File No: LTD/1766

March 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Polycup 1884

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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1766	Nuplex Industries (Aust.) Pty Ltd	Polymer in Polycup 1884	ND*	≤ 50 tonnes per annum	Component of filter media

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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

Hazard classification	*Hazard statement*
Acute aquatic toxicity (Category 2)	H401: Toxic to aquatic life
Chronic aquatic toxicity (Category 2)	H411: 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 reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
  - Avoid skin and eye contact

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures

consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

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

Storage

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

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
- the polymer has a number-average molecular weight of less than 1,000 Da;
- the polymer is intended to be used as component of filter cartridges for drinking water;
- the polymer is intended to be used in filter media for food and beverages;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of filter media for industrial life science applications, 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 product containing 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)
Nuplex Industries (Aust.) Pty Ltd (ABN: 25 000 045 572)
49-61 Stephen Road
BOTANY NSW 2019

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 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, polymer constituents, and analogue identity.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA, Canada and Europe

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polycup 1884 (contains the notified polymer at ≤ 35% concentration in aqueous solution)

OTHER NAME(S)
Delfloc 763
Reten 763
Chemvisions PA1884

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
79.6%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	1,3-Dichloro-2-propanol		
CAS No.	96-23-1	*Weight %*	0.065
Hazardous Properties	Carc. Cat. 2; R45 T; R25 Xn; R21 Conc ≥ 25%: T; R45; R25; R21 ≥ 3% Conc < 25%: T; R45; R22 ≥ 0.1% Conc < 3%: T; R45		
Chemical Name	3-Chloro-1,2-propanediol		
CAS No.	96-24-2	*Weight %*	0.61
Hazardous Properties	Repro. Cat. 2; R60 Carc. Cat. 2; R45 T; R25/23 Xn; R48/22 Xi; R41 (NICNAS)		

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)

Chemical Name	Ammonium Sulphate		
CAS No.	7783-20-2	*Weight %*	19.7

ADDITIVES/ADJUVANTS
None

DEGRADATION PRODUCTS
Combustion products include carbon dioxide, carbon monoxide, hydrogen chloride and phosgene.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Amber liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-12 °C*	(M)SDS
Boiling Point	100 °C at 101.3 kPa*	(M)SDS
Density	1,120 kg/m^3 at 20 °C*	(M)SDS
Vapour Pressure	Not determined	Expected to be low based on the high molecular weight
Water Solubility	Fully miscible	(M)SDS
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional groups. However, significant hydrolysis is not expected in the environmental pH range of 4 – 9.
Partition Coefficient (n-octanol/water)	Not determined	Expected to be < 1 based on the water solubility
Adsorption/Desorption	Not determined	The notified polymer is expected to be immobile in soil based on its high molecular weight and presence of cationic functionality which will adsorb to soil and sediment.
Dissociation Constant	Not determined	The notified polymer is a salt and will be ionised under environmental conditions (pH 4-9)
Flash Point	Not determined	Introduced as an aqueous solution
Flammability	Not determined	Introduced as an aqueous solution
Autoignition Temperature	Not determined	Introduced as an aqueous solution
Explosive Properties	Not determined	Not expected to be explosive based on structure
Oxidising Properties	Not determined	Not expected to be oxidising based on structure

*For the imported product containing the notified polymer at ≤ 35% concentration in aqueous solution

DISCUSSION OF PROPERTIES

Reactivity
The notified polymer is expected to be stable under normal conditions of use. Depolymerisation, hydrolysis, photo and thermal degradation may occur under extreme conditions.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported into Australia as an aqueous solution at ≤ 35% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	6	20	40	50	50

PORT OF ENTRY
Sydney

TRANSPORTATION AND PACKAGING
The notified polymer as an aqueous solution at ≤ 35% concentration will be imported in 1000 kg intermediate bulk containers (IBCs). The final filter media containing the notified polymer at ≤ 3.5% concentration will be packed in plastic bags for international distribution or plastic bound filter cartridges for local distribution.

USE
The notified polymer will be used as a component of filter media for use in filter cartridges for industrial life science applications (i.e. life science applications not covered under the Therapeutic Goods Act).

OPERATION DESCRIPTION
Preparation of filter mixture
The resin solution containing the notified polymer at ≤ 35% concentration will be transferred from the IBC directly into a blending vessel using gravity. The resin solution will be mixed with water before being manually transferred into a mixing tank where it will be combined with a cellulose pulp mixture. The combined mixture (containing the notified polymer at < 1% concentration) will then be pumped into a pulping machine.

