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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

New OLOA 271

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FULL PUBLIC REPORT

New OLOA 271

1. APPLICANT

Chevron Chemical Australia of Level 22, 385 Bourke Street, Melbourne, Victoria 3000 (ABN 75 001 010 037) has submitted a standard notification statement in support of their application for an assessment certificate for New OLOA 271.

2. IDENTITY OF THE CHEMICAL

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

The notified chemical is similar to OLOA 271 assessed previously as NA/692.

3. PHYSICAL AND CHEMICAL PROPERTIES

The following physicochemical data pertain to the notified chemical in a lubricating oil solvent at 75-80%.

Appearance at 20°C & 101.3 kPa:	Dark brown viscous liquid.
Boiling Point:	Not determined. Chemical decomposes before boiling.
Specific Gravity:	0.982 g/mL at 15°C
Vapour Pressure:	4.9×10^{-5} kPa at 25°C. See comments below.
Water Solubility:	< 100 µg/L
Partition Co-efficient (n-octanol/water):	log P_{ow} = > 8
Hydrolysis as a Function of pH:	No hydrolysable groups are present.
Adsorption/Desorption:	Expected to adsorb strongly to soil. See comments below.

Dissociation Constant:	Not determined.
Flash Point:	212 °C
Flammability Limits:	Not determined. Combustible.
Autoignition Temperature:	Not expected to auto-ignite.
Explosive Properties:	Not explosive.
Reactivity/Stability:	Will react in the presence of strong oxidising agents.

3.1 Comments on Physico-Chemical Properties

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

The water solubility of OLOA 271 (NA/692) was determined to be ≤39 mg/L by TOC analysis of equilibrated solutions based on per cent carbon data. In Rausina et al (1996) the water solubility of New OLOA 270 (NA/889), is stated as 83 ppb using Semipermeable Membrane Devices (SPMDs) and is based on the water solubility determined for oil additive detergents that are stated to be similar in structure. The level stated is consistent with the notified chemical containing long hydrophobic alkyl chains.

Measurement of the n-octanol/water partition coefficient was attempted using an HPLC method and only brief details were provided. However, only 2.3% of the compound could be dissolved in acetonitrile and this had a log P_{ow} of 5.85. The insoluble material can be assumed to have a log $P_{ow} > 8$, and, on this basis, the notified 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.

No dissociation data was provided. However, the structure of the notified chemical suggests it will be weakly acidic (Morrison and Boyd, 1976). Despite the notifier claiming that the notified 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 as the notified chemical is a UVCB
Additives/Adjuvants:	Lubricating oil

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as an antioxidant, detergent and anticorrosion additive for

marine diesel oil lubricants. New OLOA 271 will be imported alone or in up to 5 oil additive packages at 60-80% (45-65% notified chemical). Final concentration of New OLOA 271 in lubricants will be 15-20% (11-16% notified chemical).

The notified chemical will be imported by marine bulk, in marine isotanks or in 208L steel drums at a rate of up to 300 tonnes per year for the first 5 years.

6. OCCUPATIONAL EXPOSURE

Exposure

The following 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, 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 271	Maximum Potential Exposure Duration
Marine Terminal		
Unloading (1 or 2)	60 - 100	0.5 hours/day; 2 days/year.
Sampling & Analysis (1 or 2)	60 - 100	0.5 hours/day; 2 days/year.
Loading tanker trucks (1 or 2)	60 - 100	0.5 hours/day; 4 days/year.
Equipment Cleaning (1 or 2)	< 1	4 hours/day; 1 day/year.
Blending Facility		
Transfer to additive storage tank (1 or 2)	15 - 100	1 hour/day; 4 days/year.
Analysis & Sampling (1 or 2)	15 - 100	0.5 hours/day; 11 days/year.
Transfer to blending tank and finished storage tank	15 - 100	Data not provided
Packaging- Drum Filling (1 or 2)	15 - 20	8 hours/day; 3 days/year.
Loading tanker trucks (1 or 2)	15 - 20	2 hours/day; 13 days/year.
Equipment Cleaning (1 or 2)	<1	3 hours/day; 2 day/year.

ISO tank & Drum Cleaning (1 or 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 or rail 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 or rail tanker. During sampling and analysis of the additive package, there may be skin contact as sampling containers, devices and analytical equipment are handled. The notified chemical is of low volatility and, therefore, inhalation exposure is unlikely.

