opening of valves and connection of tubes when pumping into printers. Service technicians may come into contact with the notified polymer during printer servicing and maintenance.

Once the paper treatment solution is dried the notified polymer will be strongly absorbed onto the paper matrix and will not be available for exposure.

Dermal and ocular exposure to workers should be mitigated through the use of personal protective equipment (PPE) including coveralls, gloves and goggles. Inhalation exposure is expected to be negligible given the expected low vapour pressure of the notified polymer.

6.1.2. Public Exposure
The paper treatment products containing the notified polymer will only be used for industrial applications and will not be sold to the public. The public may come into contact with the printed paper containing the notified polymer. However once the paper treatment solution is dried the notified polymer will be strongly absorbed onto the paper matrix and will not be available for exposure.

6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on products containing 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 = 500-3334 mg/kg bw; harmful
Mouse, skin sensitisation – Local lymph node assay[#]	evidence of sensitisation
Mutagenicity – bacterial reverse mutation*	non mutagenic

* Test substance was SC-506 (contains 60% notified polymer)
[#] Test substance was Pre-Coat (contains ≤ 50% notified polymer)

Toxicokinetics.
The notified polymer is of high molecular weight (NAMW > 1000 Da), highly charged and water soluble hence it is unlikely to be readily absorbed through the skin or gastrointestinal (GI) tract**.** However, the notified polymer

contains a high percentage of low molecular weight species (< 500 Da), hence absorption cannot be totally ruled out. Given the expected low vapour pressure of the notified polymer, inhalation exposure is not expected.

Acute toxicity.
The test substance containing 60% notified polymer was found to be harmful by the oral route in rats (LD50 > 500 and < 3334 mg/kg bw, equivalent to LD50 > 300 and < 2000 mg notified polymer/kg bw). The toxicity is considered to be caused by the notified polymer as the other components of the test substance are expected to be of low acute toxicity.

There are no acute dermal toxicity studies available for the notified polymer. The notified polymer is not expected to be readily absorbed through the skin based on its high molecular weight.

There are no acute inhalation data available for the notified polymer. The notified polymer is predicted to have a low vapour pressure based on its high molecular weight.

Irritation and sensitisation.
No irritation studies were provided for the notified polymer. The notified polymer contains a structural alert for irritation/corrosion. The notified polymer is predicted to have a low vapour pressure based on its high molecular weight and will not be used in spray applications. Thus, inhalation exposure is not expected.

The test substance containing ≤ 50% notified polymer was found to be a skin sensitiser in a LLNA study. The positive response in the LLNA study is considered to be attributed to the notified polymer as the other components in the test substance are not expected to cause sensitisation. Furthermore, the notified polymer contains a structural alert for sensitisation.

Repeated Dose Toxicity.
No repeated dose toxicity data was provided for the notified polymer.

Mutagenicity/Genotoxicity.
The notified polymer was negative in a bacterial reverse mutation assay.

Health hazard classification
Based on the available information, the notified polymer is 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. The recommended hazard classification is presented in the following table.

Hazard classification	***Hazard statement***
Acute Toxicity (Category 4)	H302 – Harmful if swallowed
Skin sensitisation (Category 1)	H317 - May cause an allergic skin reaction

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):
R22: Harmful if swallowed
R43: May cause sensitisation by skin contact

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer is harmful by the oral route, a skin sensitiser and a potential irritant. Systemic toxicity is not known; however, dermal absorption is expected to be limited.

Printer operators and service technicians will be at risk of irritating and sensitising effects when handling the notified polymer as introduced at up to 50% concentration. However, exposure is expected to be limited by the largely automated and enclosed processes, exhaust ventilation and the expected use of PPE including coveralls, impervious gloves and goggles. Therefore, provided that the stated PPE is used and engineering controls are in place to limit exposure, the risk to the health of workers is not considered to be unreasonable.

