File No: LTD/1687

December 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Nalcolyte® 7135

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

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

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

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

TABLE OF CONTENTS

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/1687	Ecolab Pty Ltd	Polymer in Nalcolyte® 7135	ND*	≤ 500 tonnes per annum	Sludge dewatering aid in wastewater treatment

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As only limited toxicity information was provided, the notified polymer cannot be classified 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 category 1	H400 - Very toxic to aquatic life
Chronic category 1	H410 - Very toxic to aquatic life with long lasting effects

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

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

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

- 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 as introduced:
  - Impervious gloves
  - Protective clothing
  - Safety glasses

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

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

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- The notified polymer should be disposed of to landfill.

Storage

- The following precautions should be taken by the notifier and end users regarding storage of the notified polymer:
  - Avoid contact with strong alkalis and strong oxidisers

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
  - the polymer has a number-average molecular weight of less than 1,000;
  - additional information on sensitisation properties of the polymer becomes available;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a sludge dewatering aid in wastewater treatment, 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 SDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ecolab Pty Ltd (ABN: 59 000 449 990)
2 Drake Avenue
MACQUARIE PARK NSW 2113

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, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, polymer constituents, residual monomers, additives/adjuvants, use details, identity of recipients and analogue details.

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
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Nalcolyte® 7135 (contains the notified polymer at 30-60% concentration in aqueous solution)
OWP-219
P80B0

MOLECULAR WEIGHT
> 10,000 Da

ANALYTICAL DATA
Reference NMR, FTIR and SEC/MALLS spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: amber liquid (product, aqueous solution containing 30-60% notified polymer)

Property	Value	Data Source/Justification
Freezing Point	< -12.1 °C	SDS of the product
Boiling Point	102 °C	SDS of the product
Density	1,140 kg/m^3 at 21.1 °C	SDS of the product
Vapour Pressure	Not determined	Expected to be low based on high molecular weight
Water Solubility	Not determined	Expected to be soluble in water based on the predominately hydrophilic structure, SDS data and its use in aquatic systems.
Hydrolysis as a Function of pH	Not determined	Not expected as the notified polymer does not contain any readily hydrolysable functionalities

Partition Coefficient (n-octanol/water)	Not determined	Not expected to partition from water to the octanol phase based on its predominately hydrophilic nature
Adsorption/Desorption	Not determined	The notified polymer has high molecular weight and is a cationic polymer. It is expected to adsorb to sludge, sediments and soils.
Dissociation Constant	Not determined	The notified polymer is a salt and will be ionised at the environmental pH range (4-9).
Particle Size	Not applicable	Introduced as an aqueous solution
Flash Point	No flash point observed up to the boiling point (102 °C)	Provided by the notifier
Flammability	Not determined	Introduced as an aqueous solution
Autoignition Temperature	Not determined	Introduced as an aqueous solution
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES

Reactivity
The notified polymer is expected to be stable under normal conditions of use.

The notifier stated that contact of the notified polymer with strong alkalis may generate heat, splattering or boiling and toxic vapours.

The SDS of the product containing the notified polymer states that contact of the polymer with strong oxidisers may generate heat, fire, explosion and/or toxic vapours.

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 not be manufactured in Australia. It will be imported as an aqueous solution at a concentration between 30 and 60%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	100	200	300	400	500

PORT OF ENTRY
Sydney

TRANSPORTATION AND PACKAGING
The notified polymer as an aqueous solution at 30-60% concentration is expected to be imported by ship in 1,000 L high density polyethylene (HDPE) Schutz tote boxes and transported in original packages by truck to the warehouses for distribution. All storage locations for the solution of the notified polymer are expected to have secondary containment available.

USE
The notified polymer will be used as a sludge dewatering aid in wastewater treatment. The use concentration of the polymer in the wastewater is expected to be below 200 ppm (0.02%).

OPERATION DESCRIPTION
The notified polymer as introduced in an aqueous solution will not be reformulated or repackaged in Australia. It will be used directly at the wastewater treatment plants (WTPs).

At the WTPs, the notified polymer will be dosed directly from the imported containers via a mixing pump into the wastewater stream at a concentration of < 200 ppm (0.02%). The waste sludge will then be dewatered using belt filter presses or centrifuges.