Lubricant Blending Plant

The notified chemical in additive packages arriving in either isotanks, road or rail 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. For unloading of drums, workers will connect a pump line to the drum. During unloading from the three types of containers, incidental dermal and ocular contact to splashes, drips and spills may occur as pump lines are connected or disconnected. Whole body exposure to mists containing the notified chemical may occur if emptied drums are steam cleaned for reuse 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 200L 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 and blended lubricant in storage tanks will be sampled for laboratory analysis and incidental dermal and ocular contact from splashes, drips and spills may occur during sampling and analytical procedures.

Marine Vessels

Ship or dockside workers may receive dermal and ocular 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 may not be 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 claims 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 blending activities are reported by the notifier to be well educated in the handling of additive packages.

7. PUBLIC EXPOSURE

The notified chemical is not available for sale to the public and will be used as a lubricant additive, primarily for use in ocean-going vessels. Since the notified chemical will be used in engines not handled by the public, the possibility of exposure of the public to the notified substance is considered to be low.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The blending operations are performed at specially constructed sites owned and operated by petroleum companies, and up to two of these sites in Australia may be involved in producing the 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.

The additive packages containing the new material will be delivered to and stored at the blending facilities in isotanks or drums. It is anticipated that there will be minimal release of New OLOA 271 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 271 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 271 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 271 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 both uses skilled tradesmen will be undertaking all maintenance of the equipment so spills and leaks will be kept to a minimum and cleaned up immediately. Fresh oil may be added to the engines/hydraulics over time to keep levels constant and to maintain the effectiveness of the oil but generally the machinery will undergo a major service once a year. Since this will

involve skilled tradesmen, used oil generated from the draining of the oil or engine repair will be incinerated or sent for recycling.

8.2 Fate

In the case of accidental release to land, the anticipated high adsorption/desorption property of the notified chemical indicates that it 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. 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.

Mead (1998a) conducted a ready biodegradability study on OLOA 271 using the OECD TG 301B Method, but it was not defined as to whether this test was performed on OLOA 271 or New OLOA 271. Sealed bottles containing the test substance (5 mg/L) and inorganic nutrient medium were inoculated with activated sewerage sludge bacteria and incubated for up to 28 days at 21°C. Biodegradation was assessed by the determination of CO2 produced. The test substance attained 2% degradation after 28 days. Sodium benzoate was used as the standard substance and attained 61% degradation after 28 days. Therefore, OLOA 271 may not be termed readily biodegradable.

The expected high log P_{ow}, molecular weight and low rate of biodegradation of New OLOA 271, 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, 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

No toxicological data were provided for New OLOA 271. Analogue data provided were for OLOA 271, assessed under NICNAS as NA/692.

9.1 Acute Toxicity

Summary of the acute toxicity of OLOA 271

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} >5000 mg/kg	Driscoll, 1998a
acute dermal toxicity	rat	LD_{50} >2000 mg/kg	Driscoll, 1998b
skin irritation	rabbit	moderately irritating	Driscoll, 1998c
eye irritation	rabbit	slightly to moderately	Driscoll, 1998d

		irritating	
skin sensitisation	guinea pig	Slightly sensitising	Driscoll, 1998e; Morris, 1998

9.1.1 Oral Toxicity (Driscoll, 1998a)

Species/strain:	Rat, Sprague-Dawley CD
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	Single limit dose of 5000 mg/kg; administered by gavage as a dispersion in arachis oil BP
Test method:	OECD TG 401
Clinical observations:	Hunched posture was observed commonly with additional signs of diarrhoea and pilo-erection. isolated signs of ataxia, lethargy, ptosis, decreased respiratory rate, laboured respiration and red-brown staining around eyes were also observed. All animals recovered by day 4 after dosing.
Mortality:	One female died 2 days after dosing – not related to treatment.
Morphological findings:	No abnormalities were observed.
LD_{50}:	> 5000 mg/kg
Result:	The notified chemical analogue was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Driscoll, 1998b)

Species/strain:	Rat, Sprague-Dawley CD
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	Single, 24-hour semi-occluded, dermal application to intact skin at 2000 mg/kg bodyweight
Test method:	OECD TG 402
Clinical observations:	No signs of systemic toxicity were observed. Signs of dermal irritation including slight to moderate erythema, desquamation, leathering and fissuring were noted.

Mortality: None

Morphological findings: No abnormalities were observed.

LD_{50}: > 2000 mg/kg

Result: The notified chemical analogue was of low acute dermal toxicity in rats.

9.1.3 Inhalation Toxicity

Data were not provided.

9.1.4 Skin Irritation (Driscoll, 1998c)

Species/strain: Rabbit, New Zealand White

Number/sex of animals: 6 males

Observation period: 72 hours for determination of Primary Irritation Index;
14 days for determination of reversibility of changes.

Method of administration: Single four hour, semi-occluded application (0.5mL of notified chemical analogue, pH 5.5) to intact skin of shorn dorsal flank.

