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1 May 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

CP 7077

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

CP 7077

1. APPLICANT

Chevron Chemical Australia of Level 22, 385 Burke Street, Melbourne Victoria 3000 has submitted a standard notification statement in support of their application for an assessment certificate for CP 7077.

2. IDENTITY OF THE CHEMICAL

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

Trade Name:	OLOA 271 (containing a maximum of 70 % of the notified chemical)

The notified chemical is a UVCB.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	dark brown, viscous liquid
Melting Point:	not provided (pour point 15°C)
Specific Gravity:	0.982 g/cm^3 at 20ºC
Vapour Pressure:	no data presented; notifier claims that it should be negligible for this chemical, and the MSDS states 0.000013 kPa at 20°C
Water Solubility:	≤ 39 mg/L
Partition Co-efficient (n-octanol/water):	expected to be >3; see comments below

Hydrolysis as a Function of pH:	no data presented; see comments below
Adsorption/Desorption:	no data presented; see comments below
Dissociation Constant:	no data presented
Particle Size:	not applicable as the notified chemical is liquid
Flash Point:	212°C
Flammability Limits:	no data presented; expected to be flammable
Autoignition Temperature:	no data presented
Explosive Properties:	not explosive
Reactivity/Stability:	not reactive; stable under normal conditions

Comments on Physico-Chemical Properties

Measurements of pour point, specific gravity, water solubility and flash point were performed by Analytical Sciences at the Chevron Research & Technology Company, Richmond, California. A full test report was submitted for water solubility only.

According to the notifier, no boiling point could be determined for CP 7077. At about 215ºC, components begin to distill away. At about 420ºC the final components begin to decompose. The notifier has also indicated that the vapour pressure is negligible due to the notified chemical's ionic nature.

Concentrations of the notified substance in water were determined by the total organic carbon (TOC) analysis of the equilibrated solutions based on per cent carbon information.

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

The notifier has estimated the partition coefficient to be > 3. Though there are no test reports to support this claim, the estimated value seems appropriate due the high molecular weight and high hydrocarbon content of the substance. This value is relatively high and the chemical can be expected to bind strongly to, or be associated with, soil and sediment. Hence, due to the detergent nature of OLOA 271 (strong surface activity) and micelle formation tendencies, the OLOA 271 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 nature of this substance and the tendency to form micelles indicates dissociation is unlikely.

4. PURITY OF THE CHEMICAL

Degree of Purity: 99% (typical range 97-100%)

Toxic or Hazardous Impurities: none

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

Chemical name:	Dilution Oil 100 N
Synonyms:	heavy paraffinic petroleum distillate
Weight percentage:	1 (range 0-3)
CAS No.:	64741-88-4 and 64742-54-7
:	The dilution oils are not classified as hazardous based on the results of the DMSO extraction procedure as defined by IP 346. The DMSO extract is routinely well below 3 %.

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

CP 7077 is a detergent, added to a lubricating oil formulation for marine diesel engines in large ocean-going vessels. Its purpose is to prevent deposits, but also acts as an acid neutraliser and antioxidant. It reduces deposits on pistons and in the engine crankcase and controls oxidation in the lubricant at high temperatures.

It is to be imported as part of a lubricating oil additive preparation, comprising a maximum 70 % of the preparation. The preparation will be blended into the final lubricating oil in Australia. The concentration of CP 7077 in the final lubricating oil will range from 10 to 40 %.

An estimated 400 tonnes of additive, containing approximately 280 tonnes of the notified chemical, will be imported annually for the first five years.

6. OCCUPATIONAL EXPOSURE

CP 7077 will be imported as a component (70 %) of a lubricating oil additive and will be shipped in 200 litre steel drums, or in bulk. The additive will be reformulated into the final lubricating oil at various customer sites comprising the major oil companies around Australia, for use in diesel engines of ocean-going vessels.

Since the notified chemical will always be handled in solution in Australia, the most likely means of exposure will be via skin and eye contact. Inhalation exposure may occur if mists or aerosols are generated at any time (e.g. during mixing of solutions).