Preparation of filter sheet
Once pulping is complete, automated processes will be used to transfer the slurry mixture (containing the notified polymer at < 1% concentration) to a holding tank and then onto a porous vacuum extractor belt to remove most of the water and form a fibrous sheet. The semi-dried sheet will then be passed through an air-heated oven where the notified polymer at ≤ 3.5% concentration will be cured.

Manufacture of filter discs
The dried filter sheets (containing the bound notified polymer at ≤ 3.5% concentration) will be die cut to size (depending on application) using automated processes. Cut discs will be packaged into plastic bags (for international distribution) or plastic bound cartridges (for local distribution). Cartridges (containing multiple discs) will then be packed individually into plastic bags for distribution.

End-use
Customers will remove the filter cartridges from the plastic bags (using the lifting handles on the cartridge where present) and insert into the filtration equipment. At the end of their life they will be removed and disposed of according to customer's internal processes.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	0.5	20
Process worker	0.5	20

EXPOSURE DETAILS
Transport and storage workers are not expected to be exposed to the notified polymer at ≤ 35% concentration except in the event of an accident.

Manufacture of the filter mixture
Dermal and ocular exposure to the notified polymer at ≤ 35% concentration may occur during the manual connection and disconnection of transfer hoses and operation of valving between blending, mixing and pulping tanks. Exposure may also occur during equipment cleaning/maintenance. Exposure to the notified polymer is expected to be minimised by the stated use by the notifier of PPE (including safety glasses, face masks, gloves, and coveralls).

Preparation of filter sheet
Dermal and ocular exposure to the notified polymer at ≤ 3.5% concentration may occur during the connection and disconnection of transfer hoses between the pulping machine, holding tank and vacuum extractor belt, as well as during equipment cleaning/maintenance. Exposure to the notified polymer is expected to be negligible given these processes will be automated. Exposure to the notified polymer during transfer to the air-heated oven may also occur, but is expected to be negligible given the automated nature of the process. Exposure to the notified polymer is expected to be further minimised by the stated use by the notifier of PPE (including safety glasses, face masks, gloves, and coveralls).

Once the filter sheets containing the notified polymer at ≤ 3.5% concentration have dried, the notified polymer will be cured and unavailable for exposure.

Manufacture of filter discs
Workers may have direct dermal contact with the dried filter sheets or filter discs containing the notified polymer at ≤ 3.5% concentration. However, at this stage in the manufacturing process the notified polymer will be cured within the polymer matrix of the filter sheets/discs and will not be available for exposure. Exposure to the notified polymer is expected to be further minimised by the stated use by the notifier of PPE (including gloves and coveralls).

End-use
Workers are not expected to be directly exposed to the notified polymer at ≤ 3.5% concentration based on the encapsulation of the filter discs within the filter cartridge. However, should direct dermal contact occur, the notified polymer will be cured within the polymer matrix of the filter discs and will not be available for exposure.

6.1.2. Public Exposure
Public exposure to the notified polymer at ≤ 3.5% is not anticipated, as the filter media containing the notified polymer will only be used in industrial life sciences applications.

6.2. Human Health Effects Assessment
No toxicity data were submitted for the notified polymer. The results from toxicological investigations conducted on analogues of the notified polymer are summarised in the table below. The analogues and notified polymer may be considered to be very similar in chemical structure and physico-chemical properties and therefore the endpoints presented below are likely to reflect the toxicity of the notified polymer. Details of the studies of the analogues can be found in Appendix A.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity[1]	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute oral toxicity[2]	LD50 > 5000 mg/kg bw; low toxicity
Rat, acute dermal toxicity[2]	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation[2]	moderately irritating
Rabbit, eye irritation[2]	slightly irritating

[1]Test substance: 12.5% analogue 1 in aqueous solution
[2]Test substance: ~25% analogue 2 in aqueous solution

Toxicokinetics.
Absorption of the notified polymer across biological membranes is likely to be limited, based on the relatively high molecular weight (MW > 1000 Da), high water solubility and ionic character. However, the notified polymer contains a notable amount of low molecular weight species, which may be absorbed. Hazardous impurities are also present, albeit in very low concentrations.

Acute toxicity.
Analogue 1 at 12.5% concentration in aqueous solution and analogue 2 at ~25% concentration in aqueous solution were found to be of low acute oral toxicity in rats.

Analogue 2 at ~25% concentration in aqueous solution was found to be of low acute dermal toxicity in rats.

