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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Component of OLOA 246R

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FULL PUBLIC REPORT**Component of OLOA 246R****1. APPLICANT**

Chevron Oronite Australia of 520 Collins St, Level 8, Melbourne VIC 3000 (ABN 001 010 037) has submitted a standard notification statement in support of their application for an assessment certificate for Component of OLOA 246R.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae and molecular weight have been exempted from publication in the Full Public Report and the Summary Report.

Trade Name: OLOA 246R

Other Names: long chain alkarylsulphonate calcium salt
AS650 calcium salt
synthetic calcium sulphonate

Method of Detection and Determination: can be detected at 10 ppb by HPLC

Characterisation methods

UV/Visible spectroscopy

Infrared spectroscopy

¹³C nmr spectroscopy

Spectral Data:

UV/Vis	326.5(sh), 272, 261.5, 220.5 nm
IR	2955, 2924, 2854, 1600, 1462, 1378, 1364, 1203, 1142, 1054, 1012, 832, 762, 722, 698, 661, 605, 588 cm ⁻¹
¹³ C nmr	128, 126.8, 126.4, 126, 79, 78.7, 78, 37.1, 36.7, 32.6, 31.6, 30, 29.4, 29.1, 27.8, 26.9, 26.5, 24.5, 22.8, 20.2, 19.5, 19.1, 13.9, 11.3 ppm

3. PHYSICAL AND CHEMICAL PROPERTIES

OLOA 246R contains 54 % notified chemical in lubricating oil solvent. The notified chemical is never isolated. The physical and chemical properties below are generally those of the product OLOA 246R rather than of the notified chemical.

Appearance at 20°C and 101.3 kPa:	black viscous liquid
Boiling Point:	decomposes before boiling
Specific Gravity:	0.924 at 15°C
Vapour Pressure:	notified chemical not expected to be volatile; vapour pressure of OLOA 246R 4.9×10^{-5} kPa at 25°C (lubricating oil)
Water Solubility:	< 0.1 mg/L at 25°C
Particle Size:	not applicable as OLOA 246R is a viscous liquid
Partition Co-efficient (n-octanol/water):	$\log P_{ow} > 6.7$
Hydrolysis as a Function of pH:	no hydrolysis expected in the range $4 < \text{pH} < 9$
Adsorption/Desorption:	expected to adsorb strongly (see comments below)
Dissociation Constant:	not determined (see comments below)
Flash Point:	> 200°C
Autoignition Temperature:	> 200°C
Flammability Limits:	combustible liquid (see comments below)
Explosive Properties:	not expected to be explosive
Reactivity/Stability:	expected to be stable under normal conditions

3.1. Comments on Physico-Chemical Properties

The notified chemical does not contain any hydrolysable functional groups though strong acid will neutralise the calcium salt. Hence, the substance is expected to be stable in water with respect to the environmental pH range 5 – 9.

The n-octanol/water partition coefficient was determined using reverse phase HPLC. No test report was submitted though brief details were provided. Due to the strong dispersant nature of the chemical, it can be expected to bind strongly to, or be associated with, soil and sediment. Hence, due to the detergent nature of OLOA 246R (strong surface activity) and

micelle formation tendencies, the OLOA 246R will tend to partition from water to solids or organic matter.

The notified chemical will not dissociate. Although the chemical contains calcium salts, the complex organic nature of this substance and the tendency to form micelles indicates dissociation is unlikely.

Due to the low volatility of the notified chemical, flammability limits in air could not be determined. The oil will burn if preheated, and is a Class C2 combustible liquid.

4. PURITY OF THE CHEMICAL

Degree of Purity: 54 % in lubricating oil

Hazardous Impurities:

<i>Chemical name:</i>	calcium hydroxide
<i>CAS No.:</i>	1305-62-0
<i>Weight percentage:</i>	0.5 %
<i>Toxic properties:</i>	On the NOHSC <i>List of Designated Hazardous Substances</i> (NOHSC, 1999b) Eye, skin, mucous membrane and respiratory system irritant (Sax & Lewis, 1996) NOHSC exposure standard 5 mg/m ³ TWA

**Non-hazardous Impurities
(> 1% by weight):**

<i>Chemical name:</i>	long chain alkylated benzene
<i>Weight percentage:</i>	10 %
<i>CAS No.:</i>	none allocated

Additives/Adjuvants:

<i>Chemical name:</i>	distillates, hydrotreated heavy paraffinic
<i>Synonyms:</i>	lubricating oil
<i>CAS No.:</i>	64742-54-7
<i>Weight percentage:</i>	46 %
<i>Toxic properties:</i>	On the NOHSC <i>List of Designated Hazardous Substances</i> (NOHSC, 1999b) Classified as a carcinogen, R45(2) unless the DMSO extract under the procedure as defined by IP 346 is shown to be less than 3 %

or

<i>Chemical name:</i>	distillates, solvent refined heavy paraffinic
<i>Synonyms:</i>	lubricating oil
<i>CAS No.:</i>	64741-88-4
<i>Weight percentage:</i>	46 %
<i>Toxic properties:</i>	On the NOHSC <i>List of Designated Hazardous Substances</i> (National Occupational Health and Safety Commission, 1999b) Classified as a carcinogen, R45(2) unless the DMSO extract under the procedure as defined by IP 346 is shown to be less than 3 %

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as a detergent in hydraulic fluid lubricating oils. The purpose of the additive is to reduce deposits in hydraulic systems caused by excess heat, and to provide rust inhibition for exposed metal parts.

