File No: NA/894

April 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

CHEMICAL IN NEW OLOA 260

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Director
Chemicals Notification and Assessment

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CHEMICAL IN NEW OLOA 260

1. APPLICANT

Chevron Oronite Australia of Level 22, 385 Bourke Street, MELBOURNE VIC 3000 (ARBN 001 010 037) has submitted a standard notification statement in support of their application for an assessment certificate for CHEMICAL IN NEW OLOA 260.

2. IDENTITY OF THE CHEMICAL

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

Other Names: Zinc dialkaryl dithiophosphate (ZDDP)

Marketing Name: NEW OLOA 260

CHEMICAL IN NEW OLOA 260 is referred to as NEW OLOA 260 from hereon.

3. PHYSICAL AND CHEMICAL PROPERTIES

The data below represent the physicochemical properties of the notified chemical at 65% in lubricating oil.

Appearance at 20°C & 101.3 kPa:	Dark brown viscous liquid, petroleum odour
Boiling Point:	Decomposes before boiling
Specific Gravity:	0.998
Vapour Pressure:	4.89×10^{-5} kPa at 25°C
Water Solubility:	Not determined but expected to be <0.1 mg/L at 25°C
Viscosity:	0.000943 m^2/sec at 40°C
Partition Co-efficient (n-octanol/water):	log P_{ow} 5.2
Hydrolysis as a Function of pH:	Not determined but expected to be stable
Adsorption/Desorption:	Not determined but expected to strongly adsorb to soils
Dissociation Constant:	Not determined
Flash Point:	>110°C (Pensky Martin closed cup)
Flammability Limits:	Will burn in the presence of enough heat and oxygen
Autoignition Temperature:	>200°C
Explosive Properties:	Not known to be explosive
Reactivity/Stability:	Will react in the presence of strong oxidising agents. Stable to acid and base.
Particle Size:	Not applicable as notified chemical is a viscous liquid.

3.1 Comments on Physico-Chemical Properties

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

The water solubility of zinc dialkyl dithiophosphate (ZDDP) (C8), is stated as 1.40 mg/L using Semipermeable Membrane Devices (SPMDs) and inductively coupled plasma atomic emission spectroscopy detection (Rausina GA Biggs WR Gala WR Stonebraker PM Crecelius EA 1996). As the notified chemical has a longer carbon chain, it is expected to be less soluble.

Measurement of the n-octanol/water partition coefficient was performed by HPLC and only brief details were provided with no test report available.

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 it would have a high K_{OC} and adsorb strongly to the organic component of soils and sediments.

Based on its chemical structure, the notified chemical is expected to be slightly acidic and remain as an anion in the environmental pH range of 4-9.

4. PURITY OF THE CHEMICAL

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

Hazardous Impurities:

Chemical name:	Tetrapropenylphenol
CAS No.:	74499-35-7
Weight percentage:	<0.5
Chemical name:	Phenol, (tetrapropenyl) derivatives manufacture of distillation residues
CAS No.:	220794-73-0
Weight percentage:	0.1%

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

Additives/Adjuvants: 35% diluent oil, hydrotreated or solvent refined, heavy paraffinic distillates. Exact details of solvent are claimed as exempt.

5. USE, VOLUME AND FORMULATION

NEW OLOA 260 is to be used primarily in natural gas engine oils to protect against oxidation and wear, with minor use in automotive heavy duty diesel oil formulations. The notified chemical will be imported at 1 to 10% in combination with other lubricating oil additives in five to 10 different additive packages. The final concentrations of NEW OLOA 260 in finished oils will be 0.5 to 1.5% (0.3 to 1.0% notified chemical).

The notified chemical will be imported in 5200 L marine isotanks or 200 L steel drums. The notified chemical, in additive package, will be offloaded at marine terminals in either Melbourne or Brisbane and transported to blending facilities by either road or rail. The notifier estimates that import volumes for the notified chemical will be initially up to 10 tonnes per annum and expects that the import volumes will gradually decrease to possibly nil over the next five years.

NEW OLOA 260, in additive package, is blended in an enclosed and fully automated process. Blending of the additive package into oils will occur at approximately five sites across Australia. Finished oil will be packaged into 1 L bottles, 200 L drums or sold in bulk in tank trucks.

6. OCCUPATIONAL EXPOSURE

6.1 Exposure

The table below identifies the nature of work done where occupational exposure to the notified chemical, in additive package, may occur at a marine terminal assuming the package arrives in 5200 L isotanks or 200 L steel drums. The table also identifies the nature of work done during blending of the additive package into finished natural gas or heavy duty diesel engine oils.

Nature of Activity & Number of Workers	*% NEW OLOA 260*	*Maximum Potential Exposure Duration*
MarineTerminal		
Sampling & Analysis (1 to 2)	10	0.5 hour/day; 7 days/year.
Blending Facility		
Transferring to storage tank (1 or 2)	10	1 hour/day; 2 days/year.
Sampling & Analysis (2 to 4)	1 to 10	0.5 hour/day; 6 days/year.
Drumming & Bottling (1 to 2)	0.5 to 1.5	8 hours/day; 5 days/year.
Loading road tankers (1-2)	0.5 to 1.5	1 hour/day; 2 days/year.
Equipment Cleaning (1 to 2)	<1	3 hours/day; 1 day/year.
ISO tank & Drum Cleaning (1 to 2)	<1	8 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. During sampling and analysis of the additive package there may be skin contact as sampling devices and analytical equipment are manipulated. NEW OLOA 260 is of low volatility and inhalation exposure unlikely.

Lubricant Blending Plant
The notified chemical in additive package arriving in either 200 L drums or isotanks will be unloaded and transferred to storage tanks via 10 cm hosing which workers will fasten. Fastening takes about 10 minutes. A special air back flush system is used to prevent spillage during transfer. The notifier states that adherence to ISO 9001 procedures will limit spills and leaks. For unloading of drums workers will connect a pump line to the drum. Unloading activities may cause incidental skin contact to splashes, drips and spills to occur as pump lines are connected or disconnected. Whole body exposure to mist may occur if emptied drums are steam cleaned for re use or disposal.

