File No: NA/253

Date: 17 August, 1995

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

OLOA 270

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989,* and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Human Services and Health.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

For Enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 565-9466 **FAX (61) (02) 565-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

OLOA 270

1. APPLICANT

Chevron Chemical Company of State Bank Building, Level 22, 385 Bourke St Melbourne, Victoria, 3000, Australia has submitted a standard notification for assessment of OLOA 270.

2. IDENTITY OF THE CHEMICAL

OLOA 270 has ben classified as hazardous by Worksafe Australia due to its skin sensitisation properties. However, for commercial reasons, the chemical name has been exempted from publication in the Full Public Report and the Summary Report.The conditions of this being permitted are:

- A descriptive generic name be used to identify the substance in public reports and the MSDS,
- The relevent employee unions shall be informed of the conditions of use of OLOA 270,
- The full chemical name shall be provided to any health professionals in the case of a legitimate need where exposure to the chemical may involve a health risk,
- The full chemical name shall be provided to those on site who are using the chemical and to those who are involved in planning for safe use, etc. in the case of legitimate need,
- Confidentiality will expire after a 3 year period,
- The chemical will be identified as a sensitiser in the Health Effects Section of the MSDS, and that reference to its assessment by NICNAS be made on the MSDS.
- These conditions shall be published in the Chemical Gazette.

Chemical Abstracts Service (CAS) Registry No.:	not available
Other name:	Phenalate, sp & cp 7053 long chain alkyl phenate, calcium salts.
Trade name:	OLOA 270

Molecular formula: see attachment 1

Structural formula: see attachment 1

Method of detection and determination:
The compound may be detected and analysed by infrared, ^{13}C NMR and UV spectroscopy.

Spectral data: Major peaks and impurities identified by mass spectrometry.

3. PHYSICAL AND CHEMICAL PROPERTIES (1).

Appearance at 20°C and 101.3 kPa:	Dark brown viscous liquid
Melting Point/Boiling Point:	Expected to decompose before boiling point is reached.
Specific Gravity/Density:	0.00118 kg/m^3 at 15°C
Vapour Pressure:	0.000037 Pa at 25°C
Water Solubility:	40.9 mg/L at 20°C
Fat Solubility:	Not provided
Partition Co-efficient (n-octanol/water) log P_{ow}:	>6.6
Hydrolysis as a function of pH:	Stable to base, strong acid will neutralise salt, reaction limited. `
Adsorption/Desorption:	OLOA 270 having strong surface activity will partition from water to solids or organic matter.
Dissociation Constant pK_a**:**	Will not dissociate
Flash Point:	>180°C
Flammability Limits:	Not quantified but is combustible.
Combustion Products:	Not provided
Pyrolysis Products:	Not provided
Decomposition Temperature:	Not provided

Decomposition Products:	Not provided
Autoignition Temperature:	>200°C
Explosive Properties:	Not known to be explosive
Reactivity/Stability:	Will react with and should be stored away from strong oxidising materials
Particle size distribution:	Not applicable

4. PURITY OF THE CHEMICAL

Degree of purity:
As manufactured in lube oil it will be 59.1% pure. Without the oil it will be 89.1% pure.

Impurities:

.	**Chemical name:**	Phenol, tetrapropenyl derivatives
	CAS No.:	74499-35-7
	Weight percentage:	2%
	Chemical name:	Phenol, C_{18-30} derivatives
	CAS No.:	68784-24-7
	Weight percentage:	2%
	Chemical name:	Sulfurised 2-hydroxybenoic acid, tetrapropenyl and C_{18-30} alkyl derivatives, calcium salts.
	CAS No.:	not available
	Weight percentage:	<2%
	Chemical name:	Phenol C_{18-30} alkyl derivatives calcium salts.
	CAS No.:	not available
	Weight percentage:	2%
	Chemical name:	Phenol, tetrapropenyl derivatives calcium salts.
	CAS No.:	not available
	Weight percentage:	2%

Additive/Adjuvant:

.	**Chemical name:**	Solvent neutral oil.
	CAS No.:	64741-88-4
	Weight percentage:	30%

It is unknown whether the skin sensitisation reaction associated with this chemical is a product of the chemical itself or the impurities. Given the relative percentages however, it is more likely that it is due to the notified chemical. All compounds within the formulation have been identified however, by Mass Spectrometry.

