

File No: LTD/1164

4 January 2005

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Acrylic Ester Copolymer in TOLAD 3514 Additive

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
National Occupational Health and Safety Commission
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1161 or + 61 2 6279 1163.

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
Chemicals Notification and Assessment**

TABLE OF CONTENTS

1.	APPLICANT AND NOTIFICATION DETAILS	4
2.	IDENTITY OF CHEMICAL	4
3.	COMPOSITION.....	4
4.	INTRODUCTION AND USE INFORMATION.....	5
5.	PROCESS AND RELEASE INFORMATION.....	5
5.1.	Distribution, transport and storage.....	5
5.2.	Operation description.....	5
5.3.	Occupational exposure.....	6
5.4.	Release.....	6
5.5.	Disposal	7
5.6.	Public exposure.....	7
6.	PHYSICAL AND CHEMICAL PROPERTIES.....	7
7.	TOXICOLOGICAL INVESTIGATIONS	10
7.1.	Acute toxicity – oral	10
7.4.	Irritation – skin	11
8.	ENVIRONMENT.....	12
8.1.	Environmental fate.....	12
8.1.1.	Biodegradability.....	12
8.1.2.	Bioaccumulation	12
8.1.3.	Combustion and Air Emissions.....	13
8.2.	Ecotoxicological investigations	13
8.2.1.	Acute toxicity to fish.....	13
8.2.2.	Acute toxicity to aquatic invertebrates.....	14
8.2.3.	Acute toxicity to algae	14
9.	RISK ASSESSMENT	15
9.1.	Environment	15
9.1.1.	Environment – exposure assessment.....	15
9.1.2.	Environment – effects assessment	15
9.1.3.	Environment – risk characterisation.....	15
9.2.	Human health.....	15
9.2.1.	Occupational health and safety – exposure assessment	15
9.2.2.	Public health – exposure assessment.....	15
9.2.3.	Human health - effects assessment	16
9.2.4.	Occupational health and safety – risk characterisation	16
9.2.5.	Public health – risk characterisation.....	16
10.	CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS.....	16
10.1.	Hazard classification.....	16
10.2.	Environmental risk assessment.....	16
10.3.	Human health risk assessment	17
10.3.1.	Occupational health and safety.....	17
10.3.2.	Public health.....	17
11.	MATERIAL SAFETY DATA SHEET	17
11.1.	Material Safety Data Sheet	17
11.2.	Label	17
12.	RECOMMENDATIONS.....	17
12.1.	Secondary notification	18
13.	BIBLIOGRAPHY	18

Acrylic Ester Copolymer in TOLAD 3514 Additive

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Baker Petrolite (ABN 20 04 752007) of 5 Walker Street, Braeside, VIC, 3195.

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 Identity

Spectral data

Purity and nature of impurities

Import Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Physico-chemical data

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

No

NOTIFICATION IN OTHER COUNTRIES

Canada: transitional substance (1995), full notification (1998) NSN no.1384

USA (1994) EPA no. P94-2157

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

The notified polymer is not isolated and therefore does not have a trade or marketing name. The notified polymer is a component of the following:

Intermediate containing notified polymer: M2412

Commercial product containing notified polymer: TOLAD 3514 Additive

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Gel Permeation Chromatography (GPC), Infrared Spectroscopy.
Remarks	Two GPC spectra were submitted, both confirmed the NAMW >1000. The peaks in the Infrared Spectra were consistent with the structural formula given.
TEST FACILITY	Petrolite (1995), Baker Petrolite (2004a)

3. COMPOSITION

DEGREE OF PURITY

High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

All residual monomers are present at below the relevant cut offs for classification of the notified polymer as a hazardous substance.

DEGRADATION PRODUCTS

Degradation of polymer not expected under normal conditions of storage and use.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

No natural loss of monomers, other reactants, additives or impurities is anticipated under normal conditions of storage and use.

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as a component (20%) of a fuel additive package.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	3-10	3-10	3-10	3-10	3-10

USE

The notified polymer is a conductivity additive for use in diesel fuels, which can be used in either the industrial or public sector.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY

Not specified

IDENTITY OF MANUFACTURER/RECIPIENTS

The imported additive package containing the notified polymer will be shipped to Baker Petrolite, 5 Walker St, Braeside VIC, 3195 for repacking or relabelling before being distributed to refineries.