Test method: OECD TG 404

Draize scores (Driscoll, 1998c):

	Animal #					
Time after treatment (days)	***1***	***2***	***3***	***4***	***5***	***6***
Erythema/eschar						
1	2[a]	2	2	2	2	2
2	2	2	2	1	2	2
3	2	2	2	1	2	2
4	2	?	2	1	2	2
7	0	?	?	0	?	?
14	0	?	0	0	?	0
Oedema						
1	2	3	2	1	2	2
2	2	3	2	1	2	2
3	2	2	2	1	2	2

4	2	?	2	1	2	2
7	0	0	0	0	0	0
14	0	?	0	0	?	0

[a] see Attachment 1 for Draize scales
? indicates where adverse reactions prevented accurate evaluation of erythema/oedema

Comment: The notified chemical analogue produced well defined erythema and slight to moderate oedema (mean scores of 2 for erythema/eschar formation and 2 for oedema for 24, 48 and 72 hours);

Other reactions included light brown discolouration of the epidermis, loss of skin elasticity and flexibility, crust formation, desquamation, scabbing and reduced or increased fur growth. No corrosive effects were observed.

After 14 days the reactions induced by the notified chemical analogue were not fully reversed.

Result: The notified chemical analogue was moderately irritating to the skin of rabbits.

9.1.5 Eye Irritation (Driscoll, 1998d)

Species/strain: Rabbit, New Zealand White

Number/sex of animals: Group 1 : 1 female, 5 males
Group 2 : 3 males

Observation period: 14 days

Method of administration: Group 1 (unirrigated): 0.1mL of notified chemical analogue, pH 5.5 instilled into the conjunctival sac of the left eye. Right eye remained untreated.

Group 2 (irrigated): same as Group 1, except the chemical was washed out after 30 seconds.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation									
Animal	***1 day***		***2 days***		***3 days***		***4 days***		***7 days***	
Cornea	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***
1 (female)	1[1]	1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0

3	1	3	2	2	1	1	1	1	0	0					
4	0	0	0	0	0	0	-	-	-	-					
5	0	0	0	0	0	0	0	0	0	0					
6	1	2	2	1	2	1	1	1	0	0					
Iris															
1 (female)	0			0			0			0			0		
2	0			0			0			0			0		
3	1			1			0			0			0		
4	0			0			0			-			-		
5	0			0			0			0			0		
6	1			1			0			0			0		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1 (female)	2	2	2	2	2	1	2	2	1	2	2	0	1	0	0
2	2	2	1	2	2	0	2	2	0	2	2	0	1	0	0
3	2	2	1	2	2	1	1	1	0	1	1	0	0	0	0
4	1	1	1	1	1	0	0	0	0	-	-	-	-	-	-
5	2	2	0	2	2	0	2	1	0	2	1	0	1	0	0
6	2	3	2	2	3	2	2	2	2	2	2	0	1	0	0

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge
- indicates observation not required

Comments:

All eyes demonstrated positive effects, with all effects reversed within the 14 day observation period.

Diffuse to translucent corneal opacity was observed in 3 eyes, iridial inflammation in 2 and conjunctival irritation in all treated eyes.

Mean scores for corneal opacity, iris lesion, conjunctival redness and conjunctival chemosis were 0.6, 0.2, 1.7 and 1.8, respectively (for 24, 48 and 72 hours).

The maximum individual score in irrigated eyes (24 – 72 hours) was 1 for conjunctival redness and chemosis.

Conjunctival irritation noted in all three irrigated eyes. However, no corneal or iridial effects were noted.

Result:

The notified chemical analogue was slightly to moderately irritating to the eyes of rabbits.

9.1.6 Skin Sensitisation – Maximisation Test (Driscoll, 1998e)

Species/strain: Guinea pig, Dunkin-Hartley albino

Number of animals: 20 test and 10 controls in main study; all females

Induction procedure: Day 1: Intradermal injections to a clipped area (40mm x 60mm) of the shoulder region, each animal received 3 pairs of intradermal injections (0.1 mL/site) as follows:

- Freund's Complete Adjuvant (FCA): distilled water (1:1 v/v)
- 5 % w/v of notified chemical analogue in arachis oil BP
- 5 % w/v of notified chemical analogue in a 1:1 mixture of FCA and distilled water
- for the negative control group, the notified chemical analogue was replaced with arachis oil BP

Day 7: Shoulder area was re-clipped and subsequently treated with a topical application of 75 % v/v notified chemical analogue (occluded for 48 hours); arachis oil BP was substituted in the negative control group.