The number and categories of workers that may be exposed to the notified chemical are estimated as follows :

waterside workers	2-4
transport drivers (per customer)	1-2
warehouse workers (per customer)	2-4
QC technicians (per customer site)	1-2
blending and packaging workers (per customer site)	2-4
marine engine mechanics	10-20.

The total number of workers involved in transportation, reformulation and drumming in Australia is expected to be less than 100.

Transport and storage (1-2 hours/day; 10 days/year)
Upon receipt at the waterside docks, the containers (drums or bulk) will be conveyed to the various customer sites (blending plants). Transport within Australia will be by rail car or tank truck.

At the blending plant, the contents of the imported containers will be transferred to a bulk storage tank through a 10cm diameter hose. There is potential for worker exposure from spills and splashes during the coupling and uncoupling of the hose. Workers will wear gloves, coveralls and eye protection. A special air-back flush system is incorporated to prevent such losses and the area is bunded to contain spills. Worker exposure may also occur during the cleaning of containers after transfer to storage tanks.

The blending process (1-2 hours/day; 20 days/year)
The additive is blended with motor oil and various other ingredients (e.g. dispersants, anti-foam, zinc dithiophosphate) by pumping the lubricant oil and additives through computer controlled valves that meter the precise delivery of the components into a blending tank. Mixing takes place at 60^{o}C.

After blending, the product is sampled from the tank by quality control workers who test the physico-chemical properties of the blend. The finished diesel engine lubricant is then packaged into 200 litre drums, or as bulk in tank trucks. The drumming facility uses automated weigh scales to fill the drums. Bungs and labels are applied by the operators. The CP 7077 is present at a maximum concentration of 40 %. A typical batch size will be sufficient for one ship (i.e. 6000 kg of the notified chemical).

Exposure to the notified chemical is possible during the drum filling and quality control work. However, all workers are equipped with standard protective clothing, as well as standard safety goggles/glasses and hand protection. Workers will receive training in all aspects of occupational health and safety relevant to CP 7077. Facilities are stated to be well ventilated, while the transfer of notified chemical between containers and the blending process are fully automated and performed in enclosed systems. Exposure in the event of accidental spillage will be controlled by local bunding and barriers, while spills are to be collected by suction and sent to on-site waste treatment facilities utilising American Petroleum Institute (API) oil-water separation and sand filtration.

Worker exposure may also occur during the cleaning and maintenance of the blending tank and equipment.

End Use
At the ship, the oil is transferred from the bulk containers to storage tanks via hoses. The notifier states that procedures (not described) are in place to ensure that spillage is minimised during transfer. However, skin contact with the notified chemical may occur during coupling and uncoupling the transfer hoses.

During its use in the diesel engine, the majority of the notified chemical will be combusted (98 %). The balance will consist of calcium deposits.

Marine engine mechanics may be exposed to the notified chemical during maintenance and overhaul of the ships' engines. These workers are stated to wear protective clothing but not normally safety goggles and glasses or gloves.

7. PUBLIC EXPOSURE

As the notified chemical is intended to be used in an industrial environment during all phases of its life cycle, including transport, reformulation, use and disposal, the potential for public exposure to the notified chemical is considered to be negligible.

8. ENVIRONMENTAL EXPOSURE

Release

The OLOA 271 containing additive package will arrive at the customer's blending plant by rail car or tank truck. The oil is transferred to a storage tank through a hose and an air back flush system prevents any spillages. The notifier estimates that 10 kg per annum of the new substance would be released during this process. The hose end is kept in an oily drain when not in use and the contents of the drain are treated on site. The rail cars or tank trucks are generally cleaned with steam and the waste water treated on site and it is estimated that 100 kg per annum will be released during this process.

Waste water containing OLOA 271 is sent to an on-site chemical waste water system that includes an API water and oil separator, air flotation and sand filtration. As a result of API oil separation no more than 5 % of the OLOA 271 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 notifier estimates that 20 kg per annum of the new substance would be released during the unloading process.

