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March 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

2-Oxepanone, homopolymer, 2-[(1-oxo-2-propen-1-yl)oxy]ethyl ester

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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.

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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
STD/1553	MacDermid Printing Solutions LLC	2-Oxepanone, homopolymer, 2-[(1-oxo-2-propen-1-yl)oxy]ethyl ester	Yes	≤ 10 tonnes per annum	Component of UV-cured printing plates

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 of 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*
Eye Irritation (Category 2)	H319 – Causes serious eye irritation
Skin Irritation (Category 2)	H315 – Causes skin irritation
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):

R36: Irritating to eyes
R38: Irritating to skin
R43: May cause sensitisation by skin contact

The environmental hazard classification according to the *Globally Harmonised System of 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 3	H402 – Harmful to aquatic life
Chronic Category 3	H412 – Harmful to aquatic life with long lasting effects

Human health risk assessment
Provided that the recommended PPE is used and engineering controls are in place to limit exposure, 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 reported 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:
  - Eye Irritation (Category 2): H319 – Causes serious eye irritation
  - Skin Irritation (Category 2): H315 – Causes skin irritation
  - Skin Sensitisation (Category 1): H317 – May cause sensitisation by skin contact

The above should be used for products/mixtures containing the notified polymer, if applicable, based on the concentration of the notified polymer present and the intended use/exposure scenario.

Health Surveillance

- As the notified polymer presents a skin sensitisation health hazard (or is a skin sensitiser), 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

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified polymer:
  - Enclosed, automated processes, where possible
  - Local exhaust 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
  - Avoid inhalation
  - Clean up any spills or soiled personal protective equipment promptly
  - Avoid contact with waste materials contaminated with the notified polymer

- 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:
  - Impervious gloves
  - Chemical goggles
  - Protective clothing
  - Respiratory protection if inhalation exposure may occur

  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 of 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

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- further information becomes available on the acute toxicity, repeated dose toxicity, carcinogenicity and toxicity for reproduction of the notified polymer;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of UV-cured printing plates, 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.

(Material) Safety Data Sheet
The (M)SDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Macdermid Printing Solutions LLC (ABN: 95 066 897 363)
29 Dennis Street
CAMPBELLFIELD VIC 3061

NOTIFICATION CATEGORY
Standard: Synthetic polymer with Mn < 1,000 Da (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants 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, toxicological and ecotoxicological endpoints (exception: fresh water algal toxicity)

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
MIRAMER M100D

CAS NUMBER
110489-05-9

CHEMICAL NAME
2-Oxepanone, homopolymer, 2-[(1-oxo-2-propen-1-yl)oxy]ethyl ester

OTHER NAME(S)
2-Oxepanone homopolymer, 2-[(1-oxo-2-propenyl)oxy]ethyl ester (IECSC)
2-Oxepanone, homopolymer, 2-[(1-oxo-2-propenyl)oxy]ethyl ester (IECSC, DSL, NZIoC)
Ester 2-[(1-oxopropen-2-yl)oxy]ethylique de l'homopolymere de l'oxepan-2-one (French) (DSL)
2-Oxepanone homopolymer 2-[(1-oxo-2-propenyl)oxy]ethyl ester (ECL)
ε-Caprolactone homopolymer monoester with 2-hydroxyethyl acrylate
Caprolactone homopolymer ester with hydroxyethyl acrylate
Poly(ε-caprolactone) ester with 2-hydroxyethyl acrylate

MOLECULAR FORMULA
$(C_6H_{10}O_2)_x.C_5H_8O_3$

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 85%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: clear liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Expected to be < 0 °C
Boiling Point	266 °C (pressure unknown)	(M)SDS
Density	1,099 kg/m^3 at 20 °C	(M)SDS
Vapour Pressure	4 × 10^{-4} kPa at 20 °C	(M)SDS
Water Solubility	Not determined	Expected to have limited solubility in water based on the molecular structure.
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities; however, not expected to hydrolyse significantly under environmental conditions (pH 4-9).
Partition Coefficient (n-octanol/water)	log Pow = 0.878-2.493	Measured according to OECD TG 117*.
Adsorption/Desorption	Not determined	Expected to partially partition to soil and sediment based on the molecular weight and structure.
Dissociation Constant	Not determined	Contains no dissociable functionalities.
Flash Point	130 °C (pressure unknown)	(M)SDS
Flammability	Not determined	Not expected to form flammable vapour based on the low vapour pressure and the high flash point.
Autoignition Temperature	Not determined	Not expected to undergo autoignition.
Explosive Properties	Not determined	Not expected to have explosive properties based on the structure.
Oxidising Properties	Not determined	Not expected to have oxidising properties based on the structure.