Challenge procedure: Day 21: Occluded 24 hour application of 25 % v/v notified chemical analogue in arachis oil BP to a clipped area (50mm x 70mm) on the left flank of each animal.

Rechallenge procedure: Day 42: Test group animals rechallenged on previously untreated skin with 10 % and 25 % v/v notified chemical analogue in arachis oil BP; Similar treatment to a control group not previously exposed to the notified chemical analogue but which had received intradermal injections of FCA.

Test method: OECD TG 406, Magnusson and Kligman maximisation test

Challenge outcome:

Challenge concentration	***Test animals***		***Control animals***	
	24 hours*	***48 hours****	***24 hours***	***48 hours***
25%	1/20**	0/20	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Rechallenge outcome:

Challenge concentration	***Test animals***		***Control animals***	
	24 hours*	***48 hours****	***24 hours***	***48 hours***
25%	1/20**	0/20	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Comment: There were no dermal reactions in either test or control groups with 10% challenge. With 25% challenge, 3 of 20 test animals showed very slight erythema and 1 of 20 showed well defined erythema (rated as a single positive response). Slight oedema was observed also in one test animal. At rechallenge, a single test animal showed very slight erythema.

Result: In this adjuvant-type test, the notified chemical analogue was at most slightly sensitising to the skin of guinea pigs.

9.1.7 Skin Sensitisation – Buehler Test (Morris, 1998)

Species/strain: Guinea pig, Dunkin-Hartley albino

Number of animals: 20 test animals, 10 naive controls and eight pilot animals; equal numbers of males and females included in each group

Induction procedure: The left shoulder of each animal was clipped and treated epidermally with 0.3 mL of 25% w/v notified chemical analogue in mineral oil using a Hill Top chamber.

Three induction exposures each of six hours duration, at intervals of 6 or 7 days were applied to the one site.

For the negative control group, the notified chemical analogue was replaced with mineral oil.

Challenge procedure: Two weeks after the last induction, induced animals were exposed to 5% w/v notified chemical analogue in mineral oil at a previously untreated site.

Similar treatment to an additional group of 10 naive control animals, not previously exposed to the notified chemical analogue.

Test method: Adaptation of the method of Ritz and Buehler (1980)

Challenge outcome:

Challenge concentration	***Test animals***		***Control animals***	
	24 hours*	***48 hours****	***24 hours***	***48 hours***
5%	6/20**	0/20	1/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Comments:	Six of 20 test animals and 1 of 10 control animals showed slight but confluent, or moderate patchy erythema (rated as a positive response) at 24 hours. All other test and control animals exhibited slight, patchy erythema. All test animals and 9 out of 10 controls exhibited slight, patchy erythema at 48 hours. Overall, the severity of responses between the test and control groups was comparable at 24 hours (mean scores of 0.7 and 0.6, respectively). The incidence of positive responses appeared higher in the test group (30 %) compared with the controls (10 %).
Result:	In this non-adjuvant-type test, the notified chemical analogue was slightly sensitising to the skin of guinea pigs.

9.2 28-Day Oral Repeated Dose Toxicity (Jones, 1998)

Species/strain:	Rat, Crl:CD BR
Number/sex of animals:	5 males, 5 females per group
Method of administration:	Gavage
Dose/Study duration::	0, 100, 500 or 1000 mg/kg in corn oil; once daily for 28 consecutive days.
Test method:	According to EC Annex to Directive 92/69/EEC, Part B, Method B.7

Clinical observations:
No mortalities were recorded. For much of the dosing period, salivation and wet coat were seen post-dosing for up to 2 hours in both sexes receiving 1000 mg/kg/day and to a lesser extent at 500 mg/kg/day. Hunched posture post-dosing, for up to 5 hours duration, was observed for all males and females receiving 1000 mg/kg/day, particularly during weeks 3 and 4. Hair loss was seen for all males and females receiving 1000 mg/kg/day and to a slightly lesser extent for females receiving 500 mg/kg/day. Males receiving 100 or 500 mg/kg/day also showed slight hair loss.

Throughout the treatment period, statistically significant reductions in bodyweight gain and food consumption were observed for males receiving 1000 mg/kg/day.

Clinical chemistry / Haematology
Males receiving 1000 mg/kg/day showed statistically significant increases in total white blood cell counts due to higher numbers of lymphocytes, basophils, monocytes and large unstained cells compared with controls.

Reduced cholesterol was seen for all male and female treated groups, the effect being dose-related to a degree, but most marked at 500 and 1000 mg/kg/day. Increased glutamic

pyruvic transaminase (GTP) values were noted for both sexes receiving 1000 mg/kg/day and females receiving 500 mg/kg/day.