The oil blending process involves combining lubricating oil blend stocks, pour point depressants, foam inhibitors and additive package in a blending tank. It is estimated that 20 kg per annum of the notified substance will be released during this process. The blend tank is periodically cleaned with lube oil that is either recycled into future blends or is incinerated after separation from waste water. The notifier estimates that 100 kg per annum of the new substance is further released during this process.

After blending, the finished marine products are packaged into 200 L drums or sold as bulk in tank trucks. The notifier estimates that another 20 kg per annum of the new chemical is released during this process. After filling, the delivery lines are placed over oily drains which catch any spilt product. The lines are cleaned with lube oil which is recycled during future blending operations or incinerated. The notifier estimates that 20 kg per annum of the new substance is released during the product loading process.

These losses are summarised in the following table:

Possible Source of Release	***Annual Quantity Expected to be released***
Transfer from transport to storage containers	10 kg
Residue in storage containers/cleaning by steam	100 kg
Transfer to blending tanks	20 kg
Cleaning of blending tank	100 kg
Transfer to drums	20 kg
Charging of ships	20 kg

Overall, 270 kg of waste OLOA 271 is released/annum/customer 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 13.5 kg of OLOA 271 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 spilt product could be sucked up with the remaining product in the on-site waste water system. The finished lubricant will be sold in drums or bulk to owners of large ocean going diesel powered vessels.

During use, OLOA 271 is not substantially altered and does not decompose in the crankcase

due to its high thermal stability. However, this material is burned in the engine oil during oil consumption. The insolubles and particulate matter become coated with OLOA 271 detergent and can be filtered out of the oil. The lost detergent properties in the oil are replaced as fresh oil is added. Generally, used oils from oil drains are not generated from marine service. Fresh oil is continuously added during engine operation unless the engine is brought in for maintenance or overhaul. Used oil from these maintenance operations is likely to be incinerated or sent to a used oil recycler.

Fate

The amount of waste OLOA 271 disposed of to sewer is expected to be minimal as waste water from the blending operations is treated on-site and the hydrocarbon fraction is separated and incinerated. Any remaining OLOA 271 present in waste water disposed of 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 271 entering receiving waters is remote.

Biodegradation
A study was performed to assess the ready biodegradability of OLOA 271 using the Closed Bottle Test (OECD TG 301D). Sealed bottles containing the test substance (6.5 mg/L) and inorganic nutrient medium were inoculated with activated sewerage sludge bacteria and incubated for up to 28 days at 20°C. Biodegradation was assessed by the determination of CO_2 produced. The test substance attained 2 % degradation after 28 days. Therefore, OLOA 271 may not be termed readily biodegradable.

Bioaccumulation
No studies were provided. 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 expected limited exposure to water is likely to inhibit the bioaccumulation potential of OLOA 271.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of CP 7077

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} >5 g/kg	Driscoll, 1998a
acute dermal toxicity	rat	LD_{50} >2 g/kg	Driscoll, 1998b
skin irritation	rabbit	moderate irritant	Driscoll, 1998c
eye irritation	rabbit	slight to moderate irritant	Driscoll, 1998d
skin sensitisation	guinea pig	weak sensitiser	Driscoll, 1998e; Morris, 1998

9.1.1 Oral Toxicity (Driscoll, 1998a)

Species/strain:	rat/Sprague-Dawley CD
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	single limit dose of 5000 mg/kg; administered by gavage as a dispersion in arachis oil BP
Test method:	limit test, as in EC Annex to Directive 92/69/EEC and OECD TG 401
Clinical observations:	hunched posture was common, with additional signs of diarrhoea and pilo-erection; isolated signs of ataxia, lethargy, ptosis, decreased respiratory rate, laboured respiration and red-brown staining around eyes; all animals recovered by day 4 after dosing
Mortality:	one female died 2 days after dosing – not related to treatment
Morphological findings:	no abnormalities observed
LD_{50}:	> 5000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Driscoll, 1998b)

