File No: STD/1366

March 2011

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

SR494

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

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1. APPLICANT AND NOTIFICATION DETAILS

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

DIC Australia Pty Limited (ABN: 12 000 079 550)
42 Sunmore Close,
Heatherton, VIC 3202

NOTIFICATION CATEGORY
Standard: Synthetic Polymer with Mn < 1000 Da (more than 1 tonne per year).

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, polymer constituents, residual monomers/impurities, 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: melting point, boiling point, vapour pressure, water solubility, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, flash point, flammability, autoignition temperature, acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, skin irritation, eye irritation, skin sensitisation, repeated dose toxicity, induction of point mutations, induction of germ cell damage, chromosome damage, acute toxicity fish, acute immobilisation/reproduction Daphnia sp., algal growth inhibition, bioaccumulation and biodegradation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sartomer SR494

OTHER NAME(S)
Alkoxylated pentaerythritol tetraacrylate

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

The notified polymer is a liquid and hence any additives and residual monomers can be released.

DEGRADATION PRODUCTS
Stable under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< 0°C	Estimate by notifier
Boiling Point	588.65°C at 101.3 kPa	Calculated (EPIWIN)
Density	1,140 kg/m^3 at 25°C	MSDS
Viscosity	108 cP at 25°C	MSDS
Vapour Pressure	1.94×10^{-5} kPa at 25°C	Calculated using the Modified Grain Method (EPIWIN)
Water Solubility	1.311×10^{-2} g/L	Calculated* (WSKOW v1.41, US EPA 2009)
Hydrolysis as a Function of pH	Not determined	Not expected to hydrolyse at environmental pH (4-9)
Partition Coefficient (n-octanol/water)	log Pow = 1.04	Calculated* (KOWWIN v1.67, US EPA 2009)
Adsorption/Desorption	log K_{oc} = 0.82, 3.83	Calculated* (KOCWIN v2.00, US EPA 2009). The two values were calculated by the Kow and MCI methods respectively.
Dissociation Constant	Not determined	No dissociable functionality
Flash Point	> 93°C	MSDS (Estimated)
Flammability	Not determined	Not expected to be highly flammable
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosophores.

*Calculated for a representative polymer (MW = 630)

DISCUSSION OF PROPERTIES
Reactivity
The notified polymer is intended to polymerise when exposed to UV (ultraviolet) and EB (electron beam) radiation. The notified polymer may prematurely polymerise when the following conditions are present: high temperatures, inhibitor depletion, impurities, oxidation and exposure to radiation.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured within Australia. The notified polymer will be imported in finished printing inks at concentrations of 10-40%.

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

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

PORT OF ENTRY
Sydney and Melbourne

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in containers up to 10 kg in size.

USE
The notified polymer will be used as a component (10-40%) of industrial printing inks. The inks containing the notified polymer will be cured using UV/EB radiation. The majority of the notified polymer will be used in inks for printing on vinyl, canvas and shade cloth, with a smaller amount (up to 5%) being used for paper printing.

OPERATION DESCRIPTION
The notified polymer will not be manufactured or reformulated within Australia. Printing inks containing the notified polymer at concentrations of 10-40% will be imported in the finished packaging ready for use. During printing, the imported ink will be transferred directly from the container to the printing head via automated lines. The printing machines will be automated and the notified polymer will be cured through exposure to UV/EB radiation at the end of the printing process. Local fume extraction is expected to be provided for the printing machines and residual ink within printing equipment will be wiped clean using rags and solvents. These rags and dirty solvents will be disposed of by the printing company through licensed waste disposal contractors.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

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

EXPOSURE DETAILS
Exposure to the notified polymer during transport and storage of the printing inks containing the notified polymer is not expected, except in the unlikely event of an accident where the packaging may be breached.

Dermal and ocular exposure to the notified polymer in inks at concentrations up to 40% may occur during quality control testing of the ink products, cleaning and maintenance of printing equipment and during replacement of the ink bottles. Further exposure is not expected as the printing process is mainly automated. PPE such as gloves and eye protection are also expected to be worn during the printing process further reducing exposure.

