

File No: NA/289

October 1997

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

DP 3448

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989*, and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**DP 3448****1. APPLICANT**

FMC (Australia) Ltd of 2-4 Overseas Drive NOBLE PARK VIC 3174 has submitted a limited notification statement in support of their application for an assessment certificate for the polymer, DP 3448.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, DP 3448 is not considered to be hazardous. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, polymer constituents and residual monomers have been exempted from publication in the Full Public Report and the Summary Report.

Trade names: DP 3448; Belclene 494

Method of detection and determination: the chemical can be identified by infrared (IR) and nuclear magnetic resonance (NMR) spectra; the impurities and by-products can be quantified by high performance liquid chromatography (HPLC)

3. PHYSICAL AND CHEMICAL PROPERTIES

The physical and chemical properties listed below are that of Belclene 494, which contains approximately 40% of the notified polymer in aqueous solution, as the polymer is imported in this form and never isolated.

Appearance at 20°C and 101.3 kPa: clear to slightly turbid, pale yellow liquid

Odour: slight

Freezing point: -15°C

Boiling point: 103-105°C

Specific gravity: 1.39 at 20°C

Vapour pressure: not determined - expected to be the same as water

Water solubility:	soluble in all proportions at 20°C (pH = 5.0)
Partition co-efficient (n-octanol/water):	$\log P_{ow} < 1$ (estimated)
Hydrolysis as a function of pH:	stable at both 0°C and 50°C for twelve weeks at pH 2 and 12
Adsorption/Desorption:	not determined
Dissociation constant:	not determined
pH:	4.5-5.5
Flash point:	not determined
Flammability limits:	not determined
Combustion products:	oxides of carbon, nitrogen, phosphorous, and sulfur may be formed
Explosive properties:	not determined
Reactivity/Stability:	hydrolytically stable; stable to chlorine; nitrites, sulphites and alkaline materials cause decomposition; thermally stable < 280°C

Comments on Physico-Chemical Properties

The notifier notes that "the polymer is expected to form ions in water to a substantial degree" as it is this property (dissociation) that gives the polymer its functionality as a scale inhibitor. It is therefore expected that adsorption to soils would be high. Hydrolysis test reports were unavailable, however the polymer has no functionalities that are expected to be subject to hydrolysis under expected environmental conditions of use.

4. PURITY OF THE CHEMICAL

Impurities in the notified polymer are present below the cut-off levels for classification as a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances* (1). They are therefore permitted to be exempt from publication.

5. INDUSTRIAL USE

The notified polymer will not be manufactured in Australia but will be imported as an aqueous solution in the formulation known as Belclene 494. Belclene 494 is a multifunctional scale and corrosion control additive for open evaporative cooling systems.

The expected import volume of the notified chemical is > 1 tonne per annum of the notified chemical for the first 5 years.

6. OCCUPATIONAL EXPOSURE

The notified polymer will be imported into Australia in the formulation known as Belclene 494. This product will be transported to and stored in FMC warehouses in 205 L “Mauser” drums prior to distribution to customers. Minimal product repacking may also take place at FMC warehouses. Workers involved in the transport operation should only be exposed to the chemical in the event of accidental spills. The product will then be distributed to several customer sites where end-use formulations will be prepared.

At the customer sites, the product will be weighed, pumped into the blending vessel, mixed with other chemicals to produce end-use formulations of varying concentrations and finally transferred to 20 L and 200 L polymer drums for dispatch to users. Exposure to mists and volatile organic impurities is also possible during these operations. Approximately 2 workers per formulation site will be involved in these operations.

In the end use application, the solution containing the notified polymer is introduced into the cooling system via the system’s suction hose which is placed directly into the formulation container. The solution is then added at a controlled rate (resulting in a maximum concentration of 50mg/L) by a metering pump or system, through a closed system, into the water to be conditioned. Approximately 100-150 workers (application operators) will be involved in this operation at customer sites. An additional 350 laboratory technicians may also be exposed to dilute (50 ppm polymer) solutions during analytical procedures. Exposure to the polymer is also possible during the periodic cleaning of cooling circuits.

In summary, the main sources of occupational exposure to the notified polymer will be during blending of formulations and addition to the cooling system.

7. PUBLIC EXPOSURE

No exposure to the public is expected during storage and transport except in the case of accidental spillage. However, the exposure will be minimal if spills are contained and cleaned up by the recommended practices as outlined in the Material Safety Data Sheet (MSDS).