Based on the results of these studies and the limited potential for the notified polymer to cross biological membranes, the notified polymer is expected to be of low acute oral and dermal toxicity.

Irritation.
Analogue 2 was found to be moderately irritating to the skin in rabbits when tested at ~25% concentration in aqueous solution. The study was conducted at abraded and intact skin sites. Very slight to slight oedema and slight to well-defined erythema was observed. Signs of irritation were still present at the end of the 72 hour observation period; however, there was evidence to suggest that the irritating effects were reversible. Irritation effects observed were similar at both the abraded and intact skin sites. Based on the result of this study, the notified polymer may be irritating to skin.

Analogue 2 was found to be slightly irritating to the eye in rabbits when tested at ~25% concentration in aqueous solution. The analogue polymer caused a slight to moderate increase in conjunctival redness, with all effects fully reversed by the end of the study period. Based on the results of this study, the notified polymer may be irritating to eyes.

The irritating potential of the notified polymer is further supported by the presence of a structural alert for irritation.

Sensitisation.
No skin sensitisation studies were provided for the notified polymer. The notified polymer contains a structural alert for sensitisation. However, given the limited potential for the notified polymer to be dermally absorbed the potential for the notified polymer to cause sensitising effects is limited.

Health hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on studies conducted on analogue polymers, the notified polymer is expected to be of low acute oral and dermal toxicity but may be irritating to the skin and eyes. Although the notified polymer contains a structural alert for sensitisation, the potential to cause sensitising effects is low given the limited potential for dermal absorption. No studies on repeated dose toxicity were provided, however the risk of systemic effects from repeated exposure is expected to be low given the expected limited potential for the notified polymer to cross biological membranes. The critical health effect of the notified polymer is therefore as a possible skin and eye irritant.

During preparation of the filter mixture, workers may be exposed to the notified polymer at up to 35% concentration. At these concentrations the notified polymer may present as a slight skin and eye irritant. Safe work practices should therefore be employed to avoid skin and eye contact during this process. The expected use of personal protective equipment by workers (including safety glasses, gloves, and coveralls) should minimise this risk. The risk of irritation effects at other times during the manufacture of the filter media is not expected given the low concentration (≤ 3.5%) of the notified polymer.

Overall, based on the expected low hazard profile of the notified polymer, the risk to workers is not considered to be unreasonable.

6.3.2. Public Health
Under the proposed use the public is not expected to be exposed to the notified polymer. Therefore the risk to the public 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 into Australia as a component of formulated aqueous products. There will be no exposure to the environment from manufacture, reformulation or repacking activities as these operations will not take place in Australia. Exposure of the notified polymer to the environment is not expected during transportation except in the event of a spill. Spills are assumed to be contained, collected and disposed to landfill.

RELEASE OF CHEMICAL FROM USE

The notified polymer at < 1% is expected to be used by a single Australian customer as a component of filter media for use in filter cartridges for industrial life science applications. The notified polymer will be utilised in a completely automatic system and will be incorporated in the finished filter paper. No environmental release of the notified polymer from the filter cartridge manufacturing process is expected. Small spills and leaks that may occur are expected to be washed with water and collected for disposal.

RELEASE OF CHEMICAL FROM DISPOSAL

The notifier has stated that, at the filter cartridge manufacturing site, the maximum amount of notified polymer released daily to sewer is expected to be 0.12 kg. The amount of the notified polymer released to the sewer is expected to be 31.2 kg per annum. All waste from the manufacturing site is expected to be treated at the public sewage treatment plant (STP). It is expected that residues in the import containers would be washed out on-site and the rinsates recycled or treated in the on-site water treatment facility.

7.1.2. Environmental Fate

The notified polymer is not expected to be readily biodegradable. The notified polymer is expected to be stable to hydrolysis in the environmental pH range of 4–9. Abiotic degradation mediated by hydrolytic mechanisms is therefore expected to be slow.

The notified polymer is not expected to be fully removed from the effluents of waste water treatment plants. Although the notified polymer has a high water solubility, some of notified polymer discharged in treated effluent is expected to partition to sludge and sediment, based on the high molecular weight and presence of cationic moiety in the structure. The rate of abiotic degradation may be slow based on the apparent hydrolytic stability of the notified polymer and it may persist in the water column. Although potentially persistent in the water compartment, the notified polymer is unlikely to bioconcentrate in aquatic organisms based on the low estimated log Kow and the relatively large molecular weight.

