File No: LTD/1520

October 2011

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Sartomer CN-294E

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 Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Full 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

TABLE OF CONTENTS

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/1520	International Sales & Marketing Pty Ltd, Flint Group Pty Ltd and DIC Australia Pty Ltd	Polymer in Sartomer CN-294E	Yes	≤20 tonnes per annum	An additive in UV/EB cured ink products for flexographic and lithographic printing

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the data provided for analogue chemicals, the notified polymer should be considered as though it is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:

R36/38: Irritating to eyes and skin.
R43: May cause sensitisation by skin contact.

and

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

	Hazard category	*Hazard statement*
Eye irritation	2	Causes eye irritation
Skin irritation	2	Causes skin irritation
Skin sensitisation	1A	May cause sensitisation by skin contact
Aquatic toxicity	Acute category 1	Very toxic to aquatic life
	Chronic category 1	Very toxic to aquatic life with long lasting effects

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

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the assessed use pattern, the notified polymer is not considered to pose an unacceptable risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Safe Work Australia should consider the following health hazard classification for the notified polymer:
  - R36/38: Irritating to eyes and skin
  - R43: May cause sensitisation by skin contact.

- The following risk phrases are recommended in the workplace on products/mixtures containing the notified polymer:
  - Concentration ≥ 20% : R36/R38, R43
  - ≥1% Concentration < 20% : R43

Health Surveillance

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

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced in ink products:
  - Local exhaust ventilation should be in place during all operations involving handling of the notified polymer.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced in ink products:
  - Avoid contact with eyes and skin.
  - Do not inhale fumes/vapours.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure during handling of ink products containing at up to 80% of the notified polymer, particularly during manual replacement of ink bottles, cleaning of ink residuals, servicing the printing machine, and cleaning printing equipment:
  - Gloves
  - Safety glasses
  - Protective clothing
  - Respiratory protection (particularly during heating ink products containing notified polymer)

  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 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 chemical 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 as an additive in UV/EB cured ink products for flexographic and lithographic printing, or is likely to change significantly;
- the amount of polymer being introduced has increased from 20 tonnes/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 a 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.

FULL PUBLIC REPORT

Polymer in Sartomer CN-294E

1. APPLICANT AND NOTIFICATION DETAILS ALL

APPLICANT(S)
International Sales & Marketing (ABN: 36 467 259 314)
260-262 Highett Road
Highett VIC 3190

Flint Group Pty Ltd (ABN: 79 006 659 178)
25-51 Berends Drive,
Dandenong South VIC 3175

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, CAS number, Molecular and structural formulae, Molecular weight, Analytical data, Degree of purity, Polymer constituents, Residual monomers, Impurities, Use details, Import volume, and Analogue details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting point, Boiling point, Vapour pressure, Water solubility, Hydrolysis as a function of pH, Partition coefficient, Dissociation constant, Flash point, Flammability limits

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL ALL

MARKETING NAME(S)
Polymer in Sartomer CN-294E (product containing the notified polymer at up to 80%)

OTHER NAME(S)
Acrylated polyester oligomer
Polyester acrylate

MOLECULAR WEIGHT
Mn Value >1000 Da

ANALYTICAL DATA
Reference IR spectra was provided.

3. COMPOSITION

DEGREE OF PURITY >75%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
The notified polymer contains a hazardous impurity classified by the notifier as R41 (Risk of serious eye damage), that is present above the concentration cut-off.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

ADDITIVES/ADJUVANTS None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
As the notified polymer is in a liquid form, all of the residual monomer content is available for release.