Blending of the additive package into finished lubricant occurs in a closed system at 60°C and is computer controlled, thereby excluding the potential for occupational exposure. The blended lubricant is transferred automatically to a storage tank. From here it can either be dispensed directly into tanker trucks via 10 cm pump lines or packaged into 1 L bottles or

200 L drums. Drum filling is an automated process and worker intervention is not required unless the filling line operation requires adjustment. However, workers are required to insert bungs and label the drums and skin contact with contaminated drum surfaces may occur.

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

Engine maintenance
When changing lubricant, it is inevitable that mechanics will receive skin contact given the nature of the job and that personal protective equipment is not widely used by this trade group. Accidental eye contact may occur, particularly while mechanics are working under vehicles.

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

7. PUBLIC EXPOSURE

The finished engine oil products will mainly be used by mechanics, as well as by the public. The users may come into contact with both fresh and used motor oils (up to 1% of the notified chemical) while working on engines. The most likely route of exposure for the notified chemical is skin contact. Inhalation exposure is expected to be minimal, as the notified chemical is not likely to be volatile.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The blending operations are performed at specially constructed sites owned and operated by lubricant manufacturers, and up to twenty sites in Australia may be involved in producing lubricants which contain the notified chemical. Release to the environment prior to end use 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 the blending facilities in 200 L steel drums and transferred to storage tanks. It is anticipated that there will be minimal release of the notified chemical 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. Empty drums containing residual notified chemical would be steam cleaned, with the resultant aqueous waste sent to on-site waste-water treatment facilities.

The finished lubricants will be sold in bottles, drums and bulk to industrial and commercial customers. The notifier did not provide any information on the expected release volumes and routes of disposal for the lubricant products containing the notified chemical. If the worst case is assumed, where containers are disposed of to landfill and not recycled, and a maximum of 1% of the import volume remains in containers after transfer to engines, up to 100 kg of the notified chemical would be released to landfill as residues remaining in the lubricant containers.

The notified chemical is not substantially altered during use and does not decompose in crankcases because it is thermally stable. However, it is burned in the engine during oil consumption, with most of the ash remaining after combustion returning to the sump as insolubles, or emitted as particulate matter in the exhaust. The notified chemical will be attracted to and coat insoluble materials (soot particles, insoluble resins) and can be filtered or centrifuged out of the oil. Over time, fresh oil containing the notified chemical may be added to keep sump levels constant and to maintain the effectiveness of the oil, or during maintenance, the oil may be drained completely and replaced with new oil. In most cases where specialised technicians perform oil changes or repairs, the used oil generated will be incinerated or sent for recycling. However, in the case of passenger vehicles where DIY enthusiasts perform at home oil changes, a significant percentage of the oil sold for use in these vehicles is released inappropriately. Information presented at an API 1997 Conference, showed that of oil sold for use in the automotive market, 14% was sold to DIY enthusiasts (Snow 1997). Of this oil, approximately 13% was collected for recycling, 32% was lost or consumed during use, and the remaining 55% was released inappropriately eg buried, tipped into landfill, used for weed control, tipped into stormwater, stored etc.

Since the use of the lubricating oils will occur throughout Australia, any releases resulting from use or disposal of old oil will be very diffuse, and release of the notified material in high concentrations is unlikely except as a result of accidents during transport.

8.2 Fate

In the case of accidental release to land, the anticipated high adsorption/desorption properties of the notified polymer 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.

No biodegradation tests were performed on the notified chemical but it is not expected to be readily biodegradable, as with the majority of lubricant additives (Cisson CM Rausina GA Stonebraker PM 1996). While the notified polymer is not readily biodegradable, any released to landfill or associated with soil is expected to slowly degrade through the biotic and abiotic processes, resulting in the formation of water, and oxides of carbon, sulphur and phosphorus and the zinc component becoming associated with the water compartment. Incineration would lead to water vapour and oxides of carbon, sulphur and phosphorus and zinc assimilated into ash. Sludges from waste treatment plants or oil recycling facilities could also be incinerated.

The expected high log P_{OW} and low rate of biodegradation of OLOA 260, indicate the potential for bioaccumulation (Connell DW 1989). However, the high molecular weight (over 1000) and the unlikely direct exposure to the water compartment, will limit the potential for bioaccumulation.

9. EVALUATION OF TOXICOLOGICAL DATA

OLOA 260

Toxicological data on the notified chemical, NEW OLOA 260 are not available. In support of claims for Variation of the Schedule requirements, the notifier submitted investigations into acute oral and dermal toxicity and skin and eye irritation potential, for OLOA 260 which differs from the notified chemical in the nature of the alkyl phenol side chain. All testing was conducted on OLOA 260 which contains the analogue at 65% in lubricating oil.

The skin irritation potential of OLOA 260 was investigated in a number of studies using New Zealand White (NZW) rabbits, involving 4 or 24 hour application of 0.5 mL of test substance, to abraded and intact skin. In addition, a comparison of the effects of test substance removal on the skin irritation potential of two OLOA 260 formulations (produced by different manufacturing processes) was investigated. The findings from these studies are summarised at Section 9.1.3.

Inhalation studies have not been conducted.

The data on OLOA 260 are accepted for the purposes of assessing affects after single exposure. Although some studies predate recognised principles of good laboratory practice they are included here for completeness and are used as supportive evidence of potential toxicity.

ZDDP

Investigations into skin sensitisation potential, repeat dose toxicity and genotoxicity are not available for the notified chemical or OLOA 260. Instead, data for shorter-chain analogues were available, and submitted in the zinc dialkyldithio phosphates (ZDDP) SIDS Initial Assessment Report (CMA 1995). The report, yet to be endorsed by the OECD Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Plastics and Biotechnology, is a compilation of unpublished data collected by the Chemical Manufacturer's Association (US) on toxicological investigations of two ZDDP:

Phosphorodithioic acid, O,O-bis(2-ethylhexyl) ester, zinc salt (CAS# 425-91-58); and

Phosphorodithioic acid, O,O-diisooctyl ester, zinc salt (CAS# 28629-66-5).

The SIDS Profile Summary for the two ZDDP is reproduced at Section 9.2. Original studies have not been sighted. The ZDDP are of lower molecular weight and have a shorter carbon chain than the notified chemical. The data on ZDDP provide some indication of the notified chemical's potential for skin sensitisation potential, chronic toxicity and genotoxicity and are accepted for this assessment.