The majority (> 95%) of the notified polymer is expected to be separated from the treated water and precipitated into the sludge cake produced during the process. The final concentration of the notified polymer in the sludge cake (containing 20% solids) is estimated as < 400 ppm (0.04%). Depending on the quality of the sludge cake, the final solid waste will be transported by truck and used in agriculture, forestry or landfill where the solid may be naturally dried to contain the notified polymer at < 0.2%.

Treated water containing negligible levels of residual notified polymer will be recycled within the WTPs.

Empty containers of the notified polymer will be rinsed during the end use and then recycled by container recyclers.

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)*
Warehouse operators	2	6
Transport workers	20	6
WTP workers (receiving)	1	6
WTP workers (process)	0.3	12

EXPOSURE DETAILS
Warehouse operators, transport workers and receiving WTP workers handling the imported solution of the notified polymer are not expected to have potential for exposure to the polymer unless there is an accidental release of the aqueous solution containing 30-60% notified polymer. Common personal protective equipment (PPE) including protective clothing, gloves, face masks and safety glasses are expected to reduce the possibility of accidental exposure.

WTP workers involved in the processes of connecting, transferring and mixing the solution of the notified polymer into the wastewater streams may have potential for dermal and ocular exposure to drips and spills bearing up to 30 - 60% of the notified polymer. PPE including coveralls, chemical gloves, face masks and safety glasses are recommended to reduce the possibility of exposure.

WTP and transport workers handling the dewatered sludge cake may have potential for dermal and ocular exposure to the notified polymer at concentrations < 0.04%. Use of protective clothing, gloves and safety glasses would reduce the exposure potential.

6.1.2. Public Exposure
Public exposure to high concentration (30-60%) of imported aqueous solution of the notified polymer is not expected.

Recycled water treated with the notified polymer may be accessible by the public. However, the residual level of the notified polymer in the treated water is negligible.

Sludge cake containing the notified polymer at < 0.2% concentration will be used for landfill, agriculture or forestry where the public may come into contact with the notified polymer. However, the notified polymer will be bound to the sludge solids and will ultimately be broken down by microbes present in the soil.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer. Information on the expected health effects of the notified polymer are based on toxicological studies conducted on a product containing an acceptable analogue of the notified polymer in aqueous solution (the concentration of the analogue polymer is unknown but is expected to be similar to the concentration of the notified polymer as introduced in Nalcolyte® 7135).

The toxicological information provided on the product containing the analogue polymer is summarised in the following table.

Endpoint	*Result and Assessment Conclusion*	*Data Source*
Acute oral toxicity in animal	LD50 > 5,000 mg/kg bw; low toxicity	Summary, analogue
Acute dermal toxicity in animal	LD50 > 2,000 mg/kg bw; low toxicity	Summary, analogue
Skin irritation	slightly irritating	Summary, analogue
Eye irritation	slightly irritating	Summary, analogue
Mutagenicity – bacterial reverse mutation	non mutagenic	SDS, analogue

Toxicokinetics, metabolism and distribution

No information on the toxicokinetic characteristics of the notified polymer was provided. The notified polymer is water soluble and has a high molecular weight (> 10,000 Da); hence absorption across biological membranes is not expected.

Acute toxicity

Acute toxicity studies on the notified polymer were not provided. Based on summarised toxicological information on a product containing the analogue polymer, the notified polymer is expected to be of low acute oral and dermal toxicity.

Irritation and sensitisation

No skin and eye irritation information on the notified polymer was provided. According to summarised toxicological information on a product containing the analogue polymer, the notified polymer may be slightly irritating to the skin and eyes. This is consistent with the notified polymer containing a structural alert for irritation/corrosion. However, irritation should be limited by the high molecular weight of the notified polymer. The notified polymer also contains a residual monomer that is above the cut-off concentration for classification as an eye irritant. However, this residual monomer is not present at a level above the cut-off concentration in the product containing the notified polymer as introduced.

A skin sensitisation study on the notified polymer or an analogue was not provided. The notified polymer contains a structural alert for skin sensitisation. However, given the high molecular weight of the notified polymer, the potential for skin sensitisation is expected to be limited.

Repeated dose toxicity

A repeated dose toxicity study was not provided for the notified polymer or the analogue. Given the high molecular weight of the notified polymer absorption across biological membranes and hence the potential for systemic toxicity is not expected.