DEGRADATION PRODUCTS
Degradation products are not expected.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Clear liquid

Property	Value	Data Source/Justification*
Melting Point/Freezing Point	<20°C	Estimated
Boiling Point	593°C at 101.3 kPa	Estimated for analogue
Density	1140 kg/m^3 at 25°C	MSDS for the product
Vapour Pressure	8.6 x 10^{-12} kPa at 25°C.	Estimated for analogue
Water Solubility	14.62 × 10^{-3} g/L at 20°C	Calculated for an analogue using WSKOW v1.41; US EPA (2009)
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable groups, however is expected to be hydrolytically stable due to its anticipated limited water solubility.
Partition Coefficient (n-octanol/water)	log Pow = 3.75	Calculated for an analogue using KOWWIN v1.67; US EPA (2009)
Adsorption/Desorption	log K_{oc} = 2.78	Calculated for an analogue using KOCWIN v2.00; US EPA (2009)
Dissociation Constant	Not determined	The notified polymer has no dissociable functions
Particle Size	Not estimated	The ink product containing the notified polymer is in liquid form.
Flash Point	93°C at 101 kPa	MSDS for the product
Flammability	Not determined	Not expected to be flammable, based on flash point
Autoignition Temperature	Not determined	Not expected to undergo autoignition
Explosive Properties	Not determined	Not expected to be explosive, based on chemical structure

*There are no physico-chemical data available for the notified polymer. The US EPA EPI Suite model could not be used to estimate physico-chemical properties for the notified polymer, as the notified polymer falls outside of the domain of applicability for most of these parameters. Therefore, estimated physico-chemical properties for an analogue (Analogue 1) were used.

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

Reactivity
Stable under normal conditions. High temperatures, inhibitor depletion, accidental impurities, or exposure to radiation or oxidising agents may cause spontaneous polymerizing reaction generating heat/pressure. Closed containers may rupture or explode during runaway polymerization.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table, the notified polymer is not classified as hazardous 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 as a component (up to 80%) of finished ink products.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	20	20	20	20	20

PORT OF ENTRY
Sydney or Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
International Sales & Marketing
Flint Group Pty Ltd

TRANSPORTATION AND PACKAGING
Finished inks (containing up to 80% of the notified polymer) will be imported in 5 kg bottles or 10 kg plastic buckets (flexographic and lithographic inks) and will be transported from port of entry to notifiers' warehouse facilities by road.

USE
Additive in UV/EB cured ink products for flexographic and lithographic printing.

OPERATION DESCRIPTION
Finished ink products containing the notified polymer (at up to 80%) will not be manufactured in Australia and will be imported for direct shipping to the notifiers. Inks will not be reformulated, but will be colour matched into the finished ink products at the notifier's site.

Although printing processes are essentially automated, some parts of the printing processes do require manual assistance. Ink bottles are manually connected to the printing machine via an inlet and attached to a flexible tube which supplies the ink head. Separate ink bottles are provided for each of the required colours for printing. Inks are automatically injected into printing machines.

While printers are running, printer operators monitor the operation and keep the substrate (eg vinyl, paper) feeders stocked and attend to substrate jams. Any residual ink within printing equipment will be wiped clean using rags and solvents. Cleaning rags and 'dirty solvents' are normally disposed of by the printing company through licensed waste disposal contractors. Exhaust ventilation is fitted to commercial machines to remove solvent and any other airborne ink components. After printing, the notified polymer will be fixed (UV or EB-cured) with other ink ingredients onto the substrate matrix.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

NUMBER AND 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	30 min to 6 hours/day	25 (max)
Printer operators	> 1000	1-2	25 (max)
Service technicians	200	8	200
Wholesale printer supplies	> 1000	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 essentially automated, workers can be exposed to ink products during certain

parts of the process.

Dermal exposure is possible when ink bottles are manually connected to the printing machine via an inlet and attached to a flexible tube, which supplies the ink head. From ink bottles, inks are automatically injected into printing machines.

As the printing processes (flexographic and lithographic) are mainly automated, printer operators are not expected to be exposed to the notified polymer significantly. Dermal and ocular exposure is possible during the replacement of ink bottles (manual process) and may also occur for short durations during the colour matching process (ie ink handling procedures). However, exposure will be minimised by the use of local exhaust ventilation and also by wearing gloves and goggles. Inhalation exposure will be limited due to the low vapour pressure of the notified polymer and also by the employment of local exhaust ventilation in areas surrounding printing machines.