Species/strain:	rat/Sprague-Dawley CD
Number/sex of animals:	five/sex
Observation period:	14 days
Method of administration:	single, 24-hour semi-occluded, dermal application to intact skin (shorn flank) at a dose level of 2000 mg/kg bodyweight
Test method:	according to OECD TG 402
Clinical observations:	no signs of systemic toxicity observed; signs of dermal irritation, including slight to moderate erythema, desquamation, leathering and fissuring
Mortality:	no deaths observed during the study
Morphological findings:	no abnormalities observed
LD_{50}:	> 2000 mg/kg
Result:	the notified chemical was of low acute dermal toxicity in rats

9.1.3 Skin Irritation (Driscoll, 1998c)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	6 males
Observation period:	72 hours for determination of Primary Irritation Index 14 days for determination of reversibility of changes
Method of administration:	single four hour, semi-occluded application (0.5mL of notified chemical, pH 5.5) to intact skin of shorn dorsal flank
Test method:	OECD TG 404

Draize scores (Driscoll, 1998c):

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

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

Comment:

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

other reactions included light brown discolouration of the epidermis, loss of skin elasticity and flexibility, crust formation, desquamation, scabbing and reduced or increased fur growth; no corrosive effects observed;

after 14 days the reactions induced by the notified chemical were not fully reversible;

Primary Irritation Index = 3.9

Result:

the notified chemical was moderately irritating to the skin of rabbits

9.1.4 Eye Irritation (Driscoll, 1998d)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	Group 1 : 1 female, 5 males Group 2 : 3 males
Observation period:	14 days
Method of administration:	Group 1 (unirrigated): 0.1mL of notified chemical, pH 5.5 instilled into the conjunctival sac of the left eye (right eye = control) Group 2 (irrigated): same as Group 1, except the chemical was washed out after 30 seconds
Test method:	according to OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation									
Animal	***1 day***		***2 days***		***3 days***		***4 days***		***7 days***	
Cornea	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***
1 (female)	1[1]	1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0
3	1	3	2	2	1	1	1	1	0	0
4	0	0	0	0	0	0	-	-	-	-
5	0	0	0	0	0	0	0	0	0	0
6	1	2	2	1	2	1	1	1	0	0
Iris										
1 (female)	0		0		0		0		0	
2	0		0		0		0		0	
3	1		1		0		0		0	
4	0		0		0		-		-	
5	0		0		0		0		0	
6	1		1		0		0		0	

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

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

Comments:

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

diffuse to translucent corneal opacity observed in 3 eyes, iridial inflammation in two and conjunctival irritation in all treated eyes;

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

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

conjunctival irritation noted in all three irrigated eyes, however, no corneal or iridial effects were noted;

no effects were observed after 72 hours

Result:

the notified chemical was a slight to moderate irritant to the eyes of rabbits

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

Species/strain:

albino guinea pig/Dunkin-Hartley

Number of animals:

20 test and 10 controls in the main study; all females

Induction procedure:

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

- Freund's Complete Adjuvant (FCA) : distilled water (1:1 v/v)
- 5 % w/v of notified chemical in arachis oil BP
- 5 % w/v of notified chemical in a 1:1 mixture of FCA and distilled water
-

for the negative control group, the notified chemical was replaced with arachis oil BP

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

Challenge procedure:

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

Rechallenge procedure

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

Test method:

Magnusson and Kligman maximisation test, according to OECD Guideline No. 406

Challenge outcome:

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

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

Rechallenge outcome:

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

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

Comment: there were no dermal reactions in either group with the 10 % challenge; for the 25 % challenge, different animals exhibited skin reactions after the first challenge and the rechallenge

Result: there was slight evidence that the notified chemical was sensitising to the skin of guinea pigs

9.1.6 Skin Sensitisation – Buehler Test (Morris, 1998)

Species/strain: albino guinea pig/Dunkin-Hartley

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

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

three induction exposures of six hours duration, at intervals of 6 or 7 days, were applied to the one site;

for the negative control group, the notified chemical was replaced with mineral oil

Challenge procedure: two weeks after the last induction, induced animals exposed to 5% w/v notified chemical in mineral oil on a previously untreated site;