Mutagenicity/Genotoxicity

No mutagenicity/genotoxicity information on the notified polymer was provided. The SDS of the product containing the analogue polymer states that the result of an Ames test on the product using *S. typhimurium* strain of TA100 showed negative results.

Health hazard classification

As only limited toxicity information was provided, the notified polymer cannot be classified 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).

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains residual monomers and an adjuvant that are classified as hazardous according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. These are not present at levels in the product containing the notified polymer as introduced above the cut off concentrations for classification.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Limited information is available on the hazard of the notified polymer. It has potential for slight skin and eye irritation. The potential for skin sensitisation also cannot be ruled out as the structure of the notified polymer carries sensitisation alerts.

Warehouse and transport workers handling the imported notified polymer in original packaging are not expected to have contact with the notified polymer, except in the case of an accident. During clean-up of an accidental spill, use of PPE by the workers would minimise risk.

WTP workers may have contact with the notified polymer at concentrations up to 60% during the end-use. Workers handling the dewatered sludge cake may come into contact with the notified polymer at a concentration < 0.04%. There may be a potential for skin irritation and sensitisation for workers who have contact with the notified polymer at high concentrations (30-60%). However the risk is expected to be minimised by the use of PPE and safe work practices.

Provided control measures are in place to minimise exposure to the notified polymer as introduced at high concentrations, the risk of the notified polymer to the health of workers is not expected to be unreasonable.

6.3.2. Public Health

As the sludge containing the notified polymer up to 0.2% concentration when dried will be used for landfill, agriculture or forestry, general public may come into contact with the notified polymer in the sludge solids. However, the notified polymer in the sludge is expected to be at low concentrations, bound to the solids and ultimately broken down by microbes in the soil.

Recycled water treated with the notified polymer is expected to contain only negligible amount of residual polymer and will not pose unreasonable risk to the public.

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

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be introduced into Australia in an aqueous solution which will be used at wastewater treatment plants (WTPs). No release of the notified polymer to the environment is expected from manufacture, reformulation or repacking as these activities will not occur in Australia.

RELEASE OF CHEMICAL FROM USE

The notified polymer is designed to be used at WTPs for sludge treatment. At the WTPs, the notified polymer will be dosed directly from the imported containers via a mixing pump into the wastewater stream and be mixed with sludge. The majority (> 90% of the total import volume) of the notified polymer is estimated to adsorb to the sludge (Boethling RS & Nabholz JV, 1997). The sludge will then be dewatered using belt filter presses or centrifuges. Less than 10% of the notified polymer may remain in the filtrate produced from the dewatering of the treated sludge. The filtrate will be recycled within the WTPs and most of notified polymer present in the filtrate is expected to be removed by further partitioning to other solids present. Therefore, less than 1% (= 10% × 10%) of the notified polymer is expected to be released to surface waters. The sludge cake will be transported by truck and used in agriculture, forestry or landfill where the sludge will be naturally dried.

RELEASE OF CHEMICAL FROM DISPOSAL

Empty containers of the notified polymer will be rinsed during the end use and then recycled by container recyclers.

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified polymer. The notified polymer is not expected to hydrolyse under environmental conditions. Whilst no biodegradability data was submitted for the notified polymer, the notified polymer was indicated to be inherently biodegradable (BOD/COD = 0.43) based on the additional information provided by the notifier and the SDS data.

The notified polymer is a cationic polymer with high molecular weight. Therefore, most of the notified polymer (> 99%) is expected to be removed from the waste water by sorption to sludge or other solids during the waste water treatment at WTPs. The sludge containing the notified polymer is expected to be disposed of to landfill or used in agriculture and/or forestry soils. Small amounts of the notified polymer (< 1%) may be released to surface waters, which will sorb to organic material and disperse.

The notified polymer is not expected to bioaccumulate in aquatic life based on its high molecular weight and expected high water solubility. The notified polymer is likely to degrade and form low molecular weight metabolites in STPs, surface waters, soils and landfill based on its indicated inherent biodegradability. The notified polymer is expected to degrade in both the aquatic and terrestrial compartments through biotic and abiotic processes to form water, oxides of carbon and nitrogen, and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer was indicated to be used by eight WTPs which have a total water capacity of ~ 250 ML per day. It is estimated that 10% of the total import volume of the notified polymer will be released as wastewater produced from the sludge treatment processes (Boethling RS & Nabholz JV, 1997). The produced wastewater will be recycled at WTPs and the notified polymer is expected to be further removed (> 90%) from the effluent at WTPs. Assuming the release occurs over 365 days per year, the Predicted Environmental Concentration (PEC) has been calculated as summarised in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	500,000	kg/year
Proportion expected to be released to sewer	10%	
Annual quantity of chemical released to sewer	50,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	136.986	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	250	ML/day
Removal within STP	90%	Mitigation
Dilution Factor – River	1	
Dilution Factor – Ocean	10	
PEC - River:	54.79	µg/L
PEC - Ocean:	5.48	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of ~ 4,900 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1,500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified polymer may approximate ~ 33 mg/kg in applied soil. This assumes that degradation of the notified polymer occurs in the soil within 1 year from application. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated biosolids application, the concentration of notified polymer in the applied soil in 5 and 10 years may approximate ~ 160 mg/kg and ~ 320 mg/kg, respectively.

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 54.79 µg/L may potentially result in a soil concentration of approximately ~ 360 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately ~ 1,800 µg/kg and ~ 3,600 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the products containing the notified polymer and an analogue polymer are summarised in the table below. The test for toxic effects on algae was conducted for

the product containing the analogue polymer. The tests for toxic effects on fish and daphnia were conducted for the product containing the notified polymer. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity		
1. Acute toxicity to Fathead Minnow (*Pimephales promelas*)	LC50 (96 h) = 0.30 mg/L	Very toxic to fish
2. Acute toxicity Rainbow Trout (*Salmo gairdneri*)	LC50 (96 h) = 0.23 mg/L	
3. Chronic toxicity to Fathead minnow (*Pimephales promelas*)	NOEC (7 d) = 0.25 mg/L	
Daphnia Toxicity		
1. Acute toxicity to *Daphnia magna*	LC50 (48 h) = 0.42 mg/L	Very toxic to aquatic
2. Chronic toxicity to *Ceriodaphnia dubia*	NOEC (7 d) = 0.13 mg/L	invertebrates
Algal Toxicity *(Skeletonema costatum)*	E_rC50 (72 h) = 1.4 mg/L NOE_rC (72 h) = 0.375 mg/L	Toxic to algae

The measured ecotoxicity endpoints indicate the notified polymer is acutely very toxic to aquatic life according to the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS, United Nations, 2009). Therefore, the notified polymer is formally classified as "Acute Category 1; Very toxic to aquatic life" under the GHS.

The notifier provided chronic endpoints for fish and daphnia, indicating that the notified polymer may be considered to be toxic to aquatic life. However, the tests for fish and daphnia chronic toxicity were not conducted over 21 days, following the OECD test guideline, but were conducted over 7 days. Therefore, these endpoints cannot be used for the notified polymer's long-term hazard classification under the GHS. Based on its acute toxicity and lack of ready biodegradability, the notified polymer is formally classified as "Chronic Category 1; Very toxic to aquatic life with long lasting effects" under the GHS.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) has been calculated using the ecotoxicity endpoint determined for the most sensitive species (Invertebrate NOEC = 0.13 mg/L*)*, an assessment factor of 100 and a mitigation factor of 110. An assessment factor 100 is used here as although chronic NOEC are available from species representing three trophic levels, the endpoint for algae were analogue data and the chronic results for fish and daphnia were determined in 7 days, less than the OECD standard of 21 days.

The notified polymer is expected to be less toxic to aquatic life in surface waters than the results reported here as surface waters tend to have higher total organic content and dissolved organic content than the test media used in these ecotoxicological studies. Dissolved organic content will reduce the toxicity of cationic polymers to the aquatic organisms. Therefore, the actual toxicity of the notified polymer in surface waters is expected to be reduced. Based on the calculated charge density of the notified polymer, a mitigation factor of 110 is used for the calculation of the PNEC (Boethling & Nabholz, 1997).