Dermal and ocular exposure is also possible to trained technicians/chemists from testing of liquid ink products (containing up to 80% of notified polymer) and also from undertaking ink quality control operations such as viscosity checking. Due to small sampling size (20 mL) and the use of PPE such as overalls, gloves and goggles by workers, dermal and ocular exposure is expected to be limited.

Dermal and ocular exposure is also possible 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. Any exposure to service technicians will be minimized by the expected use of PPE and also by the use of exhaust ventilation, which is fitted to commercial machines to remove solvent and any other airborne ink components.

Dermal, ocular, and inhalation exposure is also possible to workers cleaning equipments during and after use. However, as cleaning workers will wear overalls, goggles, and gloves and respirator/dust mask to prevent exposure to notified polymer and solvent cleaning products, exposure is expected to be limited.

After printing, the notified polymer will be fixed (UV or EB 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 and ink products containing the notified polymer are only for use in industrial situations and will not be sold to general public. Therefore, the general public will not be exposed to the notified polymer as such. However, the general public may come in contact with the printed substrates containing the notified polymer. The notified polymer, once released onto the substrate, is cured on the substrate and is expected to remain bound to the substrate print matrix and will not be bioavailable for exposure. Thus, exposure to the general public, when handling products containing the notified polymer, is expected to be low.

6.2. Human Health Effects Assessment

No toxicological data were submitted on the notified polymer. The notified polymer is not expected to be significantly absorbed from the gastrointestinal or respiratory tract, or via the skin, due to its high molecular weight (>1,000 Da), and expected low water solubility.

As the notified polymer contains an acrylate functional group, which is considered to be of high concern, the notified polymer is likely to cause skin and eye irritation (HSIS, 2007; TSCA, 2002), and skin sensitisation (TSCA, 2002; Barratt, 1994). Analogue data submitted by the notifier on acrylate and methacrylate group, summarised in the table below, support these conclusions. In addition, the notified polymer, based on the results from analogue chemicals, is likely to be of low acute oral, dermal and inhalation toxicity, and not mutagenic or genotoxic.

Endpoint	*Result and Conclusion*				
	Analogue 2	Analogue 3	Analogue 4	Analogue 5	Analogue 6
Rat, acute oral toxicity	LD50 >5000 mg/kg bw; low toxicity	LD50 >3000 mg/kg bw; low toxicity	LD50 >9000 mg/kg bw; low toxicity	LD50 >5000 mg/kg bw; low toxicity	LD50 >8000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 7500 mg/kg bw; low toxicity	LD50 > 1500 mg/kg bw; low toxicity	LD50 >5000 mg/kg bw; low toxicity	LD50 > 5000 mg/kg bw; low toxicity	LD50 > 2500 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	LC50 >1.4 mg/L/8 hour;	LC50 >10.3 mg/L/4 hour;	LC50 >30 mg/L/4 hour;	Not available	Not available
Rabbit, skin irritation	severely irritating	Not available	moderate irritating	slightly irritating	Not available
Rabbit, eye irritation	irritating	Not available	moderate irritating	slightly irritating	Not available
Guinea pig, skin sensitisation	evidence of sensitisation	Not available	evidence of sensitisation	no evidence of sensitisation	evidence of sensitisation
Mouse, skin sensitisation – Local lymph node assay	evidence of sensitisation	weak sensitiser	evidence of sensitisation	Not available	Not available
Rat, repeat dose <Inhalation> toxicity – 90 days.	NOAEL = 23 mg/kg bw/day. LOAEL = 0.225 mg/L (68 mg/kg bw/day)	NOAEL = 84 (male) and 111 (female) mg/kg bw/day	Not available	Not available	Not available
Mutagenicity – bacterial reverse mutation	non mutagenic	non mutagenic	non mutagenic	non mutagenic	-
Genotoxicity – in vitro <Mammalian Chromosomal Aberration test>	non genotoxic	Not available	Not available	Not available	Not available
Genotoxicity – in vivo <in vivo cytogenetic assay-clastogenicity>	non genotoxic	Not available	Not available	Not available	Not available
Carcinogenicity	evidence of carcinogenicity through dermal route (>21%)	no evidence of carcinogenicty	no evidence of carcinogenicty	no evidence of carcinogenicty	-

Health hazard classification
Based on the data provided for analogue chemicals, the notified polymer should be considered as though it is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:

R36/38: Irritating to eyes and skin.
R43: May cause sensitisation by skin contact.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The primary risk to workers from exposure to the notified polymer is skin and eye irritation, and skin sensitisation, based on the presence of an acrylate functional group.