Inhalation exposure is not expected due to the low vapour pressure calculated for the notified polymer and the use of local exhaust ventilation in areas surrounding the printing machines to avoid inhalation exposure to solvents.

6.1.2. Public exposure
The finished printing inks containing the notified polymer will not be sold to the public. The public may come into contact with the inks containing the notified polymer after application to substrates. However, once the inks are cured and dried, the notified polymer will be bound within a polymer matrix and will not be bioavailable.

6.2. Human health effects assessment

No toxicity data were submitted for the notified polymer. The results from toxicological investigations conducted on an analogue (analogue 1) of the notified polymer are summarised in the table below. Analogue 1 has the same reactive functional groups as the notified polymer and therefore it is considered acceptable to derive the toxicity of the notified polymer.

Endpoint	*Result and Assessment Conclusion*

Rat and rabbit, acute oral toxicity	LD50 > 5000 mg/kg bw; low toxicity
Rat and rabbit, acute dermal toxicity	LD50 > 5000 mg/kg bw; low toxicity
Rabbit, skin irritation	moderately irritating
Rabbit, eye irritation	moderately irritating
Guinea pig, skin sensitisation	evidence of sensitisation
Rat, repeat dose dermal toxicity – 28 weeks.	NOAEL = 3 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Mutagenicity – fungal reverse mutation	non-mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test using Chinese Hamster Ovary cells	clastogenic (no genotoxicity at HGPRT locus)
Genotoxicity – in vitro mammalian chromosome aberration test using Mouse Lymphoma cells	clastogenic (chromosomal aberration in 21/100 at 0.7 μg/mL
Genotoxicity – in vivo mouse micronucleus assay	non-genotoxic
Carcinogenicity	non carcinogenic

Toxicokinetics.
The notified polymer may be absorbed across biological membranes, based on the favourable physical-chemical properties (log Pow = 1.04, water solubility of 13.11 mg/L), however the moderately high molecular weight > 500 Da could limit absorption. Dermal absorption of analogue 1 was confirmed from the effects seen in the repeated dermal exposure studies and therefore the notified polymer is also expected to be absorbed through the skin. While no evidence for acute toxic effects were observed for analogue 1, given the properties of the notified polymer the possibility of absorption across the gastrointestinal tract cannot be ruled out.

Acute toxicity.
Analogue 1 of the notified polymer was found to be of low acute oral and dermal toxicity (LD50 > 5000 mg/kg bw) in studies conducted in rats and rabbits, respectively (IUCLID, 2000). The notified polymer is therefore expected to be of low acute oral and dermal toxicity. No acute inhalation toxicity studies were provided.

Irritation and Sensitisation.
Analogue 1 was found to be moderately irritating to the skin and eyes of rabbits (IUCLID, 2000). The notified polymer is therefore expected to be irritating to the skin and eyes.

Analogue 1 was shown to produce evidence of skin sensitisation in 6 separate studies on guinea pigs (NTP, 1991). The notified polymer is therefore expected to be a skin sensitiser.

Repeated Dose Toxicity.
Analogue 1 has been tested in a range of repeated dose dermal toxicity tests on both rats and mice (NTP, 2005). In two 28 day tests, one on rats and one on mice, where the animals were dosed 5 times per week (16 days) irritation was seen at the site of application at doses of 50 mg/kg bw/day and above in rats and at 12.5 mg/kg bw/day (lowest dose tested) and above in mice. Also in the 28 day study on mice thymus weights of males treated at 50 mg/kg bw/day or greater were significantly decreased. Atrophy of the thymus occurred in male mice dosed at 100 and 200 mg/kg bw/day

Two 14 week studies, one in mice and the other with rats, were conducted on analogue 1. Irritation effects at the site of application were seen in both studies at dose levels of 12 mg/kg bw/day. Male rats dosed at 12 mg/kg bw/day and female rats at 0.75 and 12 mg/kg bw/day had decreased thymus weights.