Due to the presence of cationic functionality, the notified polymer has the potential to strongly adsorb to soil and sediment in the sludge fraction. Therefore, only a low proportion of the notified polymer is expected to remain in the effluent water from both on-site waste water treatment plants and municipal water treatment plants to which treated effluent may be discharged. Sludge containing the notified polymer is expected to be sent to landfill for disposal.

In either landfill or water, the notified polymer is expected to decompose to water, oxides of carbon, and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

Filter Cartridge Manufacture

Considering the high water solubility of the notified polymer, and based on OECD Emission Scenario Documents on Pulp, Paper and Board Industry (ENV/JM/MONO(2009)25) for one individual paper manufacturing mill, the daily release of the notified polymer to waste water (E_{water}) before any treatment plant, whether on-site or off-site, was calculated as follows:

$$E_{water} = C_{wastewater} \times Flow_{wastewater}$$
$$= (1/100) \times 12 \times 1000$$
$$= 120 \text{ g/day}$$

E_{water} (g/day): Emission per day to waste water from paper manufacturing process; (OECD, ENV/JM/MONO(2009)25);
$C_{wastewater}$ (%): Concentration of the notified polymer in waste water from paper manufacturing processes;
$Flow_{wastewater}$ (L/day): Waste water generated from the whole plant; default value (OECD, ENV/JM/MONO(2009)25).

The waste water containing the notified polymer released to sewer is expected to be treated at a sewage treatment plant (STP). The log P_{OW} is expected to be < 1 and that up to 1% of the notified polymer will remain in the water column in the STP with 0% removed in sludge. Therefore, the daily release of the notified polymer to surface water (E_{STP_water}) from an individual STP was calculated as follows:

$$E_{STP\_water} = E_{water} \times F_{STP\_water}$$
$$= 120 \times 0.01$$
$$= 1.2 \text{ g/day}$$

E_{STP_water} (g/day): Emission to surface water from STP effluent;
F_{STP_water} (unitless): Fraction of notified polymer remaining in water after STP treatment.

For a conservative scenario, it is assumed that waste water will be released to a moderately-sized STP and be diluted by the daily average water flow at the STP. The resultant predicted environmental concentration (PEC) in river was calculated as following:

$$PEC_{river} = E_{STP\_water} \div F_{daily\_individual\ STP\_flow}$$
$$= 1.2 \div 358$$
$$= 0.0033 \text{ µg/L}$$

PEC_{river} (µg/L): Predicted environmental concentration in river;
$F_{daily\text{-}individual\ \ STP\_flow}$ (ML/day): Individual STP daily average water flow (358ML, Eastern Treatment Plant, Victoria).

Based on the above calculated PEC of 0.0033 µg/L for river water, the PEC for seawater can be calculated as 0.00033 µg/L by dividing by a factor of 10.

7.2. Environmental Effects Assessment

The notifier has submitted ecotoxicity studies based on an analogue polymer which is considered to be similar to the notified polymer. The results from ecotoxicological investigations conducted on the analogue polymer are summarised in the table below. Details of these studies can be found in Appendix C

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 6.1 mg/L	Toxic to fish
Daphnia Toxicity	48 h NOEC 1.3 mg/L	Toxic to Aquatic invertebrates

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified polymer is considered to be acutely toxic to fish and aquatic invertebrates. Based on the toxicity to aquatic organisms the notified polymer is formally classified under the GHS as “Acute category 2; Toxic to aquatic life”. Based on the acute toxicity of the notified polymer, and in the absence of ready biodegradability data, it is formally classified under the GHS as “Chronic category 2; Toxic to aquatic life with long lasting effects”.

7.2.1. Predicted No-Effect Concentration

The hazard data for the notified polymer indicates that, after allowing for the mitigating effects of organic carbon in surface waters, the most sensitive ecotoxicological endpoint is for daphnia. The endpoint for daphnia was therefore selected for the calculation of the PNEC below. An assessment factor of 1000 was used as only two trophic level toxicities were reported. The chronic endpoint for Daphnia was used for determination of the PNEC.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Daphnia	1.3	mg/L
Assessment Factor	1000	
PNEC:	1.3	µg/L

7.3. Environmental risk assessment

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	0.0033	1.3	0.0025
Q - Ocean:	0.00033	1.3	0.0002

The risk quotient (Q = PEC/PNEC) for aquatic exposure is calculated to be < 1 based on the above calculated PEC and PNEC. The Q value of < 1 indicates the notified polymer is not expected to pose an unreasonable risk to the aquatic environment from its proposed use pattern at the proposed maximum import volume

