File No: LTD/1177

August 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Belclene 499

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

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

This Full Public Report is 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:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, 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

FULL PUBLIC REPORT

Polymer in Belclene 499

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Bio-lab Australia Pty Ltd (ABN: 77 586 695 893)
61-63 Canterbury Road
Montrose VIC 3765

Swift and Company Ltd (ABN: 44 000 005 578)
372 Wellington Road
Mulgrave VIC 3170

NOTIFICATION CATEGORY
Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical name;
CAS Number;
Molecular formula;
Structural formula;
Molecular weight;
Spectral data;
Polymer constituents;
Hazardous impurities/residual monomers;
Non hazardous impurities/residual monomers;
Estimated import volumes;
Identity of manufacturers/recipients;
Spectral data.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
Canada (2003).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Belclene 499 (contains 50% of the notified polymer).

METHODS OF DETECTION AND DETERMINATION

METHOD	^{1}H and ^{31}P Nuclear Magnetic Resonance (NMR) Spectroscopy.
Remarks	Reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
High.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
No hazardous impurities are present at above the relevant cutoffs for classification of the notified polymer as a hazardous substance.

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

Chemical Name Sodium salt of a strong acid.
Weight % < 5

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED POLYMER (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as a 50% aqueous solution in 205 L drums, which are suitable for Class 8 Dangerous Goods.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	3-10	3-10	3-10	10-30	10-30

USE
The notified polymer will be used as a component of formulated scale and corrosion inhibitors in open industrial and commercial evaporation cooling systems.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
The notified polymer will be imported through Melbourne and Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS
National chemicals suppliers and distributors.

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 205 L drums suitable for the transport of Class 8 Dangerous Goods and transported by road or rail.

5.2. Operation description

Imported product will be transported to the distributor's warehouses prior to distribution to customers. Minimal product repacking (< 100 kg per annum) may also take place at these warehouses. The product will then be distributed to customer sites where end-use formulations will be prepared.

At the customer sites, the product will be weighed, and then pumped or poured into the blending vessel, mixed with other chemicals to produce end-use formulations of varying concentrations of the notified polymer (2-20%) and finally transferred to 20 L and 200 L polymer drums for dispatch to users.

In the end use application the solution containing the notified polymer is introduced into the cooling system via the system's suction hose that is placed directly into the formulation container. The solution is then added at a controlled rate by a metering pump or system, through a closed system, into the water

to be conditioned. Application to water systems is usually at the rate producing concentrations of 20 mg/L for scale control up to 50 mg/L for corrosion control.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and storage	10	4 hours/day	10 days/year
Warehouse	10	1 hour/day	50 days/year
Reformulation process operator	20	1.5 hours/day	50 days/year
Quality control	10	0.5 hour/day	50 days/year
Packaging	10	4 hours/day	50 days/year
End use	500	0.5 hours/day	200 days/year

Exposure Details

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

At blending sites, skin and eye contact to the imported product containing 50% notified polymer, from splashes, drips and spills, is possible for the workers involved in weighing the product, and pumping or pouring it into the blending vessels. There is also the potential for respiratory and ocular exposure to the mist that may be formed by pump glands. Reformulation process operators will wear personal protective equipment (PPE) such as gloves, eye protection and overalls and will use respiratory protection when there is a chance of mist formation. Laboratory staff will take samples of the formulated product (2-20% notified polymer) for testing, and may have some dermal exposure. Packaging workers are unlikely to be exposed, except if there is an accident, as they will handle the reformulated product in sealed 20-200 L drums.

In most cases, end users will drop the suction hose of the system for dosing the cooling circuit directly into the container. When changing the suction hose, gloves are worn, and exposure should be minimal. When cleaning of the cooling circuit is required, the PPE required to be worn to protect cleaning workers from Legionella bacteria or the associated chlorination step of the clean-out process is sufficient to protect workers from exposure to the notified polymer.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Since the notified polymer will not be manufactured locally, there will be no environmental exposure associated with this process in Australia. The product containing the notified polymer will be incorporated into cooling water-treatment products in a small number of formulating plants in Australia. The notifier states that generation of waste is limited to traces remaining from the clean up of any spill, trace residues in empty packaging and materials used to clean equipment. The amount of the polymer that will be released due to cleaning is expected to be low, as manufacturers will recycle drum washings and equipment rinse waters, into the next formulation batch. Any polymer released during formulation is expected to be removed during in-house effluent treatment.