In a 28 week study in mice with analogue 1 the heart, kidney and lung weights of female animals in the 12 mg/kg bw/day dose group were significantly increased. Male animals in the 12 mg/kg bw/day dose group showed an increase in heart weights and female animals in the 12 mg/kg bw/day dose group showed an increase in heart and kidney weights. The lung weights of male and female animals in the 6 and 12 mg/kg bw/day dose groups were decreased relative to controls. Based on these studies the NOAEL for analogue 1 was established as 3 mg/kg bw/day, although there were effects seen at lower concentrations than this they were either due to the irritating nature of the notified chemical or there was no dose response relationship seen.

Mutagenicity.
Analogue 1 was not found to be non-mutagenic to *Saccharomyces cerevisiae* and *Salmonella typhimurium* cells using a reverse mutation test with and without metabolic activation (NTP, 1991). However, analogue 1 was found to be clastogenic to K1BH4 Chinese Hamster ovary cells and L5178Y mouse lymphoma cells *in vitro* (NTP, 1991). When applied to mice by skin painting for 6 months analogue 1 produced no increase in

micronucleus frequency (NTP, 2005). Although there were positive results for genotoxicity in 2 different species cells tested *in vitro*, considering negative *in-vivo* data and mutagenicity data, the notified polymer is not considered genotoxic.

Carcinogenicity.
An 80 week (dermal exposure) study with analogue 1 in 50 mice produced no evidence of tumours. The notified polymer is not expected to be clastogenic based on the test conducted using analogue 1 (NTP, 1991).

Observations on Human Exposure.
Analogue 1 has been shown to cause skin sensitisation reactions in humans (NTP, 1991).

Health hazard classification
Based on the available data on the analogue chemical the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:
Xi: R36 Irritating to eyes.
Xi: R38 Irritating to skin.
Xi: R43 May cause sensitisation by skin contact.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Based on tests conducted on an analogue the notified polymer is expected to be irritating to the eyes and skin, and a skin sensitiser.

The main route of exposure to the notified polymer (up to 40% concentration) is expected to be dermal exposure, during processes such as quality control testing of the ink products, cleaning and maintenance of printing equipment and during replacement of the ink bottles. Exposure to the notified chemical is expected to be reduced by the automated processes and the use of PPE.

As the notifier has described the operations to be highly controlled, and good worker practices (including PPE use) are in place during limited activities where worker handling is required, the risk of adverse effects is significantly reduced and is considered acceptable under the occupational settings described.

6.3.2. Public health
The finished printing inks containing the notified polymer will not be sold to the public. The public may have dermal exposure to printed material containing the notified polymer; however, once the inks are cured and dried, the notified polymer will be bound within a polymer matrix and will not be bioavailable. Therefore the risk to the public from the notified polymer is not considered to be unacceptable.

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. The potential for release of inks containing the notified polymer from transport is estimated to be ≤ 1% of total imported volume of ink. Spills are expected to be collected using inert solids and will be 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 2% of ink was estimated by the notifier to be released to sewer from equipment washing. Up to 1% of ink is estimated to be released from spills however spilled notified polymer is likely to polymerise on exposure to UV light.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer will be used in inks for printing on vinyl, canvas and shade cloth and is expected 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 5%) will be used for paper printing. Of the 5% notified polymer applied to paper, half of this amount is expected to be recycled. Residues in empty containers will comprise up to 2% of annual ink import volume. 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

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.

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, at least 50% 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.

The analogue of the notified polymer was found to be readily biodegradable. However, whilst the analogue has common reactive groups to the notified polymer it differs in its backbone structure and is therefore not considered an entirely representative analogue with respect to biodegradability. Compounds with a similar backbone have been found to be biodegradable but not rapidly biodegradable (Madsen et al., 2001). Therefore the notified polymer is likely to be biodegradable and is not expected to persist in the environment. The notified polymer is not anticipated to bioaccumulate due to its calculated low partition coefficient and high molecular weight

For the details of the environmental fate study, refer to Appendix A.