TRANSPORTATION AND PACKAGING

The additive package containing the notified polymer is imported in 200 L drums by sea. It is repacked into 1300 L bulk shuttle tanks for distribution to the refineries. The expected mode of transport is by road.

5.2. Operation description

No manufacture or reformulation of the additive package containing the notified polymer occurs in Australia.

Repacking

The additive package containing 20% notified polymer is pumped from the import drums to the shuttle tanks for transportation. Transfer hoses are connected and disconnected at the start and end of the decanting process.

Empty drums are taken to a drum disposal unit where they will be disposed of by an approved method for hydrocarbon material. Often the approved method is incineration.

Fuel Formulation

The additive package containing 20% notified polymer will be transferred to a permanent base tank by gravity feed. Connector hoses will be used during this process and these will be disconnected upon completion of the filling process. The base tank is permanently connected to the fuel flow line through a positive displacement pump, which then delivers the fuel additive product to the diesel fuel. The finished diesel fuel will typically contain 1-5 ppm of the notified polymer. The finished diesel fuel is transferred to transport or storage tanks through the refinery distribution system.

Empty bulk containers are returned to suppliers for cleaning and refilling.

End Use

At service stations or industrial end user sites, the diesel fuel will be transferred to underground tanks. When required the diesel fuel would be pumped directly into automobile/jet fuel tanks.

5.3. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Fuel Formulation	2	1 hour	1/month

Exposure Details

Repacking

Exposure to drips and spills of the notified polymer at a concentration of 20% could occur during connection and disconnection of the transfer hoses. Workers may also be exposed to container residues from the cleaning of emptied bulk containers.

Fuel Formulation

During the transfer of the fuel additive to the permanent base tank, exposure to drips and spills of the notified polymer at a concentration of 20% could occur from connection and disconnection of the connector hoses. Gloves and goggles are worn during this process. Fixed closed systems are used to transfer the fuel additive to the fuel line, therefore no exposure is expected except in the event of an accident. Limited exposure to up to 5 ppm of the notified polymer may occur during transfer of the final formulated diesel fuel.

End Use

Exposure of transport drivers, service station personnel or industrial end users to drips and spills of the notified polymer at a concentration up to 5 ppm, may occur during the connection and disconnection of transfer hoses and during fuel fills.

5.4. Release

RELEASE OF CHEMICAL AT SITE

No manufacturing of the notified polymer will occur in Australia and consequently there will be no domestic release associated with this activity. Environmental release of the notified polymer is unlikely during importation, storage and transportation of the additive package, and accidental spills, leaks and catastrophic mechanical failure during a transport accident are the most likely reasons for environmental release. Established engineering controls (eg. 200 L and 1300 L container specifications) and established emergency clean-up procedures will limit the impact on the environment of such incidents.

During repackaging, relatively minor spills and drips of the formulation containing the notified polymer may potentially occur from connection and disconnection of connection hoses. These are likely to be contained within the facility and managed according to spill response procedures.

Fuel blending is undertaken using automated procedures using computer-controlled additive injection equipment. Release during blending procedures is unlikely, with splashes and drips during pumping from drums and accidental spillage the most likely reason; however, engineering and institutional controls and procedures are likely to minimise the potential for environmental release. The blended fuel will be transported by road tanker to service stations and large fleet customers.

Residues remaining in imported drums (eg. 1% of formulation) will be disposed of to drum reconditioners using an approved method for hydrocarbons (i.e. incineration). Emptied bulk containers are returned to suppliers for cleaning and refilling, with cleaning wastes most likely incinerated.

RELEASE OF CHEMICAL FROM USE

Fuels containing the notified polymer will have a widespread and diffuse use pattern in Australia. The majority of the notified polymer will be destroyed during use within diesel and jet engines.

In general, release from bulk storage tanks (eg. underground storage tanks (USTs)) to the subsoil and groundwater environment surrounding these tanks may occur over time due to corrosion and leakage of tanks or rupture of pipes and fittings. USTs have been installed throughout Australia at terminals and refineries, fuel depots, service stations, and many private facilities and organisations have USTs for fuel storage. Not all USTs leak. However, many in Australia have and have required decommissioning and land remediation. The length of service of the tank is one of a number of factors increasing the risk of UST leakage. Other factors include the type of construction materials, presence of liners, fuel type, fittings/pipes and environmental conditions surrounding the UST. Major fuel suppliers generally have tank decommissioning and replacement programs and install leak detection equipment on their tanks to prevent leaks from occurring and to trigger pollution abatement procedures to minimise risks to the environment where leaks are detected. Except in the cases of gross spillage of fuel containing the notified polymer, eg. leakage from USTs or aboveground spillages, very little release to the soil or aquatic compartment is likely and apart from areas in the vicinity of such spills and leaks no accumulation of the notified polymer is likely in soils.