5. INDUSTRIAL USE

The notified chemical will be primarily used in the blending of marine diesel engine oils used in ocean-going vessels. It is used to reduce deposits on pistons and in the engine crankcase and to control oxidation of the lubricant from high temperatures. The mixed calcium salts of the alkylsalicylate and sulfurised alkylphenate detergents are used to formulate marine diesel engine lubricating oils. The chemical will be imported into Australia as part of a lubricating oil additive package. Estimated volume of OLOA 270 which will be imported into Australia is approximately 400,000 kg/year of the oil-containing product or 280,000 kg/year of the oil-free substance.

6. OCCUPATIONAL EXPOSURE

The additive packages containing the OLOA 270 (which will be imported into Australia) will be blended in France and/or the United States. There are approximately four Australian customers who will buy the blended products. They will be blended into finished oil at lubricating oil blending facilities owned by the Australian customers. The typical concentration of the OLOA270 (70% in an oil solution) in the final finished lubricant will be 1-15%. OLOA 270 containing additive packages will be shipped to Australia in bulk or isotanker and stored in bulk storage tanks. The OLOA 270 containing additive package products arrive at a typical Australian customer's blending plant by rail car or tank truck. The additive package is transferred to a storage tank through a four inch hose. One worker, wearing full protective clothing, gloves, and eye protection, spends 10 minutes fastening the end of the hose to the tank car. Procedures exist to ensure that there is no spillage due to loose connections between hose and tank car.

One worker, wearing full protective clothing, gloves and eye protection, spends ten minutes uncoupling the hose from the tank car. A special air back flush system prevents any spillage.

Finished oil blending is done by pumping the lubricating oil blend stocks and the additive package from their storage tanks through computer controlled valves that meter the precise delivery of the components into a blending tank. The finished lubricant is blended at about 60°C. Exposure to workers can occur during sample removal for laboratory analysis. After blending, the product is sampled from the blend tank by one or two workers to ensure the physical and chemical properties of the finished lubricant are met, wearing eye protection, gloves and protective clothing. The finished lubricant analysis is done in a laboratory by one or two workers and takes only a few minutes.

After blending, the finished marine products are packaged into 250 L drums or sold as bulk in tank trucks. Workers will be exposed to the finished lubricant during drum packaging at customer blending locations. The drumming facility uses automated weight scales to fill the drums and worker exposure occurs as the operator watches (from 1-2

metres away) to ensure the drum filling mechanism properly enters the drums before the drum is filled. The bungs and labels are put on by the operators. The cleaning of the packaging lines is done with lube oil and this oil is typically recycled during future blending operations or incinerated. Additional exposure occurs during sample removal and laboratory analysis of the finished lubricant or during loading of the bulk lubricant in the tank trucks. The finished lubricant analysis is done in a laboratory by one or two workers and takes only a few minutes. The bulk lubricant loading involves the connection of a 4 inch line to the truck and removal of the line after completion of the tank filling.

The notifier believes there are approximately 20-30 people in Australia who are involved in the transportation and drumming of finished lubricant that contains OLOA 270. The duration of exposure for each person will be between 30 minutes to 1 hour, 50 days/ year.

Inspections by the notifier of the proposed Australian lubricant manufacturers have shown the facilities to be well ventilated, with proper control systems for accidental spills and waste water treatment.

7. PUBLIC EXPOSURE

Approximately 400,000 kg/year of OLOA 270 will be imported to Australia, as a component of lubricating oil additives (typically 16%). OLOA 270 and additives will be transported by rail car or tank truck to blending plants, where blending is performed in closed tanks. The public would not be expected to be exposed to OLOA 270 during these operations. After blending, the finished products will be packaged into 250 L drums or sold as bulk in tank trucks. The finished lubricant will be used primarily in large ocean going vessels.

Lube blending procedures are stated to produce only waste water. However, waste notified chemical may be present in water used to clean additive drums and in oil used to clean blending equipment. Prior to disposal of waste water, it will be treated in an on-site chemical waste water system that includes ‘API oil-water separation’ and sand filtration. No more than 5% of any waste OLOA 270 is expected to be emulsified in waste water discharged to municipal sewers. Other waste containing the notified chemical will either be recycled or incinerated. Disposal of waste OLOA 270 is not expected to result in significant public exposure.

Only industrial use of the notified chemical is expected to occur and no public use has been anticipated.

8. ENVIRONMENTAL EXPOSURE

. Release

The OLOA 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 hose end is kept on 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.