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

Test method: an adaptation of the method of Ritz and Buehler (1980)

Challenge outcome:

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

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

Comments: 6 out of 20 test animals and 1 out of 10 control animals showed slight but confluent, or moderate patchy erythema (rated as a positive response), at 24 hours; all other test and

	control animals responding to the challenge exhibited slight, patchy erythema; all test animals and 9 out of 10 controls exhibited slight, patchy erythema at 48 hours; overall the severity of responses was comparable at 24 hours between the test and control groups (mean scores of 0.7 and 0.6, respectively), but the incidence of clear positive responses was higher in the test group (30 %) compared with the controls (10 %)
Result:	the notified chemical was a weak sensitiser to the skin of guinea pigs

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

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

Clinical observations:

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

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

Clinical chemistry / Haematology

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

Reduced cholesterol was seen for all male and female treated groups, the effect being dose-related to a degree, but most marked at 500 and 1000 mg/kg/day. Increased glutamic pyruvic transaminase (GTP) values were noted for both sexes receiving 1000 mg/kg/day and females receiving 500 mg/kg/day.

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

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

Pathology:

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

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

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

Conclusions:

Pathological changes (statistically significant), including effects on bodyweight (males), organ weights (males and females), haematology (males), biochemistry (males and females) and histopathology (males and females) were seen at 500 mg/kg/day. Adrenal weight changes and hypertrophy were found at all doses, but not always in both sexes. The authors did not consider these effects were toxicologically important. Clinical signs (salivation and hair loss) were seen at all doses. Considering these findings, a No Observed Effect Level (NOEL) cannot be established. The study authors concluded a No Observed Adverse Effect Level (NOAEL) of 100 mg/kg/day.

Comment

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

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* / *Escherichia coli* Reverse Mutation Assay

(Thompson, 1998)

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

Conclusion:	the notified chemical was not mutagenic to the bacterial strains tested

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

Species/strain:	mouse/ albino Crl : CD-1^{TM} (ICR) BR
Number and sex of animals:	2/sex/group in the range-finding study 7 males/group for the main study
Doses:	0, 500, 750, 1000 and 2000 mg/kg in the range-finding study 0, 187.5, 375 and 750 mg/kg for the main study; positive and negative controls were administered cyclophosphamide and arachis oil, respectively; in each treated group, animals were killed after 24 hours, except for the 750 mg/kg group some mice were killed after 48 hours
Method of administration:	single intraperitoneal injection
Test method:	according to OECD TG 474

Results:

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

In the main study, animals were treated with 187.5, 375 mg/kg/day, or the maximum tolerated dose from the range finding study of 750 mg/kg/day. There was a small but statistically significant increase in the incidence of micronucleated polychromatic erythrocytes in animals receiving the 187.5 and 375 mg/kg doses at 24 hours when compared with the concurrent vehicle control group. The response observed was inversely dose-related and did not exceed the upper limit of the current historical background range for vehicle control values. Therefore, it was considered that the increases had no toxicological significance.

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

The positive controls produced a marked increase in the frequency of micronucleated polychromatic erythrocytes.

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

9.4 Overall Assessment of Toxicological Data

The notified chemical displayed very low acute oral and low dermal toxicity in the rat (LD_{50} > 5000 mg/kg and LD_{50} > 2000 mg/kg, respectively). No acute inhalation toxicity data were presented. The notifier stated that no study has been conducted and that due to the high molecular weight, expected low vapour pressure and viscous nature, the notified chemical is unlikely to generate vapours during use and is not likely to pose a major hazard via inhalation.

The notified chemical produced moderate irritation to the skin of rabbits, sufficient to warrant classification as a skin irritant based on the persistence of the adverse reactions, according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1994a) (Approved Criteria).

The notified chemical was slightly irritating to the eyes of rabbits. Some evidence of skin sensitisation was noted in a Magnusson and Kligman guinea pig maximisation test. In a Buehler test, the chemical also gave equivocal results, indicating weak sensitising potential. The response is not sufficient to warrant classification as a skin sensitiser under the Approved Criteria.