5.5. Disposal

Waste material containing the notified polymer may include solvent wastes generated during equipment cleaning, spill clean up materials (eg. absorbent), and container residues and these wastes would be incinerated.

5.6. Public exposure

The notified polymer will be available to the public only after it has been mixed with diesel fuel at the refinery. Incidental exposure to the notified polymer at a concentration of 1-5 ppm could occur during filling of the automobile fuel tank.

6. PHYSICAL AND CHEMICAL PROPERTIES

It is not possible to drive all the solvent from the notified polymer and therefore the polymer is never isolated. Without the solvent the polymer is an amorphous solid which is difficult to work with. Therefore it is not possible to determine physico-chemical properties for the notified polymer itself. The following physico-chemical properties relate to the intermediate M2412 containing approximately 40% notified polymer in 2-butoxyethanol and ethylene glycol.

Appearance at 20°C and 101.3 kPa Light yellow liquid with a slight alcohol odour.

Pour Point Less than -40°C

Remarks	Physical Property report submitted. No details of methodology used.
TEST FACILITY	Baker Petrolite (2004b)

Density 974.2 kg/m³ at 16°C

Remarks	Physical Property report submitted. No details of methodology used.
TEST FACILITY	Baker Petrolite (2004b)

Vapour Pressure Not determined

Remarks	The vapour pressure of M2412 has not been determined. The notified polymer is not expected to be volatile.
---------	--

Water Solubility >1g/L at 23°C

METHOD	Preliminary test: OECD TG 105 Water Solubility
	Solubility at pH 1 and 10: In house method
Remarks	In a preliminary solubility study the intermediate M2412 was soluble (by visual observation) at 20% w/v with no layering, discoloration or floating material but there was temporary foaming

In the main solubility study a solution of 1 g/L was clear and colourless with no precipitation, and remained unaffected by pH as indicated by titration with HCl and NaOH through the pH range 1-11.2.

The presence of solvents (60%) in M2412 can affect the relevance of this test. The notified polymer contains functionalities that would confer water solubility, however, this may be somewhat offset by the hydrophobic groups present.

TEST FACILITY Baker Petrolite (1998a)

Hydrolysis as a Function of pH

Not determined

Remarks The notified polymer is not expected to hydrolyse under conditions of normal use despite its solubility and the presence of esters.

Partition Coefficient (n-octanol/water)

log Pow = 1.74 at 20°C

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks HPLC Method. Samples were prepared in duplicate by weight as a 1.0% solution in water or methanol. Standards were prepared in 200-3000 ppm per component with log Pow in the range of 0-4.

TEST FACILITY Baker Petrolite (1998b)

Adsorption/Desorption

Log Koc = 1.84 (estimated)

Remarks The notifier indicates that cationic polymers tend to become adsorbed onto negatively charged sites on dissolved and suspended solids (Cary *et al.*, 1987). The organic carbon adsorption coefficient (Koc) for the intermediate M2412 has been estimated by the notifier based on linear regression models using the octanol/water partition co-efficient and the following equation by Boethling and Mackay (2000): $\text{Log Koc} = 0.679 \text{ Log Kow} + 0.663$, where $\text{log Kow} = 1.74$.

Dissociation Constant

Not determined

Remarks Dissociation of the notified polymer is not expected within the environmentally relevant pH range of 4-9 and will remain fully charged.

Particle Size

Not determined

Remarks Notified polymer is not isolated from solution

Flash Point

59°C

METHOD In house – Setaflash Closed Cup

Remarks The presence of solvents (60%) in M2412 can affect the relevance of this test.

Flammability Limits

Not determined

Remarks The notified polymer is not expected to be flammable. Flammability limits exist for the solvent content of the intermediate.

Autoignition Temperature

Not determined

Remarks The notified polymer is not expected to autoignite. Autoignition temperatures exist for the solvent content of the intermediate.