*Full study report was not provided.

DISCUSSION OF PROPERTIES

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 of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as the neat chemical at a concentration of > 85%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	2-6	2-6	2-8	2-8	2-10

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The notified polymer (at > 85% concentration) will be imported by sea in 200 kg steel drums. These drums will be transported by road to the notifier's warehouse where it will be stored on pallets. The reformulated products containing 2% of the notified polymer will be packaged into 1,000 L intermediate bulk containers (IBCs) or 20 L steel pails and supplied by road to the end users.

USE
The notified polymer (at a concentration of 2%) will be a component of products used to produce UV-cured elastomeric printing plates.

OPERATION DESCRIPTION

Reformulation/Repackaging
The notified polymer will be transferred to a closed mixing kettle using a spear pump and mixed with other ingredients to manufacture the reformulated products in 3,000 kg batches. Samples will be taken from the closed mixing kettle for quality assessment purposes. Once the formulated products containing the notified polymer have been manufactured and tested, they will be packed into 1,000 L IBCs or 20 L pails using a pump under exhaust ventilation.

End-User Applications
The formulated products containing the notified polymer at 2% will be used to manufacture elastomeric printing plates for applications such as printing designs onto corrugated cardboard cartons. The formulated products will be transferred through a closed automated system to a plate making machine, where the formulated products containing the notified polymer will be exposed to UV light to produce an elastomeric printing plate.

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 workers	1	12
Manufacturing operators	1	80
Cleaning and maintenance workers	0.5	80
Formulation Quality Inspector	0.5	80
End user: Printing plate operators	0.5	60

EXPOSURE DETAILS
Transport and Storage
The notified polymer will be imported as the neat material at > 85% concentration. Exposure of transport and storage workers to the notified polymer is not expected, except in the event of an accidental rupture of containers.

Reformulation and use
Dermal, ocular and perhaps inhalation exposure to the neat notified polymer at > 85% concentration may occur during transfer, reformulation, sample collection and testing, packaging and transfer of the reformulated mixtures, the production of elastomeric printing plates, and general cleaning and maintenance of equipment. Exposure to the notified polymer is expected to be minimised by use of the engineering controls such as automated and enclosed systems and through the use of PPE such as chemical resistant gloves, overalls, boots and goggles. Respiratory protection may also be worn if there is inadequate ventilation and/or there is an increase in the potential for inhalation exposure. The notified polymer will be unavailable for exposure once it is cured by UV to form elastomeric printing plates.

6.1.2. Public Exposure
The notified polymer will be used for industrial print processes only and will not be available to the general public either in liquid form or as articles (elastomeric printing plates). Public exposure to the notified polymer is not expected except in the event of an accidental spill during transport.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer. As a worst case scenario, the toxicological profile of notified polymer was derived from an analogue 2-propenoic acid, 2-hydroxyethyl ester (CAS No. 818-61-1), which is a monomer in the notified polymer and has a molecular weight of 116 Da. This monomer contains the acrylate functional group which is expected to be the most significant contribution to the toxicological profile of the notified polymer while the other monomer in the polymer does not contain any functional groups of concern.

Toxicokinetics, metabolism and distribution
No data on toxicokinetics for the notified polymer was provided. For dermal absorption, molecular weights below 100 Da are favourable for absorption and molecular weights above 500 Da do not favour absorption (ECHA, 2014). Dermal uptake is more likely for liquids and chemicals with log P values between 1 and 4 (ECHA, 2014). In addition evidence of skin sensitisation or irritation increase the probability of dermal absorption occurring (ECHA, 2014). Based on the relatively low molecular weight (< 1,000 Da) and partition coefficient (log Pow = 0.878-2.493) of the notified polymer, passive diffusion across the gastrointestinal (GI) tract and dermal absorption may occur. The expected irritant effects of the notified polymer may increase the dermal absorption potential. Oral and respiratory absorption may occur through micellular solubilisation.