Reduced calcium levels were seen for females receiving 500 and 1000 mg/kg/day. Increased urea was noted for males receiving 1000 mg/kg/day. There were no corroborative microscopic changes to account for these observations.

Both sexes displayed increased alkaline phosphatase (AP) values at all doses and although there was no strict dosage relationship, the highest values were seen at 500 and 1000 mg/kg/day. There was, however, a high degree of individual variation and this finding was considered unlikely to be treatment-related.

Pathology:
A statistically significant increase in liver weight was seen for both sexes receiving 500 and 1000 mg/kg/day, the effect for females at the highest dosage also being observed macroscopically. Centrilobular hepatocyte hypertrophy was seen microscopically in the liver of both sexes receiving 500 and 1000 mg/kg/day, the effect being dose-related. For most animals receiving the highest dose, as well as one female on 500 mg/kg/day, this finding was accompanied by slight vacuolation of the periportal hepatocytes.

Males receiving 1000 mg/kg/day showed a statistically significant decrease in weights of the sexual organs (e.g. prostate, testes, seminal vesicles and epididymides). Females on the same dosage showed slightly reduced uterus weights. For the seminal vesicles/prostate, slightly reduced colloid was seen microscopically in the majority of animals receiving 1000 mg/kg/day and one male at 500 mg/kg/day. This finding was noted to be of uncertain toxicological significance.

Females at all doses and males receiving 1000 mg/kg/day showed statistically significant increases in adrenal weight compared with controls. Females also recorded kidney weight increases at 500 and 1000 mg/kg/day. Slight adrenal cortical hypertrophy was found at all doses for females and for two males receiving 1000 and one male at 500 mg/kg/day. Although the finding correlated with changes observed in adrenal weight; the effect was not dose related and of uncertain significance.

Conclusions:
Statistically significant pathological changes including effects on bodyweight (males), organ weights (males and females), haematology (males), biochemistry (males and females) and histopathology (males and females) were seen at 500 mg/kg/day. Adrenal weight changes and hypertrophy were found at all doses, but not always in both sexes. These were considered not to be toxicologically important. Clinical signs (salivation and hair loss) were seen at all doses. With these findings, a No Observed Effect Level (NOEL) could not be established. A No Observed Adverse Effect Level (NOAEL) of 100mg/kg/day was established for the notified chemical analogue.

Comment:
The authors stated that the 28 day study was conducted in order to select suitable doses for a 13 week study. Based on the results of this study, a 13 week investigation is warranted.

9.3 Genotoxicity

9.3.1 ***Salmonella typhimurium* / *Escherichia coli* Reverse Mutation Assay** (Thompson, 1998)

Strains:	*Salmonella typhimurium* TA1535, TA1537, TA98 and TA100; *Escherichia coli* WP2uvrA$^-$
Concentration range:	15-5000 μg/mL, with and without metabolic activation using rat liver microsomal S9 mix.
Test method:	OECD TG 471 and 472
Comment:	*Preliminary toxicity study* The notified chemical analogue was non-toxic to *Salmonella typhimurium* TA100 and *Escherichia coli* WP2uvrA$^-$ at the tested concentrations up to 5000 μg/plate *Range-finding and main mutation assays* In the two experiments, all bacterial strains were used at six concentrations up to 5000 μg/plate, with and without S9 metabolic activation. Precipitation occurred at the top dose but did not interfere with scoring of revertant colonies. No toxicity was observed. The notified chemical analogue caused no visible reduction in the growth of the bacterial background lawn at any dose level. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the notified chemical analogue, either with or without metabolic activation. All of the positive control chemicals used induced marked increases in the frequency of revertant colonies, both with and without metabolic activation;
Conclusion:	The notified chemical analogue was not mutagenic to the bacterial strains tested.

9.3.2 ***In vivo* Micronucleus Assay in the Bone Marrow Cells of the Mouse** (Durward,1998)

Species/strain:	Mouse, albino Crl : CD-1^{TM} (ICR) BR
Number and sex of animals:	2 males, 2 females per group in the range-finding study 7 males per group for the main study
Doses:	0, 500, 750, 1000 and 2000 mg/kg in the range-finding study 0, 187.5, 375 and 750 mg/kg for the main study; Positive and negative controls were cyclophosphamide and arachis oil, respectively;

In each treated group, animals were killed after 24 hours, except for the 750 mg/kg group where some mice were killed after 48 hours.

Method of administration: Single intraperitoneal injection

Test method: OECD TG 474

Results:
In the range-finding study, there was no marked difference in toxicity between the sexes, so males only were used in the main study. Premature deaths occurred at the two top doses, 1000 and 2000 mg/kg/day.