Explosive Properties

Not determined

Remarks From examination of the structure, there are no chemical groups that would infer explosive properties, therefore the result has been predicted negative.

Reactivity

Remarks	Expected to be stable under normal conditions of use. Hazardous polymerisation is not expected to occur.
---------	--

7. TOXICOLOGICAL INVESTIGATIONS

The following toxicological studies were conducted using the intermediate M2412 containing approximately 40% notified polymer in 2-butoxyethanol and ethylene glycol.

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral	harmful to low toxicity, LD50 3100 mg/kg bw (male), 1570 mg/kg bw (female), 2420 mg/kg bw (both)
Rabbit, skin irritation	slightly irritating

7.1. Acute toxicity – oral

TEST SUBSTANCE	M2412
METHOD	Acute Oral Toxicity, Single Level – Rats (40 CFR Part 798, EPA Health Effects Testing Guidelines – Subpart B – General Toxicity Testing).
Species/Strain	Rat/Sprague-Dawley
Vehicle	Test substance administered as supplied.
Remarks - Method	No significant protocol deviations from OECD TG 401 Acute Oral Toxicity.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw*</i>	<i>Mortality</i>
I	5 male	5000	5
II	5 male	2510	1
III	5 male	2000	1
IV	5 female	5000	5
V	5 female	2000	3
VI	5 female	1260	2

*Dose relates to amount of M2412 not the notified polymer.

LD50	3100 mg/kg bw (male), 1570 mg/kg bw (female), 2420 mg/kg bw (both)
Signs of Toxicity	All the animals treated at 5000 mg/kg bw died within two days of dosing.

For the males treated at 2510 mg/kg bw all animals appeared to be lethargic and exhibited signs of hematuria and ruffled fur. One animal died on day three. The surviving animals all appeared normal on and after day five.

For the animals treated at 2000 mg/kg bw, one male and one female died within 5 hours of dosing. The surviving males all appeared normal on and after day two. Two more females died on day two. Signs of toxicity included ruffled fur. The surviving females all appeared normal on and after day five.

For the females treated at 1260 mg/kg bw all animals appeared to be lethargic and exhibited signs of hematuria and ruffled fur. Two animals died on day two. The surviving animals all appeared normal on and after day five.

Effects in Organs	Dark red nasal and anogenital staining, dark red fluid in the gastrointestinal tract and yellowish liquid in the stomach were observed in the majority of animals that died during the study. Pale coloured lungs and dark coloured kidneys were observed in one male who died following dosing at 2510 mg/kg bw. No gross abnormalities were observed in any of the surviving animals.
-------------------	---

Remarks - Results	The solvent content is likely to contribute to the acute toxicity of M2412.
-------------------	---

CONCLUSION The intermediate M2412 is harmful to low toxicity via the oral route. Based on this study it is not possible to determine the acute toxicity of the notified polymer.

TEST FACILITY Biosearch (1994a)

7.4. Irritation – skin

TEST SUBSTANCE M2412

METHOD Primary Skin Irritation – Rabbits (40 CFR Part 798, EPA Health Effects Testing Guidelines – Subpart E – Specific Organ/Tissue Toxicity).
Species/Strain Rabbit/New Zealand White.
Number of Animals 6
Vehicle Test substance administered as supplied.
Observation Period 14 days.
Type of Dressing Semi-occlusive.
Remarks - Method No significant protocol deviations from OECD TG 404 Acute Dermal Irritation/Corrosion.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Erythema/Eschar</i>	0.56	1	72 hours	0
<i>Oedema</i>	0	1	1 hour	0

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

Remarks - Results The solvent content may contribute to the irritancy response.

CONCLUSION The intermediate M2412 is slightly irritating to the skin. Based on this study it is not possible to determine the irritancy of the notified polymer.

TEST FACILITY Biosearch (1994b)

8. ENVIRONMENT

The following biodegradability and ecotoxicological studies were conducted using the intermediate M2412 containing approximately 40% notified polymer in 2-butoxyethanol and ethylene glycol.