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE	Analogue 1 (12.5% in aqueous solution)
METHOD	OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/Sprague Dawley
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	10 (5 M, 5 F)	2000	0/10

LD50	> 2000 mg/kg bw
Signs of Toxicity	Piloerection (all males; observed at 0.5, 2 and 4 h), peribuccal staining (1 female at 0.5 and 1 h) and hypoactivity (all males at 1 h, all animals at 2 and 4 h) were variously seen in all animals on the day of dosing. All effects were reversed by day 2 Bodyweight gains were observed in all animals.
Effects in Organs	No significant abnormalities noted at necropsy
Remarks - Results	None
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Toxicol (1988)

A.2. Acute toxicity – oral

TEST SUBSTANCE	Analogue 2 (~25% in aqueous solution)
METHOD	Similar to OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/Wistar
Vehicle	Not described in study report provided
Remarks - Method	Based on method described by Hagan (1959). Animals dosed by oral gavage. Animals were observed at 1, 3, 6 and 24 h and then once daily for a total of 14 days

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	10 (5 M, 5 F)	5000	1/10

LD50	> 5000 mg/kg bw
Signs of Toxicity	All surviving animals gained in bodyweight. Single observations of slight depression was observed in 5/10 animals (at 1 h, 3 h and at day 2), with one animal showing continued depression through days 3 to 8. This animal also exhibited dry black discharge around the eyes and nose, dehydration, diarrhoea and a red and swollen penis over the observation period, even when no depression was recorded. Two animals recorded a yellow discharge around the genital area on day 2 (2 F). Four animals showed no effects.
Effects in Organs	Not described in study report provided
Remarks - Results	Study authors indicated that all animals were subject to gross necropsy, however these results were not included in the study report provided.

CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Consumer Product Testing (2000)

A.3. Acute toxicity – dermal

TEST SUBSTANCE	Analogue 2 (~25% in aqueous solution)
METHOD	Similar to OECD TG 402 Acute Dermal Toxicity – Limit Test
Species/Strain	Rabbit/New Zealand
Vehicle	Not described in study report provided
Type of dressing	Occlusive
Remarks - Method	Based on method described by Draize (1959). All animals were prepared for testing by close clipping the hair of the mid-dorsal area of the trunk (between scapulae and pelvis). The skin of animals in group 1 remained intact, while those in group 2 had their skin abraded. A single dermal application of the test substance was made. After the 24 h exposure period the test substance was washed from the skin with water. Animals were observed at 1, 3, 6 and 24 h post-exposure and then once daily for a total of 14 days.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 (2 M, 3 F)	2000	0/5
2	5 (3 M, 2 F)	2000	0/5

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Erythema and oedema were recorded at the 24 h observation. All animals (groups 1 and 2) showed well-defined erythema with very slight to slight oedema. All animals in group 2 (abraded skin) exhibited blanching.
Signs of Toxicity - Systemic	All animals in group 2 gained body weight during the study, while only 1 animal in group 1 failed to gain weight.
Effects in Organs	No gross internal changes were observed. All animals showed reddened (3/10) or slightly reddened skin. Other skin effects included (in combination or alone) scaling, swelling, blanching (2/5 group 2 animals) and dry skin.
Remarks - Results	
CONCLUSION	The test substance is of low toxicity via the dermal route.
TEST FACILITY	Consumer Product Testing (2000)

A.4. Irritation – skin

TEST SUBSTANCE	Analogue 2 (~25% in aqueous solution)
METHOD	Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6 (4 F, 2 M)
Vehicle	None
Observation Period	72 h
Type of Dressing	Occlusive.
Remarks - Method	Modified Draize method (Draize 1959). Single dermal application of 0.5 mL of undiluted test substance applied directly to two test sites (each 2.5 cm^2) per animal. Test sites were located on opposite sides of the vertebral column, the right side test site was abraded, the left side test site was non-abraded. After the 24 h exposure period the test substance was washed

from the skin with water. Observations were made at 24 h and 72 h post-exposure.

RESULTS

Lesion	*Mean Score**						*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Non-abraded	1	2	3	4	5	6			
Erythema/Eschar	0.5	1.5	1.5	2	1.5	1.5	2	> 72 h	2
Oedema	0	0.5	0	0.5	0	0	1	> 72 h	1
Abraded	1	2	3	4	5	6			
Erythema/Eschar	1	1.5	1.5	2	1.5	1.5	2	> 72 h	2
Oedema	0	0.5	0	0.5	0	0.5	1	> 72 h	1

* Calculated on the basis of the scores at 24 and 72 hours for on EACH animal.