RELEASE OF CHEMICAL FROM USE

The formulated products containing the notified polymer will be used in the cooling water of industrial and commercial cooling water systems at concentrations of 20 mg/L for scale control up to 50 mg/L for corrosion control.

The formulated product containing the notified polymer is dosed into the water to be conditioned at a controlled rate by a metering pump or apparatus as part of a closed system. In most cases, the suction hose of the system for dosing the cooling circuit is connected directly to the product container limiting release of the polymer during application. The notifier states that the customers are encouraged to properly empty and rinse the product containers several times before disposal to landfill. It is expected that the rinsate will be added to the cooling tower water.

Once used in evaporative water cooling systems, most of the imported polymer will be released with discharged cooling water.

5.5. Disposal

The notifier recommends that disposal of waste containing the notified polymer should be based on the advice of waste disposal authorities. Where possible, incineration is recommended as a method of disposal.

5.6. Public exposure

No exposure to the public is expected during the transport, storage and reformulation processes, except in the case of an accidental spillage.

During end use, a very small amount of cooling water containing the notified polymer can be lost from the system in the air passing out following the cooling process. The water droplets will evaporate, leaving the notified polymer in particulate form to which the public can be exposed.

6. PHYSICAL AND CHEMICAL PROPERTIES

The physical and chemical properties given below are for the polymer in Belclene 494, an analogue of the notified polymer.

Appearance at 20ºC and 101.3 kPa Clear pale yellow liquid.

Melting Point/Freezing Point -15ºC

Remarks Test report not provided.

Boiling Point 103-105ºC at 101.3 kPa

Remarks Test report not provided.

Density 1390 kg/m^3 at 20ºC (liquid)

Remarks Test report not provided.

Vapour Pressure Not determined

Water Solubility Soluble in all proportions at 20°C at pH = 5.

Remarks Test report not provided.

Hydrolysis as a Function of pH Stable at both 0°C and 50°C for 12 weeks at pH 2 and pH 12.

Remarks No test report was provided. The notified polymer has one potentially hydrolysable functionality, but only at extreme pH conditions.

Partition Coefficient (n-octanol/water) log P_{ow} = < 1 at 20°C (estimated)

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).

Remarks The details of estimation method were not provided in this submission.

Adsorption/Desorption Not determined.

Remarks The notified polymer can be expected to bind to metals in soils due to its chelating properties (Boethling and Nabholz 1997).

Dissociation Constant Not determined

Remarks The notifier expects the polymer to form ions in water to a substantial degree. As a salt of a very strong acid it should remain ionised throughout the pH range.

Particle Size Not applicable.

Remarks The notified polymer is component of a solution.

Flash Point Not determined.

Remarks Aqueous solution is not expected to be flammable.

Flammability Limits Not determined.

Remarks Aqueous solution is not expected to be flammable.

Autoignition Temperature Does not self ignite.

Remarks Expert opinion. Report not provided.

Explosive Properties Not explosive.

Remarks Expert opinion. Report not provided.

Reactivity

Remarks Not reactive. Stable to chlorine.

7. TOXICOLOGICAL INVESTIGATIONS

The toxicological investigations described below (except the *in vitro* corrosion study) are for the polymer in Belclene 494, an analogue of the notified polymer.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >5000 mg/kg bw	low toxicity (analogue)
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity (analogue)
Rabbit, skin irritation	non-irritating (analogue)
Rabbit, eye irritation	non-irritating (analogue)
Genotoxicity – bacterial reverse mutation	non mutagenic (analogue)
In vitro corrosion potential	not corrosive

7.1. Acute toxicity – oral

TEST SUBSTANCE	Polymer in Belclene 494
METHOD	OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/ Sprague-Dawley CD (5/sex).
RESULTS	
LD50	>5000 mg/kg bw
Signs of Toxicity	No significant signs of toxicity; 1 female had diarrhoea on day 1 only.
Effects in Organs	No gross internal lesions observed at necropsy.
Remarks - Results	Test report not provided. The report was sighted during the assessment of the polymer in Belclene 494.
CONCLUSION	The analogue is of low toxicity via the oral route.