8.1. Environmental fate

8.1.1. Biodegradability

TEST SUBSTANCE	M2412
METHOD	OECD TG 306 D Ready Biodegradability in Seawater Closed Bottle Test.
Inoculum	Indigenous micro-organisms in filtered (5 µm) natural seawater (initial population 100-1000 cpm (sterile Marine Broth extinction bottle test).
Exposure Period	28 d
Auxiliary Solvent	None; however, the test substance solution had an alcohol odour.
Analytical Monitoring	Dissolved oxygen and BOD
Remarks – Method	The oxygen consumption of a dilute solution of test substance was measured, as BOD, in seawater periodically up to 28 days. Percent degradability was calculated as (BOD/COD) x 100%, where COD is 2.31 mg O ₂ /mg test substance. Test substance concentration was 2 mg/L (nominal). Test water: salinity 31 ppt, pH 7.9, TOC 8.1 mg/L, incubation temperature 20±1°C. Test water consisted of natural seawater. The reference substance was sodium acetate (2 mg/L).

RESULTS

<i>Day</i>	<i>Test substance % degradation</i>	<i>Sodium acetate (2.0 mg/L) % degradation</i>
5	28	79
13	35	79
20	37	86
28	39	86

Remarks – Results	There were no deviations from the protocol. The test substance did not show ≥60% biodegradation (when determined by dissolved oxygen removal) within the 28 days of the test. The test substance was present at a concentration between 2-10 mg/L, within the test protocol range.
-------------------	--

CONCLUSION	The test substance did not meet the protocol criteria for biodegradation within the 28 day exposure period; however, some (40%) biodegradation occurred and this process is expected to occur over time.
------------	--

TEST FACILITY	Baker Petrolite (1998c)
---------------	-------------------------

Health Canada (2004) indicates that an EPI biodegradation prediction for a polymer of similar molecular weight gave a result of months to days-weeks using the ultimate and primary survey models, respectively. On this basis, the notified polymer may be expected to have a half-life in water of ≥182 days and would be considered persistent.

8.1.2. Bioaccumulation

REMARKS	The imported formulation containing the notified polymer has a log Pow of 1.74 and high molecular weight and would suggest a low potential for bioaccumulation.
---------	---

8.1.3. Combustion and Air Emissions

No information was available on diesel and jet engine exhaust emissions of hydrocarbons (HC), carbon monoxide (CO) and non-methane hydrocarbons (NMHC). The notifier indicates that, based on an analysis of polymer constituents, when added to fuel at a rate of 1-3 ppm, the tailpipe emissions for the fuel would be increased by 3.66-10.98 ppm for CO₂, 0.0078-0.0234 ppm for NO_x and 0.043-0.128 ppm for SO_x, which is probably over-estimated based on current catalytic equipment. These compare with the usual ranges for NO_x and SO_x of 50-2500 and 10-150 ppm, respectively (http://www.nett.ca/faq_diesel.html), indicating their presence should not contribute significantly.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	M2412
METHOD	OECD TG 203 Fish, Acute Toxicity Test – static/GLP.
Species	Fathead minnow (<i>Pimephales promelas</i>), 2.2 cm length, 0.08 g.
Exposure Period	96 h
Auxiliary Solvent	None; however, the test substance solution had an alcohol odour.
Water Hardness	174 mg/L as CaCO ₃
Analytical Monitoring	None
Remarks – Method	Preliminary and definitive studies were performed. Stock solution was prepared by weight and diluted to volume with deionised water. Mortality, sublethal effects and test conditions were monitored daily: temperature 20±2°C, pH 8.4, dissolved oxygen ≥7.8 mg/L, and 12 h light:dark photoperiod. The test was conducted in 21 L glass aquaria containing 15 L test solution (biological loading 0.05 g/L). LC50 values were calculated using pooled data from 2 replicates and Probit analysis.

RESULTS

Concentration mg/L		Number of Fish	% Mortality (average)			
Nominal	Actual		24 h	48 h	72 h	96 h
0 Control	Not determined	20 (2 replicates of 10)	0	0	0	0
1.56	“	“	0	0	0	0
3.13	“	“	0	0	5	5
6.25	“	“	30	75	95	95
12.5	“	“	85	100	100	100
25	“	“	100	100	100	100
50	“	“	100	100	100	100

LC50	4.42 mg/L (nominal) at 96 hours (95% CI 3.81-5.14).
LOEC	3.13 mg/L (nominal) at 96 hours.
NOEC (lethal and sublethal)	1.56 mg/L (nominal) at 96 hours.
Remarks – Results	There were no deviations from the protocol. The test substance was completely soluble at the test concentrations used. Behavioural effects (quiescence, surfacing, twitching, erratic swimming, on-side, dark discoloration, mucous shedding, slow and laboured respiration, gulping air respiration) were noted in fish at test concentrations of ≥3.13 mg/L.