The notified polymer may be dispersed in particulates if they are fugitive from cooling towers. The concentration in the particles of water would be very low and the emission would normally be diluted by dispersion into the surrounding atmosphere. As it is not generally permitted by Environmental Protection Authorities for blow-down from cooling towers to be directed into drains or onto soil, the polymer would be expected to have a fate in the sewerage system. The public exposure from these sources is expected to be low.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier claims that the generation of waste in re-formulation will be limited to traces remaining from the clean up of any spill, trace residues in empty packaging and materials used to clean equipment. This latter release should be very low as manufacturers have adopted the practice of re-cycling rinse water into the next formulation batch. Instructions on the clean-up of spills are given in the MSDS and appear adequate.

The polymer is expected to be added to evaporative cooling waters through a metering pump or system at rates of 20 ppm for scale control or 50 ppm for corrosion control. The notifier claims that most of the users perform multiple rinses of the finished product container before disposal, with the rinsate added to the cooling tower water. Also, the company plans to add to the MSDS for the re-formulated product a statement indicating that finished containers should be rinsed several times.

Fate

The polymer is used to scavenge positively charged aqueous ions. It is therefore expected to share the fate of these ions and be disposed of to sewer. The notifier estimates that for a cooling tower that re-circulates water at 190 kL/min, and has a "blowdown" of 230 kL/day, up to 1 kg/day will be released to sewer. 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.

Disposal of used drums with minimal polymer residues will be to landfill after rinsing. This is highlighted in the material safety data sheet (MSDS). Any waste associated with the clean up of spills and equipment will be disposed of according to the MSDS and appropriate regulations. Incineration is a possible disposal method, although strong acid receptors are needed to trap acidic phosphorous combustion products. Using OECD test guideline 301D (closed bottle test), DP 3448 can not be classified as readily biodegradable, with only 3% biodegradation after 27 day under aquatic aerobic conditions exposed to sludge/soil micro-organisms.

No bioaccumulation of the polymer is expected because of its very low P_{ow} and high water solubility (2), and its very large molecular size which is likely to inhibit membrane permeability and prevent uptake during exposure (3,4).

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicological data are required for polymers of NAMW > 1000 according to the Act. However, data for acute oral toxicity, skin and eye irritation and mutagenicity in bacteria were supplied and are evaluated below.

9.1 Acute Toxicity

Summary of the acute toxicity of DP 3448

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	rat	LD ₅₀ > 5000mg/kg	(5)
acute dermal toxicity	rat	LD ₅₀ > 2000mg/kg	(6)
skin irritation	rabbit	non-irritant	(7)
eye irritation	rabbit	slight irritant	(8)

9.1.1 Oral Toxicity (5)

<i>Species/strain:</i>	Sprague-Dawley CD rats
<i>Number/sex of animals:</i>	5 males, 5 females
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	gavage of aqueous solution
<i>Clinical observations:</i>	no significant signs of toxicity; 1 female had diarrhoea on day 1 only
<i>Mortality:</i>	nil
<i>Morphological findings:</i>	no gross internal lesions observed at necropsy
<i>Test method:</i>	OECD Guideline No. 401 (9)
<i>LD₅₀:</i>	> 5000 mg/kg
<i>Result:</i>	low acute oral toxicity in the rat

9.1.2 Dermal Toxicity (6)

<i>Species/strain:</i>	Sprague-Dawley CD rats
<i>Number/sex of animals:</i>	5 males, 5 females
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	as an aqueous solution under an occlusive wrap

<i>Clinical observations:</i>	no significant signs of toxicity
<i>Mortality:</i>	nil
<i>Morphological findings:</i>	no gross internal lesions observed at necropsy
<i>Test method:</i>	OECD Guideline No. 402 (10)
<i>LD₅₀:</i>	> 2000 mg/kg
<i>Result:</i>	low acute dermal toxicity

9.1.3 Skin Irritation (7)

<i>Species/strain:</i>	New Zealand White rabbits
<i>Number/sex of animals:</i>	3 males, 3 females
<i>Observation period:</i>	3 days
<i>Method of administration:</i>	0.5 mL of test material placed under a gauze pad then entire trunk of the animal wrapped in semi-occlusive cheesecloth bandage for four hours; test terminated after 72 hrs
<i>Draize scores (11):</i>	no scores > 1 for either erythema or oedema up to 72 hours (See Attachment 1 for Draize scales)
<i>Test method:</i>	OECD Guideline No 404 (12)
<i>Result:</i>	non-irritant to rabbit skin