Waste waster containing OLOA 270 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 270 is expected to be emulsified in the water. The waste water is further treated with pond aeration and sand filtration before its is sent to sewer. The remaining oily waste is incinerated. The notifier estimates that 1 kg per day of the new substance would be released during the unloading process.
Oil blending involves combining lubricating oil blend stocks and the additive package in a blending tank, along with pour point depressants and foam inhibitors. 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 5 kg per day of the new substance is released during this process.
After blending the finished marine products are packaged into 55 gallon drums or sold as bulk in tank trucks. After filling the delivery lines are placed over oily drains which catch any spill product. The lines are cleaned with lube oil which is recycled during future blending operations or incinerated. The notifier estimates that 1 kg per day of the new substance is released during the product loading process.
Overall, 7 kg of waste OLOA is generated per day at each of the four blending sites in Australia. Assuming that API oil separation results in 95% removal of the oil from waste water (as claimed by the notifier), then approximately 350 g of OLOA per day is likely to enter the sewers from each of the blending sites.
Spills at the blending sites are contained by plant barriers. As lube blending facilities have concrete floors, most of the spilled product could be suctioned 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 270 is not substantially altered and does not decompose in the crankcase due to their high thermal stability. However, this material is burned in the engine oil during oil consumption. The insoluble and particulate matter become coated with OLOA 270 detergent and can be filtered out of the oil. The loss of detergency 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 consistently added during engine operation unless the engine is brought in for maintenance or overhaul. Used oils from these maintenance operations would likely be incinerated or sent to an used oil recycler.

Fate

The amount of waste OLOA 270 disposed to sewer is expected to be minimal as waste water from the blending operations are treated on-site and the hydrocarbon fraction is separated and incinerated. Any remaining OLOA 270 present in waste water disposed to sewer is expected to partition from the water to suspended matter and become associated with sludge at sewerage treatment plants. Therefore, the prospect of OLOA 270 entering receiving waters is remote.

- Biodegradation (2)

A study was performed to assess the ready biodegradability of OLOA 270 using the Closed Bottle Test (OECD TG 301D). Sealed bottles containing the test substance (2 mg/L) and inorganic nutrient medium were inoculated with activated sewerage sludge bacteria and incubated for up to 28 days at 20^{O}C. The test substance attained 12%

readily biodegradation after 28 days. Therefore, OLOA 270 may not be termed readily biodegradable.

- Bioaccumulation

No studies were provided. Given the 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 270.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Tests were performed in accordance to OECD guidelines (3).

Table 1 Summary of the acute toxicity of OLOA 270

Test	Species	Outcome	Reference
Acute oral toxicity	Rat-CRL:CDBR	LD_{50} >5.0 g/kg	(4)
Acute dermal toxicity	Rat-CRL:CBDR	LD_{50} >2.0 g/kg	(5)
Eye irritation	Rabbit	slight to moderate irritant	(6)
Skin irritation	Rabbit	slight irritant	(7)
Skin sensitisation	Guinea-pig/human	is a skin sensitiser	(8,9,10,11,12)

9.1.1 Oral Toxicity (4)

LD_{50}: 5.0 g/kg *Species/strain:* CRL:CB®DR rats

Number/sex of animals: 5 *Observation period:* 14 days

Method of administration (vehicle): gavage

Clinical observations: dark staining in the urogenital area on day two and soft stools on day one. All rats appeared normal on day three through to fourteen.

Mortality: none *Morphological findings:* no abnormal findings related to the administration of the chemical.

9.1.2 Dermal Toxicity (5)

LD_{50}: 2.0g /kg *Species/strain:* CRL:CD®BR rats

Number/sex of animals: 5 *Observation period:* 14 days

Method of administration (vehicle): direct administration with occlusive dressing

Clinical observations: no adverse reaction.

Mortality: none *Morphological findings:* no abnormal findings related to the administration of the chemical.

9.1.3 Eye Irritation (6)

Result: in unwashed eyes produces a slight to moderate conjunctival irritation which cleared by 96 hours after treatment. In treated eyes receiving a wash out, the test material produced slight to moderate conjunctival irritation which cleared by 48 hours after treatment.
Species/strain: Hra: (NZW) SPF rabbits *Number/sex of animals:* 6F/3M

Method of administration: 0.1 ml of test substance in conjunctival sac.