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Polymer in Belclene 494
METHOD	OECD TG 402 Acute Dermal Toxicity.
Species/Strain	Rat/ Sprague-Dawley CD (5/sex).
Type of dressing	Occlusive.
RESULTS	
LD50	>2000 mg/kg bw
Signs of Toxicity	No significant signs of toxicity.
Effects in Organs	No gross internal lesions observed at necropsy.
Remarks - Results	Test report not provided. The report was sighted during the assessment of the polymer in Belclene 494.
CONCLUSION	The analogue is of low toxicity via the dermal route.

7.3. Irritation – skin

TEST SUBSTANCE	Polymer in Belclene 494
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3/sex
Observation Period	72 hours
Type of Dressing	Semi-occlusive.

RESULTS	No scores > 1 for either erythema or oedema up to 72 hours.
Remarks - Results	Test report not provided. The report was sighted during the assessment of the polymer in Belclene 494.
CONCLUSION	The analogue is non-irritating to the skin.

Due to the low pH of the notified polymer in Belclene 499 (pH < 2), corrosivity testing was carried out.

7.4. In vitro corrosivity potential

TEST SUBSTANCE	Belclene 499
METHOD	The corrosivity potential of the notified polymer was tested using the EpiDerm skin model (MatTek, Ashland, MA, USA). Duplicate EpiDerm tissues were treated with either 50 µL of Belclene 499, 50 µL of sterile, distilled water (negative control), or 50 µL of 8.0 N potassium hydroxide (positive control). The tissues were incubated for either 3 mins or 60 mins at 37°C in a humidified atmosphere of 5% CO_2 in air. After exposure, each EpiDerm tissue was rinsed in PBS. The viability of the skin tissue was determined via a colorimetric assay that measures cell respiration based on the reduction of MTT. Each tissue sample was incubated with MTT for 3 hours at 37°C in a humidified atmosphere of 5% CO_2 in air. The tissue was then blotted dry, and the MTT extracted. The OD_{540} of each sample of MTT was then measured, and the relative viability determined, as compared to the negative control.
Remarks - Method	This test is approved for distinguishing between corrosive and non-corrosive chemicals by the EU (ESAC, 2000).

RESULTS

Incubation time (mins)	*Test substance*	*relative viability (%)*
3	Belclene 499	91.64
3	water	100
3	potassium hydroxide	10.43
60	Belclene 499	83.07
60	water	100
60	potassium hydroxide	8.7

Remarks - Results	A substance is classed as corrosive if the relative mean viability of the tissue is <50% after 3 mins or <15% after 60 mins. The viability of the tissues exposed to Belclene 499 is >80% at both time points, indicating that it is not corrosive. The positive control gave positive results at both time points.
CONCLUSION	The notified polymer is not corrosive to human skin tissue.
TEST FACILITY	Safepharm Laboratories (2003)

7.5. Irritation – eye

TEST SUBSTANCE	Polymer in Belclene 494
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3/sex
Observation Period	72 hours

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	0	0	0	0	0
Conjunctiva: chemosis	0	0	0	1	1 hour	0
Conjunctiva: discharge	0	0	0	3	1 hour	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results: Test report not provided. The report was sighted during the assessment of the polymer in Belclene 494.

The notified polymer is more acidic than the analogue (pH 1.85 compared to pH 5 for the analogue), and thus the notified polymer is expected to be an eye irritant.

CONCLUSION: The analogue is slightly irritating to the eye.

7.6. Genotoxicity – bacteria

TEST SUBSTANCE: Polymer in Belclene 494

METHOD: OECD TG 471 Bacterial Reverse Mutation Test.
Species/Strain: *S. typhimurium*: TA 1538, TA 1535, TA 1537, TA 98, TA 100
Metabolic Activation System: Induced rat liver S9 fraction.
Concentration Range in Main Test: a) With metabolic activation: 100-10000 µg/plate
b) Without metabolic activation: 100-10000 µg/plate

RESULTS: Did not induce point mutations by base pair changes, or frame-shifts in the genome of any of the five strains used, with or without metabolic activation.

Remarks - Results: Test report not provided. The report was sighted during the assessment of the polymer in Belclene 494.

CONCLUSION: The analogue was not mutagenic to bacteria under the conditions of the test.

