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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Chemical in OLOA 224

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Chemical in OLOA 224

1. APPLICANT

Chevron Chemical Australia (ARBN 001 010 037) of Level 22, 385 Bourke St MELBOURNE VIC 3000 has submitted a standard notification statement in support of their application for an assessment certificate for Chemical in OLOA 224.

2. IDENTITY OF THE CHEMICAL

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

Marketing Name:	OLOA 224. This is a new synthesis of OLOA 224 which differs from that originally produced by the US parent company by the presence of 10% of a longer alkyl chain in one of the reaction components. The physico-chemical properties and toxicological data were generated using the previous OLOA 224 which will be referred to in the remainder of the report as "old" OLOA 224.
Method of Detection and Determination:	Infrared (IR) spectroscopy, calcium analysis.
Spectral Data:	An IR spectrum was provided.
Molecular Weight:	Approximately 660.

3. PHYSICAL AND CHEMICAL PROPERTIES

The physico-chemical properties were determined using old OLOA 224.

Appearance at 20°C & 101.3 kPa:	Dark brown viscous liquid.
Boiling Point:	Decomposes before boiling.
Specific Gravity:	0.947 at 15°C.
Vapour Pressure:	~ 5 x 10^{-5} kPa at 25°C

Water Solubility:	Expected to be < 100 ppb.
Partition Co-efficient (n-octanol/water):	log P_{ow} expected to be greater than 8.
Hydrolysis as a Function of pH:	$t_{1/2}$ = 367 hours at 50ºC at pH 4. $t_{1/2}$ = 198 hours at 50ºC at pH 7. $t_{1/2}$ = 276 hours at 50ºC at pH 9.
Adsorption/Desorption:	Expected to strongly adsorb to soil.
Dissociation Constant:	No significant dissociation expected.
Particle Size:	Not relevant for a liquid.
Flash Point:	> 200°C
Flammability Limits:	Unknown.
Autoignition Temperature:	Not expected to undergo autoignition.
Explosive Properties:	Not expected to be explosive.
Reactivity/Stability:	Will react in the presence of strong oxidising agents. Stable to acid and base.

3.1 Comments on Physico-Chemical Properties

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

The water solubility is stated as < 100 parts per billion. While such a low solubility is not unexpected for a compound containing a large saturated hydrocarbon group (as does the notified chemical), the polar nature of the phenolic and amine groups may confer some affinity for water on these portions of the molecule and give higher solubility. Also, due to the presence of the polar groups, the material may be surface active and disperse in water as droplets of emulsion. In the hydrolysis study (see below) 20 mg/L solutions were employed although some tetrahydrofuran was also present as a co-solvent. Also, in studies on ecotoxicity against zebra fish (Wyness, 1996a) a water solubility of 4 mg/L was stated for OLOA 224 although no further details were provided.

The rate of hydrolysis of the compound was determined at 50ºC in buffer solutions of pH 4, 7 and 9, with initial concentration of the test material stated as being nominally 20 mg/L (Robson, 1994). These solutions were made up by adding 1% of a nominally 2 g/L solution of the test compound in tetrahydrofuran to specified volumes of the buffers, and changes in concentration of the material were monitored over time using HPLC and UV detection. While some degradation occurred the hydrolysis half-lives were all in excess of 190 hours at 50ºC. Under ambient temperature conditions the rate would be significantly slower. Consequently, the material is expected to be stable in the environmental pH region where 4<pH<9. In

addition the low water solubility would not favour hydrolysis reactions due to the limited contact between susceptible groups and the aqueous environment.

Measurement of the n-octanol/water partition coefficient was attempted using an HPLC method. However, only 4.3% of the compound could be dissolved in acetonitrile and this had a log Pow of 5.2. Since the material has a substantial alkyl moiety, the notifier suggested a log Pow value of greater than 8.

No adsorption/desorption data were provided, but the high log Pow and high hydrocarbon content indicates that the material would have a large Koc and adsorb strongly to the organic component of soils and sediments.

No dissociation constant data were provided. The tertiary amine portion of the molecule is expected to exhibit basic properties with a pKa between 9.5 and 10.5.