Study Details	*Findings*	*Result*
9.1.1aAcute Oral Toxicity Test Substance: OLOA 260 (LCM 1310 CR 68 R 6142) GLP: No. Test Method: In house. Species/strain: Rat, Sprague-Dawley. No of animals/sex: 5 males. Dose: 15 000 mg/kg by oral gavage. Observation period: 14 days.	There was no mortality. There were no signs of toxicity. There were no gross abnormalities at necropsy.	LD50 > 15 000 mg/kg. Ref: (SOCO 1968)
9.1.1bAcute Oral Toxicity Test Substance: OLOA 260 (LCM 2812). GLP: Yes. Test Method: OECD TG 401. Species/strain: Rat, Ico. No of animals/sex: 5/sex. Dose: 2000 mg/kg by oral gavage. Observation period: 14 days.	There was no mortality. Diarrheoa was observed in two animals four hours after test substance administration. Females were observed to have a slight decrease in weight at the end of treatment. There were no treatment related gross abnormalities observed at necropsy.	LD50 > 2000 mg/kg. Ref: [Hazelton -IFT, 1986 #2]
9.1.2aAcute Dermal Toxicity Test Substance: OLOA 260 (LCM 1310 CR 68 R 6142) GLP: No. Test Method: In house. Species/strain: Rabbit, New Zealand White No of animals/sex: 2 males. Dose: 15 000 mg/kg, single occlusive application for 24 hours. Observation period: 14 days.	There was no mortality. There were no signs of toxicity. There were no gross abnormalities at necropsy.	LD50 > 15 000 mg/kg. Ref: (SOCO 1968)
9.1.2bAcute Dermal Toxicity Test Substance: OLOA 260 (C 30162) GLP: No. Test Method: OECD TG 402. Species/strain: Rat, Ico. No of animals/sex: 10 males. Dose: 2000 mg/kg, single occlusive application for 24 hours. Observation period: 14 days.	There was no mortality. There were no signs of toxicity. There were no gross abnormalities at necropsy.	LD50 > 2000 mg/kg. Ref: (Hazelton - IFT 1986a)

Study Details	*Dermal response*	*Result*
9.1.3aSkin Irritation Test Substance: OLOA 260 (LCM 1310 CR 68 R 6142). GLP: No. No. of NZW rabbits & sex: 6 males. Exposure time & dose volume: 24 hours, 0.5mL. Dressing; skin surface: Occlusive; intact & abraded. Observation times: 24 & 72 hours. Scoring method: Federal Hazardous Substances Act (USA).	At 24 hours (at removal of wrap), there was a moderate reaction, characterised by slight swelling and redness. By 72 hours (48 hours after removal) this had decreased slightly. Primary irritation score = 2.8.	Moderate skin irritant. Ref: (SOCO 1968)
9.1.3bSkin Irritation Test Substance: OLOA 260 (LCM 2812). GLP: No. No. of NZW rabbits & sex: 6 males. Exposure time & dose volume: 24 hours, 0.5 mL. Dressing; skin surface: Occlusive; intact & abraded. Observation times: 24, 48, 72, hours, 7 days. Scoring method: Draize.	Well-defined to moderate erythema and oedema at 24 hours. Most animals had very-slight to well-defined erythema and very slight oedema at 7 days, and the skin was dry and cracked. Primary irritation score = 4.3	Moderate skin irritant. Ref: SOCAL 1765, 1981.
9.1.3cSkin Irritation Test substance: OLOA 260 (LCM 2890). GLP: Yes No. of NZW rabbits & sex: 6 females. Exposure time & dose volume: 4 hours, 0.5 mL. Dressing; skin surface: Occlusive; intact & abraded. Observation times: 1, 24, 48, 72 hours, 7 days, 14 days. Scoring method: Draize.	Slight to moderate erythema and slight oedema were observed at 1, 24 and 48 hours after treatment. Maximum irritation occurred at 72 hours; moderate to severe erythema and slight to moderate oedema were observed at most sites. On day 7 most animals had slight to well-defined erythema and oedema and flakiness was observed. On day 14, one animal showed slight erythema and dry slightly flaky skin at all treatment sites. Treatment sites on the other five animals were free of irritation, but fur regrowth was less dense on treated skin as compared to untreated skin. Histological examination revealed no treatment related microscopic changes to treated skin. Trace hyperkeratosis and acanthosis were judged to be incidental findings. Primary irritation score = 3.6 Mean score, intact skin (24, 48, 72 hours): erythema, 2.6; oedema 0.9.	Moderate to severe skin irritant. Ref: (SOCAL 1985)

9.1.3dSkin Irritation Test Substance: OLOA 260 (APD 6188). GLP: Yes. No. of NZW rabbits & sex: 6 females. Exposure time & dose volume: 4 hours, 0.5 mL. Dressing; skin surface: Occlusive; intact & abraded. Observation times: 1, 24, 48, 72 hours, 7 days, 14 days. Scoring method: Draize.	No to well-defined erythema and oedema were observed at intact and abraded sites one hour after exposure. No to slight erythema persisted through 72 hours at both the abraded and intact sites in two animals. No oedema was observed. On day 7, dry and flaky skin was observed in five animals, otherwise all sites were free of irritation. One animal had slight reduced food consumption on day 4. Primary irritation score = 0.7. Mean score intact skin (24, 48, 72 hours): erythema, 0.1; oedema 0.0.	Slight skin irritant. Ref: (SOCAL 1986)
9.1.3eSkin Irritation Test Substance: OLOA 260 (Lot C 30162). GLP: Yes. No. of NZW rabbits & sex: 6 males. Exposure time & dose volume: 4 hours, 0.5mL. Dressing; skin surface: Occlusive; intact. Observation times: 1, 24, 48, 72 hours. Scoring method: Draize.	Well-defined erythema observed in most animals at 1 hour subsided to very slight erythema in all but one animal at the 72-hour observation. Slight oedema to well-defined oedema observed at 1 hour had subsided to no or slight oedema in 3 animals. Mean score (24, 48, 72 hours): erythema, 1.4; oedema 0.7.	Slight to moderate skin irritant. Ref: (Hazelton - IFT 1986b)
9.1.3f Methods of Test Substance Removal Test Substance: OLOA 260 (LCM 2890); OLOA 260 (APD 6188). GLP: Yes. No. of NZW rabbits & sex: 12 males. Exposure time & dose volume: 4 hours, 0.5mL. Dressing; skin surface: semi occlusive; intact. Observation times: 24, 48, 72, hours, 7 days, 14 days. Dry gauze was used to wipe one treatment site. The other site was rinsed with a gauze pad moistened with mineral oil followed by dry gauze. Scoring method: Draize.	On wiped sites, the two OLOA 260 substances showed similar skin irritation of slight to moderate irritation, with well defined irritation persisting in some animals to day 14. Irritation was lower on sites rinsed with mineral oil. Mean score (24, 48, 72 hours): wiped site / rinsed site OLOA 260 (LCM 2890): Erythema: 1.9 / 1.2 Oedema: 0.0 / 0.0 OLOA 260 (APD 6188): Erythema: 1.9 / 0.1 Oedema: 1.3 / 0.1	- Ref: (CEHC 1986)