The notified polymer has a relatively low vapour pressure and high molecular weight and therefore, risk of inhalation exposure is considered to be limited. However, where processes involve heating of ink products containing the notified polymer, respiratory protection should be employed to protect against possible irritation from inhalation of fumes/vapours.

Workers will be at risk most when ink bottles are manually connected to the printing machine via an inlet and attached to a flexible tube, ink bottles are manually replaced, during colour matching process (ie ink handling procedures), and during cleaning of ink residuals. However, the risk will be minimised by the use of local exhaust ventilation and also by wearing gloves and goggles. Inhalation exposure will be limited due to the low vapour pressure of the notified polymer and also by the employment of local exhaust ventilation in areas surrounding printing machines.

The risk of exposure to trained technicians/chemists will be limited due to small sampling size and the use of PPE such as overalls, gloves and goggles. Similar is the case with service technicians and workers involved in cleaning equipments. In addition, the use of exhaust ventilation, fitted on commercial machines, will limit any chance of exposure to the notified polymer, solvent and any other airborne ink components. Furthermore, workers involved in cleaning equipment will also use respirator/dust mask to minimise any inhalation exposure to the notified polymer.

As the notified polymer will be fixed along with other ink ingredients onto the substrate matrix and there is very limited potential for the release or bioavailability of the notified polymer, the notified polymer does not pose an unreasonable risk to workers handling printed material.

Therefore, based on the use of engineering controls, safe work practices and PPE, the risk to workers from using the product containing the notified polymer is not considered to be unreasonable.

6.3.2. Public Health
The ink products containing the notified polymer at up to 80% 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 as a component of industrial printing inks. As manufacturing and reformulation will take place overseas, no release of the notified polymer will occur in Australia from these activities. Spills are expected to be collected using inert solids and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
The majority of the release of the notified polymer to the environment from use will be from ink spills, wash-downs of printing equipment and from disposal of residual ink in empty containers. The notified polymer is likely to be stable within an inert matrix on printed substrate once UV-cured. A maximum of 3% of ink was estimated by the notifier to be released to sewer due to the washing of printing equipment and ink colour matching.

RELEASE OF CHEMICAL FROM DISPOSAL
The majority of the notified polymer will be used in inks for printing on vinyl, canvas and plastic packaging and is anticipated to share the fate of the printed articles which are expected to be disposed of to landfill. A minor amount of ink containing notified polymer (up to 20%) will be used for paper printing. Of the 20% notified polymer applied to paper, half of this amount is expected to be recycled. Residues in empty containers will comprise up to 1% of annual ink import volume and are expected to be disposed of to landfill. Formulated ink products will not be released directly to the environment. Hence, the total import volume of the notified polymer will predominately be disposed of to landfill with a minor amount potentially reaching the sewer.

7.1.2. Environmental Fate

No data for the environmental fate of the notified polymer were submitted. Notified polymer applied to substrates will be cured and is not expected to be bioavailable. The majority of notified polymer is expected to be disposed of to landfill where it will degrade by biotic and abiotic processes to form water and oxides of carbon and nitrogen.

Approximately half of the paper to which the ink containing the notified polymer is applied to will 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. Very little of the notified polymer is expected to partition to the supernatant water which is released to the sewer. Additionally, up to 90% of notified polymer released to sewer during the recycling process is anticipated to sorb to sludge and sediment (Boethling & Nabholz 1997) where it is also expected to degrade biotically and abiotically.