6.3.2. Public Health

The public is not expected to be exposed to the notified polymer during application and may only come into contact with printed paper containing the notified polymer. However once the paper treatment solution is dried the notified polymer will be strongly absorbed onto the paper matrix and will not be available for exposure. 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 formulated aqueous products. The products will be in 10 L cartridges fitted with a valve for connection to a printer intake port. The products will be distributed by road to a third-party warehouse where it will be stored until required for delivery to a single end-use facility. There will be no exposure to the environment from manufacture, reformulation or repacking activities as these operations will not take place in Australia. Exposure of the notified polymer to the environment is not expected during transportation except in the event of a spill. Spills are assumed to be contained, collected and disposed to landfill.

RELEASE OF CHEMICAL FROM USE

The products containing the notified polymer will be used for commercial-scale printing and will not be available to the public. At the end-use facility, the products will be pumped directly from the cartridge to the coating rollers of an inkjet printer. The notified polymer will be coated onto the paper prior to deposition of ink onto the pre-treated paper surface. The polymer will be fixed onto the paper surface and will be air-dried before leaving the printer. Release of the notified polymer during use will be limited to leaks and spills which are expected to account for ≤ 0.3% of the total import volume of the notified polymer. Leaks and spills are expected to be collected using a sorbent material and disposed of to landfill. Effluent containing the notified polymer produced during equipment cleaning is expected to be collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues in empty cartridges are expected to account for up to 5% of the total import volume of the notified polymer and these residues are expected to be disposed of to landfill along with the empty containers.

The majority of the notified polymer is expected to be coated on paper and share the fate of used paper which will be either disposed of to land fill or be subjected for paper recycling. It is assumed that 50% of total used paper will be recycled and therefore, 50% of the total import volume of the notified polymer is expected to be released to sewers as a result of paper recycling. Another 50% of the notified polymer will be disposed of to landfill along with the used paper.

7.1.2. Environmental Fate

The hydrolysis study indicated the notified polymer is hydrolytically stable under environmental conditions ($t_{1/2}$ > 1 year at 25°C, pH 4, 7 and 9). The notified polymer is also not expected to be readily biodegradable based on its structure and high molecular weight.

The majority of the notified polymer is expected to strongly sorb to cellulose fibres in paper after application. The printed paper will be either disposed of to landfill or be subjected for paper recycling. It is estimated that approximately 50% of the notified polymer is anticipated to be released to the aquatic environment due to the recycling of paper products containing the notified polymer. During recycling processes, waste paper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks and coatings from the fibres. The notified polymer released from paper pulp during recycling may partition to the aqueous phase, due to the high water solubility of the polymer, and be released to sewers. However, due to the potential for the notified polymer to sorb to sludge, the notified polymer is expected to be efficiently removed during paper recycling and/or the sewage treatment plant (STP) process. Notified polymer that partitions to sludge or sediment is expected to be disposed of to landfill or applied to agricultural soils. Notified polymer that enters surface waters after STP processes is not expected to cross biological membranes due to its high molecular weight and thus it is unlikely to bioaccumulate. The notified polymer is expected to eventually degrade through biotic and abiotic processes to form water, inorganic salts and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

It is assumed that 50% of the notified polymer will be washed into sewers due to paper recycling over 200 days per annum into the effluent volume nationwide, using a conservative scenario supplied by the notifier. Assuming 90% of the notified polymer will be removed during paper recycling, and a further 90% via absorption to sludge in sewage treatment plants (STPs) (Boethling & Nabholz, 1997), the resultant Predicted Environmental Concentration (PEC) in sewage effluent over 1 year for the use of 5000 kg (2500 kg washed into sewers) of the notified polymer nationwide is presented in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	5,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	2,500	kg/year
Days per year where release occurs	200	days/year
Daily chemical release:	12.50	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	99%	**Mitigation**
Daily effluent production:	4,523	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	0.028	µg/L
PEC - Ocean:	0.0028	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 27.36 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified polymer may approximate 0.182 mg/kg in applied soil. This assumes that degradation of the notified polymer occurs in the soil within 1 year from application. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated biosolids application, the concentration of notified polymer in the applied soil in 5 and 10 years may approximate 0.91 mg/kg and 1.82 mg/kg, respectively.