Draize Scores[j]

Animal	Time after instillation														
	1 day			2 days			3 days			4 days			7 days		
CORNEA:	opacity area			opacity area			opacity area			opacity area			opacity area		
1 washed	0/3		0	0/3		0	0/3		0	0/3		0	0/3		0
2 unwashed	0/6		0	0/6		0	0/6		0	0/6		0	0/6		0
IRIS															
1 washed	0/3			0/3			0/3			0/3			0/3		
2 unwashed	0/6			0/6			0/6			0/6			0/6		
CONJUNCTIVA	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]
1 washed	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2 unwashed (mean score)	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0

[a] redness [b] chemosis [c] discharge

9.1.4 Skin Irritation (7)

Result: The application of the test material to the skin of rabbits under 4-hour semi-occluded conditions resulted in only a slight erythema reaction in one animal which cleared by 72 hours. No other dermal irritation was observed The average of the 4-, 24-, 48-, and 72 -hour scores is 0.1 (considered to be only slightly irritating).

Number/sex of animals: 3F/3M *Species/Strain:* Hra: (NZW) SPF rabbits

Method of administration: semi occluded, applied as a liquid

Draize Scores[ii]*:*

Animal	Time after decontamination				
	4 hours	1 day	2 days	3 days	7 days
ERYTHEMA					
1 (Female)	0	0	0	0	0
2 (Female)	0	0	0	0	0
3 (Female)	0	0	0	0	0
4 (Male)	0	0	0	0	0
5 (Male)	0	1	1	0	0
6 (Male)	0	0	0	0	0
EDEMA					
1 (Female)	0	0	0	0	0
2 (Female)	0	0	0	0	0
3 (Female)	0	0	0	0	0
4 (Male)	0	0	0	0	0
5 (Male)	0	0	0	0	0
6 (Male)	0	0	0	0	0

9.1.6.1 Skin Sensitisation (8,9)

Result:
1) 0.5% Challenge: Following primary challenge with OLOA 270, the incidence of grade 2 or higher responses in the test group (5 animals of 20) was greater than those produced in the naive control group (0 of 10) indicating that sensitisation had been induced.

2) 2.5% Challenge: Following primary challenge with OLOA 270, the incidence of grade 2 responses in the test group (5 animals of 20) were greater than in the naive control group (0 of 10) indicating that sensitisation had been induced.

Species/strain: Hartley albino guinea-pigs **Number of animals:** 0.5% w/v 21/sex
2.5% w/v 19/sex

Induction:
Both induction and challenge were topical applications. Induction occurred once per two weeks for six weeks, the challenge occurred two weeks after last challenge.
0.5% w/v in Spectrum Mineral Oil Light U.S.P. challenge: undiluted concentration induction (n=10 animals/sex/test, 5 animals/sex/control).
2.5% w/v in Spectrum Mineral Oil Light U.S.P. challenge: 25% w/v concentration induction (n=10 animals/sex/test, 5 animals/sex/control).

Results:[iii]

Severity Scores

challenge concentration	24 hours					48 hours				
	0	±	1	2	3	0	±	1	2	3
0.5% w/v	0	7	12	1	0	0	8	7	5	0
control	1	6	3	0	0	0	8	2	0	0
2.5% w/v	0	5	13	2	0	0	7	8	5	0
control	0	7	3	0	0	0	4	6	0	0

9.1.6.2 Skin Sensitisation (10)

Result:
1) 2.5% Primary Challenge: Following primary challenge with OLOA 270, the incidence of grade 2 responses in the test group (4 of 20) was only slightly greater than that produced in the niave control group (1 of 10) suggesting the possibility of sensitisation.

2) 2.5% Rechallenge: Following rechallenge with OLOA 270, the incidence of grade 2 responses in the test group (4 of 20) was greater than that produced in the niave control group (0 of 10) indicating that sensitisation had been induced.

3) Undilute Cross-challenge: Following cross-challenge with OLOA 270, the incidence of grade 2 responses inn the test group (9 of 19) was greater than that produced by the niave control group indicating that sensitisation had been induced.
Species/strain: Hartley albino guinea-pigs *Number of animals:* 29 animals/sex

Induction:
Both induction and challenge were topical applications. Induction occurred once per two weeks for six weeks, the challenge occurred two weeks after last challenge.
A 25% w/v formulation in Spectrum Mineral Oil Light U.S.P was chosen for use at induction (n=10 animals/sex/test, 5 animals/sex/control).

Results:

Severity Scores

challenge concentration	24 hours					48 hours				
	0	±	1	2	3	0	±	1	2	3
(1) 2.5% w/v	0	4	14	2	0	0	6	10	4	0
control	0	6	4	0	0	0	5	4	1	0
(2) 2.5% w/v	0	6	10	4	0	0	9	7	4	0
control	0	3	7	0	0	0	3	7	0	0
(3) undiluted	0	2	8	7	2	0	6	9	4	0
control	0	2	8	0	0	0	8	2	0	0

(1)- Primary Challenge, (2)- Rechallenge, (3)- Cross-challenge

9.1.6.3 Skin Sensitisation (11)

Result: During the induction phase 16 subjects experienced reactions indicative of sensitisation. As a result of the number and the intensity of the observed reaction the study was terminated. Symptoms indicative of sensitisation included erythema, edema, pruritus, and papulovesicular responses.