8. ENVIRONMENT

8.1. Environmental fate

The data on ready biodegradability is for the polymer in Belclene 494, an analogue for the notified polymer.

8.1.1. Ready biodegradability

TEST SUBSTANCE	Polymer in Belclene 494
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Sludge/soil microorganisms
Exposure Period	28 days
Remarks - Results	There was 3% biodegradation after 28 days. Test report not provided. The report was sighted during the assessment of the polymer in Belclene 494.
CONCLUSION	The analogue cannot be classified as readily biodegradable according to the OECD criteria.

8.1.2. Bioaccumulation

No test results on bioaccumulation were provided. However, bioaccumulation is not expected due to the high water solubility, high molecular weight and the estimated low log P_{ow} of the notified polymer.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity

Test results were for the polymer in Belclene 494.

Species	*Test*	*Result* *(mean measured concentration of polymer)*
Rainbow Trout* (*Oncorhynchus mykiss*)	96 h (OECD TG 203)	LC50 > 958 mg/L NOEC = 958 mg/L
Water Flea# (*Daphnia magna*)	48 h (OECD TG 202)	EC50 = 466 mg/L NOEC = 118 mg/L (based on immobility and sublethal effects)
Green Alga^ (*Scenedesmus subspicatus*)	72 h growth inhibition (OECD TG 201)	EC50 = 149.5 mg/L NOEC = 149.5 mg/L

* TES (1994a)
\# TES (1994b)
^ Summary of report sighted during the assessment of the polymer in Belclene 494.

Test results used in the US Toxic Substances Control Act (TSCA) submission on an analogue of the polymer in Belclene 494 were available, although the test reports were not provided.

Species	*Test*	*Result**
Rainbow Trout (*Oncorhynchus mykiss*)	96 h (Test guideline not indicated)	LC50 > 1200 mg/L
Bluegill (*Lepomis macrochirus*)	96 h (OECD TG 202)	LC50 > 1000 mg/L
Water Flea (*Daphnia magna*)	48 h (Test guideline not indicated)	EC50 = 1800 mg/L
Green Alga (*Selenastrum capricornutum*)	96 h (Test guideline not indicated)	E_rC50 = 57 mg/L

* Source: TSCA Submission for an analogue of the polymer in Belclene 494. It is unclear whether test results are nominal or measured concentrations.

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Belclene 499
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 6.25, 12.5, 25, 50 and 100 mg/L (based on a preliminary range finding test)
Auxiliary Solvent	None
Water Hardness	Standard culture medium was used.
Analytical Monitoring	The test solutions were analysed as total organic phosphate after UV digestion. As the presence of phosphorous in algal cells and the culture media affected the results of preliminary recovery analyses, test samples were obtained with and without algae at 0 hours and corrected for the control value.
Remarks - Method	The mean cell density of control at test initiation was 9.34 x 10^3 cells/mL. The test temperature in the incubator was maintained within 24 ± 1°C throughout the test (no detailed readings available). The pH values at the start of the test (7.5 in the controls and 5.6 to 7.3 in the test substance solutions) and at the end of the test (7.8 to 7.9 in the controls and 5.6 to 8.0 in test substance solutions) were all satisfactorily maintained.

RESULTS

*Biomass**		*Growth**	
E_bC50 mg/L at 72 h	*NOEC Biomass mg/L at 72 h*	*E_rC50 mg/L (0- 72 h)*	*NOEC Growth mg/L at 72 h*
51 (44-59)[#]	12.5	74[##]	12.5

* All results are based on nominal test concentrations of the whole product.
\# 95% confidence limit.
The report indicate that it was not possible to calculate 95% confidence limits for this value as the data generated did not fit the statistical models available.

Remarks - Results	At the start, the control and test solutions were observed to be clear colourless solutions. After 72 hours, all control and most test solutions were observed to be green dispersions of various intensities (all control and 6.25 mg/L solutions - bright green, the 12.5 mg/L solutions - green, the 25 mg/L - pale green and the 50 mg/L - extremely pale green). The 100 mg/L solution was clear and colourless. The report does not indicate any abnormalities observed in algal cells or why diluted solutions were

coloured.