Remarks - Results

Blanching was recorded for the abraded test sites in 5/6 animals, with blanching continuing to at least 72 h (observed in 2/6 animals).

Very slight oedema was observed at the intact and abraded site for one female animal at the 72 h observation but not in the 24 h observation. Very slight oedema was observed in two other animals at the 24 h observation only.

At the 24 h observation 5/6 animals showed well-defined erythema at both the intact and abraded skin sites. At the 72 h observation only very slight erythema was observed at the intact and abraded sites in 4/5 of these animals, with the remaining animal still showing well-defined erythema.

One animal showed very slight erythema at the intact and abraded sites at the 24 h observation which resolved at the intact site at the 72 h observation.

Observations made after 72 h were not recorded. However, the values recorded at 24 h and 72 h indicate that the irritating effect of the test substance is likely to be reversible.

CONCLUSION

The test substance is slightly irritating to the skin.

TEST FACILITY

Consumer Product Testing (2000)

A.5. Irritation – eye

TEST SUBSTANCE

Analogue 2 (~25% in aqueous solution)

METHOD

Similar to OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain: Rabbit/New Zealand White

Number of Animals: 6 (4 M, 2 F)

Observation Period: 7 days

Remarks - Method: Modified Draize method (Draize 1959). Single intraocular application of 0.1 mL of undiluted test substance was applied directly to one eye per animal. Observations were made at 24, 48 and 72 h post-exposure.

RESULTS

Lesion	*Mean Score**						*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3	4	5	6			
Conjunctiva: redness	2	1.6	2	2	1.3	1	2	< 7 d	0

Conjunctiva: chemosis	0	0	0	0	0	0	0	-	0
Conjunctiva: discharge	0	0	0	0	0	0	0	-	0
Corneal opacity	0	0	0	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	0	0	0	-	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animals.

Remarks - Results

All animals showed slight to moderate conjunctival redness up to day 3, which persisted in 3/6 animals up to day 4. The effect was fully reversed in all animals by day 7.

No other ocular effects were recorded.

CONCLUSION

The test substance is slightly irritating to the eye.

TEST FACILITY

Consumer Product Testing (2000)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Ecotoxicological Investigations

B.1.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue 1
METHOD	Protocol for Conducting Acute Toxicity Test following TSCA 797-1400 - Static.
Species	Fathead minnows (*Pimephales promelas*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	46 mg $CaCO_3$/L
Analytical Monitoring	Not reported
Remarks – Method	After a range finding test, a definitive test was conducted in accordance with the guidelines above and in compliance with GLP standards and principles. No significant deviations to the test protocol were reported.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*			
Nominal		*24 h*	*48 h*	*72 h*	*96 h*
Control	100	0	0	0	0
2.6	100	0	0	0	0
4.4	100	0	0	0	5
7.2	100	0	20	45	80
12	100	90	100	100	100
20	100	100	100	100	100

LC50	6.1 mg/L at 96 hours.
NOEC (or LOEC)	4.4 mg/L at 96 hours.
Remarks – Results	The validity criteria for the test were met. The study protocol states that observations of stress, abnormal behaviour activity and mortality are made at 0, 24, 48 and 96 hours of exposure. During this study, biological observations on test days 2 and 3 were recorded prior to the 48 and 96 hour observation intervals. However, this deviation did not affect the results of this study.
CONCLUSION	The test substance is toxic to fish
TEST FACILITY	Springborn (1991a)

B.1.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Analogue 1
METHOD	Protocol for conducting a Static Acute Toxicity Test following TSCA 796-Test - Static.
Species	*Daphnia pulex*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	52 mg $CaCO_3$/L
Analytical Monitoring	Not reported
Remarks - Method	After a range finding test, a definitive test was conducted in accordance with the guidelines above and in compliance with GLP standards and principles. No significant deviations to the test protocol were reported.

RESULTS

Concentration mg/L *Nominal*	*Number of D. pulex*	*Number Immobilised* *24 h*	*48 h*
Control	100	0	0
1.3	100	0	0
2.2	100	0	100
3.6	100	25	100

EC50	1.7 mg/L at 48 hours
NOEC	1.3 mg/L at 48 hours
Remarks - Results	The validity criteria for the test were met.
CONCLUSION	The test substance is toxic to aquatic invertebrates
TEST FACILITY	Springborn (1991b)

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