The notified chemical will be imported in a lubricating oil additive package containing 20 – 25 % OLOA 246R and will be reformulated in Australia to produce the finished lubricants, where the concentration will be 0.5 – 1 % notified chemical (1 – 2 % OLOA 246R). The notifier indicates that approximately 10 additive package formulations will contain the notified chemical. The additive packages will be imported in 200 L drums, isotanks or bulk shipments. They will be used to blend finished hydraulic fluid lubricating oils, for example tractor oils.

The import volume for the notified chemical is expected to be in the range of 10 to 50 tonnes per annum.

6. OCCUPATIONAL EXPOSURE

Transport and Storage

Transport and storage workers are not expected to be exposed to the notified chemical during shipment in isotanks or drums except in the case of an accident involving spillage. The additive package will also be imported in bulk, and transferred from the ship to a holding tank, then to road tankers. Dermal exposure of the waterfront and transport workers to drips and spills of the additive package is possible during the connection and disconnection of the transfer hoses during these procedures. No details of the exposure control measures or personal protective equipment to be employed at these facilities was provided by the notifier.

Additive package delivered to the customer site in bulk tankers or in isotanks will be transferred to holding tanks. The notifier indicates that 1 worker will be involved in connecting and disconnecting the hose for 10 minutes per shipment, with a total exposure time of 1 hour per day, 50 days per year. The delivery system will be equipped with an air

back-flush system to minimise any spillage on disconnection. The tanker or isotank will then be steam cleaned. Dermal exposure to drips and spills of the additive package containing the notified chemical (at up to 12.5 %) is possible during these operations. Workers involved in the hose transfer are stated by the notifier to wear gloves, coveralls and eye protection.

Reformulation

The additive package containing the notified chemical will be reformulated by blending with oils and other additives, such as foam inhibitors and pour point depressants, to produce the completed lubricants. The blending will be mostly an automated in-line process in an enclosed system. Additive packages shipped in drums will be transferred into the blend tank by drum pump. The notifier states that 1 worker will be involved for 10 minutes per drum placing the drum pump and transferring the drum contents. During the connection and disconnection of drums, dermal contact with the notified chemical in the additive package (up to 12.5 % notified chemical) is possible. Transfer from drums may also be carried out by heating the drum contents to approximately 55°C and pouring the contents into a storage tank through a grille.

Transfer from storage tanks will be automated, using computer controlled valves. The finished lubricant will be sampled by one or two workers, and analysed in a laboratory by one or two workers. The notifier states that minimal exposure will occur during the laboratory testing, which will occupy several minutes per blend. The total exposure time for these workers is estimated by the notifier to be ½ hour per day, 50 days per year. Dermal exposure to the notified chemical as part of the blended lubricant (up to 1 % notified chemical) is possible during the sampling. Workers involved in the drum pump transfers and sampling the finished lubricant are stated by the notifier to wear gloves, coveralls and eye protection. Where sampling requires exposure to heated oil during the blending process, respiratory protection will be used.

The notified chemical has a very low vapour pressure and, as a mineral oil based product, a high viscosity, minimising the possibility of vapour and aerosol formation. Inhalation is therefore not expected to be an important exposure route.

The blend tank will be cleaned by rinsing with clean lubricating oil. The finished lubricants will be packaged into 1 L and 4 L containers and 200 L drums, or transferred to road tankers for bulk delivery to customers. The filling of the 1 L and 4 L containers is stated to be highly automated with little human exposure. The drum filling is stated to be automated, with an operator watching from about 1 – 2 metres distance to ensure that the drum filling mechanism enters the drum properly before filling, and also manually installing the drum bung and affixing the label. The packaging lines are cleaned with lubricating oil. Dermal exposure to drips and spills of blended lubricant (up to 1 % notified chemical) is possible in the event of a mistake during drum filling, and in installation of drum bungs. Workers are stated to be involved in this process for 4 – 8 hour per day, 50 days per year. The notifier states that the workers will wear gloves, coveralls and eye protection.

Bulk road tanker filling is performed by transfer hose. Workers will be involved in this process for 1 hour per day, 50 days per year. Dermal exposure to drips and spills of blended lubricant (up to 1 % notified chemical) is possible during the connection and disconnection of transfer hoses during the filling of bulk tankers. Workers involved in loading of road tankers are stated to wear gloves and overalls

Maintenance workers handling the equipment used for blending and filling may also come into dermal contact with residues containing the notified chemical, should maintenance be required prior to flushing the equipment.

End Use

The majority (95 %) of the products containing the notified chemical will be sold in drums or bulk to customers who will use pneumatic systems to fill lubricant sumps in hydraulic equipment. The use is estimated to be 60 – 70 % in farming applications, and 30 – 40 % in industrial applications. Dermal exposure is likely during filling and top ups, and while handling equipment which has been in contact with the lubricants. The workers who are likely to be exposed include farmers, during filling and maintenance of hydraulic equipment, mechanics who work on the hydraulic systems, and industrial tradesmen who may have contact with the oil during top ups of the equipment. Details of the protective measures used to control exposure during end use were not provided by the notifier.

7. PUBLIC EXPOSURE

There will be exposure to the notified chemical for members of the public who may periodically add hydraulic oil or change their own hydraulic oil in mobile equipment. Skin and eye contact are possible during these procedures, and personal protective equipment should be worn to reduce exposure.

The potential for public exposure apart from during maintenance of hydraulic equipment is considered to be low.

8. ENVIRONMENTAL EXPOSURE

8.1. Release

The additive package containing OLOA 246R will arrive at the customer's blending plant in drums, isotanks or in bulk tanks delivered by trucks. The oil is transferred to a storage tank through a hose with an air back flush system which prevents any spillages. The hose end is kept in an oily drain when not in use and the contents of the drain are treated on site. The tank trucks are generally cleaned with steam and the waste water treated on site.