Measured concentrations at 0 hours corrected for the control ranged from 91 to 94% of the nominal with algae present and from 90 to 102% of the nominal with no algae. After 72 hours measured concentrations where algal cells were present ranged from 86 to 95% of the nominal with the exception of the 6.25 g/L test concentration, which was 78% of nominal. As the NOEC based on growth rate was 12.5 mg/L, this result was considered to have no impact on the overall result and the nominal test concentrations were used for calculating the EC50 values.

CONCLUSION	The test substance is harmful to green algae.
TEST FACILITY	Safepharm Laboratories (2004)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The waste generated during formulation of evaporative water cooling products containing the notified polymer is expected to be limited to traces remaining from the clean up of any spill and in empty packaging. This amount released during cleaning empty containers and equipment will be very low as the rinsate is usually added to the next formulation batch. The polymer is completely soluble in water thus will be easily rinsed from containers and equipment.

Disposal of rinsed containers, containing minimal polymer residues will be to landfill. Any waste associated with the clean up of spills and equipment will be disposed of according to the MSDS and appropriate regulations. Incineration is recommended as a possible disposal method, although strong acid receptors are needed to trap acidic phosphorous combustion products.

The notified polymer is a multifunctional scale and corrosion control additive for open evaporative cooling systems, giving calcium carbonate scale control, calcium phosphate dispersancy control and general corrosion protection. The polymer is used in the products to scavenge for positively charged aqueous ions.

Once used in evaporative water cooling systems, most of the notified polymer will be disposed of with discharged cooling water to sewer. The concentration of the polymer in discharged water will vary according to the specific process. No indication is given on what proportion of this would be free polymer, although any free polymer is expected to bind with cations and other material on mixing with the sewer waste streams. Some of the polymer will remain in the water column, and the rest will move to the sludge. Boethling and Nabholz (1997) indicated lower removal rates for polyanionics having appreciable solubility or dispersibility.

The recommended maximum concentration of the notified polymer in the cooling water is 25 ppm. It is estimated that dilution of discharge water with sewer waters at 1:250 and 1:5 will occur when the discharged polymer enters a city and a country sewage treatment plant (STP), respectively.

Assuming that all of the polymer discharged enters a city or country sewer:

Calculation Parameters	*City*	*Country*
Concentration of polymer in cooling water*	25 mg/L	25 mg/L
Cooling system circulation volume	144,000 L/day	72,000 L/day
Cooling water blowdown proportion	0.15%	0.15%
Volume of water blowdown to effluent system	216 L/day	108 L/day
Quantity of polymer discharged per site	5.4 g/day	2.7 g/day
Estimate of number of circuits discharged to an STW	100	10
Quantity of polymer discharged per sewer	540 g/day	27 g/day
Volume of sewer flow	250 ML/day	25 ML/day
Concentration of polymer in the sewer	2.16 µg/L	1.08 µg/L
Concentration in receiving waters		
River (assume no dilution)	2.16 µg/L	1.08 µg/L
Ocean (1:10 dilution)	0.216 µg/L	0.108 µg/L

*Concentration derived from a feedwater of 50 mg/L calcium ion and a target maximum of 250 mg/L after concentration, requiring 25 mg/L of the notified polymer for effective control.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests (showing the highest toxicity at each trophic level) are listed below. The most sensitive species was algae with 72 hour E_bC_{50}value of 51 mg/L. This result was for the whole product (50% solution of notified polymer), and therefore was divided by 2 to convert to the active basis (25.5 mg/L).

Organism	*Duration*	*End Point*	*mg/L*
Fish*	96-h	LC_{50}	>958 (mean measured)
Daphnia#	48-h	EC_{50}	466 (mean measured)
Algae^	72-h	E_bC_{50}	51 (nominal) with 44-59 confidence limits
		E_rC_{50}	74 (nominal)

* TES (1994a)
\# TES (1994b)
^ Results of test using the product containing 50% of the notified polymer in aqueous solution.

A predicted no effect concentration (PNEC - aquatic ecosystems) of 255 µg/L has been derived by dividing the end point of 25.5 mg/L by a worst-case scenario uncertainty (safety) factor of 100 (as toxicity data are available for three trophic levels).

9.1.3. Environment – risk characterisation

The RQ values (PEC/PNEC) for the aquatic environment are given below for both the city and country sewers.