CONCLUSION	The test substance is toxic to fish under the conditions of the test, i.e. L(E)C50 1-10 mg/L, (United Nations, 2003).
------------	---

TEST FACILITY	Baker Petrolite (1998d)
---------------	-------------------------

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE M2412

METHOD Acute Toxicity to Daphnia No. L383/A172 (EC, 1992) - Static/GLP.
Species *Daphnia magna* (1st instar <24 h old)
Exposure Period 48 hours
Auxiliary Solvent None; however, the test substance solution had an alcohol odour.
Water Hardness 174 mg/L (as CaCO₃), alkalinity 119 mg/L, conductivity 55 µmhos/cm.
Analytical Monitoring None
Remarks - Method Stock solution was prepared by weight and diluted to volume with deionised water. Mortality and sublethal effects (immobilisation; unable to swim within 15 seconds after gentle agitation) were made at 24 h and 48 h. Test conditions were monitored at 0 h and 48 h: temperature 20±2°C, pH 8.4, dissolved oxygen ≥8.9 mg/L, and 14 h daylight regime. The test was conducted in glass containers with 150 mL test solution. LC50 values were calculated with pooled data from 4 replicates using the moving average method of Stephan (1977).

RESULTS

Concentration mg/L		Number of <i>D. magna</i>	% Immobilised		% Mortality	
Nominal	Actual		24 h	48 h	24 h	48 h
0 Control	Not determined	20 (4 replicates of 5)	0	0	0	0
0.39	“	“	0	0	0	0
0.78	“	“	5	5	5	5
1.56	“	“	0	5	0	5
3.13	“	“	0	20	0	15
6.25	“	“	0	60	0	50
12.5	“	“	20	90	15	85
25	“	“	40	100	30	95
50	“	“	60	100	50	100

LC50 5.76 mg/L (nominal) at 48 hours (95% CI 4.34-7.88)
EC50 (immobilisation) 4.74 mg/L (nominal) at 48 hours (95% CI 3.55-6.36)
LOEC 0.78 mg/L (nominal) at 48 hours
NOEC 0.39 mg/L (nominal) at 48 hours
Remarks - Results There were no deviations from the protocol. The test substance was completely soluble at the test concentrations used.

CONCLUSION The test substance is toxic to *Daphnia* under the conditions of the test, i.e. L(E)C50 1-10 mg/L, (United Nations, 2003).

TEST FACILITY Baker Petrolite (1998e)

8.2.3. Acute toxicity to algae

Remarks No alga aquatic ecotoxicity test data were provided. Health Canada (2004) predicted a 96 h and a chronic value for green algae of 3.26 and 0.93 mg/L, respectively, for a polymer with a cationic charge density of 1.1% amine nitrogen.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer or fuel product is not expected to be released to the environment during the proposed use pattern. Spills and leaks may potentially occur; however, their environmental impact will be minimal based on existing spill incident clean up procedures and institutional and engineering controls. Consequently no predicted environmental concentration (PEC) on a 40% product with solvent has been estimated. Very little of the notified polymer is expected to be disposed of to sewer or landfill, and its use in diesel and jet engines will likely result in its combustion and formation of water and oxides of carbon, nitrogen and sulfur.

9.1.2. Environment – effects assessment

Aquatic ecotoxicity data were available for single species of freshwater fish and crustacean. The lowest available LC50 value (fish; 4.42 mg/L) for a formulation containing 40% of the notified polymer in solvent has been used to derive a predicted no effect concentration (PNEC) of 0.004 mg/L by division by a safety factor of 1000 to account for inter and intra-species sensitivity and potential chronic effects and a paucity of ecotoxicity data.

9.1.3. Environment – risk characterisation

The proposed use pattern for the notified polymer indicates a very low potential for its release to the environment. Aquatic ecotoxicity tests performed on a formulation containing the notified polymer indicate that the polymer may be toxic to aquatic organisms and consequently any releases to the aquatic environment for this water soluble compound should be avoided and spills managed accordingly.