Study Details	*Ocular response*	*Result*
9.1.4a Eye Irritation Test Substance: OLOA 260 (LCM 1310 CR 68 R 6142) GLP: No. Test Method: In house. No. of NZW rabbits & sex: 6 males. Dose volume: 0.1 mL. Eye treatment: unirrigated. Observation times: 24, 48, 72 hours. Scoring method: not stated.	Very slight reddening of the conjunctivae including the nictitating membrane in two rabbits persisted for 72 hours. There was no discharge. There were no corneal or iridial effects. Mean scores (24, 48, 72 hours): conjunctival redness: 0.4; chemosis: 0.0; iris lesion: 0.0; corneal opacity: 0.0.	Slight eye irritant. Ref: (SOCO 1968)
9.1.4b Eye Irritation Test Substance: OLOA 260 (LCM 2812) GLP: No. Test Method: Not stated. No. of NZW rabbits & sex: 9 males. Dose volume: 0.1 mL. Eye treatment: irrigated & unirrigated Observation times: 1, 2, 3, 4, 7, 10 days. Scoring method: Draize.	There were no corneal or iridial effects. Irrigated eyes: moderate conjunctival irritation at one hour clearing by day 4. Unirrigated eyes: moderate conjunctival redness at 1 hour in all animals, persisting in one animal until day 4, with all eyes clearing by day 10. Slight chemosis had cleared by day 3. Slight to moderate discharge had cleared by day 4. Mean scores (24, 48, 72 hours): conjunctival redness: 1.5; chemosis: 0.4; iris lesion: 0.0; corneal opacity: 0.0.	Moderate eye irritant. Ref: (SOCAL 1981)
9.1.4c Eye Irritation Test Substance: OLOA 260 (Lot C 30162) GLP: Yes. Test Method: OECD TG 405. No. of NZW rabbits & sex: 6 males. Dose volume: 0.1 mL. Eye treatment: irrigated & unirrigated Observation times: 1, 24, 48, 72 hours. Scoring method: Draize.	Ulceration and translucency of the cornea was observed in all animals resolving completely by 72 hours. Moderate circumcorneal or iridial hyperaemia persisted for 72 hours. Well-defined chemosis in 3 animals persisted for 72 hours. Well defined to slight erythema was observed at one hour. Moderate erythema occurred at 24 hours. Slight to well-defined erythema persisted at 72 hours in all but one animal. One animal was found dead at the 48-hour observation period. The cause of death was not described. Mean scores (24, 48, 72 hours): conjunctival redness: 1.3; chemosis: 1.9; iris lesion: 1.0; corneal opacity: 0.6.	Moderate eye irritant. Ref: (Hazelton - IFT 1986b)

9.2a Phosphorodithioic acid, O,O-bis(2-ethylhexyl) ester, zinc salt CAS# 425-91-58 (CMA 1995)

Study	*Species*	*Protocol*	*Results*
Acute Toxicity			
oral	Rat Rat	OECD OECD	LD50 > 2000 – 5000 mg/kg LD50 > 3100 mg/kg
inhalation			No data
dermal	Rabbit	Limit test	LD50 > 5000 mg/kg. Signs of toxicity included depression, respiratory rales, reduced food consumption, muscular weakness and weight loss. Histological changes in the liver and lung were observed at necroscopy.
Irritation			
dermal	Rabbit Rabbit	OECD OECD	PII 5.59 PII 5.7
eye	Rabbit Rabbit	OECD OECD	Ocular irritation score, maximum after 96 hours: 2.35/110. Corneal opacity, roughened corneas, mild iritis, severe conjunctival irritation during 1, 2 & 3 day readings.
Skin sensitisation	Guinea-pig Guinea-pig	Maximization Buehler	Non sensitising. Weak sensitiser (4 of 30 (13%) animals with positive skin reaction).
Repeat Dose			
28 day dermal screen	Rabbit	OECD	Single dose level (25% w/v). Dermal response (erythema, atonia, desquamation and fissuring), lowered body weight and testicular effects.
21 day dermal	Rabbit (young & mature)	OECD	Single dose level (25% w/v). Dermal response (erythema, atonia, desquamation and fissuring, eschar formation and exfoliation), lowered body weight, reduced absolute and relative testes weights (more severe in younger animals) microscopic changes in testes.
28 day oral, gavage, 0, 10, 50, 125, 250, 500 mg/kg/day.	Rat	OECD	NOAEL = 10 mg/kg/day. Three males and one female dosed at 500 mg/kg/day died between study days 6 and 16; deaths were attributed to treatment. Clinical signs in the 125, 250 and 500 mg/kg/day males and females included discolouration and changes in faecal consistency, staining on body surfaces, rales, salivation and aggression. Rales and salivation were also observed in males at 50 mg/kg/day. Bodyweight gain was inhibited in males at 500 mg/kg/day through study day 12. Food consumption was slightly reduced in both sexes at 500 mg/kg/day during the first week of dosing. At necropsy, findings in the stomach in both sexes at 250 and 500 mg/kg/day were consistent with a response to a gastric irritant. Mean absolute and relative adrenal weights in both sexes at 250 and 500 mg/kg/day were increased compared to the control group values. However, there were no histopathological lesions related to this finding.