In a 28 day repeat dose oral rat study, the notified chemical caused pathological and biochemical changes at the mid and high dose, and clinical signs of salivation and hair loss at all doses. Adrenal effects seen at all doses were not believed to be toxicologically important by the study authors. A NOEL could not be established. On the basis of the results of this 28-day study, the proposed 90-day study for the notified chemical (for which the 28 day study is stated to be range-finding) is warranted.

The notified chemical was not mutagenic to the bacterial strains tested in reverse mutation assays in *Salmonella typhimurium* and *Escherichia coli*, with and without S9 metabolic activation. It also did not produce genotoxic effects in the *in vivo* mouse micronucleus assay.

Based on the toxicological data provided, the notified chemical is a hazardous substance due to its skin irritation properties and should carry the risk phrase R38, “Irritating to skin”.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided the following ecotoxicity data in support of their application.

Test	*Species*	*Result*
Acute toxicity	Rainbow trout (*Oncorhynchus mykiss*)	NOEC >1000 mg/L (as WAF)
Acute toxicity	*Daphnia magna*	NOEC = 0.56 mg/L (as WAF)** NOEC = 22 mg/L (as WAF)
Growth inhibition	Green algae (*Pseudokirchneriella subcapitata*)	NOEC = > 1000 mg/L (as WAF)
Sludge inhibition		NOEC > 1000 mg/L (as WAF)

* NOEC - no observable effect concentration

**First study undertaken for *Daphnia Magna*.

The ecotoxicity tests were performed in accordance with OECD Test Guidelines. The test substance 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 water accommodated fraction (WAF) was then withdrawn via a siphon prior to testing.

Rainbow Trout (Oncorhynchus mykiss):
The tests on rainbow trout were performed using a semi-static test methodology. Three groups of 10 fish were exposed to a nominal concentration of 1000 mg/L of the test substance as the WAF. The cumulative mortality was recorded after 3, 6, 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.

Daphnia magna:
The tests on *Daphnia magna* were performed using a 48 hour static acute immobilisation study. Two groups of 10 daphnids were exposed to nominal loading (WAF) rates of 0, 0.10, 0.18, 0.32, 0.56, 1.0, 1.8. 3.2, 5.6 and 10 mg/L. The percent immobilisation was recorded after 24 and 48 hours. The NOEC was determined to be 0.56 mg/L and considered to be very toxic.

The above was repeated due to the unexpected toxicity found in the first study. The second test was specifically developed for the testing of petroleum additives. The test was performed under static conditions using two groups of 10 daphnids exposed at nominal concentrations of 0, 13, 22, 36, 60 and 100 mg/L, for 48 hours. The 48 hour median EC_{50} was 39 mg/L WAF, based on nominal concentrations. The 48 hour NOEC was 22 mg/L.

Algal Growth Inhibition (Pseudokirchneriella subcapitata):
Pseudokirchneriella subcapitata were exposed to a WAF of the test material at a loading rate

of 1000 mg/L (in triplicate flasks) for 96 hours. Samples of the algal populations were removed daily and cell concentrations determined for each control and treatment group. The NOEC was determined to be greater than 1000 mg/L WAF loading rate.

Activated Sludge Inhibition:
The effect of CP 7077 was investigated on the respiration of activated sewage sludge. The test involved using 1000 mg/L of CP 7077 in triplicate and aerating for 3 hours at 21°C in the presence of activated sludge plus synthetic sewage as a respiratory substrate. The rate of respiration was measured after 30 minutes and 3 hours. The positive control was 3,5-dichlorophenol. The 3 hour EC_{50} and NOEC were greater than 1000 mg/L.

Results based on nominal concentrations indicate that OLOA 271 is non-toxic to the organisms tested to the limit of its water solubility. *Daphnia magna* was an exception to the above findings with the WAF being considerably more toxic.

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 into the blending process. Overall, approximately 270 kg of waste OLOA 271 will be generated per annum at each of the six 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), approximately 13.5 kg per annum of OLOA 271 is likely to enter the sewer from each of the blending sites. OLOA 271 is expected to be associated with the sludge at sewerage treatment works and its ultimate fate will either be in landfill or incineration.