In the main study, animals were treated with 187.5, 375 mg/kg/day, or the maximum tolerated dose from the range finding study of 750 mg/kg/day. There was a small but statistically significant increase in the incidence of micronucleated polychromatic erythrocytes in animals receiving the 187.5 and 375 mg/kg doses at 24 hours when compared with the concurrent vehicle control group. Because the response observed was inversely dose-related and did not exceed the upper limit of the current historical background range for vehicle control values, the increases were considered not to have toxicological significance.

No statistically significant decreases in the PCE/NCE ratio were observed in the 24 or 48 hour notified chemical dose groups when compared to their concurrent control groups. The observation of clinical signs at 750 mg/kg was taken to indicate that systemic absorption had occurred.

Positive controls showed a marked increase in the frequency of micronucleated polychromatic erythrocytes.

Conclusion: The notified chemical analogue was not genotoxic in bone marrow cells of the mouse *in vivo.*

9.3.3 Chromosome Aberration Test in Human Lymphocytes *In Vitro* (Wright, 1998)

Cells: Human peripheral lymphocytes

Metabolic activation system: Rat liver microsomal S9 mix

Dosing schedule:

Metabolic Activation	Experiment/ Study Number	Test concentration (μg/mL)	Controls
-S9	1	Treatment time = 4 hours; 0*, 62.5, 125*, 250* and 500* μg/ml	Positive: ethyl methanesulphonate (EMS) and

	2	Treatment time = 20 hours; 0*, 15.63, 31.25, 62.5*, 125*, 250* and 500* μg/ml	cyclophosphamide (CP) Negative: Ethanol vehicle
+S9	1	Treatment time = 4 hours; 0*, 62.5, 125*, 250* and 500* μg/ml	Positive: EMS and CP
	2	Treatment time = 4 hours; 0*, 15.63, 31.25, 62.5, 125*, 250* and 500* μg/ml	Negative: Ethanol vehicle

EMS - ethyl methanesulphonate
CP - cyclophosphamide
DMSO – dimethylsulphoxide
* - cultures selected for metaphase analysis

Test method: OECD TG 473

Comment: In both experiments, haemolysis was observed at 250 and 500μg/mL in both treatment groups after 4 hours. In Experiment 1, the mitotic index was reduced at 250 and 500μg/mL with metabolic activation. However, sufficient metaphases were available for scoring at both doses. An increase in cytotoxicity was observed at 250 and 500 μg/mL in Experiment 2, both with and without metabolic activation. Due to inadequate clastogenicity in positive controls, increased levels of EMS were required in a repeat of Experiment 1 (treatment time 4 hours) without metabolic activation.

No statistically significant increases in the frequency of cells with chromosome aberrations were observed for the test substance in Experiments 1 and 2.

Positive controls produced significant increases in the frequency of cells with aberrations.

Result: The notified chemical analogue was non clastogenic under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

No toxicological data were provided for the notified chemical. Analogue chemical toxicological endpoints are extrapolated to the notified chemical.

The notified chemical analogue displayed very low acute oral and low dermal toxicity in the rat (LD_{50} > 5000 mg/kg and LD_{50} > 2000 mg/kg, respectively). No acute inhalation toxicity data were provided. In rabbits, the notified chemical induced moderate and persistent skin irritation and slight to moderate eye irritation.

In a Buehler test for skin sensitisation, slight, confluent or moderate patchy erythema were observed in 6 of 20 test animals compared to 1 in 10 control animals. These conspicuous results were observed on a background of all other test and control animals showing slight patchy erythema. In contrast, in a Magnusson and Kligman guinea pig maximisation test, only a single test animal showed well defined erythema (rated as a single positive response) and 3 test and 1 control animal showed very slight erythema indicating at most only slight sensitisation. Taken together, these studies indicate some sensitisation potential for the test chemical and, therefore, by analogy, the notified chemical but the data are insufficiently conclusive for hazardous classification.

In a 28 day repeat dose oral rat study, the notified chemical analogue caused pathological and biochemical changes at the mid and high dose and clinical signs of salivation and hair loss at all doses. Non-dose-related adrenal effects were seen at all doses but were of uncertain toxicological importance. A NOEL could not be established but a NOAEL of 100mg/kg/day was derived for the notified chemical analogue. The authors stated that the 28 day study was conducted in order to select suitable doses for a 13 week study. Based on the results of this study, a 13 week investigation is warranted.

The notified chemical analogue was not mutagenic in *Salmonella typhimurium* and *Escherichia coli* reverse mutation assays either in the presence or absence of metabolic activation. Also, it was not clastogenic in an *in vivo* mouse micronucleus assay and an *in vitro* human lymphocyte chromosome aberration test.