Location	PEC µg/L	PNEC µg/L	Risk Quotient (RQ)
<u>City</u>			
River (no dilution)	2.16 µg/L	255	8.4×10^{-3}
Ocean outfall (1:10 dilution)	0.216 µg/L	255	8.4×10^{-4}
<u>Country</u>			
Inland river (no dilution)	1.08 µg/L	255	4.2×10^{-3}

\# PEC and the RQ values calculated assuming that all the notified polymer discharged into sewer partitioned into water during the sewage treatment process.

The RQ values for the aquatic environment, for city and country use and assuming that the polymer is not removed in STP, are significantly below 1 for both freshwater and marine water, indicating no immediate concern to the aquatic compartment. Further, a significant part of the notified polymer can be expected to be adsorbed to sludge in STP, considerably reducing the PEC and the risk quotients.

Based on the proposed use pattern the notified polymer is not expected to pose an unacceptable risk to the health of aquatic life. Bioaccumulation is not expected.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

During transport and storage, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached.

At blending sites, there may be exposure to 50% notified polymer, from splashes, drips, spills and the formation of mist that may be formed by pump glands. Process operators will wear PPE such as gloves, overalls and eye protection, and will use respiratory protection when there is a chance of mist formation. Due to these precautions, exposure via the dermal, ocular and inhalation routes is expected to be low. Laboratory staff will take samples of the formulated product for testing, and there may be some dermal exposure, although gloves and lab coats will be worn. Packaging workers are unlikely to be exposed, except if there is an accident, as they will handle the reformulated product in sealed 20-200L drums.

End users may come into dermal or ocular contact with products containing to up to 20% notified polymer, from splashes and drips when changing the suction hose. Gloves are worn, and exposure should be minimal. Exposure during cleaning of the cooling circuit is unlikely, as a high level of PPE is required due to potential exposure to Legionella bacteria and the associated chlorination step of the clean-out process.

9.2.2. Public health – exposure assessment

No exposure to the public is expected during the transport, storage and reformulation processes, except in the case of an accidental spillage.

During end use, the notified polymer may escape in particulate form as evaporation of water from water droplets occurs. As the concentration of the notified polymer in the water droplets would be <50 mg/L and the emission would be diluted by dispersion into the surrounding atmosphere, exposure to the public via this route will be very low.

9.2.3. Human health – effects assessment

The notified polymer is highly water soluble with NAMW > 1000. The polymer in Belclene 494 was used as an analogue for the toxicity studies, and was of low toxicity via the oral and dermal routes in the rat with both LD_{50} > 2000 mg/kg. The analogue was not an irritant to the skin of the rabbit and was a slight irritant to the eye of the rabbit. It was not mutagenic in bacteria.

Due to the low pH of the notified polymer (pH 1.85 compared to pH 5 for the analogue), corrosivity testing was carried out, with in vitro testing determining that the notified polymer is not corrosive.

The notified polymer is not classified as a skin irritant, based on analogue data. Specifically, the in vitro corrosivity test on the notified polymer returned very similar results to an in vitro corrosivity test on the analogue chemical. As this analogue is not a skin irritant, the notifier has determined that the notified polymer is also not a skin irritant due to the similar results of the corrosivity test.

Due to the low pH, and results of eye irritation tests on analogue chemicals with a similar pH, the notifier has classified the notified polymer as an eye irritant. Based on this information, the notified polymer should be classified as a hazardous substance, and the appropriate risk phrase is:

R36 – Irritating to eyes.

9.2.4. Occupational health and safety – risk characterisation

The exposure of transport, storage and warehouse workers to the notified polymer is expected to be negligible.

Although testing on an analogue indicated there is no evidence of a health hazard, the notified polymer in solution has a significantly lower pH than the analogue used in the testing, and thus may be irritating to eyes and mucus membranes. The most likely point of dermal, ocular and inhalation exposure to the imported solution (containing 50% notified chemical) is for workers involved in reformulation, from splashing and the formation of mists. The use of respiratory and eye protection, as outlined in the MSDS, will greatly reduce the risk of ocular and inhalation exposure, and dermal exposure will be minimised through PPE, including gloves and overalls. Laboratory workers may be exposed to small amounts of notified polymer, but will wear gloves, eye protection and a lab coat to control exposure.

During end use, there is a possibility of dermal and ocular exposure to up to 20% notified polymer when the cooling system's hose is placed into a container of water treatment product. Gloves will be worn during this process to control exposure and possible irritant effects. The eye irritancy potential of the product is dependant on the pH of the product, rather than being based solely on the concentration of notified polymer.