7.1.3 Predicted Environmental Concentration (PEC)

PECs (ocean and river) have been calculated assuming that 5% of the total imported notified polymer will be applied to paper and half of this amount will be recycled. A further 2% of notified polymer was estimated to reach the aquatic compartment due to equipment washing. The amount of notified polymer removed from effluent due to adsorption to sludge in STPs was estimated to be at least 50% (Boethling & Nabholz, 1997) and it was assumed the release of the notified polymer occurred 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	10,000	kg/year
Proportion expected to be released to sewer	4.5%	
Annual quantity of chemical released to sewer	450	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1.73	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	50%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.204	µg/L
PEC - Ocean:	0.020	µg/L

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on an analogue 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 harmful to aquatic invertebrates with long lasting effects
	Study 2: NOEC (14 d) = 0.51 mg/L	Harmful to aquatic invertebrates with long lasting effects
Algal Toxicity	E_rC_{50} (96 h) = 2.13 mg/L NOEC (96 h) = 1.70 mg/L	Toxic to algae

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 were incomplete data for the chronic endpoints for all three trophic levels of the analogue of the notified polymer, the most stringent classification for the long term effects of the analogue of the notified chemical was applied and this was based on the most sensitive acute endpoint. Therefore as the notified polymer has not been demonstrated to be readily biodegradable and based on the analogue's acute and chronic ecotoxicity endpoints, the notified polymer is classified as very 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 (analogue 2) was used to calculate the PNEC. Analogue 2 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. An assessment factor of 500 was used as although ecotoxicity results for three acute trophic endpoints and two chronic endpoints were available.

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	0.20	0.26	**0.786**
Q - Ocean	0.02	0.26	**0.079**

The risk quotient (Q = PEC/PNEC) for aquatic exposure is calculated to be < 1 based on the above calculated PEC and PNEC values. The calculated risk quotient is an upper limit since it is likely more than 50% of notified polymer will be bound to sludge during recycling processes and in STPs where it is expected to biodegrade. Furthermore, 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 unacceptable risk to the aquatic environment from its proposed use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] with the following risk phrases:

Xi: R36 Irritating to eyes.
Xi: R38 Irritating to skin.
Xi: 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***
Skin corrosion/irritation	Category 2	Causes skin irritation
Serious eye damage/eye irritation	Category 2*	Causes eye irritation
Skin sensitisation	Category 1*	May cause an allergic skin reaction
Aquatic toxicity	Acute category 1	Very toxic to aquatic life
	Chronic category 1	Very toxic to aquatic invertebrates with long lasting effects

* Neither of these categories were further refined into subcategories due to a lack of detailed studies.

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

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not expected to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Use the following risk phrases for products/mixtures containing the notified polymer:
  - Conc ≥ 20%: Xi; R36, R38, R43
  - 1% ≤ Conc < 20%: Xi; R43

Health Surveillance

- As the notified polymer is expected to be a skin sensitiser, employers should carry out health surveillance for any worker involved in its handling.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Coveralls
  - Goggles
  - Gloves

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

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified 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(2) of the Act; if
  - the function or use of the polymer has changed from a component of industrial printing inks up to 40% concentration, 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.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of 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.

APPENDIX A: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

A.1. Environmental Fate

A.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue 2 of the notified polymer
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.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue 2 of the notified polymer
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

TEST FACILITY Exempt Information

A.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Analogue 2 of the 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	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

TEST FACILITY Exempt Information

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

TEST SUBSTANCE Analogue 2 of the notified polymer

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 harmful to aquatic invertebrates with long lasting effects. 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 harmful to aquatic invertebrates with long lasting effects

TEST FACILITY Exempt Information

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

TEST SUBSTANCE Analogue 2 of the notified polymer

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 harmful to aquatic invertebrates with long lasting effects

TEST FACILITY Exempt Information

A.2.5. Algal growth inhibition test

TEST SUBSTANCE Analogue 2 of notified polymer

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 toxic to algae.
TEST FACILITY	Exempt Information

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