Species/strain: Human *Number of individuals***:** 100

Induction: 9 topical applications of undiluted test article over 3 weeks.

9.1.6.4 Skin Sensitisation (12)

Result: Following primary challenge using undiluted test article the incidence and severity of grade 1 responses in the test group were essentially comparable to those produced by the naive control group indicating sensitisation had not been induced.

Species/strain: Hartley albino guinea-pigs *Number of animals:* 19/sex

Induction: undiluted test article (n=10 animals/sex/test, 5 animals/sex/control).

Results:

Severity Scores

challenge concentration	24 hours					48 hours				
	0	±	1	2	3	0	±	1	2	3
undiluted	0	7	11	0	0	0	15	3	0	0
control	0	5	5	0	0	0	9	1	0	0

9.2 Repeated Dose Toxicity (13)

Result: Based on the results of this study, no significant toxicological effect was observed. There were significant increases in mean ALT levels and liver weights suggesting the liver as a possible target organ for any toxicological effects, but there were no microscopic changes to support this.

Species/strain: CRL:CD®BR rats *Number/sex/dose:* 6 (subchronic)
6 (recovery)
12(reproduction)

Method of administration (vehicle): peanut oil-administered by gavage

Dose/ Duration of administration: 0, 100, 500, 1000 mg/kg/day-dose volume of 5ml/kg/day for 28 days.

Toxicologically Significant Observations:

1.Clinical

Subchronic Phase- Clinical signs associated with OLOA 270 administration were limited (2-4 animals/sex) and occurred one hour following treatment at the 1000 mg/kg/day dose. These included brown matting or staining on various body surfaces, tan staining around the mouth and salivation. Some of these clinical signs were also noted in at the 100 & 500 mg/kg/day dose at lower incidence levels.

Reproduction Phase- Clinical signs associated with OLOA 270 administration occurred one hour following treatment primarily at the 1000 mg/kg/day dose in both males and females. These included brown matting or staining on various body surfaces, clear matting and/or tan staining around mouth and salivation. These effects were also noted at 500 mg/kg/day but at a much lower incidence

2.Clinical Chemistry/Haematology

Subchronic Phase:

a: Hematology

Hematology parameters in the treated males were similar to control values at week 4 and week 6 (recovery phase) evaluations. Differences were noted between treated groups

and concurrent controls but these were not considered significant as they fell within range of WIL historical data.

b: Serum Chemistry
At the week 4 evaluation, the group mean ALT value in the 1000 mg/kg/day was significantly higher ($p<0.01$) .The ALT level was comparable to control values by week 6. Statistically significant differences ($p<0.05,0.01$) were noted between the control and treated groups but these were inconsistent between the sexes or within the ranges of WIL historical control data and so were not considered significant.

3.Necropsy Findings/ Histopathology
Subchronic Phase
a:Macroscopic Examination
No adverse effects.

b: Organ Weights
A significant increase ($p<0.05$) in group mean absolute liver weight in the 1000 mg/kg/day males was noted at the week 4 evaluation. Mean testicular weights relative to the final body weight was significantly higher ($p<0.05$) in the 1000 mg/kg/day indicating a potential adverse response to the testes.

c: Microscopic Examination
No adverse effects.

Reproductive Phase
a: Macroscopic Examination
No adverse effects.

b: Organ Weights
Significant increases ($p<0.05,0.01$) in mean liver (1000 mg/kg/day males and females; 500 mg/kg/day females) and kidney (500 & 1000 mg/kg/day males) weights relative to final body weight. These were not attributed to treatment based on lack of significance in other weight parameters and the absence of microscopic changes.

c: Microscopic changes
No adverse effects.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (14)

Result: The results indicate that under the conditions of the study, in both an initial and confirmatory assay, OLOA 270 did not cause a positive increase in the numbers of revertants per plate of any tester strains either in the presence or absence of microsomal enzymes.

Strains: *Salmonella typhimurium* (TA98, TA100, TA1535, and TA1537) and *Escherichia coli* (WP2*uvrA*)

Concentration range: 33.3, 100, 333, 1000, 3300 & 10,000 μg/ plate both in the presence or absence of microsomal enzymes produced from Arolclor® (S9).