Waste water containing OLOA 246R is sent to an on-site chemical waste water system that includes an American Petroleum Institute (API) water and oil separator, air floatation and sand filtration. As a result of API oil separation no more than 5 % of the OLOA 246R is expected to be emulsified in the water. The waste water is further treated with pond aeration and sand filtration before it is sent to the sewer. The remaining oily waste is incinerated.

The oil blending process involves combining lubricating oil blend stocks, additive package, pour point depressants and foam inhibitors in a blending tank. The blend tank is periodically cleaned with lube oil that is either recycled into future blends or is incinerated.

After blending, the finished products are packaged into 1 and 4 L containers, 200 L drums or sold as bulk in tank trucks. The notifier estimates that 1 kg per day of the new chemical is released during this process. After filling the delivery lines are cleaned with lube oil which is

recycled during future blending operations or incinerated.

The notifier estimates that approximately 1 kg per day of the notified chemical may be released as a result of reformulation and repackaging at each of the 10 oil blending sites around Australia. As it is estimated that reformulation/repackaging activities will be conducted on 50 days per year, a maximum of 50 kg per site per year will be released. Therefore approximately 500 kg per year will be released Australia wide. Assuming that API oil separation results in 95 % removal of the oil from waste water (as claimed by the notifier), then approximately 2.5 kg of OLOA 246R per annum is likely to enter the sewers from each of the blending sites.

Spills at the blending sites are contained by plant barriers. As lube blending facilities have concrete floors, most of the spilled product could be collected by suction, with the remaining product going to the on-site waste water system. Accidental spills during transportation of the additive packages or finished oil could result in OLOA 246R contaminating soils or waterways.

During use OLOA 246R is not substantially altered and does not decompose in the hydraulic system due to its high thermal stability. Used oil generated from oil drains (fresh oil is added during equipment operation or repair) is expected to be recycled at approved recycling centres. Hydraulic oil is expected to be changed less regularly than sump oil in automobiles, though given the predicted high rural use, many oil changes likely to be carried out by the farm owners on site.

The notifier estimates that up to 10 % of the finished hydraulic oil could be lost to the environment due to leaks and spills during vehicle top-ups.

Improper disposal of waste oil may account for the greatest level of environmental exposure, and the notifier has estimated that up to 50 % of the used oil will be improperly disposed of and dumped into the environment. ANZEC (Australian and New Zealand Environment and Conservation Council, 1991) estimates the rate of improper disposal to be approximately 35 % and a paper presented by Robert Snow to the Used Oil Management Conference 1997 (Snow, 1997) estimates the amount of waste hydraulic oil generated to be approximately 40 % of the sales volume.

Worst case release estimates are summarised in the following table.

Worst Case Release Estimates:

Release Stage	Annual Release (kg)	%	No. of days	Daily Release (kg)
Reformulation/ Repackaging	500	1	50	10
End use	5000	10	300	16.7
Disposal	22250	50	300	74.2
Total	27750	55.5%		101

8.2. Fate

The amount of waste OLOA 246R disposed to sewer from reformulation sites is expected to be minimal as waste water from the blending operations are treated on-site and the hydrocarbon fraction is separated and incinerated. Any remaining OLOA 246R present in waste water disposed to sewer is expected to partition from the water to suspended matter and become associated with sludge at sewerage treatment plants. Therefore, the prospect of OLOA 246R entering receiving waters in significant quantities as a result of blending operations is remote.

Waste oil containing the notified chemical may account for the greatest level of environmental exposure. Some end users may elect to drain the waste oil and store for collection by a contractor. However, given the high expected rural use, it is realistic to assume that smaller and more remote facilities may dispose of the oil by open burning, or other unapproved disposal method such as use as a dust suppressant or fence preservative, or by pouring it on the ground or down drains to the sewer, and hence ultimately to sediment and the water table.

Biodegradation

No ready biodegradation tests were performed on the notified chemical. However, the submission states that OLOA 246R is not expected to biodegrade to any significant degree as it is designed to be resistant to biodegradation to survive the severe thermal conditions experienced in motor vehicle sumps. The low water solubility of the notified chemical also means that it is not readily available to microorganisms.

Bioaccumulation

Given the expected high partition co-efficient of the notified substance and its low biodegradation potential, the notified substance would have the potential to bioaccumulate should the substance be spilt to waterways or onto soils. However, the large molecular size of the chemical and its low water solubility (<1 mg/L) is likely to inhibit the bioaccumulation potential of OLOA 246R.

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicity data for the notified chemical or for the product, OLOA 246R, were provided by the notifier. Analogue toxicity data have been provided for a similar material, OLOA 246S, which differs from the notified chemical in the type of alkyl group present. It contains 54 % active ingredient in mineral oil, similar to OLOA 246R. OLOA 246S was notified and assessed under NICNAS as NA/178.