While limited information is available on the effect of use of the notified polymer on fuel economy and tailpipe emissions from calculations based on the low rate of use (typically 1-3 ppm) in fuel, the notified polymer is not expected to significantly affect these parameters.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Repacking

During transfer of the additive package from the import drums to the transport tanks, exposure to drips and spills of the notified polymer at a concentration of 20% could occur. Up to 250 drums may be repacked per annum.

Although exposure to notified polymer could occur during cleaning of the emptied bulk containers, personal protective equipment (PPE) usually worn for such activities would limit this exposure.

Fuel Formulation

Incidental exposure to drips and spills of the notified polymer could occur during transfer of the fuel additive to the permanent base tank. However, exposure is expected to be low due to the concentration of the notified polymer (20%), the limited exposure frequency (12 per annum) and the use of PPE. Exposure to the notified polymer during transfer to the fuel line is expected to be negligible due to the use of closed systems. Following fuel formulation, exposure to the notified polymer is expected to be negligible due to the low concentration of the notified polymer (5 ppm).

End Use

Exposure of transport drivers and service station or industrial user personnel to drips and spills may occur during the connection and disconnection of transfer hoses and during fuel fills. Exposure is expected to be negligible due to the closed systems used and the low concentration of notified polymer in the fuel (up to 5 ppm).

9.2.2. Public health – exposure assessment

Incidental exposure could occur during filling of the automobile fuel tank. Given the low concentration (up to 5 ppm), the event frequency and the minimal direct contact with fuel under normal circumstances, public exposure is expected to be minimal.

9.2.3. Human health - effects assessment

Acute toxicity.

The intermediate M2412 containing 40% notified polymer was found to be of low toxicity to harmful in an acute oral toxicity study in rats. As both ethylene glycol and 2-butoxyethanol are classified as 'harmful if swallowed' (NOHSC, 2003) the solvent content is likely to contribute to the acute toxicity of M2412. Based on this study it is not possible to determine the acute toxicity of the notified polymer.

Irritation and Sensitisation.

In a skin irritation study, the intermediate M2412 containing 40% notified polymer was found to slightly irritate to rabbit skin. It is therefore possible that this intermediate would cause an irritancy response in the eye. Although neither 2-butoxyethanol nor ethylene glycol are classified as 'irritating to skin', irritation has been observed in studies with rats with 2-butoxyethanol (NICNAS, 1996) and ethylene glycol induces mild dermal irritation in rabbits and guinea-pigs (CICAD, 2002). Therefore, the solvent content may contribute to the irritancy response. Based on this study it is not possible to determine the irritancy of the notified polymer.

Hazard classification for health effects.

Based on the available data, it is not possible to classify the notified polymer as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

9.2.4. Occupational health and safety – risk characterisation

The notified polymer may be harmful if swallowed and irritating to eyes and skin. Prior to fuel formulation, there is potential for workers involved in the transfer of the additive package and the cleaning of the bulk containers to be exposed to the notified polymer at a concentration of 20%. As the risk of skin and eye irritation cannot be ruled out, workers should wear protective eyewear, protective clothing and impervious gloves to limit exposure.

Following fuel formulation, the risk to all workers is expected to be low due to the predicted negligible exposure.

9.2.5. Public health – risk characterisation

Although the notified polymer may be a skin and eye irritant, the risk to public health is expected to be negligible due to the negligible exposure predicted.

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

10.1. Hazard classification

Based on the available data, it is not possible to classify the notified polymer as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

and

There is insufficient data to classify the notified polymer including its toxicity to aquatic organisms using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003). This system is not mandated in Australia and carries no legal status.

10.2. Environmental risk assessment

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 Negligible Concern to public health when used in the proposed manner.

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, 1994a). 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, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during transfer of the notified polymer as introduced and during cleaning of the transport containers:
 - Avoid skin and eye contact
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
 - Protective eyewear, protective clothing and impermeable gloves.

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.

Disposal

- Waste product may be hazardous and may require specific waste disposal management in accordance with State/Territory waste disposal regulations. Waste materials containing the notified polymer should be incinerated. Emptied imported drums containing residues of the notified polymer should be sent for drum reconditioning (with wastewater treatment and incineration of concentrated waste) for drum recycling or metal recycling.