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (15)

Result: OLOA 270 did not induce a significant increase in micronuclei in bone marrow polychromatic erythrocytes under the conditions of this assay and is considered negative in the mouse bone marrow micronucleus test.

Species/strain: ICR mice

Number and sex: 65/sex *Doses:* 1250, 2500 & 5000 mg/kg

Method of administration (vehicle): OLOA 270 was solubilised in peanut oil and administered by intraperitoneal injection.

9.3.2 Chromosomal Aberration Assay in Chinese Hamster Ovary (CHO) Cells with Multiple Harvests (16)

OLOA 270 was investigated for tis potential to cause chromosomal aberrations in the Chinese hamster ovary (CHO) cell line with or without metabolic activation.

Preliminary experiments were performed in order to determine the toxicity of OLOA 270 to the cells. Complete cytotoxicity was observed in the cultures treated with 1650 & 5000 μg/ml. In the non activation studies the negative and solvent controls utilised corn oil/10% Pluronic mixture to solubolise the test article, as well as a 10% Pluronic solution. In the activation studies S9 was added. The positive control agents which were used in the assays were mitomycin C (MMC)(0.04 & 0.08 μg/ml) for the non-activation series and cyclophosphamide (CP)(0.750 & 1.00 μg/ml) for the metabolic activation series.

Two experiments were performed using cultures in the absence or presence of metabolic activation provided by rat liver S9. In the studies without metabolic activation, cells were treated with OLOA 270 (50.0, 125, 250, 500, 750 & 1000 μg/ml) 24 hours after culture initiation for 21.33 & 45.25 hours. The OLOA 270 was removed from the cultures by washing and the cells were harvested 24.42 & 48.33 hours from initiation from treatment respectively for analysis. In the studies involving metabolic activation, cells were treated 24 hours after culture initiation for 6 hours with S9 and OLOA 270 (10.0, 50.0 150 325, 750, 1500, 2250 & 2290 μg/ml). The cells were then washed and incubated before harvesting 24.75 hours from the initiation from treatment for analysis.

Cultures treated with 50.0, 150, 325 & 750 μg/ml from the activation assay and with 10.0 & 50.0 μg/ml from the non-activation control assay were analysed for chromosomal aberration. No significant increase in cells with chromosomal aberrations was observed at the concentrations analysed.

The test article, OLOA 270, was considered negative for inducing chromosomal aberrations in Chinese Hamster ovary cells under both non-activation and activation conditions of this assay.

9.4 Overall Assessment of Toxicological Data

OLOA 270 was of low acute oral and dermal toxicity in rats. It was a slight to moderate skin and eye irritant in rabbits. In guinea-pigs it was found be a skin sensitiser, as well as having some extreme sensitising effects on human subjects. Repeat oral administration of OLOA 270 at up to 1000 mg/kg/day for 28 days produced effects suggestive of developing hepatotoxicity (increased liver weights and raised ALT levels) from 500 mg/kg/day but no microscopic changes were seen. OLOA 270 was not mutagenic in *S. typhimurium* or *E. coli*, nor did it cause chromosomal damage in Chinese hamster ovary cells *in vitro* nor mouse bone marrow cells *in vivo.* Based on the results presented the notified chemical is classed as a hazardous irritant due to its sensitising properties.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following studies have been provided.

Test	Species	Result
Acute toxicity (17)	Rainbow trout	96h LC50 > 1000 mg/L (as WAF) NOEL ≥ 1000 mg/L (as WAF)
Acute toxicity (18)	*Daphnia magna*	48h EC50 > 1000 mg/L (as WAF) NOEL ≥ 1000 mg/L (as WAF)
Growth inhibition (19)	Green algae (*Selenastrum capricornutum*)	48h EC50 = 370 mg/L (as WAF) NOEL = 250 mg/L (as WAF)

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. Results are based on nominal concentrations and indicate that OLOA 270 is practically non-toxic to the organisms tested.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Environmental exposure from the oil blending sites is expected to be low as the majority of the waste from the process is incinerated or recycled back into the blending process. Overall, 7 kg of waste OLOA is generated per day at each of the four blending sites in Australia. Assuming that API oil separation results in 95% removal of the oil from waste water (as claimed by the notifier), then approximately 350 g of OLOA 270 per day is likely to enter the sewers from each of the blending sites. OLOA 270 is expected to be associated with the sludge at sewerage treatment works (STW). Any OLOA 270 present in the effluent from STW is likely to be at levels < 1 ppm, as a result of dilution (sewage inflows >100 ML/day) and adsorption.