9.1 Acute Toxicity

Summary of the acute toxicity of OLOA 246S

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	rat	LD ₅₀ > 5000 mg/kg	(Mercier,

			1997d)
acute dermal toxicity	rat	LD ₅₀ > 2000 mg/kg	(Mercier, 1997c)
skin irritation	rabbit	slight irritant	(Mercier, 1997b)
eye irritation	rabbit	slight irritant	(Mercier, 1997a)
skin sensitisation	guinea pig	sensitiser	(Morris, 1993)

9.1.1 Oral Toxicity (Mercier, 1997d)

<i>Species/strain:</i>	rat/Ico: OFA.SD(IOPS Caw)
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	gavage, dose level 5009 mg/kg, test material used as received
<i>Test method:</i>	OECD TG 401
<i>Mortality:</i>	there were no deaths during the study
<i>Clinical observations:</i>	no clinical signs of toxicity were observed during the study
<i>Morphological findings:</i>	no gross abnormalities were observed on day 14
<i>LD₅₀:</i>	> 5009 mg/kg
<i>Result:</i>	OLOA 246S was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Mercier, 1997c)

<i>Species/strain:</i>	rat/Ico: OFA.SD(IOPS Caw)
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	15 days
<i>Method of administration:</i>	semi-occluded patch; 24 hour exposure dose level: 2007 mg/kg; test material used as received

<i>Test method:</i>	OECD TG 402
<i>Mortality:</i>	there were no deaths during the study
<i>Clinical observations:</i>	no clinical signs of toxicity were observed during the study
<i>Morphological findings:</i>	no gross abnormalities were observed on day 14
<i>Dermal observations:</i>	very slight erythema was seen in two animals on days 2, 4 and 5; on day 3 one animal showed well defined erythema and one very slight erythema; desquamation was seen in two animals on days 5 and 6; no dermal abnormalities were observed from day 7 onwards
<i>LD₅₀:</i>	> 2007 mg/kg
<i>Result:</i>	OLOA 246S was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

No inhalation toxicity data were presented by the notifier, with the argument that because the notified chemical has a very low vapour pressure (less than 4.9×10^{-5} kPa at 25°C) and a viscosity of 35 cSt at 100°C, it is unlikely to present an inhalation hazard either as a vapour or as an aerosol. This argument was accepted for the purposes of this assessment.

9.1.4 Skin Irritation (Mercier, 1997b)

<i>Species/strain:</i>	rabbit/New Zealand White
<i>Number/sex of animals:</i>	6 males
<i>Observation period:</i>	7 days
<i>Method of administration:</i>	0.5 mL of test material as supplied was applied to clipped intact skin and secured under a gauze patch for 4 hours; at the end of this time, residual material was removed with olive oil and gauze; animals were examined for skin lesions 1, 24, 48 and 72 hours and 7 days following application of the test substance
<i>Test method:</i>	OECD TG 404

Draize scores (Draize, 1959):

Time after

Animal #

<i>treatment (days)</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>	<i>6</i>
<i>Erythema</i>						
1	0 ^a	0	1	2	1	1
2	0	0	0	1	0	1
3	0	0	0	1	0	1
<i>Oedema</i>						
1	0	0	0	1	0	1
2	0	0	0	1	0	0
3	0	0	0	0	0	0

^a see Attachment 1 for Draize scales

Comment: all Draize scores were zero at the 7 day observation

Result: OLOA 246S was slightly irritating to the skin of rabbits

9.1.5 Eye Irritation (Mercier, 1997a)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 6 males (non-rinsed)
3 males (rinsed)

Observation period: 7 days

Method of administration: 0.1 mL of test material applied as supplied into conjunctival sac of the right eye of each animal; animals were examined for eye lesions 1, 24, 48 and 72 hours and 7 days after test substance application

Test method: OECD TG 405

Draize scores (Draize, 1959) of unirrigated eyes:

<i>Animal</i>	<i>Time after instillation</i>									
	<i>1 hour</i>		<i>1 day</i>		<i>2 days</i>		<i>3 days</i>		<i>7 days</i>	
<i>Cornea</i>	<i>o</i>	<i>a</i>	<i>o</i>	<i>a</i>	<i>o</i>	<i>a</i>	<i>o</i>	<i>a</i>	<i>o</i>	<i>a</i>
1	0 ¹	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0

5	2	1	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0
<hr/>										
<i>Iris</i>										
1	1		0		0		0		0	
2	1		1		0		0		0	
3	1		0		0		0		0	
4	0		0		0		0		0	
5	1		0		0		0		0	
6	1		0		0		0		0	
<hr/>										
<i>Conjunctiva</i>	<i>r</i>	<i>c</i>	<i>r</i>	<i>c</i>	<i>r</i>	<i>c</i>	<i>r</i>	<i>c</i>	<i>r</i>	<i>c</i>
1	2	1	2	1	1	1	1	1	0	0
2	2	1	2	1	2	1	1	1	0	0
3	2	2	2	2	2	2	2	2	0	0
4	2	1	2	2	2	2	2	1	0	0
5	2	2	2	1	2	2	2	2	0	0
6	2	1	1	2	1	2	1	2	0	0

¹ see Attachment 1 for Draize scales

o = opacity a = area r = redness c = chemosis

Mean scores:
(non-irrigated eyes, 24, 48, 72 hour observation)

corneal opacity	0.0
iridal lesions	0.06
redness of conjunctiva	1.7
chemosis of conjunctiva	1.6

Mean scores:
(irrigated eyes, 24, 48, 72 hour observation)

corneal opacity	0.0
iridal lesions	0.0
redness of conjunctiva	0.78
chemosis of conjunctiva	0.33

Comment: all lesions were found to be reversible within 7 days; the mean scores for irrigated eyes were lower than those observed for non-irrigated eyes

Result: OLOA 246S was slightly irritating to the eyes of rabbits

9.1.6 Skin Sensitisation (Buehler method) (Morris, 1993)

Species/strain: guinea pig/Hartley

Number of animals: 10/sex (test group)
5/sex (irritation control)