7.1.3. Predicted Environmental Concentration (PEC)

Some of the notified polymer will be applied to paper and will reach the aquatic compartment due to paper recycling. However, it is expected that this fraction of polymer will be cured on exposure to UV light and will therefore not be bioavailable. Aquatic PECs (ocean and river) have been calculated assuming that 3% of notified polymer will reach the aquatic compartment due to equipment washing and ink colour matching. It was assumed that 90% of the notified polymer would adsorb to sludge in STPs (Boethling & Nabholz 1997) and release of the notified polymer occurring over 260 days per annum corresponding to release only on working days.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	20,000	kg/year
Proportion expected to be released to sewer	3%	
Annual quantity of chemical released to sewer	600	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	2.31	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	90%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.055	µg/L
PEC - Ocean:	0.005	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 4.907 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 0.033 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 0.165 mg/kg and 0.33 mg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on an analogue (Analogue 7), which contains the same reactive functional groups as the notified polymer are summarised in the table below. Details of these studies can be found in Appendix A.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) = 0.67 mg/L	Very toxic to fish
Daphnia Toxicity – Acute	EC50 (48 h) = 0.40 mg/L	Very toxic to aquatic invertebrates
Daphnia Toxicity – Chronic (reproduction)	Study 1: LOEC (21 d) = 0.13 mg/ L NOEC (21 d) < 0.13 mg/L	At least toxic to aquatic invertebrates with long lasting effects
	Study 2: NOEC (14 d) = 0.51 mg/L	Toxic to aquatic invertebrates with long lasting effects
Algal Toxicity	E_rC_{50} (96 h) = 2.13 mg/L	Toxic to algae
	NOEC (96 h) = 1.70 mg/L	Not classified for long-term hazard

Based on the ecotoxicity results on an analogue of the notified polymer, under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009), the notified polymer is considered to be toxic to algae and acutely very toxic to fish and aquatic invertebrates. As there was adequate chronic data for the two trophic levels for the analogue of the notified polymer, the most sensitive NOEC was applied. Therefore since it is unknown if the notified polymer is readily biodegradable and based on the analogue's acute and chronic ecotoxicity endpoints, the notified polymer is classified as toxic to aquatic invertebrates with long lasting effects.

7.2.1. Predicted No-Effect Concentration

The lowest endpoint from ecotoxicological studies of an analogue to the notified polymer was used to calculate the PNEC. An assessment factor of 500 was used as ecotoxicity results for three acute trophic endpoints and two chronic endpoints were available for an analogue which has the same reactive groups but different structural backbone to the notified polymer and is therefore not considered an entirely representative analogue with respect to biodegradability.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
NOEC (Daphnia Chronic)	< 0.13	mg/L
Assessment Factor	500	
PNEC:	< 0.26	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.055	0.26	0.210
Q - Ocean	0.005	0.26	0.021

The risk quotient (Q = PEC/PNEC) for aquatic exposure is calculated to be < 1 based on the above calculated PEC and PNEC values. This is considered to be an upper limit as uncured notified polymer is expected to polymerise if exposed to UV light and cured notified polymer is not expected to be bioavailable. The Q value of < 1 indicates the notified polymer is not expected to pose an unreasonable risk to the aquatic environment based on its assessed use pattern.

APPENDIX A: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

A.1. Environmental Fate

A.1.1 Ready biodegradability

TEST SUBSTANCE	Analogue 8
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Unknown
Exposure Period	28 days
Auxiliary Solvent	Unknown
Analytical Monitoring	Unknown
Remarks - Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified polymer.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
5	72	5	56
15	100	15	74
28	100	28	>83

Remarks - Results	The reference substance was degraded > 60% by day 14, indicating a valid test. Since the raw data were not available, it was not possible to determine if the other validity criteria were satisfied. However, the authors of the summary considered the study to be valid without restriction and we therefore consider that the test was valid. Although the analogue has common reactive functional groups to the notified polymer, it differs in its backbone structure and is therefore not considered an entirely representative analogue with respect to biodegradability.
CONCLUSION	The test substance is considered to be readily biodegradable. The notified polymer differed in structure to the test substance and therefore could not be inferred as being readily biodegradable.
TEST FACILITY	Exempt Information

A.2. Ecotoxicological Investigations

A.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue 7
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Flow Through
Species	*Pimephales promelas* (fathead minnow)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	186-187 mg $CaCO_3$/L
Analytical Monitoring	GC/MS
Remarks – Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified polymer. Standard protocol guidelines were followed with no

significant deviations reported. The LC50 and NOEC were determined using the trimmed Spearman-Karber method and TOXSTAT, respectively.