As levels expected to occur in receiving waters are far lower than toxic levels noted in the ecotoxicity data presented above, the notified substance is not expected to present a hazard to the environment.

OLOA 270 emitted during use is expected to be negligible, would occur in a highly dispersive manner and is therefore not expected to present a hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

OLOA 270 is expected to exhibit low acute oral and dermal toxicity and be a slight to moderate irritant to skin and eyes. OLOA 270 is a sensitising agent and therefore should not come into contact with exposed skin. It is not expected that any significant toxicity due to repeat prolonged exposure will occur, nor is it expected to be genotoxic.

The only significant health and safety risk is that of a sensitisation reaction occurring due to direct skin contact with OLOA 270. There is a potential for occupational exposure by splashing or spillage to a 6-65% formulation to occur for 30 minutes, 50 days a year during transfer of OLOA 270 from tankers to storage tanks. This will be reduced by engineering controls in the pumping hose preventing the release of OLOA 270. The packaging of the finished blended oil is done by automated machinery and supervised from 2 metres away reducing the risk of exposure to OLA 270. Some low exposure to residual OLOA 270 may occur during the application of drum bungs and labelling. The cleaning of blending vessels and equipment with lube oil and sampling of OLOA 270 in the lubricant oil for quality analysis also has a potential for occupational exposure from spashing or spillage (1-15% formulation, 30-60 minutes 50 days a year). Adequate personal protection such as gloves, shoes, eye protection and protective clothing are required at this stage to reduce the risk of skin sensitisation. There is likely to be exposure to the 1-15% formulation to end user by splashing or spillage, involved in the addition of the OLOA 270 formulation to the crankcase of large marine vessels. Personal protective measures are essential to keep occupational exposure to a minimum to prevent skin sensitisation.

No public exposure to OLOA 270 is expected to occur.

13. RECOMMENDATIONS

To minimise occupational exposure to OLOA 270 the following guidelines and precautions should be observed:

. personal protective devices which conform to and are used in accordance with Australian Standards (AS) for eye protection (AS 1336, AS 1337) (20,21), impermeable gloves (AS 2161) (22), protective clothing (AS 2919)(23) and protective shoes (AS 2210) (24) should be worn;

particular care should be taken to avoid spillage or splashing of the notified chemical;

good personal hygiene should be practiced to minimise the potential for ingestion;

. a copy of the Material Safety Data Sheet should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for OLOA 270 was provided in Worksafe Australia format (25).

This MSDS was provided by the Chevron Chemical Company as part of their notification statement. The accuracy of this information remains the responsibility of The Chevron Chemical Company.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of OLOA 270 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

1. Robson, M. (1993) *Determination of the Physico-Chemical Properties of SP-7053 Oil Free According to EC Requirements.* Report to Chevron Research and Technology Company (Hazleton UK, Report No. 512/11-a-1014).

2. Douglass, M.T., and Halls, R.W.S. (1993*) SP 7053 Ready Biodegradability (Closed Bottle Test).* Report to Chevron Research and Technology Company (Huntingdon Research Centre, Ltd. Report No. CHR 49(d)/930365).

3. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris, France.

4. Glaza, S.M. (1993) *Acute Oral Toxicity Study of SP 7053 in Rats*. Report to Chevron Research and Technology Company (Hazleton Winconsin, Inc. Project No. HWI 20901136).

5. Glaza, S.M. (1993) *Acute Dermal Toxicity Study of SP 7053 in Rats*. Report to Chevron Research and Technology Company (Hazleton Wisconsin, Inc. Project No. HWI 20901138).

6. Glaza, S.M. (1993*) Primary Eye Irritation Study of SP 7053 in Rabbits*. Report to Chevron Research and Technology Company (Hazleton Wisconsin, Inc. Project No. HWI 20901141).

7. Glaza, S.M. (1993) *Primary Dermal Irritation Study of SP 7053 in Rabbits*. Report to Chevron Research and Technology Company (Hazleton Wisconsin, Inc. Project No. HWI 20901140).

8. Morris, T.D. (1993*) Delayed Contact Hypersensitivity Study in Guinea Pigs (Buehler Technique) of SP 7053 (CO834-28-2).* Report to Chevron Research and Technology Company (Hill Top Biolabs Project No. 92-8754-21 A).

9. Kreuzmann, J.J. (1993) *Delayed Contact Hypersensitivity Study in Guinea Pigs (Buehler Technique) of SP 7053 (CO384-45-1).* Report to Chevron Research and Technology Company (Hill Top Biolabs Project No. 93-9006- 21 A).