9.1.4 Eye Irritation (8)

<i>Species/strain:</i>	New Zealand White rabbit
<i>Number/sex of animals:</i>	3 males, 3 females
<i>Observation period:</i>	3 days
<i>Method of administration:</i>	test substance (0.1 mL) instilled in conjunctival sac of one eye

Draize Scores (11):

Animal	Time after instillation											
	1 hour			1 day			2 days			3 days		
Cornea	o^a	a^b		o^a	a^b		o^a	a^b		o^a	a^b	
1	0 ⁱ	0		0	0		0	0		0	0	
2	0	0		0	0		0	0		0	0	
3	0	0		0	0		0	0		0	0	
4	0	0		0	0		0	0		0	0	
5	0	0		0	0		0	0		0	0	
6	0	0		0	0		0	0		0	0	
Iris												
1		0			0			0			0	
2		0			0			0			0	
3		0			0			0			0	
4		0			0			0			0	
5		0			0			0			0	
6		0			0			0			0	
Conjunctiv	r^c	c^d	d^e	r^c	c^d	d^e	r^c	c^d	d^e	r^c	c^d	d^e
a												
1	0	1	3	0	0	0	0	0	0	0	0	0
2	0	1	3	0	0	0	0	0	0	0	0	0
3	0	0	3	0	0	0	0	0	0	0	0	0
4	0	0	3	0	0	0	0	0	0	0	0	0
5	0	0	3	0	0	0	0	0	0	0	0	0
6	0	1	3	0	0	0	0	0	0	0	0	0

ⁱ see Attachment 1 for Draize scales

^a opacity ^b area ^c redness ^d chemosis ^e discharge

Test method: OECD Guideline No. 405 (13)

Result: slight irritant to the rabbit eye

9.2 Genotoxicity

9.2.1 Salmonella typhimurium Reverse Mutation Assay (14)

Strains: *Salmonella typhimurium* TA 98, TA 100, TA 1535, TA 1537 and TA 1538

Concentration range: 100 to 10000 µg/plate

Test method: Maron and Ames (15), OECD Guideline 471 (16)

Result: 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 (provided by rat liver S9).

9.3 Overall Assessment of Toxicological Data

DP 3448, the notified polymer in Belclene 494 was of low toxicity via the oral and dermal routes in the rat with both LD₅₀ > 2000 mg/kg. It was not an irritant to the skin of the rabbit and was a slight irritant to the eye of the rabbit. DP3448 was found to be non-mutagenic in an *in vitro* reverse mutation assay of *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538.

The notified chemical is not classified as hazardous in accordance with Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (1) with respect to the submitted data.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The ecotoxicity studies were conducted using DP 3448 (33% notified polymer) dissolved in water. The results in the table below were provided by the notifier.

Ecotoxicity test results for DP3448

Species	Test	Result*	Reference
rainbow trout (<i>Oncorhynchus mykiss</i>)	96h acute	LC ₅₀ > 958 mg/L	(17)
water flea (<i>Daphnia magna</i>)	48h acute	EC ₅₀ = 466 mg/L NOEC = 118 mg/L (based on immobility and sublethal effects)	(18)
green alga (<i>Selenastrum capricornutum</i>)	72h growth inhibition	EC ₅₀ = 149.4 mg/L	**

* mean measured concentration of polymer

** summary of report sighted by EPA

Test results for a structurally analogous polymer, 2-propenoic acid telomer with sodium 2-methyl-2-[1-oxo-2-propenyl)amino]-1-propane sulphonate and sodium phosphonate were also provided, and are summarised below.

Ecotoxicity test results for a telomer structurally analogous to DP 3448

Species	Test	Result*
rainbow trout (<i>Oncorhynchus mykiss</i>)	96h acute	LC ₅₀ > 1200 mg/L
bluegill (<i>Lepomis macrochirus</i>)	96h acute	LC ₅₀ > 1000 mg/L
water flea (<i>Daphnia magna</i>)	48h acute	EC ₅₀ = 1800 mg/L
green alga (<i>Selenastrum capricornutum</i>)	72h growth inhibition	EC ₅₀ = 57mg/L

* unclear whether test results are nominal or measured concentrations

The above information shows that these polymers are practically non-toxic or only slightly toxic to aquatic organisms.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Most of the polymer will be disposed of with overflow or discharged evaporative cooling water to sewer. The concentration of the polymer in discharged water will vary according to the process that it will be used for. The maximum concentration will be 50 ppm and the expected discharge rate will be 1 kg/day. This value is for quite a large cooling circuit (190 000 L/min circulating), with many units discharging far less quantities of the notified polymer.