4. PURITY OF THE CHEMICAL

Degree of Purity:	19.5%
Hazardous Impurities:	There are 3 hazardous impurities, 2 of which are identified as skin irritants, to a total of 1.6%.
Non-hazardous Impurities (> 1% by weight):	Total of 23.9% of non-hazardous impurities.
Additives/Adjuvants:	Lubricating oil, to a final concentration of 55%, is added during manufacture to reduce the viscosity of the notified chemical so that it can be pumped from the reactor. The oil consists of Distillates, hydrotreated heavy paraffinic (CAS No. 64742-54-7) or Distillates, solvent refined heavy paraffinic (CAS No. 64741-88-4).

5. USE, VOLUME AND FORMULATION

The notified chemical is a lubricant additive for railroad diesel engines. It is to be imported in a lubricant additive package OLOA 2000. OLOA 224 will be contained in the additive package at 15% and will be blended in railroad oils at 2.3 – 6%. The lubricant additive package containing the notified chemical is to be imported in 200 L drums and the amount of the notified chemical to be imported is up to 2.25 tonnes per annum for the first 5 years.

6. OCCUPATIONAL EXPOSURE

Transport and Storage

The drums will be transported directly to customers and should not result in worker exposure except in the event of accidental spillage.

Lubricant Blending

Drums are unloaded by drum pumps into the blending tank. Workers wear gloves, overalls and eye protection to control exposure and spend 10 minutes unloading each drum. Drums are steam cleaned and the waste water sent to an on-site chemical waste water system.

Oil blending is accomplished by pumping lubricating oil and the additive package from drums to the blending tank. Workers wearing gloves, overalls and eye protection to control exposure take samples for analysis. This takes a few minutes. The blending tank is cleaned with lubricating oil followed by water washing. Rare equipment maintenance may require workers to enter the tank. If so, the tank is flushed as described.

Following blending the finished oils are transferred to a storage tank and packaged into 200 L drums or pumped to tank trucks. Drums are filled automatically and bungs are manually inserted. Lines are cleaned with oil which is recycled into blending operations or incinerated. Bulk lubricant loading involves connection of a 10 cm line to a truck and its removal after filling. Any spilled product from the lines is caught in an oily drain over which the lines are placed.

The notifier has estimated exposure of 1 or 2 workers in each of 2 blending facilities during the different operations as follows:

Sampling:	½ hr, 1 day/year, 0.2 kg/year released
Analysis:	½ hr, 4 days/year, 5 kg/year released
Loading blending tank:	1 hr, 1 day/year, 0.2 kg/year released
Loading storage tank for finished lubricant:	½ hr, 7 days/year, 10 kg/year released
Drumming:	3 hr, 1 day/year
Tank car (finished Lubricant) cleaning:	8 hr, 2 days/year

Workers are stated to wear gloves, eye protection and overalls.

Lubricant use

Transfer of the finished lubricant to railroad engines from tank trucks or drums is accomplished by a drum pump and hoses connected directly to the railroad engine or to a storage tank for the bulk deliveries. From the storage tank, the lubricant is delivered by hose to the engine. Workers typically wear personal protective equipment for lubricant transfer. However, mechanics repairing engines typically do not wear gloves and can be expected to come into contact with lubricant on a continuing basis.

7. PUBLIC EXPOSURE

The notified chemical will not be sold to the public. Since it will be used in engines not handled by the public, the probability of exposure is low. During transport and storage at the formulation plant and transport of the formulation to end users there is limited potential for exposure of the public except in the event of an accidental spill.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The additive package containing the notified chemical will be delivered to and stored at the blending facilities in drums, and it is anticipated that very little of the additive package will be released during transfer from the storage containers to the blending tanks. All transfer operations are controlled automatically, and the blending tanks are cleaned with lube oil which is recycled for use in preparing subsequent batches of product. Any spills incurred in the blending operations are contained within concrete bunds and are either reclaimed or sent to onsite waste water treatment facilities.

Similarly, the empty drums of additive package are cleaned with steam, and the resultant waste water is sent to the water treatment facilities where the residual hydrocarbon based products are comprehensively separated from the aqueous stream using techniques which include oil/water separation, induced air flotation and sand filtration. The hydrocarbon based waste is then either incinerated or is removed by oil recycling contractors, while the aqueous stream - now containing very little hydrocarbon based material - is discharged to the sewer. The notifier states that treatment of the waste water would remove around 95% of any of the notified chemical present in the influent waste water stream.

The vapour pressure of the notified chemical is very low, so release to the atmosphere during formulation of the lubricants, and transfer and disposal operations involved in lubricant use or removing it from crankcases would be negligible.

Some release is likely during transfer of the lubricants from containers to the diesel locomotive engines, but since these operations would most likely be performed in properly appointed railway workshops release is expected to be small. Nevertheless, as a worst case scenario if it is assumed that each lubricant transfer involves 100 litres of lubricant, and that on average 1 L of lubricant containing the notified chemical (ie. 1% loss) is likely to be either spilt or left as residuals in containers as a result of transfer operations, around 50 kg (1% of import quantity) of the notified chemical could be released annually via this route. Most spills are likely to be adsorbed onto sawdust and incinerated or disposed of to landfill, while residuals left in containers would be disposed of in a similar fashion.

Unlike many engine lubricants, in locomotive diesel engines much of the oil is burnt during engine use. During periodic engine maintenance all the oil in the sumps would be removed and replaced and as this would be done at railway workshops the used oil either would be sent for recycling or possibly used as an extender for diesel fuel. Very little release of the notified chemical is expected from routine engine maintenance activities.

8.2 Fate

The notified chemical is not readily biodegradable in aerobic environments, and in a closed bottle test [OECD TG 301 D] performed on OLOA 224 only 4% degradation occurred over the 28-day test period (Douglas and Handley, 1987). However, despite the low apparent rate for biodegradation it is expected that if placed into landfill (if for example adsorbed into sawdust after accidental spills, or dumped irresponsibly) the material would be slowly degraded through the slow biological and abiotic processes operative in these facilities. Apart from some carbon dioxide, these processes could be expected to produce methane, ammonia and water.

Leaching from a landfill would be slow, and the high anticipated Koc (see Section 3.1) indicates that the chemical would not be mobile, but would adsorb into and become strongly associated with the organic component of soils and sediments. Similarly, in the event of accidental release into the water compartment, the chemical is likely to become associated with suspended organic material, and eventually be incorporated into sediments.

The notified chemical has a high log Pow, modest molecular weight (666 g/mol for the dimer) and low rate of biodegradation indicating the potential for bioaccumulation (Connell, 1989). Nevertheless, as direct exposure to the water compartment is considered unlikely, there is limited potential for bioaccumulation.

Incineration of waste oil containing the notified chemical would destroy the substance with evolution of water vapour and oxides of carbon and nitrogen, together with production of calcium compounds in the ash. Sludges from waste treatment plants or oil recycling facilities could also be incinerated.

9. EVALUATION OF TOXICOLOGICAL DATA

Most of the toxicological data were obtained with old OLOA 224 as the lube oil-containing commercial product. Old OLOA 224 (as APD 4784) contains 60% (w/w) hydrotreated heavy paraffin distillates or solvent refined heavy paraffin distillates and 40% (w/w) of the active constituent. Skin sensitisation tests were conducted on old OLOA 224 and formulations containing 15% old OLOA 224 (OLOA 2000) or 37% old OLOA 224 (OLOA 2990). Tests on finished oils containing 5.9% old OLOA 224 (XA 14328 and 16.1% OLOA 2990) also were conducted.

9.1 Acute Toxicity

Summary of the acute toxicity of OLOA 224 and formulations containing it

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 mg/kg	(Chevron, 1985a)

acute dermal toxicity	rat	LD_{50} > 5 000 mg/kg	(Chevron, 1985b)
skin irritation	rabbit	slight irritant	(Chevron, 1985c)
eye irritation	rabbit	slight irritant	(Chevron, 1985d)
skin sensitisation	guinea pig	sensitising (OLOA 224, OLOA 2990, OLOA 2000, XA 14328) or not sensitising (16.1% OLOA 2990)	(Chevron, 1993; Hill Top Biolabs, 1991, 1995; Hill Top Research, 1996; TKL Research, 1992)