10. Morris, T.D. (1994) *Delayed Contact Hypersensitivity Study in Guinea Pigs (Buehler Technique) of SP 7053 (C1234-19-4).* Report to Chevron Research and Technology Company (Hill Top Biolabs Project No. 93-8141- 21 A)

11. Boisits, E.K., Taurozzi, J., Dennis, S., Greenspan, A. H., Galvin, S.C., and Reardon, R.C. (1993) *Repeated Insult Patch Test with SP 7053 (C1234-11- 1).* Report to Chevron Research and Technology Company (TKL Research, Inc. Study No. 931023)

12. Morris, T.D. (1994) *Delayed Contact Hypersensitivity Study in Guinea Pigs (Buehler Technique) of SP 7053 in Finished Oil (C1234-19-3).* Report to Chevron Research and Technology Company (Hill Top Biolabs Project No. 93-8142-21 A).

13. Shour, M.H., Dahlgren, R.R., Holsen, J.F., Nemec, M.D, Oberholtzer, K., and Lamb, I.A. (1993) *A Combined Four-Week Repeated-Dose Oral Toxicity and Reproduction Screen in Rats with SP 7053.* Report to Chevron Research and Technology Company (WIL Research Laboratories, Inc. Project No. WIL- 187002).

14. Lawler, T.E. (1992) *Mutagenicity Test on SP 7053 (CO834-28-2) in the Salmonella-Escherichia coli/Mammalian-Microsome Reverse Mutation Assay with a Confirmatory Assay.* Report to Chevron Research and Technology Company (Hazleton Washington, Inc. Study No.15262-0-455CO).

15. Murli, H. (1992) *Mutagenicity Test on SP 7053 in an in vivo Mammalian Micronucleus Assay.* Report to Chevron Research and Technology Company (Hazleton Washington, Inc. Study No. 15262-0-409R).

16. Murli, H. (1993) *Mutagenicity Test on SP 7053 (CO 834-28-2) Measuring Chromosomal Abberations in Chinese Hamster Ovary (CHO) Cells with Multiple Harvests.* Report to Chevron Research and Technology Company (Hazleton Washington, Inc. Study No. 15262-0-437J).

17. Douglass, M.T., and Halls, R.W.S. (1993) *SP 7053 (Water Accommodated Fraction) Acute Toxicity to Rainbow Trout (Oncorhynchus mykiss*). Report to Chevron Research and Technology Company (Huntingdon Research Centre, Ltd. Report No. CHR 49(d)/930364).

18. Douglass, M.T., and Halls, R.W.S. (1993) *SP 7053 (Water Accommodated Fraction) Acute Toxicity to Daphnia magna.* Report to Chevron Research and Technology Company (Huntingdon Research Centre, Ltd. Report No. CHR 49(d)/930371).

19. Douglass, M.T., and Halls, R.W.S. (1993) *SP 7053 (Water Accommodated Fraction) Algal Growth Inhibition.* Report to Chevron Research and Technology Company (Huntingdon Research Centre, Ltd. Report No. CHR 49(d)/930368).

20. Standards Australia (1992) *Australian Standard 1337-1992*, *Eye protectors for Industrial Applications*, Standard Association of Australia Publ., Sydney, Australia.

21. Standards Australia (1994*) Australian Standard 1336-1994, Eye protection in the Industrial Environment*, Standard Association of Australia Publ., Sydney, Australia.

22. Standards Australia (1978) *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves),* Standard Association of Australia Publ., Sydney, Australia.

23. Standards Australia (1987) *Australian Standard 2919-1987 Industrial Clothing*, Standards Association of Australia Publ., Sydney, Australia.

24. Standards Australia, Standards New Zealand (1994) *Australian/New Zealand Standard 2210 - 1994 Selection, Use and Maintenance of Respiratory Protective Devices*, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ., Wellington, New Zealand.

25. National Occupational Health and Safety Commission (1990) *Guidance Note for Completion of a Material Safety Data Sheet 2nd Edition*, Australian Government Publishing Services, Canberra, Australia.

---

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

CORNEA			
Opacity rating	**rating**	**Area of Cornea involved**	
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 translu cent 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 severe	3 severe	Swelling with lids half-closed	3 mod.	Disharge with moistening of lids and hairs and considerable area around eye	3
		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

[ii] 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 by definite raising)	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

[iii]Buehler Delayed Contact Hypersensitivity Rating
0 = no reaction
± = slight, patchy erythema
1 = slight but confluent, or patchy erythema
2 = moderate erythema
3 = severe erythema with or without edema