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 polymer 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 0.028 µg/L may potentially result in a soil concentration of approximately 0.184 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 0.921 µg/kg and 1.84 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the product containing 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	LC50 (96 h) = 6.5 mg/L	Toxic to fish
Daphnia Toxicity	EC50 (48 h) = 8.5 mg/L	Toxic to aquatic invertebrates
Algal Toxicity	E_rC50 (72 h) = 0.068 mg/L NOE_rC = 0.010 mg/L	Very toxic to algae

The ecotoxicity effects of the notified polymer on fish, daphnia and algae indicate that the notified polymer is very toxic to algae on an acute basis. Therefore, the notified polymer is formally classified as “Acute Category 1, Very toxic to aquatic life” under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009).

The notified polymer is unlikely to be readily degradable and it is acutely very toxic to aquatic life. On this basis, the notified polymer is formally classified as “Chronic Category 1, Very toxic to aquatic life with long lasting effects” under the GHS.

7.2.1. Predicted No-Effect Concentration

The estimated hazard data for the notified polymer indicates that the most sensitive ecotoxicological endpoint is for algae. The chronic endpoint for algae (NOE_rC = 0.010 mg/L) is therefore selected for the calculation of the Predicted No-Effect Concentration (PNEC). An assessment factor of 100 was used as measured ecotoxicity endpoints were available from three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
NOEC (Alga).	0.01	mg/L
Assessment Factor	100	
PNEC:	0.10	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	0.028	0.1	0.28
Q - Ocean:	0.0028	0.1	0.028

The Risk Quotients (Q = PEC/PNEC) for the worst-case discharge scenario have been calculated to be less than 1 for the river and ocean, indicating that the risk to aquatic organisms is not unreasonable. The notified polymer has the potential to persist in the aquatic compartment however it is not expected to bioaccumulate based on its high molecular weight and high water solubility. On the basis of the value for Q and the assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Hydrolysis as a Function of pH

Method OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	$t_{1/2}$ *(year)*
4	25	> 1
7	25	> 1
9	25	> 1

Remarks Two samples at each pH 4, 7 and 9 were prepared at a concentration of 30 g/L with buffer solutions. The solutions were incubated for 5 days in a water bath at 50 ± 0.5 °C. The hydrolysis rate of was determined to be < 10% for each sample after 5 days, equivalent to $t_{1/2}$ > 1 year at 25 °C at pH 4, 7 and 9 according to the test guideline. Therefore, the test substance is considered hydrolytically stable and no additional testing is required.

Test Facility SCAS (2013)

Partition Coefficient (n-octanol/water) Not determined

Method OECD TG 117 Partition Coefficient (n-octanol/water).

Remarks There was no significant difference in peak area between the sample solution and blank control in the HPLC test. The test substance was presumed by the test author to have a log Pow ≥ 5.7 as no test substance eluted from the column. However, the test substance is a cationic polymer that is expected to bind to the stationary phase efficiently. The interaction of the test substance with the stationary phase of the column may have resulted in a longer retention time and higher log Pow. The actual log Pow of the test substance is expected to be much lower than 5.7 as the test substance is readily soluble in water.

Test Facility SCAS (2013)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	SC-506 (contains 60% notified polymer)
METHOD	OECD TG 420 Acute Oral Toxicity - Fixed Dose Method Method B1 *bis* Acute Toxicity (oral) of Commission Regulation (EC) No. 440/2008
Species/Strain	Rat/Wistar
Vehicle	Distilled water
Remarks - Method	Doses were adjusted for the concentration of the notified polymer.

RESULTS

Sighting Study

Dose mg/kg bw	*Administered*	*Evident Toxicity*	*Mortality*
500 (contains 300 mg notified polymer)	1	no	0
3334 (contains 2000 mg notified polymer)	1	yes	1

Signs of Toxicity	Hunched posture, ataxia, lethargy, prostration, decreased respiratory rate, laboured respiration, hypothermia, pallor of the extremities, emaciation and loss of righting reflex were observed at a dose level of 3334 mg/kg bw. This animal was killed for humane reasons 4 hours after dosing.
Effects in Organs	Pale kidneys, coloured liquid present and raised limiting ridge in the stomach were noted in the animal dosed at 3334 mg/kg bw.

Main Study

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	4 female	500 (contains 300 mg notified polymer)	0/4

Discriminating Dose	The discriminating dose could not be determined. However, the LD50 was determined by the study authors to be between 500 and 3334 mg/kg bw (equivalent to 300-2000 mg/kg bw for notified polymer).
Signs of Toxicity	No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	All animals dosed at 500 mg/kg bw showed expected bodyweight gains.
CONCLUSION	The notified polymer is harmful via the oral route.
TEST FACILITY	Harlan (2012a)

B.2. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Pre-Coat (contains ≤ 50% notified polymer)
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay Method B42 Skin Sensitidation (Local Lymph Node Assay) of Commission Regulation (EC) No. 440/2008
Species/Strain	Mouse/CBA/CaOlaHsd
Vehicle	Ethanol/distilled water (7:3)
Remarks - Method	A screening study was conducted at 100% concentration with a mouse treated daily for three consecutive days. The animal was observed twice daily for the first three days and once daily on days 4, 5 and 6. Ear

thickness measurements were taken pre-dose on day 1 and post-dose on day 3 and 6. The main study was conducted at 25%, 50% or 100% concentration (4/concentration).

A concurrent positive control was not conducted. The result of a positive control study with α-hexylcinnamaldehyde, conducted by the laboratory 2-3 weeks prior to the main study, was provided. The Stimulation Index was 13.53.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	559.58	-
25	1850.51	3.31
50	10702.32	19.13
100	10320.74	18.44

Remarks - Results

In the screening study with 100% test substance, no signs of systemic toxicity, visual local skin irritation or irritation from an increase in ear thickness equal to or greater than 25% were observed. The increase in ear thickness from day 1 to day 6 was 6.3%.

In the main study, there was one death in the group treated at 100% concentration. No signs of systemic toxicity were noted in other test animals or control animals during the test. Body weights were similar in treated and control groups.

CONCLUSION

There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the test substance.

TEST FACILITY

Harlan (2012b)

B.3. Genotoxicity – bacteria

TEST SUBSTANCE

SC-506 (contains 60% notified polymer)

METHOD

OECD TG 471 Bacterial Reverse Mutation Test
Method B13/14 of Commission Regulation (EC) No. 440/2008
Plate incorporation procedure/Pre incubation procedure

Species/Strain

S. typhimurium: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA

Metabolic Activation System

S9 preparation

Concentration Range in Main Test

a) With metabolic activation: 0, 50, 150, 500, 1500, 5000 µg/plate
b) Without metabolic activation: 0, 50, 150, 500, 1500, 5000 µg/plate

Vehicle

Sterile distilled water

Remarks - Method

Doses were adjusted for the concentration of the notified polymer. Test 1 was carried out by the plate incorporation method and test 2 by the pre incubation method.

RESULTS

Metabolic Activation	*Notified Polymer Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test	> 5000	> 5000	> 5000	negative
Present				

Test	> 5000	> 5000	> 5000	negative

Remarks - Results	The test substance caused no visible reduction in the growth of the bacterial background lawn at any dose level and was, therefore, tested up to the maximum recommended dose level of 5000 µg/plate. No test substance precipitate was observed on the plates at any of the doses tested in either the presence or absence of S9-mix. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, at any dose level either with or without metabolic activation or exposure method. The vehicle (sterile distilled water) control plates gave counts of revertant colonies within the normal range. All of the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies, both with or without metabolic activation, thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.
CONCLUSION	The test substance was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Harlan (2012c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	SC-506 (contains 60% notified polymer)
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi-static.
Species	*Oncorhynchus mykiss*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	140 mg $CaCO_3$/L
Analytical Monitoring	An electrospray mass spectrometer using an external standard
Remarks – Method	Following a preliminary rang-finding test, seven fish were exposed to test media at 13 – 14 °C under semi-static test conditions. The test media were renewed daily. Samples were taken from the control and all surviving test groups at 0 and 72 hours (fresh media) and at 24 and 96 hours (old media) for quantitative analysis. The numbers of mortality and any sub-lethal effects of fish in each test and control were recorded at 3 and 6 hours after the start of exposure and then daily throughout the test. The study was performed in compliance with Good Laboratory Practice (GLP) standards and the test was conducted in accordance with the test guideline above. No significant deviation from the protocol was reported.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*				
Nominal	*Actual*		*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	-	7	0	0	0	0	0
1.0	-	7	0	0	0	0	0
1.8	2.1	7	0	0	0	0	0
3.2	3.5	7	0	0	14	14	14
5.6	6.1	7	0	0	29	43	43
10	11	7	0	14	86	86	86