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
NOEC (Invertebrates).	0.13	mg/L
Assessment Factor	÷ 100	
Mitigation Factor	× 110	
PNEC:	= 143	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	54.8	143	0.383
Q - Ocean:	5.48	143	0.038

The risk quotient (Q) is calculated to be < 1 for both river and ocean, indicating that the notified polymer is not expected to reach ecotoxicologically significant concentrations in surface waters based on its maximum annual

use quantity and assessed use pattern. The notified polymer has a low potential for bioaccumulation and is not expected be persistent in the environment based on its indicated potential for biodegradability. On the basis of the PEC/PNEC ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.1.1. Acute toxicity to fish

TEST SUBSTANCE	Product containing the notified polymer (50%)
METHOD	United States, Environmental Protection Agency (US EPA), Ecological Research Series EPA-660/3-75-009, 1975, Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians – Static
Species	Fathead Minnow (*Pimephales promelas*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	40 - 48 mg $CaCO_3$/L
Analytical Monitoring	Not applicable
Remarks – Method	Ten fish per concentration were exposed to the test media at 22 °C with the dissolved oxygen concentration at 92 - 100% of the air saturation throughout the test. The pH values ranged from 7.7 - 8.0. All were within acceptable limits of the test guideline. The study was performed following the Good Laboratory Practice (GLP) regulations. The test was conducted in accordance with the test guideline above without significant deviation from the protocol reported.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
Control	-	10	0	0	0	0
0.056	-	10	0	0	0	0
0.10	-	10	0	0	0	0
0.18	-	10	0	0	0	0
0.32	-	10	0	0	50	60
0.56	-	10	20	80	90	100
1.0	-	10	90	100	100	100
1.8	-	10	1000	100	100	100

LC50	0.30 mg/L at 96 hours (95% confidence limit: 0.18 - 0.56 mg/L).
NOEC	0.18 mg/L at 96 hours.
Remarks – Results	The test was considered valid as all validity criteria were met. All results were based on nominal concentrations. The test substance only contains 50% of the notified polymer. Consequently, the actual toxicity effect of the notified polymer on fish is expected to be 2 times higher than the observed effects reported here. The abnormal effects of mortality, surfacing, fish near the surface, fish on the bottom of the test chambers, laboured respiration, erratic swimming and/or quiescence were observed in the 0.32, 0.56 0.1 and 1.8 mg/L test concentrations during the 96-hour exposure period.
CONCLUSION	The notified polymer is very toxic to fish
TEST FACILITY	ABC (1991)

C.1.2. Acute toxicity to fish

TEST SUBSTANCE	Product containing the notified polymer (50%)

METHOD	United States, Environmental Protection Agency (US EPA), Ecological Research Series EPA-660/3-75-009, 1975, Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians – Static
Species	Rainbow Trout (*Salmo gairdneri*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	40 - 45 mg $CaCO_3$/L
Analytical Monitoring	Not applicable
Remarks – Method	Ten fish per concentration were exposed to the test media at 12 °C with the dissolved oxygen concentration at 64 - 81% of the air saturation throughout the test. The pH values ranged from 7.4 – 7.7. All were within acceptable limits of the test guideline. The study was performed following the Good Laboratory Practice (GLP) regulations. The test was conducted in accordance with the test guideline above without significant deviation from the protocol reported.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*		
Nominal	*Actual*		*24 h*	*48 h*	*96 h*
Control	-	10	0	0	0
0.10	-	10	0	0	0
0.18	-	10	0	0	10
0.32	-	10	10	90	100
0.56	-	10	80	100	100
1.0	-	10	100	100	100

LC50	0.23 mg/L at 96 hours (95% confidence limit: 0.18 - 0.32 mg/L).
NOEC	0.10 mg/L at 96 hours.
Remarks – Results	The test was considered valid as all validity criteria were met. All results were based on nominal concentrations. The test substance only contains 50% of the notified polymer. Consequently, the actual toxicity effect of the notified polymer on fish is expected to be 2 times higher than the observed effects reported here. Surfacing, loss of equilibrium and dark discoloration of the fish were observed the test concentration of 0.18 mg/L representing a 10% effect on remaining fish after 96 hours. The abnormal effects progressed from 0.56 mg/L initially to 0.18 mg/L after 96 hours.