Extrapolating from the toxicological data provided for the analogue and in accord with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999) the notified chemical is classified Irritant (Xi) with the risk phrases R38 - Irritating to skin.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies on OLOA 271 (unclear whether for old or New) have been supplied by the notifier. The tests were carried out according to OECD Test Methods.

Species	Test	Concentrations (mg/L) (as WAF)	Result (mg/L) (as WAF)
Rainbow trout *(Oncorhynchus mykiss)* [OECD TG 203]	96 h acute	0 and 1000	NOEC* > 1000 (WAF)
Water Flea (*Daphnia magna*) [OECD TG 202]	48 h acute	0, 0.10, 0.18, 0.32, 0.56, 1.0, 1.8, 3.2. 5.6 and 10	NOEC = 0.56

Water Flea (*Daphnia magna*) [OECD TG 202]	48 h acute	0, 13, 22, 36, 60 and 100	EC_{50} = 39 NOEC = 22
Water Flea (*Daphnia magna*) [OECD TG 202]	48 h acute	0, 10, 18, 32, 56 and 100	ELR_{50} = 75 NOEC = 56
Algae (*Pseudokirchner-iella subcapita*) [OECD TG 201]	96 h growth	0 and 1000	ELR_{50} > 1000 NOEC > 1000
Sludge Inhibition [OECD TG 209]	3 h	0 and 1000	EC_{50} > 1000 NOEC > 1000

* NOEC - no observable effect concentration

In the following studies the water accommodated fraction (WAF) was prepared by stirring the mixtures of test substance in water for 24 hours, settling the mixtures for 4 hours and siphoning off the water phase containing the WAF, while ensuring that no settled or surface floating test substance was transferred. It should also be noted that none of the ecotoxicity studies made reference to the observation of precipitated material or oil in any of the test vessels. WAF samples were taken at 0 and 48 hours for TOC analysis and the results were found to be at the limit of detection of the analytical method so did not provide definitive data for the concentration and stability of the notified chemical in the test solutions.

Fish

Wetton (1998a) conducted an acute toxicity study of the notified chemical on Rainbow trout using as semi static test methodology. The study was done in triplicate with ten fish in each test vessel at a 100% WAF, ie 1000 mg/L, and a control. Over 96 hours, observations of sub-lethal effects (eg. abnormal behaviour) and mortality were taken. No mortality or sub-lethal effects were observed throughout the study. Thus, the no-observed effect concentration is equal to or greater than 1000 mg/L (WAF).

Daphnia

The first test on *Daphnia magna* was performed by Wetton (1998b) using a 48 hour static acute immobilisation study. Two groups of 10 daphnids were exposed to nominal loading (WAF) rates of 0, 0.10, 0.18, 0.32, 0.56, 1.0, 1.8, 3.2, 5.6 and 10 mg/L. The percent immobilisation was recorded after 24 and 48 hours. No immobilisation or deaths were observed in the controls or test solutions up to 1.0 mg/L; concentrations where effects were observed are shown below. The NOEC was determined to be 0.56 mg/L and considered to be very toxic.

Nominal Loading Rate (mg/L)	Cumulative Immobilised and Dead Daphnia (Initial Population: 10/Replicate)							
	24 h				48 h			
	R1	R2	Total	%	R1	R2	Total	%
1.0	0	0	0	0	2	2	4	20
1.8	0	0	0	0	9	10	19	95
3.2	5	7	12	60	10	10	20	100
5.6	10	10	20	100	10	10	20	100
10	10	10	20	100	10	10	20	100

The above test was repeated due to the unexpected toxicity found in the first study. This toxicity is said by the notifier to be caused by the formation of microemulsions in the test solutions. The second test was specifically developed for the testing of petroleum additives (Boeri et al 1998). The test was performed in a different laboratory under static conditions using two groups of 10 daphnids exposed at nominal concentrations of 0, 13, 22, 36, 60 and 100 mg/L, for 48 hours. The 48 hour median EC_{50} was 39 mg/L WAF, based on nominal concentrations. The 48 hour NOEC was calculated to be 22 mg/L.

Nominal Loading Rate (mg/L)	Cumulative Immobilised and Dead Daphnia (Initial Population: 10/Replicate)							
	24 h				48 h			
	R1	R2	Total	%	R1	R2	Total	%
Control	0	0	0	0	0	1	1	5
13	1	0	1	5	1	0	1	5
22	0	0	0	0	2	0	2	10
36	0	0	0	0	3	4	7	35
60	6	10	16	80	10	10	20	100
100	6	8	14	70	10	10	20	100

Sewell (1998) performed a third test on *Daphnia magna* at the original testing facility using the method from test 2 under static conditions with two groups of 10 daphnids exposed at nominal concentrations of 0, 10, 18, 32, 56 and 100 mg/L, for 48 hours. The 48 hour ELR_{50} was 75 mg/L WAF, based on nominal concentrations. The 48 hour NOEC was 56 mg/L.