Acute toxicity
Studies on the acute toxicity of 2-propenoic acid, 2-hydroxyethyl ester indicated oral LD50 values of 540 – 1070 mg/kg bw for rats and 601 mg/kg bw for mice (SIAM 2005). Dermal LD50 values of 154 – 298 mg/kg bw were obtained in 5 studies with rabbits while an LD50 of > 1,000 mg/kg bw was obtained with rats using the analogue 2-propenoic acid, 2-hydroxyethyl ester (SIAM 2005). Rats exposed to the analogue 2-propenoic acid, 2-hydroxyethyl ester via inhalation showed no unexpected mortality at 1,250 mg/m^3, while 1 out of 6 animals died at 1,580 and 1,870 mg/m^3, 5 out of 6 died at 2,370 mg/m^3 and 5out of 5 died at 10,580 mg/m^3. 2-Propenoic acid, 2-hydroxyethyl ester is classified as R24: toxic in contact with skin on the Hazardous Substances Information System (HSIS 2015). Based on these results, the notified polymer may be acutely toxicity via the oral, dermal and inhalation routes.

Irritation and sensitisation
2-Propenoic acid, 2-hydroxyethyl ester was severely irritating to the skin and eyes (SIAM 2005). Skin sensitisation studies in animals and humans indicated that 2-propenoic acid, 2-hydroxyethyl ester was a sensitiser and may cross-react with other acrylates in some exposed individuals (SIAM 2005). These results were consistent with the classification of 2-propenoic acid, 2-hydroxyethyl ester on the HSIS: R34: causes burns and R43: may cause sensitisation by skin contact.

The notified polymer is expected to have irritation and sensitisation potential, based on the monomer and the presentation of acrylate functional group that has been associated with irritation and skin sensitisation effects (US EPA, 2010). The notifier has also classified the notified polymer as skin and eye irritant and skin sensitiser in the (M)SDS provided.

Repeated dose toxicity
Repeated inhalation exposures to 2-propenoic acid, 2-hydroxyethyl ester to rats *via* inhalation resulted in a LOAEC of 24 mg/m^3 (SIAM 2005). Repeated dietary exposure of rats and dogs to 2-propenoic acid, 2-hydroxyethyl ester produced no adverse effects (SIAM 2005).

Mutagenicity/Genotoxicity
2-Propenoic acid, 2-hydroxyethyl ester was not mutagenic to *Salmonella typhimurium* but was to *E. coli*. No evidence of chromosomal damage was seen in *in vivo* studies (SIAM 2005).

Carcinogenicity
Rats exposed to 2-propenoic acid, 2-hydroxyethyl ester for 18 moths via inhalation showed no evidence of carcinogenic effects (SIAM 2005).

Toxicity for reproduction
In a range of *in vivo* studies with 2-propenoic acid, 2-hydroxyethyl ester there was no evidence of reproductive or developmental toxicity (SIAM 2005).

Health hazard classification
Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of 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*
Eye Irritation (Category 2)	H319 – Causes serious eye irritation
Skin Irritation (Category 2)	H315 – Causes skin irritation
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):

R36: Irritating to eyes
R38: Irritating to skin
R43: May cause sensitisation by skin contact

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymer has not been tested for any toxicological properties, however based on the data for one monomer it may be a skin and eye irritant and a skin sensitiser. Long-term adverse effects from exposure cannot be ruled out.

Workers may be at risk of irritating and sensitising effects during transfer, reformulation, sample collection and testing, packaging and transfer of the reformulated mixtures, the production of elastomeric printing plates, and general cleaning and maintenance of equipment. However, exposure is expected to be limited by the largely automated and enclosed processes, good general ventilation and the use of PPE including chemical resistant gloves, overalls, boots and goggles. If aerosols were generated during production or cleaning processes, exhaust ventilation or respiratory protection would be needed to avoid inhalation exposure. 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 notified polymer, the reformulated mixture containing the notified polymer at 2% concentration and the elastomeric printing plates, will not be sold to the public. Therefore, exposure of the public to the notified polymer is not expected and the risk is not considered 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 neat for reformulation into finished printing inks for UV-cured elastomeric printing plates. Release of the notified polymer to the environment from transport and storage is unlikely, except in the case of accidental spills and leaks. In the event of spills, the notified polymer is expected to be collected with adsorbents and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve transfer of the notified polymer into blending vessels using spear pumps, followed by blending operations that will be highly automated with equipment fitted with appropriate engineering controls. Therefore, significant release of the notified polymer from this process to the environment is not expected. The process will be followed by automated filling of the finished printing inks into transport containers of various sizes. Wastes containing the notified polymer generated during reformulation, including equipment wash water, spilt materials, and empty import containers, are estimate by the notifier to be < 1% of the import volume, or up to 100 kg. Wastes are not expected to be released to sewer, and are expected to be collected and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The majority of the notified polymeris expected to be UV-cured (chemically reacted) to form inert elastomeric printing plates. Only a small amount of waste is expected to be generated during this process. The majority of the

waste containing the notified polymer will be as a result of residues in empty product containers. These containers are expected to be sent to a chemical waste disposal site for recycling.