The exposure of workers involved in cleaning cooling systems will be negligible, due to high levels of PPE worn to protect against more hazardous substances.

9.2.5. Public health – risk characterisation

Public exposure is expected to be very low. Therefore, the risk of irritant effects to the public is also low.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

The notifier has indicated that the notified chemical is classified as hazardous. The classification and labelling details are:

R36 – Irritating to eyes.

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

Category: Acute III - hazardous to the aquatic environment.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio the notified polymer is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used as a scale and corrosion inhibitor in open industrial and commercial evaporation cooling systems.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the product containing the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The MSDS and label of products/mixtures containing the notified polymer should contain the following risk phrases:
  - [>20%]: R36 – Irritating to eyes

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer in the product Belclene 499:
  - Eye protection
  - Respiratory protection when there is a chance of mist formation
  - Gloves
  - Industrial clothing and footwear

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

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

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

Environment

Disposal

- Small amounts of the notified polymer adsorbed onto sand or earth should be disposed of as solid waste in accordance with the local regulations/advice of waste disposal authorities using a licensed waste contractor.
- Empty containers should be double rinsed into the process stream before disposal of to landfill.
- Liquid material should be incinerated. However, strong acid receptors are needed to trap acidic phosphorous combustion products.
- Prevent the spilled material from entering drains and waterways.

Emergency procedures

- Spills/release of the notified polymer should be handled by absorbing the spilled material in vermiculite, dry sand or earth and placing in properly labelled (contents and hazard symbol) containers that should be sealed.
- When a drum is leaking, seal the leak if possible and place the drum in a properly labelled overbin.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

Boethling RS and Nabholz JV (1997) Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act, Chapter 10. In: Ecological Assessment of Polymers: Strategies for Product Stewardship and Regulatory Programs. Hamilton JD and Sutcliffe R (Eds), Van Nostrand Reinhold NY.

ESAC (2000) Statement on the Application of the EpiDerm. Human Skin Model for Skin Corrosivity Testing. ECVAM Scientific Advisory Committee (ESAC), European Centre for the Validation of Alternative Methods (ECVAM).

FMC (1992a) Acute Oral Toxicity Study in Rats, - [analogue chemical], Project Study No. 194-1842, FMC Corporation, New Jersey, USA (unpublished report previously assessed by NICNAS).

FMC (1992b) Acute Dermal Toxicity study in Rats, - [analogue chemical], Project Study No. 194-1840, FMC Corporation, New Jersey, USA (unpublished report previously assessed by NICNAS).

FMC (1992c) Primary Skin Irritation study in Rabbits, - [analogue chemical], Project Study No. 194-1841, FMC Corporation, New Jersey, USA (unpublished report previously assessed by NICNAS).

FMC (1992d) Primary Eye Irritation study in Rabbits, - [analogue chemical], Project Study No. 194-1842, FMC Corporation, New Jersey, USA (unpublished report previously assessed by NICNAS).

Great Lakes Chemicals (2002) Characterisation of Belclene 499 and Comparison with Belclene 494. TP/PAG/2002/PW/12. Great Lakes Chemicals (UK) Ltd Analytical Trafford Park, UK (unpublished data submitted by notifier).

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2002) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2002)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

Safepharm Laboratories (2003) Belclene 499: Determination of Corrosive Potential in the EpiDerm Corrosivity Test. SPL Project number 1810/002. Safepharm Laboratories Limited, Derbyshire UK. (unpublished report submitted by the notifier).

Safepharm Laboratories (2004) Belclene 499: Algal Inhibition Test. Project number 1882/001. Safepharm Laboratories Limited, Derbyshire UK (unpublished report submitted by the notifier).

TES (1994a) Acute Toxicity to Rainbow Trout, Oncorhynchus mykiss, under static test conditions – [analogue chemical]. Project Study No. 194-1843, Toxicon Environmental Sciences, Florida, USA (unpublished report previously assessed by NICNAS).

TES (1994b) Acute Toxicity to the Water Flea, Daphnia magna, under static test conditions – [analogue chemical. Project Study No. 194-1844. Toxicon Environmental Sciences, Florida, USA (unpublished report previously assessed by NICNAS).

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.