RESULTS

Concentration mg/L			*Mortality*					
Nominal	*Mean Measured*	*Number of Fish*	*3 h*	*6h*	*24 h*	*48 h*	*72 h*	*96 h*
0	NC	20	0	0	0	0	0	0
0.35	0.09	20	0	0	0	0	0	0
0.62	0.15	20	0	0	0	0	0	0
1.12	0.34	20	0	0	0	1	1	1
2.01	0.82	20	0	0	0	7	13	13
3.45	1.75	20	0	0	1	20	20	20

NC = not calculated. All measurements of the control sample were < 0.04 mg/L, which was the detection limit of the analytical method.

LC50	0.67 mg/L at 96 hours (based on mean measured test concentrations)
NOEC	0.34 mg/L at 96 hours (based on mean measured test concentrations)
Remarks – Results	All validation criteria for the study were satisfied except that the mean measured concentrations of the test substance were 26-50% of the nominal concentrations. The measured concentrations should preferably be at least 80% of the nominal concentrations. In accordance with test guidelines, the measured concentrations were used to determine the study endpoints.

CONCLUSION The test substance, and by inference the notified polymer, is considered to be very toxic to fish (GHS Acute Category 1)

TEST FACILITY Exempt Information

A.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Analogue 7

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	193 - 197 mg $CaCO_3$/L
Analytical Monitoring	Conducted with an unknown method
Remarks - Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified polymer. Standard protocol guidelines were followed with no significant deviations reported.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual**		*24 h*	*48 h*
0	<0.04	20	0	0
0.5	0.24	20	0	5
1.0	0.53	20	2	13
2.0	1.21	20	5	20
4.0	2.78	20	15	20
8.0	7.40	20	20	20

*Mean of the 0, 24 and 48 h concentrations

EC50	0.40 mg/L at 48 hours (based on mean of 0, 24 and 48 h concentrations)
NOEC	< 0.24 mg/L at 48 hours
Remarks - Results	All validation criteria for the study were satisfied.

CONCLUSION The test substance, and by inference the notified polymer, is considered to be very toxic to invertebrates (GHS Acute Category 1)

TEST FACILITY Exempt Information

A.2.3. Chronic toxicity to aquatic invertebrates (Study 1)

TEST SUBSTANCE Analogue 7

METHOD OECD TG 202 part 2 "*Daphnia sp.*, Reproduction Test" – Semi Static (1993)

Species	*Daphnia magna*
Exposure Period	21 d
Auxiliary Solvent	None
Water Hardness	127 - 170 mg $CaCO_3$ /L
Analytical Monitoring	Solid/liquid extraction GC/MS
Remarks - Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified polymer. The EC50 (immobilisation) was determined using the trimmed Spearman-Karber method and the EC50 (reproduction)*, was determined using a point estimation technique.

*50% inhibition of the mean number of young produced per female compared to the control organism reproduction

RESULTS

Test Day 21			
Concentration (mg/L)		*Cumulative Percentage Immobilised* [a]	*Mean Number of Offspring Released per original female* [d]
Nominal	*Actual* [b]		
0	0	5	162.6
0.25	0.13	5	133.6
0.5	0.29	5	138.6
1	0.51	8	138.4
2	1.06	10	74.9
4	2.40	90[c]	< 1

[a] N=40
[b] Based on measured mean for Day 3, 16 and 21.
[c] Value significantly different from the control value at $p \leq 0.05$
[d] Calculated from N=30. First brood released on day 7.