Emergency procedures

- Spills/release of the notified polymer should be handled by controlling the source of the spill/leak, containing the spill/leak to prevent further environmental release to soils surface waters or groundwater. Keep spill out of sewerage system, stormwater and all bodies of water. Clean up spill as soon as possible. Use appropriate techniques such as non-combustible adsorbent material or pumping. Where feasible and appropriate, remove contaminated environmental media (eg. soil). Place contaminated materials in labelled, sealable containers for storage, handling, transportation and appropriate disposal.

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 subsection 64(1) of the Act; if
 - manufacturing of the notified polymer in Australia is proposed;
 - the notified polymer is proposed to be incorporated into finished products other than those currently proposed;
 - significant release to the aquatic environment is proposed; and
 - significant new information about the adverse environmental effects becomes available.

or

- (2) Under subsection 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.

In the event of a secondary notification due to an expected change in use pattern resulting in aquatic releases of the notified polymer, an algal ecotoxicity test report will be required to be submitted.

13. BIBLIOGRAPHY

- Baker Petrolite (1998a). OECD Method 105 – Water Solubility 105(27.05.95) Screening Study: Water Solubility of M-2412 at pH 1 and 10. (June 22 1998). MI, USA, Environmental Services Group, Baker-Petrolite Corporation (unpublished report submitted by the notifier).
- Baker Petrolite (1998b). Partition Co-efficient of M-2412 (16 June 1998). Missouri, USA, Analytical Services Group, Baker/Petrolite Corporation (unpublished report submitted by the notifier).
- Baker Petrolite (1998c). Ready Biodegradability in Seawater of M-2412 (11 June 1998). Missouri, USA, Baker-Petrolite Corporation, (unpublished report submitted by the notifier).
- Baker Petrolite (1998d). Static Acute Toxicity of M-2412 to the Fathead Minnow (*Pimephales promelas*) (9 June 1998). Missouri, USA, Baker Petrolite Corporation (unpublished report submitted by the notifier).
- Baker Petrolite (1998e). Static Acute Toxicity of M-2412 to *Daphnia magna* (22 June 1998). Missouri, USA, Baker Petrolite Corporation (unpublished report submitted by the notifier).
- Baker Petrolite (2004) GPC Characterization and Molecular Weight Distribution (Project No. 0405A106, 18 May 2004) Analytical services Report provided by notifier.
- Biosearch (1994a) Acute Oral Toxicity, LD50 – Rats (Project Number 94-8021A, 8 August 1994). Pennsylvania, USA, Biosearch Incorporated (unpublished report submitted by the notifier).

- Biosearch (1994b) Primary Skin Irritation – Rabbits (Project No. 94-8021A, 8 August 1994). Pennsylvania, USA, Biosearch Incorporated (unpublished report submitted by the notifier).
- Boethling, R. S. and Mackay, D. (2000). *Handbook of Property Estimation Methods for Chemicals*. Environmental and Health Sciences, CRC Press LLC/Lewis Publishers, Boca Raton, FL.
- Cary, G. A., McMahon, J. A. and Kuc, W. J. (1987). The effect of suspended solids and naturally occurring dissolved organisms in reducing the acute toxicities of cationic polyelectrolytes to aquatic organisms. *Environ. Toxicol. Chem.*, 6: 469-474.
- CICAD (2002) Concise International Chemical Assessment Document 45 Ethylene Glycol: Human Health Aspects. World Health Organisation, Geneva.
- EC (1992). Acute Toxicity to Daphnia. Official Journal of the European Communities No. L383/A172.
- Health Canada (2004). Transitional Chemicals Evaluation Section. Evaluation Report – Final Assessment. 22 July 2004
- NICNAS (1996) Priority existing chemical assessment report No. 6: ‘2-Butoxyethanol’. Sydney, National Industrial Chemicals Notification and Assessment Scheme.
- NOHSC (1994a) 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.
- NOHSC (1994b) 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) Draft List of Designated Hazardous Substances[NOHSC:10005(2003)]. National Occupational Health and Safety Commission, Canberra.
- Petrolite (1995) Copy of Letter and GPC Report sent from the notifier to Environment Canada concerning NN 1384 (5 January 1995). Missouri, USA, Petrolite Corporation.
- Stephan, C. E. (1977). Methods for Calculating an LC50. In: *Aquatic Toxicology and Hazard Evaluation*. Mayer, F. I. and Hamelink, J. L. eds). ASTM STP 634. American Society for Testing and Materials, PA.
- 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.