Induction procedure: test animals – test material (0.3 mL, 50 % w/v in Spectrum Mineral Oil Light U.S.P.) was applied in an occluded

chamber to a clipped area of the left shoulder for 6 hours; the residue was removed with an appropriate solvent

the induction procedure was carried out three times at intervals of 1 week

Challenge procedure:

test and control animals – at an interval of two weeks after induction, test material (0.3 mL, 5 % w/v in Spectrum Mineral Oil Light U.S.P.) was applied in an occluded chamber to a clipped area of skin which had not previously been exposed to the notified chemical

dermal responses were evaluated after 24 and 48 hours

Test method:

OECD TG 406

Challenge outcome:

<i>Response grade</i>	<i>Test animals</i>		<i>Control animals</i>	
	<i>24 hours*</i>	<i>48 hours*</i>	<i>24 hours</i>	<i>48 hours</i>
0	0**	0	0	0
±	0	0	5	3
1	5	2	5	7
2	11	14	0	0
3	3	3	0	0

• time after patch removal

• ** number of animals exhibiting response

• skin responses were graded using the following scale

0 no reaction

± slight, patchy erythema

1 slight but confluent, or moderate patchy erythema

2 moderate erythema

3 severe erythema with or without oedema

Comment:

one test animal was found dead on the day of the 24 hour scoring; the necropsy findings were stated to be those generally seen in agonal animals (agonal being defined as “pertaining to the death agony” (Dorland, 1981)); 17/19 test animals showed grade 2 or 3 responses at 48 hours compared with 0/10 controls

Result:

OLOA 246S was strongly sensitising to the skin of guinea pigs

9.2 Repeated Dose Toxicity

No data for the notified chemical have been provided. The notifier has indicated that the analogue subchronic toxicity studies which were provided as part of the NICNAS notification NA/177 (National Occupational Health and Safety Commission, 1994a) and NA/178 (National Occupational Health and Safety Commission, 1994b) should be taken as indicative of the subchronic toxicity of the notified chemical.

The analogue studies were on the related compounds AS 702 calcium sulphonate (oral) and OLOA 247E (dermal). The compositions of these alkarylsulphonates, calcium salts, are described in the Full Public Reports for NA/177 and NA/178. Both materials are appropriate analogues for the notified chemical.

In the 29-day repeat dose oral study with AS 702 calcium sulphonate, dose levels of 0 (control), 100 (low dose), 500 (mid dose) and 1000 (high dose) mg/kg/day were used. There were no statistically significant effects on body weight during the study. No treatment-related changes in food consumption, haematology, urinalysis or pathology were observed during the study. Animals treated with the high dose (both sexes) showed a significant decrease in serum cholesterol at the end of the treatment period. This effect persisted in females to the end of the recovery period. There were no other treatment-related effects on serum chemistry.

A No Observed Effect Level (NOEL) of 500 mg/kg/day OLOA 247E and a No Observed Adverse Effect Level (NOAEL) of 1000 mg/kg/day OLOA 247E were established in this study.

In the 28-day repeat dose dermal study with OLOA 247E, dose levels were 0 (mineral oil control), 0.1 (low dose), 0.5 (mid dose) and 1 mL/kg/day (high dose) test substance, applied topically for 6 hours/day, 5 days/week. Test substance was diluted in mineral oil to give a dose of 1 mL/kg/day. Skin effects were observed in treated and control animals throughout the study. The severity of the reactions was slightly greater in the treated males as compared to control males (no to well-defined erythema and no to slight erythema respectively). Treated and control females showed no to well-defined erythema. No deaths or clinical signs of toxicity were observed during the study. There were no significant effects on body weight, food consumption or haematology during the study. No treatment-related effects on serum chemistry or organ weights were observed. Gross pathology and histopathology revealed no treatment-related effects except for skin effects which were attributed to repeated treatment with mineral oil and wrapping.

A NOEL of 100 % OLOA 247E (0.95 mg/kg/day) was established in this study.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Lawler, 1997)

Strains: *Salmonella typhimurium*: TA98, TA100, TA1535, TA1537
Escherichia coli: WP2uvrA

Concentration range: 0, 100, 250, 500, 1000, 5000, 10000 µg/plate

appropriate strain specific positive control reference substances were used

Metabolic Activation System:

rat liver S9 fraction from animals pretreated with Aroclor 1254

Test method:

OECD TG 471 – plate incorporation method

Comment:

the assay was performed three times (four times for TA100), with the first two assays using a S9 mix containing 80 % S9 homogenate, rather than the standard 10 %, based on optimisation of the S9 concentration with TA100; the first assay used standard positive control concentrations and was not considered valid as no positive response was observed for the positive controls, and the vehicle control response for TA100 in the presence of S9 (59 revertants per plate) was outside the levels considered acceptable (60 - 240 revertants per plate)

the second assay with increased positive control concentrations gave appropriate positive and vehicle control responses for all strains except TA100, for which the vehicle control in the presence of S9 (58 revertants per plate) was again outside the acceptable range (60 – 240 revertants per plate)

in the absence of metabolic activation, the first two assays were considered valid; no significant increases in the number of revertant colonies was seen for any strain without metabolic activation

in the first two assays using the high S9 homogenate concentration, a dose response was observed for TA100 with 1000, 5000 and 10000 µg/plate, with the number of revertants more than doubling compared with lower doses and the vehicle controls; this was likely to be related to the production of unusual metabolic products under extreme metabolic activation conditions; no similar observations were made for the other strains

the third assay used 10 % S9 homogenate in the S9 mix and met the validity criteria in all aspects; no significant increases in the number of revertant colonies was seen for any strain with metabolic activation; similar results were seen in the fourth assay for TA100

no cytotoxicity was observed up to 10000 µg/plate in any assay; test material precipitate was observed on the plates at 1000 µg/plate and above