Genetic Toxicity			
bacterial			A mixture of six process oils containing ZDDP and another mixture of six ZDDP were found to be inactive in an Ames test.
non bacterial, *in vitro*	BALB/3T3 Clone A31-1	OECD	Morphological transformation induced with metabolic activation.
	L5178Y TK+/- Mouse	OECD	Negative in absence of metabolic activation. Equivocal in presence of metabolic activation.
non bacterial, *in vivo*			No data.
Carcinogenicity			No data.
Reproductive & Developmental Toxicity			
Single generation reproductive toxicity study with teratology screen	Rat	OECD	NOAEL – P generation and F1 generation 30 mg/kg/day. Parental toxicity was observed at dose levels of 100 & 200 mg/kg/day by mortality and clinical signs. Body weight gain and gastric irritation were evident at 200 mg/kg/day. Reproductive performance was unaffected by treatment at 30 and 100 mg/kg/day. Slightly reduced fertility indices were observed at 200 mg/kg/day, however, they were not clearly related to treatment. Neonatal toxicity mortality in the F1 generation was observed at 100 and 200 mg/kg/day. Clinical signs in F1 pups were also observed at 200 mg/kg/day.
Neurotoxicity			No data.
Experience with human exposure			A 1980 NIOSH study of workers in manufacturing plant showed no effects on male fertility or spermatogenesis.
Biological monitoring			No data.

9.2b Phosphorodithioic acid, O,O-diisooctyl ester, zinc salt CAS# 28629-66-5 (CMA 1995)

Study	*Species*	*Protocol*	*Results*
Acute Toxicity			
oral	Rat	OECD	Four independent studies. LD50 = a) 3760 mg/kg; b) 3200 mg/kg; c) 2950 mg/kg; d) 1350 mg/kg, male; 1530 mg/kg, female.
inhalation			No data
dermal	Rabbit	Limit test	LD50 > 5000 mg/kg. Signs of toxicity included depression, reduced food consumption and failure to gain weight. No deaths were observed. At autopsy, less than normal amounts of body fat and congested lungs were observed.
Irritation			
dermal	Rabbit	OECD	Five independent studies. Primary dermal irritation score, where 8 is the maximum score after 72 hours: a) 3.34; b) 6.67; c) 6.4; d) 7.4 – corrosive; e) 7.8 – corrosive.
eye	Rabbit	OECD	Three independent studies. Scores at 24 hours: a) 26/110; b) 18.2/110; c) 46.5/110.
Skin sensitisation	Guinea-pig	Maximization	Non sensitising
Repeat Dose			
dermal	Rabbit	OECD	From CMA sponsored studies from the early 1980s. Systemic effects noted were limited to male rabbits and included testicular atrophy and accessory gland effects. These effects were closely associated with significant weight loss resulting from the stress produced by the severe skin lesions following repeated dermal applications of irritating concentrations of ZDDP. Published studies have demonstrated that nutritional deficiencies and certain types of stress are capable of producing similar effects. In other repeated dermal studies, male rabbits exposed to 1% and 3% ZDDP and female rabbits exposed to 5% and 25% ZDDP (intended final use concentrations) did not exhibit any signs of reproductive toxicity or any other organ toxicity.

Genetic Toxicity			
bacterial			Analogue studies on related ZDDP: Ames tests, with and without metabolic activation, were conducted on both a C4/C8 and a C6 ZDDP. Both materials were determined to be non-mutagenic up to 1000 µg/plate in *Salmonella typhimurium* strains TA98, TA100, TA1537 & TA1538. Neither a blend of ZDDP additives nor a blend of process oils, up to 1000 µg/mL was positive in an Ames test in five strains tested.
non bacterial, *in vitro*	BALB/3T3	OECD	Analogue studies on related ZDDP: Both a C4/C8 ZDDP and a C6 ZDDP were positive, with and without metabolic activation, in a point mutation assay (Ouabain locus) at 0.3, 1.0, 3.0 µg/mL. The lowest concentration producing toxicity was 0.3 µg/mL. The C4/C8 ZDDP, without metabolic activation, produced a significant increase in morphologically transformed foci. Negative results were obtained in the presence of a metabolic activation. The C6 ZDDP was negative both with and without metabolic activation. Both materials were tested at 0.3, 1.0, 3.0 µg/mL. The lowest concentration producing toxicity was 0.3 µg/mL. 4 of 9 ZDDP (ranging in carbon chain length from C3-C10, derived from both primary and secondary alcohols) tested were found to be positive (without metabolic activation) as determined by a statistically significant increase in morphologically transformed colonies. In addition 2 of 4 ZDDP showed a significant increase in transformation frequency when the cell survival dropped below 10%. 2 of 9 ZDDP (different to the 4 above) were found to be positive in the presence of metabolic activation. In both assays, this chemical class was found to be highly cytotoxic with an extremely steep dose response curve, which made dose selection difficult and contributed to substantial variability and mixed results.

	L5178Y TK+/- Mouse	OECD	Analogue studies on related ZDDP: In the absence of metabolic activation, all 9 ZDDP (ranging in carbon chain length from C3-C10, derived from both primary and secondary alcohols) were found to be negative as demonstrated by an inability to produce a statistically significant increase in number of colonies resistant to 5-triflurothymidine. In the presence of a metabolic activation system, 2 of 9 ZDDP were found to be positive whereas the remaining ZDDP were either negative or presented equivocal results. For all 9 ZDDP tested the threshold concentrations ranged from 0.05-0.1 µL/mL (with and without metabolic activation).
	BHK 21 Hamster kidney fibroblast, cell transformation assay		Neither a blend of ZDDP additives nor a blend of process oils, up to 1000 µg/mL was positive in colony growth in soft agar cultures.
non bacterial, *in vivo*	CD-1 mice		Analogue studies on related ZDDP: Both a C4/C8 (10 and 20 mg/kg) and a C6 ZDDP (50 and 100 mg/kg) analogue were determined to be negative in a mouse micronucleus test following ip administration.
Carcinogenicity			No data. In 1982 the US Food & Drug Administration concluded that the Zn ion was not carcinogenic. In subsequent dermal carcinogenicity tests conducted in mice, new motor oils containing between 1% and 3% ZDDP were found to be inactive.
Reproductive & Developmental Toxicity			No data. See data on 2-ethylhexyl analogue at Section 9.2a.
Neurotoxicity			No data.
Experience with human exposure			No data. See data on 2-ethylhexyl analogue at Section 9.2a.
Biological monitoring			No data.