The notifier has estimated that there would be at least a 250:1 dilution of discharge water with sewer waters. The EPA agrees, given that if all of the polymer discharged entered a city sewer, then:

Amount of polymer entering sewer	50 mg/L (or ppm)
Dilution in city sewer, 250:1 (250 mL)	200 µg/L
Concentration in receiving waters (ocean, 10:1 dilution)	20 µg/L

Even for if all of the polymer discharged entered a country sewer, then:

Amount of polymer entering sewer	50 mg/L (ppm)
For a regional based site, Dilution in country sewer, 50:1 (5 mL)	1.0 mg/L
Concentration in receiving waters (river, 2:1 dilution)	0.5 mg/L

The calculations show that the concentration in the regional receiving waters would still be 2 orders of magnitude below the EC₅₀ for algae.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

According to the notifier no reports of adverse human effects have been reported for manufacture or formulation of the notified polymer in other countries.

Animal data indicate that the notified polymer is unlikely to be acutely toxic to humans via oral and dermal routes. Although no animal data were available for inhalation, a similar toxicity profile would be expected, particularly in view of the high molecular weight of the notified polymer. The polymer may be a slight eye irritant to humans as indicated by animal data and the high level of low molecular weight polymeric species in the notified polymer.

The low vapour pressure of Belclene 494 would indicate that inhalational exposure to the notified polymer is unlikely, particularly as heating is not an integral part of either formulation or end-use processes. However, both inhalation and eye contact may occur during the blending process as a result of mist formation. Skin and eye contact may also occur during end-use handling, in particular during the change over of suction hoses. Exposure is also possible during the cleaning of cooling water circuits.

Although the risk of adverse health effects from acute inhalational exposure to the notified polymer is considered low, there is a potential for eye contact during certain processes and as such, risk reduction measures should be undertaken in accordance with the recommendations in section 13. In addition, the fact that Belclene 494 will only be handled by trained workers, indicates that occupational risks will be further minimised.

Toxic products of combustion (including sulphoxides) are possible for the notified polymer. In view of the fact that the polymer will only be available as an aqueous solution, the potential for toxic POC formation during a fire hazard is considered low.

Public exposure is expected to be low. Toxicity studies showed that the notified chemical was of low toxicity and not mutagenic in a bacterial assay (the small amounts of chloroform and acrylonitrile present in the polymer are not considered toxicologically significant). In addition the high molecular weight (> 1000) of the notified chemical is expected to hinder its absorption through biological membranes. Therefore, the potential health hazard to the public is considered minimal.

It can be concluded that under normal conditions of use, there is a low risk of adverse effects to workers or the public during transport, storage and use of the notified polymer.

13. RECOMMENDATIONS

To minimise occupational health risks from exposure to DP 3448 the following guidelines and precautions should be observed:

- where reciprocating pumps are used during blending, pump glands should be properly maintained to avoid mist generation;
- local exhaust ventilation should be used during the blending process to reduce exposure to mists;
- safe work practices should be implemented to avoid splashing and spillages;
- if engineering controls and work practices are insufficient to reduce exposure to Belclene 494 to a safe level, then personal protective equipment, conforming to Australian Standards (AS) /New Zealand Standards (NZS) should be used;

chemical-type goggles conforming to AS 1336 (20) and AS/NZS 1337 (21),

impermeable gloves conforming to AS 2161 (22),

protective clothing conforming to AS 2919 (23),

respiratory protection should be used in accordance with Australian Standards (AS) /New Zealand Standards (NZS) for respiratory protection (AS/NZS 1715 (24) and AS/NZS 1716 (25);
- spills should be contained according to MSDS and disposed of according to local regulations;
- a copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Belclene 494 was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (26).

This MSDS was provided by FMC (Australia) Ltd as part of their notification statement. The accuracy of this information remains the responsibility of FMC (Australia) Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of DP 3448 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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21. Standards Australia/Standards New Zealand 1992, *Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.
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Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	Rating	Oedema Formation	Rating
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising)	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	Rating	Area of Cornea involved	Rating
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	Rating	Chemosis	Rating	Discharge	Rating
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	Rating
Normal	0 none
cFolds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe