File No: NA/893

March 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

CHEMICAL IN NEW OLOA 229

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Telephone: (61) (02) 9577 9514 FAX (61) (02) 9577 9465

Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

CHEMICAL IN NEW OLOA 229

1. APPLICANT

Chevron Oronite Australia of Level 22, 385 Bourke Street, MELBOURNE VIC 3000 (ARBN 001 010 037) has submitted a standard notification statement in support of their application for an assessment certificate for CHEMICAL IN NEW OLOA 229.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the polymer composition and details of exact import volume and customers have been exempted from publication in the Full Public Report and the Summary Report.

Other Names: NEW OLOA 5259.

Marketing Name: NEW OLOA 229

CHEMICAL IN NEW OLOA 229 is referred to as NEW OLOA 229 from hereon.

3. PHYSICAL AND CHEMICAL PROPERTIES

The listed physico-chemical properties are for the commercial product containing the notified chemical at 80% combined with lubricating oil. The lubricating oil is added to reduce the viscosity of the product to a level that enables the product to be pumped and stored. The physico-chemical data provided is for "OLD" OLOA 229, which is chemically and structurally very similar to the chemical in this notification.

No test reports were included with the submission, however the results appear to have been generated using standard petroleum industry methods.

Appearance at 20°C & 101.3 kPa: Very dark brown viscous liquid

Boiling Point: Decomposes before boiling

Specific Gravity: 1.079 at 15°C

Vapour Pressure:	0.00049 Pa at 20°C
Water Solubility:	< 100 ppb – see comments below
Partition Co-efficient (n-octanol/water):	log P_{ow} > 8 – see comments below
Viscosity:	0.0026 m^2/sec at 40°C
Particle Size:	Viscous liquid
Hydrolysis as a Function of pH:	No data provided - see comments below
Adsorption/Desorption:	No data provided - see comments below
Dissociation Constant:	No data provided - see comments below
Flash Point:	>200°C
Flammability Limits:	Not measured; will burn in the presence of enough heat and oxygen
Autoignition Temperature:	Not measured; not expected to undergo auto-ignition
Explosive Properties:	Not measured; Not known to be explosive
Reactivity/Stability:	Will react in the presence of strong oxidising agents. Stable to acid and base.

3.1 Comments on Physico-Chemical Properties

The vapour pressure is that of the refined lube oil in which the notified chemical is dissolved.

The water solubility is stated as <100 parts per billion and is based on the water solubility determined for oil additive detergents that are stated to be similar in structure (Rausina et al 1996). The solubility is consistent with the chemical containing long hydrophobic alkyl chains. In water, the calcium salt of the notified chemical would be expected to be insoluble, as illustrated by soap binding with calcium in hard water as soap scum.

Measurement of the n-octanol/water partition coefficient was attempted using an HPLC method and only brief details were provided. However, only 6.4% of the compound could be dissolved in acetonitrile and this had a log P_{OW} of 6.1. The insoluble material can be assumed to have a log P_{OW} > 8, and on this basis, the chemical is expected to have a log P_{OW} > 8.

No adsorption/desorption data were provided, but the high log P_{OW}, high hydrocarbon content and strong dispersant nature of the notified chemical indicate that the material would have a large K_{OC} and adsorb strongly to the organic component of soils and sediments.

Dissociation data for the notified chemical, which is a substituted phenol, were not supplied. Substituted phenols are weakly acidic (Morrison & Boyd 1976). Despite the notifier claiming that the chemical will not dissociate, it is possible that some dissociation will occur in the environmental pH range of 4 to 9.

4. PURITY OF THE CHEMICAL

Degree of Purity: Not applicable, the chemical is a UVCB

Hazardous Impurities:

Chemical name:	Calcium hydroxide
CAS No.:	1305-62-0
Weight percentage:	0.5%
Toxic properties:	Irritant
Chemical name:	Phenol, (tetrapropenyl) derivatives manufacture of distillation residues
CAS No.:	220794-73-0
Weight percentage:	0.1%
Toxic properties:	Skin irritant
Chemical name:	Phenol, (tetrapropenyl) derivatives
CAS No.:	74499-35-7
Weight percentage:	1%
Toxic properties:	Skin irritant
Chemical name:	Phenol, C20-30 alkyl derivatives
CAS No.:	-
Weight percentage:	1.5%
Toxic properties:	Skin irritant

Non-hazardous Impurities (> 1% by weight): Details claimed as exempt information.

Additives/Adjuvants: 20% diluent oil, hydrotreated or solvent refined, heavy paraffinic distillates. Exact details of solvent are claimed as exempt.

5. USE, VOLUME AND FORMULATION

NEW OLOA 229 is to be used as a component in the formulation of additive mixtures for marine engine lubricants. It functions as a detergent, antioxidant and base reverse agent. The notified chemical will be imported in combination with other lubricating oil additives in additive packages. The notified chemical will be present in up to five different types of imported additive packages at a concentration of 10 to 50% w/w. The final concentrations of NEW OLOA 229 in finished marine diesel engine lubricants will be 1 to 15% (0.8 to 12% notified chemical).

Approximately, 500 kg to one tonne per annum of the notified chemical will be imported in 5200 L marine isotanks or 200 L steel drums. If projected import volumes of up to 300 tonnes are realised the notified chemical will be imported in marine bulk tankers. The notified chemical in the additive package, will be offloaded at marine terminals in either Melbourne or Brisbane and transported to blending facilities by either road or rail.

NEW OLOA 229 in the additive package, is blended in a completely enclosed and fully automated process. Blending of the additive package into marine diesel engine lubricants will occur at approximately seven sites across Australia. Finished lubricant will be packaged into 200 L drums or sold in bulk in tank trucks.

6. OCCUPATIONAL EXPOSURE

Exposure

The table identifies the nature of work done where occupational exposure to the notified chemical in additive package, may occur at a marine terminal assuming that 300 tonnes per annum are imported in marine bulk tanks. Where the notified chemical arrives in isotanks or steel drums, then unloading, loading and cleaning is not necessary and exposure will not occur. The table also identifies the nature of work done during blending of the additive package into finished marine engine oils.

Nature of Activity & Number of Workers	*% NEW OLOA 229*	*Maximum Potential Exposure Duration*
MarineTerminal		
Unloading (2)	8 to 40	0.5 hour/day; 7 days/year.
Sampling & Analysis (2)	8 to 40	1 hour/day; 14 days/year.
Loading tanker trucks (2)	8 to 40	0.5 hour/day; 20 days/year.
Equipment Cleaning (2)	<1	4 hours/day; 2 day/year.
Blending Facility		
Transfer to storage tank (1 to 2)	8 to 40	1 hour/day; 3 days/year.

Analysis & Sampling (1 to 2)	8 to 40	1 hour/day; 28 days/year.
Transfer to blending tank	8 to 40	
Packaging-Drumming & Bottling (2)	0.8 to 12	8 hours/day; 2 days/year.
Loading tanker trucks (2)	0.8 to 12	0.5 hour/day; 15 days/year.
Equipment Cleaning (1)	<1	3 hours/day; 1 day/year.
ISO tank & Drum Cleaning (2)	<1	3 hours/day; 2 days/year.

Marine Terminals

The additive packages containing the notified chemical imported in drums and isotanks will not be opened but sent directly to the blending plant. Occupational exposure is not likely except in the event of a spill. Additive packages arriving via marine bulk tank will be transferred to storage tanks via hard piping, for subsequent transfer into road tankers. During transfer operations skin and eye contact may occur as workers connect and disconnect pump lines between the ship and storage tank and between the storage tank and road tanker. During sampling and analysis of the additive package there may be skin contact as sampling devices and analytical equipment are manipulated. The notified chemical is of low volatility and inhalation exposure unlikely.

Lubricant Blending Plant

The notified chemical in additive package arriving in either isotanks or road tanker will be unloaded and transferred to storage tanks via 10 cm hosing which workers will fasten. Fastening takes about 10 minutes. A special air back flush system is used to prevent spillage during transfer. The notifier estimates that by adhering to ISO 9001 procedures spills and leaks are less than 1.5 kg of additive package per annum. For unloading of drums workers will connect a pump line to the drum. For unloading from the three types of containers incidental skin contact to splashes, drips and spills may occur as pump lines are connected or disconnected. Whole body exposure to mist may occur if emptied drums are steam cleaned for re use or disposal.

Blending of the additive package into finished lubricant occurs in a closed system at 60°C and is computer controlled, thereby excluding the potential for occupational exposure. The blended lubricant is transferred automatically to a storage tank. From here it can either be dispensed directly into tanker trucks via 10 cm pump lines or packaged into 200 L drums. Drum filling is an automated process and worker intervention is not required unless the filling line operation requires adjustment. However, workers are required to insert bungs and apply drum labels so skin contact with contaminated drum surfaces may occur.

Additive package in storage tanks, and blended lubricant will be sampled for laboratory analysis and incidental skin contact from splashes, drips and spills may occur during sampling and analytical procedures.

Marine Vessels
Ship or dockside workers may receive skin and eye contact to the finished lubricant containing the notified chemical as the lubricant is transferred to the ship and during drum cleaning. Exposure to the notified chemical during engine operation is unlikely as the lubricant oil is burnt or 'sacrificed' with the fuel. Ship mechanics may be exposed to the finished lubricant during their normal work. It is inevitable that mechanics will receive skin contact given the nature of the job, scale of operations and that protective gloves are not widely used.

Control Measures and Worker Education and Training
Workers at marine terminals and lubricant blending plants and ship workers will wear coveralls, gloves and eye protection. The notifier states that inspections of their customers sites have found that their blending facilities are well ventilated, with control systems for accidental spills and wastewater treatment. The notified chemical will be handled by employees of major Australian lubricant manufacturers. Workers involved in the blending activities are reported to have received training in the handling of additive packages.

7. PUBLIC EXPOSURE

The finished lubricant is intended for use on large marine vessels. Lubricant material is pumped from storage tanks directly into vessels, where it is transported via hard piping to the engine room. The potential for public exposure is only likely in the event of an accidental or inadvertent release.

8. ENVIRONMENTAL EXPOSURE

Release

The additive packages containing the notified chemical will be delivered to and stored at the blending facilities in isotanks or drums. The blending operations are performed at specially constructed sites owned and operated by petroleum companies. Release to the environment is expected to occur only in the unlikely event of an accident during transport or an accidental leak.

It is anticipated that there will be minimal release of NEW OLOA 229 during transfer from the storage containers to the blending tanks, as a special air back flush system prevents any spillage. Blending occurs in fully enclosed automated systems. Blending tanks will be cleaned with lube oil, which will typically be recycled during subsequent blending or incinerated. Any spills incurred in the blending operations will be contained within concrete bunds and either reclaimed or sent to on-site waste-water treatment facilities where residual hydrocarbon based products will be separated from the aqueous stream by the Australian Petroleum Industry (API) process, with a claimed removal of greater than 95%. Before being released to the sewage system, the aqueous waste undergoes further treatment involving pond aeration and sand filtration. The remaining oily waste will be incinerated.

The empty drums containing residual NEW OLOA 229 will be steam cleaned, with the resultant aqueous waste being sent to on-site waste-water treatment facilities.

At marine terminals ISO procedures are in place to minimise spills. The finished lubricant containing NEW OLOA 229 is transferred to the ship-board storage tank by hoses from the delivery container. Aboard ship, the oil is pumped through hard piping to the engine. Containers holding residual NEW OLOA 229 will be cleaned by steam with the waste-water entering a treatment facility at the receiving terminal. The waste will be treated in a similar fashion to that at blending facilities.

In large marine diesel engines most of the notified chemical will be used up during combustion (98%). Over time, fresh oil is added to keep sump levels constant and to maintain the effectiveness of the oil. Used oil generated from draining oil or engine repair will be incinerated or sent for recycling.

Fate

No information on the capacity of OLOA 229 to undergo biodegradation was provided. It is expected that, if placed into landfill (for example, adsorbed onto sawdust after accidental spills), the material would be very slowly degraded through the biological and abiotic processes operative in these facilities.

In the case of accidental release to land, the anticipated high K_{OC} indicates that the material would not be mobile, but would adsorb onto and become strongly associated with the organic component of soils and sediments. Similarly, in the event of accidental release into the water compartment, it is likely to become associated with suspended organic material, and eventually be incorporated into sediments.

The high log P_{OW}, molecular weight and anticipated low rate of biodegradation of OLOA 229, indicate the potential for bioaccumulation (Connell 1990). However, direct exposure to the water compartment is considered to be unlikely and will limit the potential for bioaccumulation.

Incineration of waste oil containing the notified material would destroy the substance with evolution of water vapour and oxides of carbon and sulphur, together with production of calcium compounds that would be assimilated with the ash. Sludges from waste treatment plants or oil recycling facilities could also be incinerated.

9. EVALUATION OF TOXICOLOGICAL DATA

Test data on the notified chemical NEW OLOA 229 are not available. In support of claims for Variation to the Schedule Requirements, acute toxicity data for OLOA 229 were submitted as read across data for the assessment of the potential acute health effects of the notified chemical. OLOA 229 differs from NEW OLOA 229 in the composition of the alkyl phenol side chain. Genotoxicity data on OLOA 319 (XA-294C) were provided. OLOA 319 differs from OLOA 229 in that the carbon chain length of the linear alkyl substituent is broader (C18-30). Although some studies conducted on OLOA 229 predate the protocols described in OECD Test Guidelines and OECD Principles of Good Laboratory Practice, the test data reported are considered satisfactory for conclusions to be reached and are therefore acceptable for this assessment. On the basis that the notified chemical is highly viscous, acute inhalation studies were not conducted.

For the evaluation of effects following repeat dose testing, data from OLOA 219 (NICNAS assessment NA890) are used. OLOA 219 is structurally and compositionally similar to the notified chemical and of similar molecular weight. Data on OLOA 219 is expected to give a reasonable indication of the potential toxicity of OLOA 229 following repeat dose testing.

9.1 Acute Toxicity

Summary of the acute toxicity of OLOA 229 and OLOA 319

Test	*Species*	*Outcome*
acute oral toxicity OLOA 229	rat	LD50 > 10 000 mg/kg
acute dermal toxicity OLOA 229	rat	LD50 > 5000 mg/kg
skin irritation,	rabbit	
OLOA 229;		Moderate irritant;
OLOA 319.		Moderate irritant.
eye irritation OLOA 229	rabbit	Slight irritant
skin sensitisation OLOA 229	guineapig	Non sensitising

9.1.1 Oral Toxicity (Cavalli MS 1970)

Test substance:	OLOA 229
Species/strain:	Rat/Sprague-Dawley
Number/sex of animals:	5 males
Observation period:	14 days
Method of administration:	Oral gavage; 10 000 mg/kg
Test method:	Not identified but similar to OECD TG 401 – limit test
Mortality:	Nil
Clinical observations:	No signs of toxicity observed
Morphological findings:	No gross abnormalities detected
LD_{50}*:*	> 10 000 mg/kg
Result:	OLOA 229 was of low acute oral toxicity to the rat.

9.1.2 Dermal Toxicity (Cavalli MS 1970)

Test substance:	OLOA 229
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	4 males
Observation period:	14 days
Method of administration:	A single, 24-hour occlusive application of 5 000 mg/kg of test substance to abraded (2 rabbits) and intact skin (2 rabbits).
Test method:	OECD TG 402
Mortality:	Nil
Clinical observations:	No signs of toxicity observed
Morphological findings:	No gross abnormalities detected
LD_{50}:	> 5000 mg/kg
Result:	OLOA 229 was of low dermal toxicity to the rabbit.

9.1.3.1 Skin Irritation (Cavalli MS 1970)

Test substance:	OLOA 229
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	6 males
Observation period:	3 days; observations done at 24 and 72 hours.
Method of administration:	A single, 24-hour occlusive application of 0.5 mL of test substance to abraded and intact skin on each rabbit.
Test method:	Not stated but similar to OECD TG 404

Dermal scores for intact skin:

Time after treatment (days)	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6***
Erythema						
1	[a]2	1	2	2	1	1
3	3	3	3	3	2	2
Oedema						
1	2	0	1	1	1	1
3	1	1	2	2	1	1

[a] see Attachment 1 for Draize scales

Comment: Scoring was done in accordance with the Federal Hazardous Substances Act which adopts a scoring system similar to the Draize scale.
There was mild to moderate erythema and oedema on all animals at 24 hours. By 72 hours, the reaction had increased.

Result: OLOA 229 was moderately irritating to rabbit skin.

9.1.3.2 Skin Irritation (Chevron Environmental Health Center Inc 1986a)

Test substance: OLOA 319

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 6 males

Observation period: 14 days

Method of administration: A single, 4-hour occlusive application of 0.5 g of test substance to abraded and intact skin sites on each rabbit.

Test method: Not stated but similar to OECD TG 404

Dermal scores for intact skin:

Time after treatment (days)	***Animal #***											
	1		***2***		***3***		***4***		***5***		***6***	
Erythema	***F***	***R***	***F***	***R***	***F***	***R***	***F***	***R***	***F***	***R***	***F***	***R***
1 hour	1	1	2	2	1	1	2	2	1	1	1	1
1	1	1	2	1	0	0	0	0	0	0	1	2
2	1	1	2	2	1	1	1	1	1	1	1	1
3	2	1	2	1	1	1	1	1	1	1	1	1
7	0	0	0	0	0	0	0	0	1	1	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0
Oedema	***F***	***R***	***F***	***R***	***F***	***R***	***F***	***R***	***F***	***R***	***F***	***R***
1 hour	0	0	0	0	0	0	1	0	0	0	0	0
1	0	0	0	0	0	0	0	0	0	0	1	1
2	0	0	1	0	0	0	0	0	0	0	0	0
3	0	0	1	0	0	0	0	0	0	0	0	0
7-14	0	0	0	0	0	0	0	0	0	0	0	0

[a] see Attachment 1 for Draize scales. *F* – front. *R* – rear.

Comment: Slight to well defined erythema and slight oedema persisted to 72 hours. At day 7, animals exhibited slight erythema. Treated skin sites were clear of all irritation by day 14.

Result: OLOA 319 was moderately irritating to rabbit skin.

9.1.4 Eye Irritation (Cavalli MS 1970)

Test substance: OLOA 229

Species/strain: Rabbit/New Zealand white.

Number/sex of animals: 6 males

Observation period: 3 days

Method of administration: A single instillation of 0.1 mL of neat test substance into the conjunctival sac of the right eye of each animal. The left eye served as the control.

Test method: Not stated but similar to OECD TG 405

Ocular response: No corneal or iridial effects were observed.
Conjunctival effects (Grade 1 redness) were observed in two

	animals at the 24-hour observation period resolving by the 48 hour observation period.
Result:	OLOA 229 was slightly irritating to rabbit eye.

9.1.5 Skin Sensitisation (Hill Top Research Ltd 1996)

Test substance:	OLOA 229
Species/strain:	Guineapig/Hartley
Number of animals:	10/sex (test group), 5/sex (naïve control group)
Test method:	OECD TG 406 Buehler Technique
Maximum Concentration not giving rise to irritating effects in irritation screen:	Irritancy was observed at 0.5%, the lowest concentration tested.
Induction procedure:	test animals: Days 1, 7 and 14: 0.3 mL of 25% w/v concentration of test substance in mineral oil applied, via a Hill Top Chamber, to the clipped skin of the left shoulder for 6 hours;
Challenge procedure:	test and naïve control animals: Day 28: same procedure as induction phase, except 0.3 mL of 25% w/v concentration of test substance in mineral oil test substance was applied to a previously non-treated site; Grading of dermal responses occurred 24 and 48 hours post exposure.

Number of animals exhibiting dermal responses at challenge:

Challenge concentration	***Test Animals***		***Naïve Control Animals***	
	24 hours*	***48 hours****	***24 hours****	***48 hours****
1%	Grade 0.5 – 17/20 Grade 1 – 3/20	Grade 0.5 – 18/20	Grade 0.5 – 9/10 Grade 1 – 1/10	Grade 0.5 – 10/10

*time after patch removal.
Grade 1 = slight but confluent, or moderate patchy erythema; Grade 0.5 = slight, patchy erythema.

Challenge outcome:	Following primary challenge the incidence and severity of Grade 1 responses in the test group (3 of 20) was comparable to those produced by the naïve control group (1 of 10) indicating that sensitisation had not been induced.
Result:	OLOA 229 was non sensitising to guineapig skin

9.2 Repeat Dose Testing

Six repeat dose studies in rats were provided in NICNAS Assessment NA890 covering subchronic toxicity, neurotoxicity, reproductive toxicity, and developmental toxicity. They are summarised in the table below. The lowest NOAEL or NOEL for subchronic (oral), reproductive and development toxicity is determined to be 50 mg/kg/day. The lowest NOAEL for neurotoxicity is ≥1000 mg/kg/day and the lowest NOEL for dermal toxicity is >250 mg/kg/day. The overall NOEL for OLOA 219 is established at 50 mg/kg/day.

Study	***Dose*** *(mg/kg/day)*	***NOEL/NOAEL*** *(mg/kg/day)*	***Findings at higher dose.***
28 day, oral; (WIL Research Laboratories Inc 1993)	0, 50, 200,1000	NOEL=50 (subchronic)	Clinical signs, reduced bodyweight gains and changes in organ weights.
		NOAEL ≥1000 (neurotoxicity)	Highest dose tested.
		NOEL=50 (reproductive)	Reduced bodyweights, and decrease in live litter size.
28 day, dermal; (SOCAL 1986)	0, 20, 100, 250	NOEL ≥250 (dermal)	Highest dose tested.
Developmental, oral; (CEHC 1990)	0, 50, 300, 1000	NOEL=300 (parental)	Reduced bodyweight gains and food consumption.
		NOEL=50 (developmental)	Malformation.
Developmental, oral; (WIL Research Laboratories 1994)	0, 50, 300, 1000	NOEL=300 (parental).	Reduced bodyweights and food consumption.
		NOEL=300 (developmental)	Malformation.
Oral, two-generation; (WIL Research Laboratories 1995b)	0, 50, 300, 1000	NOAEL=50 (parental)	Mortality, clinical signs, reduced bodyweight gains, and changes of organ weights.
		NOAEL=300 (reproductive)	Lower fertility indices.
		NOAEL=50 (developmental)	Lower pup survival rates, live litter sizes and pup bodyweights.

Oral reproductive & developmental; (WIL Research Laboratories 1995a)	0, 50, 250 (in finished oil)	NOEL ≥250 (reproductive & developmental)	Highest dose tested

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Chevron Environmental Health Center Inc 1986b)

Test Substance:	XA-294C (OLOA 319)
Strains:	*Salmonella typhimurium*: TA100, TA1535, TA98, TA1537
Auxillary metabolic activation system:	Liver S9 fraction from rats induced with Aroclor 1254
Concentration range:	0, 100, 250, 500, 1 000, 5 000 10 000 μg/plate of test substance suspended in ethanol. Each concentration was tested in triplicate, with or without metabolic activation, in two independent experiments. Appropriate strain specific positive control reference substances were used.
Test method:	OECD TG 471 – plate incorporation assay
Comment:	The test substance precipitation was not completely miscible with the top agar at and above 100 μg/plate. Toxicity characterised by growth inhibition was not observed at up to 10 000 μg/plate. There was no increase in the number of revertant colonies above the control, or demonstration of a dose response relationship, either in the presence or absence of metabolic activation at any test concentration. Concurrent positive controls used in the test induced marked increases in the frequency of revertant colonies and the activity of the S9 fraction was found to be satisfactory.
Result:	OLOA 319 was non mutagenic under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

On the basis of findings from testing conducted on OLOA 229 the notified chemical is expected to have very low acute oral and low dermal toxicity, be moderately irritating to skin and slightly irritating to eyes. Skin sensitisation potential is not expected. On the basis of

negative findings with OLOA 319, the notified chemical is not expected to be mutagenic in bacterial test systems.

Six repeat dose studies conducted in rats were provided in the submission covering subchronic toxicity, neurotoxicity, reproductive toxicity, and developmental toxicity. The overall NOEL for OLOA 219 is established at 50 mg/kg/day, based on general signs of toxicity such as body and organ weight changes. Except for an isolated study, fertility and developmental toxicity were observed only at parental toxicity levels. Being structurally and compositionally similar, the notified chemical is not expected to show dissimilar effects in repeat dose testing as that observed with OLOA 219.

Hazard Assessment
On the basis of the data supplied, the notified chemical is not classified a hazardous substance in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicity data for OLOA 229 were provided. However, ecotoxicity data for the chemicals CMA #607 (Chemical Manufacturers Association) and CMA #503 were provided as surrogates for OLOA 229. The notifier states that these CMA chemicals are almost identical to the notified chemical in that they are both calcium long-chain alkyl phenate sulphides. The majority of the tests were conducted according to OECD protocols, and the data is summarised in the table and discussed below.

ACUTE TOXICITY DATA

Test	*Species*	*Results (Nominal) mg/L*
Acute Toxicity [OECD 203]	Fathead minnow *Pimephales promelas*	LC_{50} (96 h) > 1000 NOEC (96 h) > 1000 Dispersion
Acute Toxicity [OECD 203]	Fathead minnow *Pimephales promelas*	LC_{50} (96 h) > 1000 NOEC (96 h) > 1000 WAF
Acute Toxicity [OECD 203] Preliminary Test	Sheepshead minnow *Cyprinodon variegatus*	WSF at 10 g/L No mortality
Acute Immobilisation [OECD 202]	Water flea *Daphnia magna*	EC_{50} (48 h) > 1000 NOEC (48 h) < 100 WAF
Acute Toxicity (no method specified)	Brown shrimp *Crangon crangon*	LC_{50} (96 h) > 100 NOEC (96 h) < 100
Acute Toxicity [OECD Section 2, General Procedures]	Mysid shrimp *Mysidopsis bahia*	LC_{50} (96 h) = 1800 NOEC (96 h) < 500 WSF

Growth Inhibition [OECD 201]	Freshwater alga *Selenastrum capricornutum*	E_bC_{50} (96 h) > 500 $NOEC_b$ (96 h) > 500 E_rC_{50} (96 h) > 500 $NOEC_r$ (96 h) > 500 WAF
Respiration Inhibition [OECD 209]	Activated sludge bacterium	EC_{50} (3 h) > 1000

EC_{50}: Daphnia test - The concentration estimated to immobilise 50% of the daphnia.
EC_{50}: Activated sludge test - The concentration at which the respiration rate of activated sludge bacteria is 50% of that shown by the control.
E_bC_{50}: The concentration of test substance that results in a 50% reduction in growth of alga relative to the control.
E_rC_{50}: The concentration of test substance that results in a 50% reduction in growth rate of alga relative to the control.
LC_{50}: Median lethal concentration.
NOEC: No Observed Effect Concentration.
$NOEC_r$: No Observed Effect Concentration (based on the average number of cells/mL).
$NOEC_b$: No Observed Effect Concentration (based on average specific growth rate).
WAF: Water Accomodated Fraction.
WSF: Water Soluble Fraction.

10.1 ACUTE TOXICITY AGAINST FISH

10.1.1 Fathead minnow (Dispersion method) (TR Wilbury Laboratories Inc 1994b)

The tests on this freshwater species were conducted over 96 hours under static conditions at nominal concentrations of 0, 100, 300 and 1000 mg/L. Each test solution was equipped with a mechanical stirrer. Each test was conducted in duplicate using 10 fish per test vessel, pH levels of 7.9 to 8.4 and a dissolved oxygen range of 7.4 to 9.0 mg/L. The water used was dechlorinated tapwater adjusted to a hardness of 160 to 180 mg/L as $CaCO_3$. All non-control test vessels had test substance stuck to weigh boats and floating on the surface throughout the test. In addition, test vessels containing 1000 mg/L had test substance on the bottom of test vessels.

There was no mortality at any test concentration. Exposure of fathead minnows to CMA #607 resulted in a 96 hour LC_{50} > 1000 mg/L, which is the highest tested concentration, and a NOEC estimated to be 1000 mg/L.

10.1.2 Fathead minnow (WAF) (EnviroSystems Division Resource Analysts Inc 1993b)

The acute toxicity of the WAF of 100, 300 and 1000 mg/L mixtures of CMA #607 was investigated over 96 hours under static renewal conditions. Preparation of the WAF involved stirring the mixtures of test substance in water for 24 hours, settling the mixtures for one hour and siphoning off the water phase containing the WAF and ensuring that no settled or surface floating test substance was transferred. A control sample was also tested. Each concentration was tested in duplicate, using 10 fish per test vessel, pH levels of 7.0 to 8.0 and a dissolved oxygen range of 7.4 to 8.7 mg/L. The water used was filtered well water adjusted to a hardness of 176 mg/L as $CaCO_3$.

Except for one fish in the control group, all fish survived. No sublethal effects were noted during the test. Exposure of fathead minnows to CMA #607 resulted in a 96 hour LC_{50} >

1000 mg/L (expressed as the nominal amount of test substance used to prepare the WAF) and a NOEC of 1000 mg/L (nominal).

10.1.3 Sheepshead Minnow (Springborn Bionomics Inc 1986b)

A tiered approach was employed to determine the acute lethal effect of CMA #503 on sheepshead minnow, a salt-water fish species. A Tier I preliminary study was conducted using a 100% WSF for a maximum of 96 hours with daily renewal of the test and control solutions. Preparation of the 100% WSF test solution involved stirring (16 to 20 hours) 150 grams of CMA #503 in 15 liters of dilution water with a subsequent settling period of two hours. Duplicate WSFs and duplicate control samples, containing none of the test substance, were tested. Each test involved using 10 fish per test vessel, pH levels of 7.8 to 8.1 and a dissolved oxygen range of 6.2 to 7.6 mg/L. The water used was filtered natural seawater.

There was no mortality at any test concentration. Based on these results the 100% WSF (10 g/L) of CMA 503 is not toxic to the test population of sheepshead minnows. A Tier II definitive study was not required as less than 50% mortality was observed during the exposure period.

10.2 ACUTE TOXICITY AGAINST INVERTEBRATES

10.2.1 *Daphnia magna* (EnviroSystems Division Resource Analysts Inc 1993a)

The acute toxicity of the WAF of 100, 300 and 1,000 mg/L mixtures of CMA #607 to daphnia was investigated over 48 hours under static renewal conditions. A control sample containing none of the test substance was also tested. Preparation of the WAF involved the same preparation as described for fathead minnow (WAF). A duplicate for each level was tested, using 10 daphnia per test vessel, pH levels of 7.0 to 8.5 and a dissolved oxygen range of 8.4 to 8.7 mg/L. The water used was filtered well water adjusted to a hardness of 176 mg/L as Ca CO_3.

There was 100 per cent survival in the control group. In the WAF of three test concentrations there was 75 to 95 per cent survival. Insoluble material was not observed during the test. No sublethal effects were observed during the test, although some of the daphnia exposed to each concentration were floating. Exposure of daphnia to CMA #607 resulted in a 48 hour EC_{50} > 1000 mg/L (expressed as the nominal amount of test substance used to prepare the WAF) and a NOEC of < 100 mg/L, the lowest nominal concentration tested.

10.2.2 Brown shrimp (Huntingdon Research Centre Ltd 1988)

The acute toxicity of CMA 503 to this salt-water invertebrate was conducted over 96 hours under semi-static conditions at nominal concentrations of 0, 100, 500 and 1000 mg/L of CMA 503. On a daily basis surviving shrimps were temporarily removed while each aquarium was thoroughly cleaned and refilled with fresh seawater. The test substance was heated to 90°C to aid dispensing, and introduced directly onto the surface of the water away from a stirrer that was installed in each test solution. Each test concentration was tested in duplicate, with 10 fish per test vessel. The pH level and dissolved oxygen of the control were measured as 8.3 and 9.9 mg/L respectively and synthetic seawater was used. It was observed that there was very poor dispersion of CMA 503 with only a few small globules circulating

throughout the water column. Most of the test substance adhered to the screens around the shielded propeller stirrers.

There was 90 percent survival in the control group. The test concentrations 500 and 1000 mg/L were terminated after 48 hours due to the viscous nature of the test substance sticking the dead and live shrimps together. From the cumulative mortality data it is probable that the 48 to 96 hour LC_{50} values lie between 100 to 500 mg/L (ie > 100 mg/L, nominal), although it should be stressed that much of the adverse effects were probably due to physical rather than chemical properties. The NOEC is < 100 mg/L, the lowest nominal concentration tested.

10.2.3 Mysid Shrimp (Springborn Bionomics Inc 1986a)

To determine the acute toxicity of CMA #503 on this salt-water invertebrate, a Tier II definitive study was conducted under static renewal test conditions, with daily renewal of the test solution during a 96 hour exposure period. A Tier I preliminary study and a Tier II rangefinding study preceded the definitive test.

Test solutions were WSF of CMA #503 made up in filtered natural sea water at nominal concentrations of 0, 500, 1000, 2000, 4000 and 8000 mg/L. Test solutions of CMA #503 were prepared separately for each test concentration. Preparation involved addition of the requisite quantity of test substance to dilution water, stirring the mixture for 24 hours followed by a settling period of 24 hours, and the siphoning of the WSF away from each mixture so as to avoid transferring settled or surface floating test substance. Each test was conducted in duplicate using 10 mysids per vessel, and pH and dissolved oxygen levels were 7.9 to 8.1 and 4.7 to 7.1 mg/L, respectively.

Despite the first mortalities being observed at 72 hours for the 500 mg/L treatment, where the number of mortalities for one of the duplicates was 30% and the other duplicate 0%, the number of mortalities tended to increase for treatment levels greater than 1000 mg/L. For example, for duplicates of each treatment level, mortalities increased from 10% at 1000 mg/L (48 hours) to 70% at 8000 mg/L (48 hours). At 8000 mg/L, the highest nominal concentration tested, mortalities for the duplicates were 100% and 90%. It was noted that for exposure to the 4000 and 8000 mg/L treatments, all surviving mysids at each 24 hour observation interval were lethargic.

Probit analysis provided a 96 hour LC_{50} of 1800 mg/L (1400-2400, 95% confidence interval nominal) and a corresponding 96 hour NOEC of < 500 mg/L (nominal). It can be concluded that CMA #503 displays some toxicity to mysids, at concentrations below the level of its solubility in water.

10.3 ACUTE TOXICITY AGAINST ALGAE

(TR Wilbury Laboratories Inc 1994c)

A test on algal growth inhibition was performed under static conditions at 22 to 25°C over 96 hours on the freshwater alga *Selenastrum capricornutum* with the WAF of five concentrations of CMA #607 and a dilution water control. Preparation of the WAF involved mixing the solutions of CMA #607 for 24 hours, settling for one hour and siphoning off the WAF. The test substance was not heated prior to preparation of the WAF and the nominal concentrations of WAF were 0, 63, 130, 250, 350 and 500 mg/L. Each test, including the control was conducted in triplicate with the cell density determined visually by means of

direct microscopic examination with a hemocytometer. The water used for testing was sterile enriched media adjusted to a pH of 7.5.

It was noted that the test vessels containing WAF at 500 mg/L were cloudy at test initiation and insoluble material adhering to the inside of the test vessel, was observed from 24 hours. The EC_{50} values could not be calculated because cell growth by algae exposed to all five concentrations of WAF was greater than 50% of the control at 24, 48, 72 and 96 hours, resulting in a 96 hour E_bC_{50} and E_rC_{50} of > 500 mg/L (highest tested nominal concentrations).

No effects (size differences, unusual cell shapes, colours, flocculations) were noted in any of the treatments. Analysis of the results using acceptable statistical methods (eg. Kruskal and Wallis' test and Dunnett's test) provided a 96 hour $NOEC_b$ of > 500 mg/L (based on the average number of cells/mL at each concentration) and a 96 hour $NOEC_r$ of > 500 mg/L (based on the average specific growth rate).

An aliquot of test media taken from each 500 mg/L WAF at 96 hours, when cultured in fresh media for an additional 72 hours, revealed that the WAF at this nominal concentration was algistatic rather than algicidal.

10.4 ACTIVATED SLUDGE RESPIRATION INHIBITION

(TR Wilbury Laboratories Inc 1994a)

A test on the inhibition of activated sewage sludge respiration by CMA #607 was conducted under static conditions at 19.8 to 20.1°C. Nominal concentrations were 0, 100, 300 and 1000 mg/L, with each concentration tested in duplicate. Insoluble test material was observed on the bottom of test vessels. Preparation of the test solutions involved direct addition of CMA #607 to sterilised, filtered, dechlorinated tap water, without the use of a solvent. At time 0 for each test vessel, an aliquot of synthetic sewage was diluted to volume with water containing the appropriate concentration of CMA #607, followed by addition of an aliquot of microbial inoculum. After a three-hour incubation period the dissolved oxygen content was measured for 10 minutes. Inhibition of the activated sludge respiration was <50% of the control rate at all tested concentrations, indicating that CMA #607 was not acutely toxic. Exposure of the sludge to CMA #607 resulted in an EC_{50} > 1000 mg/L. The three-hour EC_{50} determined during a reference toxicant test with this batch of activated sludge and 3,5-dichlorophenol was 12 mg/L, thereby confirming the validity of the test. It is noted that the remaining requirement for validation of the test, that is, that control respiration rates are within 15% of each other, was not met. However, the slightly greater difference was considered to have minimal impact and not effect the validity of the test.

10.5 CONCLUSION

Ecotoxicity data for two chemicals similar to the notified chemical indicate that based on the conditions of the individual tests, these chemicals are not toxic to three species of fish, two species of micro-invertebrates and alga up to the level of their solubility in water. However, one of the chemicals exhibited some toxicity to mysid shrimp, at concentrations below the level of its solubility in water, and some likely physical effects in brown shrimp. In addition, the chemical tested against alga was shown to be algastatic. Treatment of activated sludge bacterium with one of these chemicals caused some inhibition in respiration, but was not shown to be toxic to the bacterium.

Based on the claimed similarity of the surrogate chemicals to the notified chemical, the ecotoxicity data for the surrogate chemicals indicate that the notified chemical should not be toxic to the organisms tested up to its level of solubility in water, except for mysid shrimps.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical is considered to be low provided that the material is used as a component of marine diesel engine lubricants. Release to the environment is expected to occur only in the unlikely event of an accident during transport or an accidental leak. It is expected that minimal waste will be generated from lubricant formulation and use, and this waste would either be incinerated or placed into landfill.

In large marine diesel engines most of the notified chemical will be consumed during combustion (98%). Very little release is anticipated from maintenance activities.

Over time, fresh oil is added to keep sump levels constant and to maintain the effectiveness of the oil. Used oil generated from draining oil or engine repair will be incinerated or sent for recycling.

The notified chemical has a high value for log P_{OW} and if released to the soil compartment would become strongly associated with the organic component of soils and sediments and is not expected to be mobile in these media.

No biodegradation data was provided for the notified chemical, but if released to landfill or if associated with soil, it is expected to slowly degrade through the various biological and abiotic processes operative in these situations to water, sulphides and oxides of carbon, with the calcium component associating with soil minerals. Incineration would lead to water vapour and oxides of carbon and sulphur, with the calcium being assimilated into ash.

Based on a variety of ecotoxicity tests for surrogate chemicals conducted against a number of freshwater and marine organisms (fish, invertebrates and algae), NEW OLOA 229 is not expected to be toxic to the aquatic species against which the surrogates have been tested, up to its level of solubility in water. However, NEW OLOA 229 may exhibit some level of toxicity to mysid shrimps, below its level of solubility in water. The high partition coefficient and presumed low biodegradability of NEW OLOA 229 indicate the potential for bioaccumulation if spilt into waterways. However, very little of the chemical is likely to reach the aquatic compartment and a hazard to aquatic organisms is not considered likely.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

By analogy, the toxicity of the notified chemical is not expected to differ substantially from that of OLOA 229 and OLOA 219. NEW OLOA 229 is expected to have very low acute oral, and low dermal toxicity. It may be slightly irritating to eyes and moderately irritating to skin but is not expected to be sensitizing to skin. From investigations into organ or systemic effects, neurotoxic effects or reproductive effects following repeated exposure, the lowest NOEL is 50 mg/kg/day. NEW OLOA 229 is not expected to be genotoxic. On the basis of

the read across data supplied for the endpoints investigated, NEW OLOA 229 would not be classified as a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999).

Occupational Health and Safety
The blending of the additive package, containing the notified chemical at 0.8 to 12% into marine diesel engine lubricants will occur in automated, closed systems. Exposure to the additive package containing the most concentrated forms of the notified chemical will be limited to incidental skin contact to the additive package during the procedures involved in connection and disconnection of pump lines and during sampling for laboratory analysis. Other scenarios of exposure to the notified chemical are at concentrations of less than 1% and also limited to incidental skin contact. The toxicological profile, mode of use, use of personal protective gear and *in situ* engineering controls, indicate that significant risks to human health through occupational exposure to the notified chemical are unlikely. Control measures are required to reduce the risk of skin irritation.

Public Health
The notified chemical is not available for sale to the public. Since the notified chemical will be used in marine vessel engines not handled by the public, the risk of exposure of the public to the notified chemical is considered to be low. The notified chemical will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to NEW OLOA 229 the following guidelines and precautions should be observed:

- Workers should receive regular instruction on good occupational hygiene practices in order to minimise personal contact, and contamination of the work environment with lubricant material.

- Chemical impervious clothing and gloves are necessary to prevent skin contact - consideration should be given to the ambient environment, physical requirements and other substances present when selecting protective clothing and gloves. The notifier recommends Viton, nitrile, silver shield gloves. Good hygiene practices dictate that eye protection be worn routinely. Workers should be trained in the proper fit, correct use and maintenance of their protective gear. Guidance in the selection, personal fit and maintenance of personal protective equipment can be obtained from:

Protective eyewear:	AS 1336 (SAA 1997);
	AS/NZS 1337 (SAA/SANZ 1992).
Chemical impermeable clothing:	AS 3765.2 (SAA 1990).
Impermeable gloves:	AS 2161.2 (SAA/SANZ 1998).
Occupational footwear:	AS/NZS 2210 (SAA/SANZ 1994).

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

NEW OLOA 229 is not determined to be a hazardous substance. The finished lubricant may contain hazardous ingredients making the overall finished lubricant hazardous. Therefore, workplace practices, control procedures and hazard communication products consistent with provisions of State, Territory and Commonwealth legislation based on the *National Model Regulations for the Control of Workplace Hazardous Substances* (NOHSC 1994b) must be in operation.

NEW OLOA 229 is identified as a C2 combustible liquid and should be stored, handled and used in accordance with AS 1940 (SAA 1993).

Spillage of formulations containing NEW OLOA 229 should be avoided. Spillages should be cleaned up promptly and in accordance with the instructions on the notifiers MSDS.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 1994a).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, the Director must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise, and secondary notification of the notified chemical may be required. No other specific conditions are prescribed.

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Attachment 1

The Draize Scale (Draize, 1959) 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 (Draize *et al*., 1944) 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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	3 severe	Swelling with lids half-closed to completely closed	4 severe		

IRIS

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

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