The ecotoxicity data for the notified chemical indicate that it is not toxic to fish, algae or sludge growth. The toxic levels for daphnia are high but due to the low amounts released into the aquatic compartment and the dispersion of the notified substance amongst the six potential blending sites, the exposure will be low. Hence the overall environmental hazard of the notified chemical will be low when used in marine diesel engine oils.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is of low acute oral and dermal toxicity. The notified chemical produced moderate and persistent irritation to the skin of rabbits, sufficient to warrant classification as a skin irritant, according to the Approved Criteria. The risk phrase R38 ‘Irritating to skin’ should be applied. The notified chemical was slightly irritating to the eyes of rabbits. In Magnusson and Kligman and Buehler tests, the chemical was a weak sensitiser to guinea pig skin, however, the response was insufficient to warrant classification as a skin sensitiser under the Approved Criteria. The results are, however, sufficient to indicate that precautions should be taken to avoid skin contact with the notified chemical.

In a 28 day repeat dose oral rat study, the notified chemical caused pathological and biochemical changes at the mid and high dose, and clinical signs of salivation and hair loss at all doses. The toxicological significance of adrenal effects seen at all doses is uncertain. A NOEL could not be established. On the basis of the results of this 28-day study, the proposed 90-day study for the notified chemical (for which the 28 day study is stated to be range-finding) is warranted.

The notified chemical was not mutagenic in *in vivo* and *in vitro* test systems. The paraffinic petroleum distillate listed as an impurity in the notified chemical is a Category 2 carcinogen, with a concentration cutoff 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. The notifier has provided information which shows that the condition is satisfied in this case, and accordingly classification will not be required.

Occupational Health and Safety
The notified chemical will be imported in bulk vessels or 200 L drums as a component (up to 70 % (w/w)) of a lubricant additive package. The additive package will be reformulated in Australia, by blending with engine oil. The final product is then repackaged into containers for transport to the industrial end user, generally in 200 L drums or bulk tanks.

Dermal exposure would be the predominant route of occupational exposure to the notified chemical. Inhalation exposure is expected to be minimal because 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 irritant and possible 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 and blending the additive into oil may be exposed to drips and spills of the additive package, containing 70 % notified chemical. Occupational exposure to the drips and spills of the final lubricating oil containing up to 40 % notified chemical is possible for workers handling of the final lubricating oil and during disposal. Workers involved in cleaning and maintenance of tanks and blending equipment, and of the engines using the final lubricating oil, may also have general dermal exposure to oil residues. It is recommended that all workers handling the notified chemical and the lubricating oil containing the notified chemical, including ships engineers, wear gloves when potentially exposed.

Waterside workers are unlikely to be exposed to the notified chemical under normal working conditions, unless contamination occurs via damaged packaging. With intact packaging, the occupational health risk posed to these workers is considered negligible.

Public Health
Based on the negligible exposure to the public, it is considered that the notified chemical will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

- That the 90 day repeated dose study report be forwarded to NICNAS when completed to determine whether further regulatory action is required;

- That the additive package and the oil containing the additive be labelled with the following risk phrases

  R38 'Irritating to skin'
  R45(2) 'Causes cancer'

  unless it can be demonstrated that R45(2) is not required;

- The notified chemical may be recommended to the National Occupational Health and Safety Commission for consideration for inclusion in the NOHSC List of Designated Hazardous Substances.

To minimise occupational exposure to notified chemical the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard AS 1336 (Standards Australia, 1994) and comply with Australian/New Zealand Standard AS/NZS 1337 (Standards Australia/Standards New Zealand, 1992); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990); impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);

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

- Good personal hygiene should be practised to minimise the potential for ingestion;

- Workers should be advised to report any skin changes to the occupational health and safety officer at their workplace; and

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

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994b).