LC50	6.5 mg/L at 96 hours (95% confidence limits: 4.6 - 10 mg/L).
NOEC	2.1 mg/L at 96 hours.
Remarks – Results	Based on the average measured concentration of the test media, the highest test concentration resulting in 0% mortality was determined to be 2.1 mg/L. The lowest test concentration resulting in 100% mortality was greater than 11 mg/L. No sub-lethal effects of test fish were observed during the test. All validity criteria for the test are satisfied.
CONCLUSION	The test substance is toxic to fish.
TEST FACILITY	Harlan (2013a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	SC-506 (contains 60% notified polymer)
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test and Reproduction Test - Static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	An electrospray mass spectrometer using an external standard
Remarks - Method	Following a preliminary range-finding test, twenty daphnids (4 replicates of 5) were exposed to test media at 20 – 21 °C under static test conditions. Samples were taken from the control and each test group at 0 and 48 hours for quantitative analysis. The study was performed in compliance with Good Laboratory Practice (GLP) standards and the test was conducted in accordance with the test guideline above. No significant deviation from the protocol was reported.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	< limit of Quantitation (LOQ)	20	0	0
1.0	0.76	20	0	0
3.2	2.94	20	0	0
10	9.58	20	2	13
32	31.7	20	10	20
100	96.2	20	14	20

EC50	8.5 mg/L at 48 hours (95% confidence limits: 6.6 - 11 mg/L)
NOEC	3.2 mg/L at 48 hours
Remarks - Results	The measured concentrations of the test substance in each test medium were determined to be 92 - 100% of the nominal concentration. Therefore, it was considered justifiable to calculate the EC50 values in terms of the nominal test concentrations. All validity criteria for the test are satisfied.

CONCLUSION The test substance is toxic to aquatic invertebrates

TEST FACILITY Harlan (2013b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE SC-506 (contains 60% notified polymer)

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: Control, 0.010, 0.032, 0.10, 0.32 and 1.0 mg/L Actual: < LOQ, < LOQ, < LOQ, < LOQ, 0.178 and 0.851 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	An electrospray mass spectrometer using an external standard
Remarks - Method	Following a preliminary rang-finding test, algae was exposed to test media with constant illumination and shaking at 24 ± 1 °C. Samples of the algal population were removed daily and cell concentration was determined for each control and treatment group. Samples were taken from the control and each test group at 0 and 72 hours for quantitative analysis. The study was performed in compliance with Good Laboratory Practice (GLP) standards and the test was conducted in accordance with the test

guideline above. No significant deviation from the protocol was reported.

RESULTS

Biomass		*Growth*	
E_bC50	*NOE_bC*	*E_rC50*	*NOE_rC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
0.025	0.010	0.068	0.010
95% confidence limit: 0.023 - 0.027		95% confidence limit: 0.053 – 0.086	

Remarks - Results

The measured concentrations were variable and were not close to the nominal concentrations, which was inconsistent with the results obtained in the fish and daphnia tests. This may be due to the test substance binding to any receptive surfaces. Given the test substance was known to be stable, it was considered justifiable that the algae were exposed to near nominal concentrations throughout the duration of the test. Therefore, the EC50 values were calculated in terms of the nominal test concentrations.

All validity criteria for the test are satisfied.

CONCLUSION

The test substance is very toxic to algae.

TEST FACILITY

Harlan (2013c)

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