RELEASE OF CHEMICAL FROM DISPOSAL
The notified polymer cured in elastomeric printing plates is expected to be disposed of to landfill at the end of its serviceable life.

7.1.2. Environmental Fate
No environmental fate data was submitted for the notified polymer. The notified polymer will be UV-cured (chemically reacted) to form inert elastomeric printing plates and is not expected to be bioavailable. The majority of the cured 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.

The notified polymer is not expected to be released to sewers or aquatic environments. However, in the unlikely case whereby the notified polymer is released to waste waters, it is expected to be partially removed from effluent by sorption to sediment where it will degrade by biotic and abiotic processes. The notified polymer is not expected to bioaccumulate, due to its low partition coefficient (log P_{OW} = 0.878-2.493). Therefore, in surface waters and in landfill, notified polymer is expected to disperse and eventually degrade by biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)
Predicted environmental concentrations (PECs) for riverine and marine environments have been calculated assuming that up to 2% of notified polymer may accidentally be released to sewer. These releases may occur from equipment cleaning or spills at a reformulation site situated in a typical metropolitan area. It has been assumed that there will be no removal of the notified polymer from effluent in sewage treatment plants (STPs). It was also assumed that release of the notified polymer occurred over 260 days per annum, corresponding to the number of working days per annum.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	2%	
Annual quantity of chemical released to sewer	200	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	0.769	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.170	µg/L
PEC - Ocean:	0.0170	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 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 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.170 µg/L may potentially result in a soil concentration of approximately 1.13 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymer in the applied soil in 5 and 10 years may be approximately 5.67 µg/kg and 11.3 µg/kg, respectively.

7.2. Environmental Effects Assessment
The results from an ecotoxicological investigation conducted on the notified polymer are summarised in the table below. Details of this study can be found in Appendix A.

Endpoint	*Result*	*Assessment Conclusion*
Algal Toxicity	72 h EL50 = 47.49 mg/L (WAF*) 72 h NOEL = 27.5 mg/L (WAF*)	Harmful to algae

*Water Accommodated Fraction

Based on the above acute ecotoxicological endpoints for the notified polymer, it is expected to be harmful to algae. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified polymer is formally classified as "Acute Category 3; Harmful to aquatic life". Based on its acute ecotoxicity and its unknown potential for biodegradability, the notified polymer is formally classified as "Chronic Category 3; Harmful to aquatic life with long lasting effects".

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the available acute ecotoxicological endpoint for algae. A safety factor of 1,000 was used given an acute endpoint for only one trophic level is available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EL50 (Algae, 72 h)	47.49	mg/L
Assessment Factor	1,000	
Mitigation Factor	1.00	
PNEC:	47.49	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.170	47.49	**0.0036**
Q - Ocean	0.0170	47.49	**0.00036**

The Risk Quotients for discharge of treated effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. Whilst the cured notified polymer is not expected to be biodegradable, it is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual importation volume, and assessed use pattern in UV-cured elastomeric printing plates, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

A.1 Ecotoxicological Investigations

A.1.1 Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	ESA SOP 103 Green Alga, *Selenastrum capricornutum*, Growth Test
Species	*Selenastrum capricornutum* (green alga)
Exposure Period	72 hours
Concentration Range	Nominal: 13.7-439.6 mg/L Actual: Not determined
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	None reported
Remarks - Method	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. A saturated solution of the test substance was prepared by adding one part of the test substance to nine parts USEPA media, then stirred for 24 h before settling for 1 h. No significant deviations in protocol were reported.

RESULTS

Biomass		*Growth*	
E_bL50	*NOE_bL*	*E_rL50*	*NOE_rL*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
47.49 (95% CI 45.08-48.00)	27.5	Not determined	Not determined

Remarks - Results	The results of the test were provided as a study summary, and a full test report was not submitted. Based on the study summary, the 72 h E_bL50 and NOE_bL were determined to be 47.49 mg/L (WAF) and 27.5 mg/L (WAF), respectively, based on nominal concentrations.
CONCLUSION	Under the study conditions, the notified polymer is considered to be harmful to algae.
TEST FACILITY	Ecotox Services Australasia (2015)

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