9.3 Overall Assessment of Toxicological Data

Summary of the acute toxicity of OLOA 260:

Test	*Species*	*Outcome*
Acute oral toxicity (Section 9.1.1b)	rat	LD50 > 2000 mg/kg
Acute dermal toxicity (Section 9.1.2b)	rat	LD50 > 2000 mg/kg
Skin irritation (Section 9.1.3)	rabbit	Moderate
Eye irritation (Section 9.1.4)	rabbit	Moderate

OLOA 260 in lubricating oil was tested in a number of single exposure studies. On the basis of the data supplied for OLOA 260, the notified chemical is expected to be of low acute oral and dermal toxicity. Inhalation studies have not been conducted. OLOA 260 has low vapour pressure and is viscous and is not expected to present an inhalation hazard. Differing formulations of OLOA 260 caused varying degrees of severity of the dermal response ranging from slight to moderate. Skin irritation continued, or dry, flaky skin was observed in studies where the observation period was greater than 3 days. In addition, fur regrowth was observed to be less dense following application of OLOA 260 (LCM 2890). Based on these findings combined OLOA 260 causes skin irritation of sufficient concern to be classified as a skin irritant (NOHSC 1999). OLOA 260 is moderately irritating to eyes causing lesions to the cornea and iris and conjunctival irritation. The score for iridial effects obtained in the study at Section 9.1.4c meets the criteria for classification as an eye irritant (NOHSC 1999).

Besides similar acute toxicity to OLOA 260 as described above, ZDDP was a weak skin sensitiser in a Buehler test. In repeated dose toxicity data for the shorter chain analogue ZDDP, repeated dermal application (25% w/v for 21 or 28 days) in rabbits induced dermal irritation, lower body weight, testicular atrophy and related microscopic changes in testes. Oral administration at 10 – 500 mg/kg bw/day for 28 days caused death, clinical signs, gastric irritation, depressed food consumption and body weight gain, with a NOAEL at 10 mg/kg bw/day. The NOAEL was 30 mg/kg bw/day in a reproduction study on rats, based on parental and neonatal toxicity, including higher mortality for both parents and pups, clinical signs and/or reduced fertility indices at higher doses. However, a 1980 NIOSH study showed no effects on male fertility or spermatogenesis in workers exposed in a manufacturing plant. In genotoxicity studies, some chemicals of this group induced morphological transformation in BALB/3T3 mouse embryo cell and equivocal effects in L5178Y TK +/- mouse lymphoma mutagenesis assays, whereas negative results were obtained in the Ames bacterial mutagenicity test and cell transformation assay on BHK21 Hamster kidney fibroblast in vitro, and the mouse micronucleus test in vivo.

The two ZDDP have shorter carbon chains, are of lower molecular weight, share similar physical and chemical properties and can be taken as representing the most severe toxicological effects (dermal toxicity, developmental effects and in vitro mutagenicity) of the notified chemical.

Hazard Classification
Results from non-GLP studies are excluded from hazard classification.

The hazard classification of NEW OLOA 260 is based on that of OLOA 260. On the basis of skin and eye effects NEW OLOA 260 is classified as an Irritant (Xi) R36/38 Irritating to eyes and skin, in accordance with the *Approved Criteria for Classifying Hazardous Substances.*

No hazard classification is made for skin sensitisation, repeat dose effects or genotoxicity in the absence of data on the notified chemical or a more closely related analogue.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicity data for the notified chemical were provided. However, ecotoxicity data for the chemicals CMA #510 (Chemical Manufacturers Association) and CMA #617 were provided as surrogates for the notified chemical. CMA is also known as OLOA 260. The tests were conducted according to OECD protocols, and the data is summarised and discussed below.

10.1 Summary of Biotic Effects

Test	***Species***	***Results***
acute toxicity [OECD 203]	Sheepshead Minnow *(Cyprinodon variegatus)*	LC50 (96 h) = 290 mg/L (WSF) NOEC < 26 mg/L (WAF)
acute toxicity [OECD 203]	Fathead Minnow *(Pimephales promelas)*	LC50 (96 h) = 29 mg/L (WSF) NOEC = 12.5 mg/L (WAF)
acute toxicity (WAF) [OECD 203]	Fathead Minnow *(Pimephales promelas)*	LC50 (96 h) = 95 mg/L (WAF) NOEC = 31 mg/L (WAF)
acute toxicity (WAF) [OECD 202]	*Daphnia magna*	EC50 (48 h) = 1.2 mg/L (WAF) NOEC <1 mg/L (WAF)
acute toxicity (WAF) [OECD 201]	Algae *(Selenastrum capricornutum)*	Cell Density: EC50 (96 h) = 5.8 mg/L (WAF) NOEC = 3 mg/L (WAF) Growth Rate: EC50 (96 h) = 8.7 mg/L (WAF) NOEC = 3 mg/L (WAF)
Respiration Inhibition [OECD 209]	Sludge	EC50 (3 h) > 1000 mg/L

NOEC - no observable effect concentration.
WAF – water accommodated fraction.
WSF – water soluble fraction.

10.2 Fish, Acute Toxicity

Sheepshead Minnow (Springborn Bionomics Inc 1986)
A tiered approach was employed to determine the acute lethal effect of CMA #510 on sheepshead minnow, a salt-water fish species. A Tier I preliminary study was conducted using a 100% WSF at a nominal concentration of 10 g/L for a maximum of 96 hours with daily renewal of the test and control solutions. Based on the results of this preliminary test, a Tier II definitive test was conducted with test solutions of nominal concentrations of 0.026, 0.064, 0.16, 0.40 and 1.0 g/L. Preparation of the 100% WSF test solutions involved stirring (24 hours) an appropriate amount of the notified chemical in 15 litres of dilution water with a subsequent settling period of 24 hours. The WSF of each concentration was separated from floating or settled material by slowly pumping 5 L of WSF from a point midway in the aquarium into two replicate test aquaria. Duplicate control samples, containing none of the test substance, were tested. Each test involved using 10 fish for each test vessel, pH levels of 7.5 to 7.8 and a dissolved oxygen range of 5.2 to 6.8 mg/L. The water used was filtered natural seawater.

Observations were performed at 24, 48, 72 and 96 hours. There was no mortality in the controls and at 0.064 g/L. There was one death at 0.026 g/L and 20% mortality at 0.16 g/L. At test concentration 0.40 g/L there was 100% mortality at 24 hours in one replicate and no mortality in the other until 96 hours when 20% mortality was observed. There was 100% mortality in the highest concentration (1.0 g/L) at 24 hours.