CONCLUSION	The notified polymer is very toxic to fish
TEST FACILITY	ABC (1983)

C.1.3. Short-term chronic toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	EPA/600/4-91/002, 1994, United States, Environmental Protection Agency (US EPA), Short-term method for estimating the chronic toxicity of effluents and receiving waters to fresh water organisms (3rd ed.).
Species	Fathead minnow (*Pimephales promelas)*
Exposure Period	7 days
Auxiliary Solvent	None
Water Hardness	95 - 113 mg $CaCO_3$/L
Analytical Monitoring	Not applicable
Remarks – Method	Following the range-finding test, four fish per concentration were exposed to the test medial with the control run in parallel. The test was conducted

in accordance with the test guideline above without significant deviation from the protocol reported.

RESULTS

Test Day 7		
Nominal concentration (mg/L)	Mean Percent Survival (%)	Mean dry weight of the test fish ± SD* (mg)
Control	95	0.46 ± 0.06
0.13	100	0.53 ± 0.06
0.25	98	0.48 ± 0.03
0.5	0	-
1.0	0	-
2.0	0	-

*SD = Standard Deviation

NOEC (based on survival)	0.25 mg/L at 7 days
NOEC (based on growth)	0.25 mg/L at 7 days
Remarks – Results	Each test met minimum control organism performance requirement defined by the US EPA. The reference toxicity IC25 value was within the expected ranges of values, indicating normal test organism sensitivity. The test was conducted for 7 days instead of 21 days as per the OECD test guideline. Therefore, the notified polymer is unable to be classified for its long-term hazardous effect on fish based on the results above.
CONCLUSION	The notified polymer is considered to be toxic to fish with long lasting effects
TEST FACILITY	Era (2000)

C.1.4. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Product containing the notified polymer (50%)
METHOD	United States, Environmental Protection Agency (US EPA), Ecological Research Series EPA-660/3-75-009, 1975, Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians – Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	160-180 mg $CaCO_3$/L
Analytical Monitoring	Not applicable
Remarks - Method	Ten daphnia per concentration were exposed to the test media at around 20 ± 2 °C with the dissolved oxygen concentration at 98 - 101% of the air saturation throughout the test. The pH values ranged from 8.1 – 8.3. All were within acceptable limits of the test guideline. The study was performed following the Good Laboratory Practice (GLP) regulations. The test was conducted in accordance with the test guideline above without significant deviation from the protocol reported.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Mortality (%)*	
Nominal	*Actual*		*24 h*	*48 h*
Control	-	20	0	0
0.18	-	20	0	0
0.32	-	20	0	6
0.56	-	20	0	14
1.0	-	20	0	20
1.8	-	20	19	20

LC50	0.42 mg/L at 48 hours (95% confidence limit: 0.36 – 0.50 mg/L).
NOEC	< 0.18 mg/L at 48 hours
Remarks - Results	The test was considered valid as all validity criteria were met. All results were based on nominal concentrations. The test substance only contains 50% of the notified polymer. Consequently, the actual toxicity effect of the notified polymer on fish is expected to be 2 times higher than the observed effects reported here. The no-effect concentration was determined to be < 0.18 mg/L since effects were observed in all test concentrations after 48 hours. The abnormal effects of daphnids tending to the bottom of the test vessels, daphnids coated with and/or trailing extraneous material were observed in the 0.18, 0.32, 0.56 and 1.0 mg/L test concentrations.
CONCLUSION	The notified polymer is very toxic to aquatic invertebrates
TEST FACILITY	ABC (1990)

C.1.5. Short-term chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	United States, Environmental Protection Agency (US EPA), EPA/600/4-91/002, 1994, Short-term method for estimating the chronic toxicity of effluents and receiving waters to fresh water organisms
Species	*Ceriodaphnia dubia*
Exposure Period	7 days
Auxiliary Solvent	None
Water Hardness	95-113 mg $CaCO_3$/L
Analytical Monitoring	Not applicable
Remarks - Method	Following the range-finding test, 10 daphnids per concentration were exposed to the test medial with the control run in parallel. The test was conducted in accordance with the test guideline above without significant deviation from the protocol reported.