EC50 (immobilisation)	1.61 mg/L [e]
EC50 (reproduction)	1.02 mg/L [e]
NOEC (immobilisation)	1.06 mg/L [e]
NOEC (reproduction)	< 0.13 mg/L [e]

[e] At 21 d, based on mean measured concentrations

Remarks - Results All validation criteria for the study were satisfied. A reproduction NOEC was not calculated. Therefore based on the LOEC of 0.13 mg/L the NOEC was determined to be < 0.13 mg/L and hence indicates that the test substance, and by inference the notified polymer, should be categorised as at least toxic to aquatic invertebrates with long lasting effects, given the uncertainty of its biodegradability rate. Based on the NOEC result for immobilisation, the test substance, and therefore the notified polymer, cannot be classified for long-term hazard.

CONCLUSION	The test substance, and by inference the notified chemical, is considered to be at least toxic to aquatic invertebrates with long lasting effects (GHS Chronic Category 2 as the ready degradability of the notified polymer is unknown)
TEST FACILITY	Exempt Information

A.2.4. Chronic toxicity to aquatic invertebrates (Study 2)

TEST SUBSTANCE	Analogue 7
METHOD	OECD TG 202 part 2 "*Daphnia sp.*, Reproduction Test" – Semi Static (1993)
Species	*Daphnia magna*
Exposure Period	14 d
Auxiliary Solvent	None
Water Hardness	128 - 169 mg $CaCO_3$ /L
Analytical Monitoring	Solid/liquid extraction GC/MS
Remarks - Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified polymer. The EC50 (immobilisation) was determined using the trimmed Spearman-Karber method. The EC50 (reproduction)[*], was determined using a point estimation technique.

[*]50% inhibition of the mean number of young produced per female compared to the control organism reproduction

RESULTS

Test Day 14			
Concentration (mg/L)		*Cumulative Percentage Immobilised* [a]	*Mean Number of Live Young Released per original female*[d]
Nominal	*Actual*[b]		
0	0	3	66.9
0.25	0.11	5	43.2
0.5	0.28	8	52.6
1	0.51	0	59.3
2	1.09	3	28.0
4	2.50	68[c]	<1

[a] N=40
[b] Mean values from Day 2 initial and Day 3 final measurements.
[c] Value significantly different from the control value at $p \leq 0.05$
[d] Calculated from N=30. First brood released on day 7.

EC50 (immobilisation)	1.99 mg/L [e]
EC50 (reproduction)	0.97 mg/L [e]
NOEC (immobilisation)	1.09 mg/L [e]
NOEC (reproduction)	0.51 mg/L [e]

[e] At 14 d, based on mean measured concentrations

Remarks - Results	All validation criteria for the study were satisfied.
CONCLUSION	The test substance, and by inference the notified polymer, is considered to be toxic to aquatic invertebrates with long lasting effects (GHS Chronic Category 2 as the ready degradability of the notified polymer is unknown)
TEST FACILITY	Exempt Information

A.2.5. Algal growth inhibition test

TEST SUBSTANCE	Analogue 7

METHOD	OECD TG 201 Alga, Growth Inhibition Test - Static
Species	*Pseudokirchneriella subcapitata*
Exposure Period	96 hours
Concentration Range	Nominal: 0.0, 0.7, 1.3, 2.7, 5.3 and 10.6 mg/L Actual: < 0.04, 1.13, 1.70, 2.66, 5.22 and 9.39 mg/L
Auxiliary Solvent	None
Water Hardness	Unknown
Analytical Monitoring	GC/MS
Remarks - Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified polymer.

RESULTS

E_rC_{50} *mg/L at 96 h*	*NOEC* *mg/L at 96 h*
2.13	1.70

Remarks - Results	The increase in the mean algal biomass in the inoculum control within 72 hours was a factor of 7.4 which is less than the minimum 16 fold factor required by the test guideline. The lower than expected growth rate was thought to be due to the use of vessels which did not allow air exchange or introduction of ambient CO_2, which are both essential for algal propagation. Based on the dose response of algal growth inhibition this study was considered valid.
CONCLUSION	The test substance, and by inference the notified polymer, is acutely toxic to algae (GHS Acute Category 2) and not classified for long-term hazard
TEST FACILITY	Exempt Information

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