Exposure of sheepshead minnow to CMA #510 resulted in a 96 hour LC50 = 0.29 g/L (expressed as the nominal amount of test substance used to prepare the WSF) and a NOEC of <0.026 g/L. Since it was unclear how much material was in solution (as it was not measured) it can be concluded that CMA #510 is toxic to this species below its water solubility limit.

Fathead minnow (Dispersion method) (TR Wilbury Laboratories Inc 1994c)
The tests on this freshwater species were conducted over 96 hours under static conditions at nominal concentrations of 0 (control), 12.5, 25, 50 100 and 150 mg/L. Each test solution was equipped with a mechanical stirrer, thereby continuously mixing the test substance and dilution water. Each test was conducted in duplicate using 10 fish per test vessel, pH levels of 8.1 to 8.6 and a dissolved oxygen range of 8.2 to 9.2 mg/L. The water used was dechlorinated tapwater adjusted to a hardness of 160 to 180 mg/L as $CaCO_3$. It was observed that all non-control test vessels had insoluble material floating on the surface and were cloudy throughout the test.

There was no mortality in the control and at 12.5 mg/L. At 25 mg/L, mortality was 15% at 24 hours, increasing to 30% at 96 hours. At the higher concentrations 100 % mortality had occurred in all vessels by 24 hours.

Exposure of fathead minnow to CMA #617 resulted in a 96 hour LC50 of 29 mg/L (expressed as the nominal amount of test substance used to prepare the WSF) and a NOEC of 12.5 mg/L. CMA #617 is clearly toxic to this species well below its solubility in water limit.

Fathead minnow (WAF) (TR Wilbury Laboratories Inc 1994d)
The acute toxicity of the WAF of 31, 63, 130, 250 and 500 mg/L mixtures of CMA #617 was investigated over 96 hours under static renewal conditions. Preparation of the WAF involved stirring the mixtures of test substance in water for 24 hours, settling the mixtures for 1 hour and siphoning off the water phase containing the WAF. The 500 mg/L WAF had a surface slick and was cloudy at the 0, 3 and 24-hour observations, the 130 mg/L WAF had a surface slick at 24 hours and the 250 mg/L WAF was cloudy after 24 hours. A control sample containing none of the test substance was also tested. A duplicate for each level was tested, using 10 fish per test vessel, pH levels of 7.9 to 8.4 and a dissolved oxygen range of 6.1 to 9.5 mg/L. The water used was filtered well water adjusted to a hardness of 176 mg/L as $CaCO_3$.

There were no deaths in the control exposure and at 31 mg/L. At 63 mg/L a mortality of 5% was observed at 96 hours, at 130 mg/L 80% mortality occurred at 24 hours increasing to 90% at 72 hours and at the higher concentrations 100 % mortality occurred in all vessels by 24 hours.

Exposure of fathead minnow to CMA #617 resulted in a 96 hour LC50 of 95 mg/L (expressed as the nominal amount of test substance used to prepare the WAF) and a NOEC of 31 mg/L. Again CMA #617 is clearly toxic to this species well below its solubility in water limit.

10.3 Acute toxicity, *Daphnia* sp. (TR Wilbury Laboratories Inc 1994b)
The acute toxicity of the WAF of 1.0, 1.5, 2.5, 4.0 and 6.0 mg/L mixtures of CMA #617 to *Daphnia magna* was investigated over 48 hours under static renewal conditions. A control sample containing none of the test substance was also tested. Preparation of the WAF involved the same preparation as described for fathead minnow. The 2.5 mg/L WAF had a surface slick at the end of the test and the 4.0 and 6.0 mg/L WAF had a surface slick at the beginning and end of the test. A duplicate for each level was tested, using 10 daphnids in each test vessel, pH levels of 8.1 to 8.3 and a dissolved oxygen range of 7.7 to 9.3 mg/L. The water used was filtered well water adjusted to a hardness of 176 mg/L as $CaCO_3$.

One hundred percent survival occurred in the control exposure, at test concentration 1 mg/L a mortality of 5% occurred. At 1.5 mg/L a mortality of 55% was observed at 96 hours, at 2.5 mg/L 65% mortality occurred at 24 h increasing to 75% at 48 hours. At 4.0 mg/L 70% mortality occurred at 24 hours increasing to 95% at 48 hours and at the highest concentration 85% mortality occurred at 24 hours with 100 % mortality by 48 h.

Exposure of daphnids to CMA #617 resulted in a 48 hour EC50 of 1.2 mg/L (expressed as the nominal amount of test substance used to prepare the WAF) and a NOEC of <1.0 mg/L. CMA #617 is clearly toxic to this species well below its solubility in water limit.

10.4 Alga Growth Inhibition Test (TR Wilbury Laboratories Inc 1994e)
A test on algal growth inhibition was performed under static conditions at 22 to 25°C over 96 hours on the freshwater alga *Selenastrum capricornutum* with the WAF of five concentrations of CMA 617 and a dilution water control. Preparation of the WAF involved mixing the solutions of CMA 617 for 24 hours, settling for 1 hour and siphoning off the WAF. The test substance was not heated prior to preparation of the WAF and the nominal concentrations of WAF were 0 (control), 0.5, 1.0, 3.0, 12 and 50 mg/L. Each test, including the control was conducted in triplicate with the cell density determined visually by means of

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

No effects (such as size differences, unusual cell shapes, colours, flocculations) were noted in any treatment. Analysis of the results using acceptable statistical methods (Kruskal and Wallis' test and Dunnett's test) provided a 96-hour EC50 of 5.8, EC50 of 8.7, 96 hour NOEC of 3 mg/L (based on the average number of cells/mL at each concentration) and a 96-hour NOEC of 3 mg/L (based on the average specific growth rate). CMA #617 is clearly toxic to this species well below its solubility in water limit.

An aliquot of test media taken from each 50 mg/L WAF at 96 hours, when cultured in fresh media for an additional 72 hours, revealed that the WAF at this nominal concentration was algistatic rather than algicidal.