Algae

Mead (1998b) conducted an algal growth inhibition study of the notified substance on unicellular green algae using OECD TG 201. *Pseudokirchneriella subcapitata* were exposed to a WAF of the test material at a loading rate of 1000 mg/L (in six replicate flasks) for 96 hours. Samples of the algal populations were removed daily and cell concentrations determined for each control and treatment group. As no growth inhibition was observed, the NOEC was determined to be greater than 1000 mg/L WAF loading rate.

Sludge

The effect of the notified chemical was investigated on the respiration of activated sewage sludge (Mead 1998c). The test involved using a chemical concentration of 1000 mg/L in triplicate aerated for a period of 3 hours at 21°C in the presence of activated sludge plus synthetic sewage as a respiratory substrate. The rate of respiration was measured after 30 minutes and 3 hours. The positive control used was 3,5-dichlorophenol. The 3 hour EC_{50} and NOEC were greater than 1000 mg/L.

The ecotoxicity data for the notified chemical indicate that it is not toxic to fish, algae and bacteria up to the limit of its water solubility, but does show toxicity to daphnia below this limit.

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.

Very little release is anticipated from maintenance activities. Used oil generated from the draining of oil or engine repair will be incinerated or sent for recycling.

The chemical is expected to have a high log P_{ow} value 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.

The notified chemical is not readily biodegradable, however if released to landfill or if associated with soil, it is expected to slowly degrade through the biotic and abiotic processes resulting in the formation of water, and oxides of carbon, with the calcium component associating with soil minerals. Incineration would lead to water vapour and oxides of carbon, with the calcium being assimilated into ash.

From the ecotoxicity data provided New OLOA 271 is not expected to be toxic to fish, algae or bacteria up to the limit of its water solubility, but does show toxicity to daphnia below this limit. The expected high partition coefficient and low biodegradability of the notified chemical 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 271 (NA/692). The notified chemical analogue displayed very low acute oral and low dermal toxicity in the rat. No acute inhalation toxicity data were provided. In rabbits, the notified chemical induced moderate and persistent skin irritation and slight to moderate eye irritation.

Slight skin sensitisation properties were indicated in a Magnusson and Kligman guinea pig maximisation test and a Buehler test. Data are insufficient for classification of the notified chemical as a skin sensitiser.

In a 28 day repeat dose oral rat study, a NOAEL of 100mg/kg/day was derived for the notified chemical analogue on the basis of pathological and biochemical changes at a mid and high dose and clinical signs of salivation and hair loss at all doses.

Genotoxicity data provided for the notified chemical analogue showed that it was not mutagenic in *Salmonella typhimurium* and *Escherichia coli* reverse mutation assays either in the presence or absence of metabolic activation. Also, it was not clastogenic in an *in vivo* mouse micronucleus assay and an *in vitro* human lymphocyte chromosome aberration test.

Extrapolating from the toxicological data provided for the analogue and in accord with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999) the notified chemical is classified Irritant (Xi) with the risk phrases R38 - Irritating to Skin.

Occupational Health and Safety

The blending of imported New OLOA 271 and additive packages containing New OLOA 271 at 60–80% (45-65% notified chemical) into marine diesel engine lubricants will occur in automated, closed systems. Exposure to the notified chemical will be limited to incidental skin and to a lesser extent eye contact during 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 20% and also limited to incidental skin contact. Overall, 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 and the potential, albeit slight, for skin sensitisation.

Public Health

The notified chemical is not available for sale to the public. Since it 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 risk to public health when used in the proposed manner.

13. RECOMMENDATIONS

- 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;

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;

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

New OLOA 271 is determined to be a hazardous substance. The finished lubricant may also contain other hazardous ingredients. 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.

Guidance in selection of protective eyewear may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/ Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994a); for respirators, in AS/NZS 1715 (Standards Australia/ Standards New Zealand, 1994b) and AS/NZS 1716 (Standards Australia/ Standards New Zealand, 1994c) or other internationally accepted standards.

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* (National Occupational Health and Safety Commission, 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.

16. REFERENCES

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Wright NP (1998) Chromosome aberration test in human lymphocytes in vitro. SPL Project Number: 703/132. Safepharm Laboratories Limited, Derby, UK

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.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
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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