RESULTS

Nominal concentration, percentage of *Ceriodaphnia dubia* survival and cumulative mean number of offspring released

Test Day 7		
Nominal concentration (mg/L)	Mean Percent Survival	Mean Number of Offspring Released per female (SD)[a]
Control	100	25.7 ± 3.1
0.13	100	25.6 ± 3.4
0.25	100	20.8 ± 4.0
0.5	100	3.8 ± 3.5
1.0	0	0.0 ± 0
2.0	0	0.0 ± 0

*SD = Standard Deviation

NOEC (based on survival)	0.5 mg/L at 7 days
NOEC (based on reproduction)	0.13 mg/L at 7 days
Remarks - Results	Each test met minimum control organism performance requirement defined by the US EPA. The reference toxicity IC25 value was within the expected ranges of values, indicating normal test organism sensitivity. The test was conducted for 7 days instead of 21 days as per the OECD test guideline. Therefore, the notified polymer is unable to be classified for its long-term hazardous effect on aquatic invertebrates based on the results above.

CONCLUSION	The notified polymer is considered to be toxic aquatic invertebrates with long lasting effects
TEST FACILITY	Era (2000)

C.1.6. Algal growth inhibition test

TEST SUBSTANCE	Product containing the analogue polymer (50%)
METHOD	International Standard 10253 (1997), "Water quality-marine algal growth inhibition test with Skeletonema costatum and Phaeodactylum tricornutum" - Static
Species	*Skeletonema costatum*
Exposure Period	72 hours
Concentration Range	Nominal: Control, 0.375, 0.75, 1.5 and 3.0 mg/L Actual: Not determined
Auxiliary Solvent	None
Water Hardness	Reported as 31.5-31.6‰ salinity
Analytical Monitoring	Not applicable
Remarks - Method	The study was performed following the Good Laboratory Practice (GLP) regulations. The test was conducted in accordance with the test guideline above without significant deviation from the protocol reported. Following a range-finding test, the test flasks were incubated at 20 ± 2.4 °C under constant white light. There was no renewal of test media during the 72-hour exposure period. The pH values ranged from 7.96 – 8.67. All were within acceptable limits of the test guideline.

RESULTS

Biomass		*Growth*	
E_bC50 (mg/L at 72 h)	*NOE_bC (mg/L)*	*E_rC50 (mg/L at 72 h)*	*NOE_rC (mg/L)*
0.90	0.375	1.4	0.375

Remarks - Results	The test was considered valid as all validity criteria were met. All results were based on nominal concentrations. The test substance only contains 50% of the notified polymer. Consequently, the actual toxicity effect of the notified polymer on fish is expected to be 2 times higher than the observed effects reported here.
CONCLUSION	The analogue and, by inference, the notified polymer are toxic to algae
TEST FACILITY	FAWLEY (1998)

BIBLIOGRAPHY

ABC (1983) Acute Toxicity of [product containing the notified polymer] to Rainbow Trout (*Salmo gairdneri*) (Study No. 30129, March 1983) Oak Brook, Illinois, USA, Analytical Bio-Chemistry Laboratory, Inc., Nalco Chemical Company (Unpublished report submitted by the notifier)

ABC (1990) Acute Toxicity of [product containing the notified polymer] to *Daphnia magna* (Study No. 38784, November 1990) Columbia, Missouri, USA, Analytical Bio-Chemistry Laboratory, Inc., Nalco Chemical Company (Unpublished report submitted by the notifier)

ABC (1991) Acute Toxicity of [product containing the notified polymer] to Fathead Minnow (*Pimephales promelas*) (Study No. 38785, April 1991) Columbia, Missouri, USA, Analytical Bio-Chemistry Laboratory, Inc., Nalco Chemical Company (Unpublished report submitted by the notifier)

Boethling RS & Nabholz JV (1997) Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton JD & Sutcliffe R, ed. Ecological Assessment of Polymers; Strategies for product stewardship and regulatory programs. New York, Van Nostrand Reinhold, pp 187–234.

Era (2000) Chronic Toxicity Evaluation of Nalco®98LT062 and Nalcolyte®7135 (Study No. 4500349831, September 2000) Duluth, Minnesota, USA, Era Laboratories, Inc, Nalco Chemical Company (Unpublished report submitted by the notifier).

FAWLEY (1998) Algal Growth Inhibition by Test Substance [product containing the analogue polymer] (Study No. FTR 015/98, December 1998) Southampton, SO45 1TW, UK, FAWLEY Aquatic Research Laboratories Ltd, Nalco/Exxon Energy Chemical Ltd (Unpublished report submitted by the notifier)

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.