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, secondary notification will be required if the results of the 90 day repeat dose toxicity study mentioned in the report of the 28 day repeat dose toxicity study becomes available to the notifier, and if evidence of human skin sensitisation is found. Secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

Driscoll R (1998a) *SP 7077 (C1829-49): Acute Oral Toxicity Study in the Rat*. SPL Project Number: 703/088. Safepharm Laboratories Limited, Derby, UK.

Driscoll R (1998b) *SP 7077 (C1829-49): Acute Dermal Toxicity Study in the Rat.* SPL Project Number: 703/089. Safepharm Laboratories Limited, Derby, UK.

Driscoll R (1998c) *SP 7077 (C1829-49): Acute Dermal Irritation Test in the Rabbit*. SPL Project Number: 703/090. Safepharm Laboratories Limited, Derby, UK.

Driscoll R (1998d) *SP 7077 (C1829-49): Primary Eye Irritation Test in the Rabbit*. SPL Project Number: 703/091. Safepharm Laboratories Limited, Derby, UK.

Driscoll R (1998e) *SP 7077 (C1829-49): Magnusson & Kligman Maximisation Study in the Guinea Pig*. SPL Project Number: 703/092. Safepharm Laboratories Limited, Derby, UK.

Durward R (1998) *SP 7077 (C1829-49): Micronucleus test in the Mouse*. SPL Project Number: 703/093. Safepharm Laboratories Limited, Derby, UK.

European Commission (1992a) *EEC Methods for the Determination of Toxicity, Part B, Annex to Commission Directive 92/69/EEC*. Official Journal of the European Communities No. L383A, December 1992.

European Commission (1992b) *EEC Methods for the Determination of Physico-Chemical Properties, Part A, Commission Directive 92/69/EEC*. Official Journal of the European Communities No. L383A, December 1992.

Jones K (1998) *SP 7077 (C1829-49). Toxicity Study by Oral Administration to CD Rats for 4 Weeks*. Huntingdon Life Sciences Ltd., Cambridgeshire, UK.

Morris TD (1998) *Delayed Contact Hypersensitivity Study with SP 7077 in Guinea Pigs (Buehler Technique)*. Hill Top Project Number: 97-8517-21. Hill Top Research, Inc., Miamiville, OH.

National Occupational Health and Safety Commission (NOHSC, 1994a) *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (NOHSC, 1994b) *National Code of Practice for the Preparation of Material Safety Data Sheets* [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

Ritz HL and Buehler EV (1980). In, *Current Concepts in Cutaneous Toxicity* (VA Drill and T Lazar, eds.). Academic Press. Pp. 25-40.

Standards Australia (1987) *Australian Standard 2919-1987, Australian Standard Industrial Clothing*. Standards Australia, Sydney.

Standards Australia (1990) *Australian Standard 3765.1-1990, Australian Standard Clothing for Protection Against Hazardous Chemicals Part 1: Protection Against General or Specific Chemicals*. Standards Australia, Sydney.

Standards Australia (1994) *Australian Standard 1336-1994, Australian Standard Eye Protection in the Industrial Environment*. Standards Australia, Sydney.

Standards Australia/Standards New Zealand (1992) *Australian/New Zealand Standard 1337-1992, Australian/New Zealand Standard Eye Protectors for Industrial Applications*. Standards Australia and Standards New Zealand, Sydney/Wellington.

Standards Australia/Standards New Zealand (1994) *Australian/New Zealand Standard 2210-1994, Australian/New Zealand Standard Occupational Protective Footwear*. Standards Australia and Standards New Zealand, Sydney/Wellington.

Standards Australia/Standards New Zealand (1998) *Australian/New Zealand Standard 2161.2-1998, Australian/New Zealand Standard Occupational Protective Gloves Part 2: General Requirements*. Standards Australia and Standards New Zealand, Sydney/Wellington.

Thompson, PW (1998) *SP 7077 (C1829-49):* Salmonella typhimurium *and* Escherichia coli */ Mammalian – Microsome Reverse Mutation Assay*. SPL Project Number: 703/083. Safepharm Laboratories Limited, Derby, UK.

Attachment 1

The Draize Scale 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 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