Result: OLOA 246S was not considered mutagenic either with or without metabolic activation, under standard test conditions

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Ivett, 1997)

Species/strain: mouse/Crl:CD-1(ICR) BR

Number and sex of animals: 5/sex/dose/harvest time

Doses: 50, 100, 200 mg/kg

Method of administration: single intraperitoneal injection; test material dissolved in peanut oil; dose volume 10 mL/kg; bone marrow was collected 24, 48 and 72 hours after test material administration

Test method: OECD TG 474

Mortality: two males in the high dose group were found dead, one at 42 hours and one at 66 hours; one 48 hour harvest high dose female was found hypoactive and prostrate at 42 hours

Comment: high mortalities were observed at 275 mg/kg and above during rangefinding studies; a highest dose of 200 mg/kg was chosen for the study

there was no significant difference in micronuclei formation in any of the test animals; a decrease in the polychromatic erythrocyte/normal chromatic erythrocyte ratio was observed for the 50 mg/kg 24 hour females and the 200 mg/kg 48 hour males

a positive control was used and induced a statistically significant increase in micronucleated polychromatic erythrocytes indicating that the test system responded in an appropriate manner

Result: OLOA 246S did not induce a significant increase in micronucleated polychromatic erythrocytes in the bone marrow cells of the mouse

9.4 Overall Assessment of Toxicological Data

No toxicity data for the notified chemical or for the product, OLOA 246R, were provided by the notifier. The notifier submitted analogue data for OLOA 246S, a product containing a similar alkarylsulphonate, calcium salt, for acute oral and dermal toxicity, skin and eye irritation, skin sensitisation and genotoxicity. The notifier stated that the analogue subchronic toxicity studies for the related compounds AS 702 calcium sulphonate and OLOA 247E

(submitted in NICNAS notifications NA/177 and NA/178) should be taken as indicative of the toxicity of the notified chemical. OLOA 246S was the subject of NICNAS notification NA/178.

The acute oral toxicity of OLOA 246S in rats is very low ($LD_{50} > 5000$ mg/kg) and the acute dermal toxicity of OLOA 246S in rats is low ($LD_{50} > 2000$ mg/kg). It is a slight irritant to rabbit eyes and skin.

In a Buehler skin sensitisation study in guinea pig, OLOA 246S was found to be strongly sensitising, with 17/19 test animals showing grade 2 or 3 responses at 48 hours compared with 0/10 controls. The notifier states that no anecdotal evidence of skin sensitisation in humans handling calcium sulphonate additives has been found over 60 years of use. No formal health surveillance data was presented.

A 28-day repeated dose study with the analogue AS 702 calcium sulphonate administered orally showed the only treatment-related effect to be decreased serum cholesterol in both male and female rats given 1000 mg/kg. A NOEL of 500 mg/kg was established in the study. The analogue OLOA 247E administered dermally at 1 mL/kg/day for 28 days produced no treatment-related effects (all doses including 100%).

OLOA 246S was not found to be mutagenic in bacteria and did not induce an increase in micronuclei in the *in vivo* mouse micronucleus assay. Similar negative results were found for the analogues AS 702 calcium sulphonate and OLOA 247E in bacterial mutagenicity, mouse micronucleus and mouse lymphoma cell assays in the NICNAS assessment NA/178 (National Occupational Health and Safety Commission, 1994b).

Hazard Classification of OLOA 246R

Based on the analogue data, the acute oral and dermal toxicity and skin and eye irritation are below the thresholds for classification as a hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (NOHSC, 1999a). In 28 day repeat dose oral and dermal studies, no organ dysfunction or systemic toxicity was observed. There was no evidence of mutagenicity *in vitro* or *in vivo*.

However, based on the findings of the skin sensitisation study in guinea pigs, OLOA 246S would be classified as a skin sensitizer according to the Approved Criteria and the risk phrase R43 "May cause sensitisation by skin contact" should also be applied to OLOA 246R.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

<i>Test</i>	<i>Species</i>	<i>Results</i>
acute toxicity	fathead minnow <i>Pimephales promelas</i>	$LC_{50}(96 \text{ h}) = >1000 \text{ mg/L (WAF)}$ $NOEC = 1000 \text{ mg/L (WAF)}$ $LC_{50}(96 \text{ h}) = 84 \text{ mg/L (dispersion method)}$ $NOEC = <62.5 \text{ mg/L (dispersion method)}$
acute toxicity	sheepshead minnow (<i>Cyprinodon variegatus</i>)	$LL_{50} (96 \text{ h}) = >10 \text{ g/L (WSF)}$

acute toxicity	brown shrimp (<i>Crangon crangon</i>)	LC ₅₀ (96 h) = >10 g/L (dispersion method) NOEC = <100 mg/L (dispersion method)
acute toxicity	<i>Daphnia magna</i>	EC ₅₀ (48 h) = 19 mg/L (WAF) NOEC = 15 mg/L (WAF)
growth inhibition	freshwater algae Cell (<i>Selanastrum capricornutum</i>)	Density: EC ₅₀ (96 h) = 490 mg/L (WAF) NOEC(96 h) = 250 mg/L (WAF) Growth Rate: EC ₅₀ (96 h) = >1500 mg/L (WAF) NOEC(96 h) = 250 mg/L (WAF)
sludge inhibition		EC50(3 h) = >1000 mg/L

* NOEC - no observable effect concentration

The ecotoxicity tests were performed in accordance with OECD Test Guidelines.