10.5 Activated Sludge, Respiration Inhibition Test (TR Wilbury Laboratories Inc 1994a)
A test on the inhibition of activated sewage sludge respiration by CMA 617 was conducted under static conditions at 20.5 to 20.7°C with three concentrations of CMA 617 and controls. Nominal concentrations were 0 (control), 100, 300 and 1000 mg/L, with each test level in duplicate and a surface slick observed on the top of non-control test vessels with globules of test substance distributed throughout the test media. Preparation of the test solutions involved direct addition of CMA #617 to sterilised, filtered, dechlorinated tap water, without the use of a solvent. At time 0 for each test vessel, an aliquot of synthetic sewage was diluted to volume with water containing the appropriate concentration of CMA 617, followed by addition of an aliquot of microbial inoculum. After a 3-hour incubation period the dissolved oxygen content was measured for 10 minutes.

Inhibition of the activated sludge respiration was <50% of the control rate at all tested concentrations, indicating that CMA 617 was not acutely toxic. Exposure of the activated sludge to CMA 617 resulted in an EC50 >1000 mg/L, the highest tested nominal concentration. The three hour EC50 determined during a reference toxicant test with this batch of activated sludge and 3,5-dichlorophenol was 41 mg/L, thereby confirming the validity of the test and the remaining requirement for validation of the test viz. that control respiration rates are within 15% of each other.

10.6 Conclusion
Ecotoxicity data for the notified chemical indicate that based on the conditions of the individual tests, the chemical shows varying degrees of toxicity to fish, micro-invertebrates and alga tested up to the level of its solubility in water. However, it was found to be practically non-toxic to bacteria at the level of its water solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical is considered to be low provided that it is used as a component of natural gas and 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 by trained technicians with any used oil collected from the draining of the oil or engine repair incinerated or sent for recycling. However, a small percentage of the lubricant may be disposed of inappropriately down drains or to the environment if changed by DIY motorists.

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

The notified chemical is not expected to be readily biodegradable. However, if released to landfill or if associated with soil, it is expected to slowly degrade through biotic and abiotic processes resulting in the formation of water and oxides of carbon, sulphur and phosphorus. The zinc component will associate with the water compartment. Incineration would lead to water vapour, oxides of carbon, sulphur and phosphorus and the zinc assimilated into ash.

The ecotoxicity data provided indicate that the notified chemical is not toxic to bacteria up to the limit of its water solubility, but is toxic to fish, and particularly toxic to daphnia and algae, 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 the high molecular weight (>1000) suggests that a hazard to aquatic organisms is unlikely.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment
On the basis of studies conducted on OLOA 260, NEW OLOA 260 is expected to be of low acute oral and dermal toxicity. Inhalation studies have not been conducted but OLOA 260 is not expected to present an inhalation hazard. OLOA 260 is moderately irritating to eyes and skin. The hazard classification of NEW OLOA 260 is based on that of OLOA 260. NEW OLOA 260 is classified as an Irritant (Xi) R36/38 Irritating to eyes and skin under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999).

Further testing would be required to investigate the toxicological effects of NEW OLOA 260 after repeated exposure and the potential for sensitisation or genotoxicity. Testing for these endpoints on ZDDP, which are shorter chain analogues of the notified chemical, indicate toxicity after repeated dermal exposure, developmental effects and in vitro mutagenicity.

Occupational Health and Safety

Exposure to the additive package containing the most concentrated forms of the notified chemical (up to 10%) is expected to be limited to incidental skin contact to the additive package and is most likely during the procedures involved in connection and disconnection of pump lines and during sampling for laboratory analysis. Other scenarios of exposure to the notified chemical are at concentrations of less than 1.5% and this would also be limited to incidental skin contact. On the basis of low concentration of notified chemical, mode of use, use of personal protective gear and in situ engineering controls, significant risks to human health (systemic toxicity and skin and eye effects) through occupational exposure to the notified chemical are unlikely.

Public Health
Members of the public may have dermal contact with the notified chemical when using the engine oil products containing NEW OLOA 260. Given that the exposure is expected to be brief and intermittent, in small amounts and at low concentrations, the notified chemical is unlikely to pose a significant hazard to public health. Based on the use pattern of the notified chemical and its potential toxicological properties, NEW OLOA 260 is considered not to pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to formulations containing NEW OLOA 260 the following guidelines and precautions should be observed:

- Workers should receive regular instruction on good occupational hygiene practices in order to minimise personal contact, and contamination of the work environment with lubricant material. Follow the MSDS for the removal of contaminant material in the event of skin and eye contamination.

- Protective clothing and gloves are necessary in high exposure activities where skin contact is likely - consideration should be given to the ambient environment, physical requirements and other substances present when selecting protective clothing and gloves. Good hygiene practices dictate that eye protection be worn routinely. Workers should be trained in the proper fit, correct use and maintenance of their protective gear. Guidance in the selection, personal fit and maintenance of personal protective equipment can be obtained from:

Protective eyewear:	AS 1336 (Standards Australia 1994); AS/NZS 1337 (Standards Australia/Standards New Zealand 1992).
Protective clothing:	AS 3765.2 (Standards Australia 1990)
Impermeable gloves:	AS 2161.2 (Standards Australia 1998)
Protective footwear:	AS/NZS 2210.1 (Standards Australia/Standards New Zealand 1994a); AS/NZS 2210.2 (Standards Australia/Standards

New Zealand 1994b).

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

The finished lubricant may contain hazardous ingredients making the overall finished lubricant hazardous. Therefore, workplace practices, control procedures and hazard communication products consistent with provisions of State, Territory and Commonwealth legislation based on the *National Model Regulations for the Control of Workplace Hazardous Substances* (NOHSC 1994b) must be in operation.

NEW OLOA 260 is classified as a combustible liquid (C2) in accordance with AS 1940 (Standards Australia 1993) and stored and handled in compliance with State, Territorial and Commonwealth regulation for storage and handling of dangerous goods.

Spillage of formulations containing NEW OLOA 260 should be avoided. Spillages should be cleaned up promptly and in accordance with the instructions on the notifiers MSDS.

14. MATERIAL SAFETY DATA SHEET

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

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under subsection 64(1) of the Act the notifier is to advise of any new toxicological data on OLOA 260 or NEW OLOA 260 available for assessment.

Under the Act, the director must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise.

The Director is to be advised in writing within 28 days of any new information. Secondary notification of the notified chemical may be required.

16. REFERENCES

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Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

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

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

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

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
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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Draize J. H. (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49 : 2-56.