The water accommodated fraction (WAF) test substances used in the above studies was prepared by mixing the test oil:water solution for 24 hours and then allowed to settle for approximately one hour. The WAF was then withdrawn via a siphon prior to testing. The dispersion method used in the above studies was prepared by direct dispersion of the test substance in water with the aid of shielded propeller stirrers.

Fathead Minnow (Pimephales promelas):

The WAF tests on fathead minnow were performed using a static test methodology (Ward, 1994c). Three groups of 10 fish were exposed to a nominal concentration of 100, 300 and 1000 mg/L of the test substance as the WAF, each made up separately. The cumulative mortality was recorded after 3, 24, 48, 72 and 96 hours. There were no sub-lethal effects or mortalities recorded in the 30 fish exposed for a period of 96 hours. The Lethal Loading Rate (LLR) and No Observable Effect Concentration (NOEC) were greater than 1000 mg/L (WAF).

The Dispersion Method tests on fathead minnow were performed under static conditions at 22°C with five concentrations of lubricant additive CMA 603 and a dilution water control (Ward, 1994a). All non-control test vessels had oil on the surface and were cloudy throughout the test. Two groups of 10 fish were exposed to concentrations of 62.5, 125, 250, 500 and 750 mg/L of the dispersed test substance. The cumulative mortality was recorded after 3, 24, 48, 72 and 96 hours. Mortality of 50 % occurred in the 62.5 mg/L concentration at the 96 h observation and in the 125 mg/L concentration at 24 h observation. There was 70 % mortality in fish at 250 mg/L concentration at the 24 h observation and 100 % mortality in the 500 and 750 mg/L concentrations at the 24 h observation. There were no deaths at any concentration at the 3 h observations.

Sheepshead Minnow (Cyprindon variegatus):

A Tier 1 preliminary study was conducted using "100% Water Soluble Fraction (WSF)" of the test substance for 96 h (Nicholson, 1986). Ten fish were placed into a jar and exposed to the 100 % WSF solution. They were examined after 0, 24, 48, 72 and 96 hours of exposure. The 96 h mortality of the fish tested at 100 % WSF was 0 %. Based on this result no Tier 2 toxicity test was considered necessary.

Brown shrimp (Crangon crangon):

Semi-static test conditions were used to perform acute toxicity tests on brown shrimp (Douglas & Sewell, 1988). There was no significant mortality or other adverse reactions in 20 shrimp exposed to concentrations of up to 10 g/L for 96 h. A fine dispersion was observed throughout the water column in the 4 test concentrations of 100, 500, 1000 and 10000 mg/L. The test concentration of 10000 mg/L had a foaming brown oily scum on the surface of the water.

Daphnia magna:

The tests on *Daphnia magna* were performed using a 48 hour static acute immobilisation study (Ward, 1994b). Two groups of 10 daphnids were exposed to nominal loading (WAF), rates of 0, 10, 15, 25, 40 and 60 mg/L. The percent immobilisation was recorded after 24 and 48 hours. The NOEC was determined to be 15 mg/L and considered to be slightly toxic with an $EC_{50} = 19$ mg/L (WAF). The 10 and 15 mg/L concentrations recorded no mortalities at 24 or 48 hours. Approximately 50 % mortality occurred in the 25, 40 and 60 mg/L concentrations at 24 h observation and 100 % mortality occurred at the 48 h observation.

Algal Growth Inhibition (Selenastrum capricornutum):

Selenastrum capricornutum were exposed to a WAF of the test material at loading rates of 250, 500, 700, 1000 and 1500 mg/L (in triplicate flasks) for 96 hours (Magazu & Boeri, 1994). Samples of the algal populations were removed daily and cell concentrations determined for each control and treatment group. The EC_{50} was determined to be greater than the 1500 mg/L WAF loading rate.

Activated Sludge Inhibition:

The inhibition of activated sludge respiration by CMA 603 was tested using 100, 300 and 1000 mg/L in duplicate and aerated for a period of 3 hours at 20°C in the presence of activated sludge plus synthetic sewage as a respiratory substrate (Ward & Boeri, 1994). The rate of respiration was measured after 30 minutes and 3 hours. The 3 hour EC_{50} was greater than 1000 mg/L.

The ecotoxicology findings are based on nominal concentrations and indicate that OLOA 246R is likely to be relatively non-toxic to the organisms tested (up to the limits of its water solubility) based on the results of the similar chemical CMA 603. *Daphnia magna* was one exception to the above findings with the WAF being nominally slightly toxic. However, since the WAF contains very low concentrations of the test substance (< 2 % according to the measured TOC values), the actual toxicity may be much higher. The dispersion test on fathead minnows also showed higher toxicity though it is unclear whether this was the result of a physical or chemical effect.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Environmental exposure from the oil blending sites is expected to be low as the majority of the waste from the process is incinerated or recycled back into the blending process. Overall, approximately 50 kg of waste OLOA 246R is generated per annum at each of the ten potential blending sites in Australia. Assuming that API oil separation results in 95 % removal of the oil from waste water (as claimed by the notifier), then approximately 2.5 kg per annum of OLOA 246R is likely to enter the sewers from each of the blending sites. OLOA 246R is expected to be associated with the sludge at sewerage treatment works and its

ultimate fate will either be landfill or incineration.

The ecotoxicity data for the notified chemical indicate that it is unlikely to be toxic to fish, algae or bacteria up to the limit of its solubility. However, the toxicity levels for daphnia and the dispersion to fish are higher but cannot be quantified due to the uncertain exposure levels.

The notifier estimates that up to 50 % of the notified chemical may be released to the environment due to improper disposal of the waste hydraulic oil. This oil would be expected to be disposed of by burning, down drains, to landfill or possibly just poured onto the soil. OLOA 246R entering sewers will be adsorbed to the sludge due to its low water solubility and large molecular size and will be disposed of to landfill or incinerated. Waste chemical that is improperly disposed of in remote rural locations is also unlikely to enter the water compartment due to the low water solubility of the notified chemical, and hence should not present a significant hazard to aquatic organisms.

The notified chemical is unlikely to present a hazard to the environment when imported and used according to the outlined directions. Improper disposal of waste oil by unapproved methods significantly increases the risks to the environment from this chemical and this practice should be discouraged.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

No toxicity studies were presented for the notified chemical or the product, OLOA 246R. Analogue data for similar long chain alkarylsulphonate calcium salts were provided. OLOA 246S, containing around 50 % of the analogue to the notified chemical, is of very low acute oral and low dermal toxicity. OLOA 246S was slightly irritating to the eyes and skin of rabbits.

In a Beuhler skin sensitisation study in guinea pigs, OLOA 246S was found to be strongly sensitising, although the notifier states that no anecdotal evidence of skin sensitisation in humans handling calcium sulphonate additives has been found over 60 years of use. Based on the analogue data, the risk phrase R43 "May cause sensitisation by skin contact" is warranted for the notified chemical.

The notifier has indicated that the analogue subchronic toxicity studies which were provided as part of the NICNAS notification NA/177 and NA/178 should be taken as indicative of the subchronic toxicity of the notified chemical. In a 28 day repeat dose oral rat study, a NOEL of 500 mg/kg/day was established for the analogue to the notified chemical, AS 702 calcium sulphonate. Decreased serum cholesterol was observed in both male and female rats given 1000 mg/kg. In a 28 day repeat dose dermal rat study with the analogue OLOA 247E, no systemic toxicity was seen.

The three analogues of the notified chemical mentioned above were not mutagenic in *in vivo*

and *in vitro* test systems. The paraffinic petroleum distillates listed as adjuvants with the notified chemical are Category 2 carcinogens, with concentration cutoffs of 0.1 %, unless the petroleum distillate is shown to satisfy the condition that it contains less than 3 % DMSO extract as measured by IP 346.

Occupational Health and Safety

The notified chemical will be imported in drums, isotanks or in bulk vessels as a component (20 – 25 % OLOA 246R) of a lubricant additive package. The additive package will be reformulated in Australia, by blending with oils and other additives. The final product is then repackaged into 1 L and 4 L containers and 200 L drums, or transferred to road tankers for bulk delivery to customers.

Dermal exposure would be the predominant route of occupational exposure to the notified chemical. Inhalation exposure is expected to be minimal because the product containing the notified chemical and the finished oil are viscous and therefore have reduced potential to generate aerosols. In addition, the notified chemical has a very low vapour pressure, so vapour accumulation in the workplace air is not likely. The notified chemical is a skin sensitiser, and so protective gloves and clothing should be worn when the possibility of exposure to drips and spills exists.

Workers involved in transferring the imported oil additive containing the notified chemical, including bulk oil terminal workers and transport workers, and workers involved in blending the additive into oil may be exposed to drips and spills of the additive package, containing 20 – 25 % OLOA 246R (10.8 – 13.5 % notified chemical). Occupational exposure to the drips and spills of the final hydraulic oil containing 0.5 – 1 % notified chemical is possible for workers handling the final hydraulic oil. Workers involved in cleaning and maintenance of tanks and blending equipment may also have general dermal exposure to oil residues. It is recommended that all workers handling the notified chemical and the hydraulic oil containing the notified chemical wear gloves when potentially exposed.

Occupational exposure to the products containing the notified chemical will occur for a range of customers who use hydraulic equipment. The use is estimated to be 60 – 70 % in farming applications, and 30 – 40 % in industrial applications. Dermal exposure is likely during filling and top ups, and while handling equipment which has been in contact with the hydraulic oils. The workers who are likely to be exposed include farmers, during filling and maintenance of hydraulic equipment, mechanics who work on the hydraulic systems, and industrial tradesmen who may have contact with the oil during top ups of the equipment. Dermal and ocular exposure to the notified chemical at a concentration of 0.5 – 1 % is possible. It is recommended that the workers wear protective clothing and use appropriate protective gloves while working with hydraulic oils containing the notified chemical, as the notified chemical is a hazardous substance at a concentration of 1 %.

Public Health

The potential for public exposure to the notified chemical during transport, storage, or arising from its disposal is considered to be low. Exposure may occur for members of the public who deal with hydraulic equipment. The health risk would be expected to be similar to that during occupational exposure for tradesmen and farmers detailed above. Overall, it is considered that the notified chemical will not pose a significant hazard to human health.

13. RECOMMENDATIONS

To minimise occupational exposure to Component of OLOA 246R the following guidelines and precautions should be observed:

- Products containing the notified chemical at above 1 % should be classified as skin sensitisers with the risk phrase R43;
- Personal protective equipment during blending operations and end use should include industrial clothing, impermeable gloves and occupational footwear;
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees;
- Used oil containing the notified chemical should only be disposed of by approved methods.

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

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

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, 1994).

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

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

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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Attachment 1

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

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

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

CORNEA

<i>Opacity</i>	<i>Rating</i>	<i>Area of Cornea involved</i>	<i>Rating</i>
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

<i>Redness</i>	<i>Rating</i>	<i>Chemosis</i>	<i>Rating</i>	<i>Discharge</i>	<i>Rating</i>
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

<i>Values</i>	<i>Rating</i>
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