9.1.1 Oral Toxicity (Chevron, 1985a)

Species/strain:	Rat/Sprague-Dawley.
Number/sex of animals:	5/sex.
Observation period:	14 days.
Method of administration:	Oral (gavage); vehicle: peanut oil; dose: 5 g/kg.
Test method:	OECD TG 401
Mortality:	None.
Clinical observations:	The majority of animals exhibited pale or soft faeces on days 1 and/or 2.
Morphological findings:	None related to treatment.
LD_{50}:	> 5 000 mg/kg
Result:	The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Chevron, 1985b)

Species/strain:	Rabbit/New Zealand White (NZW).
Number/sex of animals:	4 females, 6 males initially and a fifth female 3 weeks later.
Observation period:	14 days.
Method of administration:	Under occlusive dressing for 24 hours; dose 5g/kg.
Test method:	OECD TG 402
Mortality:	One control male.

Clinical observations:	Ocular discharge in 1 male, scabbed skin in 1 male; ocular discharge, diarrhea, scabbed skin (1 female for each clinical sign), dry and flaky skin (2 females).
Morphological findings:	One female had severe dermatitis of unknown origin, upon histological examination.
LD_{50}:	> 5 000 mg/kg
Result:	The notified chemical was of low dermal toxicity in rats.

9.1.3 Inhalation Toxicity

No data provided.

9.1.4 Skin Irritation (Chevron, 1985c)

Species/strain:	Rabbit/NZW.
Number/sex of animals:	6 females.
Observation period:	7 days.
Method of administration:	0.5 mL of the test substance was applied to 2 intact and 2 abraded skin sites on the back of each animal for 4 hours under semi-occlusive dressing.
Test method:	OECD TG 404
Comment:	The test substance caused slight erythema at one intact site and slight oedema at the other intact site in one animal 1 hour after patch removal but no other effects in any animal at 1, 2, 3 or 7 days after patch removal. For the abraded sites, slight erythema was observed in 4 animals at one hour and in 1 animal at 24 and 72 hours after patch removal.
Result:	The notified chemical was slightly irritating to the skin of rabbits.

9.1.5 Eye Irritation (Chevron, 1985d)

Species/strain:	Rabbit/NZW.
Number/sex of animals:	9 females, 3 irrigated.
Observation period:	7 days.
Method of administration:	0.1 mL into the conjunctival sac of one eye. The untreated

eye serves as control. Rinsed eyes received 250 mL of distilled water for one minute after a 30-second exposure.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation																	
Animal	***1 hour***			***1 day***			***2 days***			***3 days***			***4 days***			***7 days***		
Cornea	No scores above zero.																	
Iris	No scores above zero.																	
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	1	0	0	0	0	0	0	0	All scores zero								
2	2	0	0	0	0	0	0	0	0	“								
3	2	1	0	2	1	0	1	0	0	“								
4	2	0	0	1	0	0	0	0	0	“								
5	2	0	0	1	0	0	1	0	0	“								
6	1	0	0	2	1	0	1	0	0									

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge

Comment: Rinsing was not palliative.

Result: The notified chemical was slightly irritating to the eyes of rabbits.

9.1.6 Skin Sensitisation (Buehler Technique)

9.1.6.1 OLOA 224 (Hill Top Biolabs, 1991)

Species/strain: Guinea pig/Dunkin-Hartley.

Number of animals: 10 control/ 20 test/ 10 rechallenge with naïve control.

Induction procedure:

test group: day 1, week 2, week 3 (intervals of 5 – 9 days)	0.3 mL of the undiluted test substance placed in a 25 mm Hill Top Chamber applied to the left shoulder and occluded for 6 hours.
control group:	As for test group using light mineral oil as diluent.

Challenge procedure:

Approximately 2 weeks after last	Same exposure procedure using undiluted test substance as for induction phase but at a different skin site.

induction
exposure

Rechallenge procedure: Same procedure as for challenge conducted at least 6 days later.

Test method: OECD TG 406

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
Undiluted	**12/16	10/16	6/10	1/10

Rechallenge outcome:

	Test animals		***Control animals***	
Rechallenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
Undiluted	**16/16	16/16	2/10	0/10

* time after patch removal
** number of animals exhibiting positive response (ie Draize score ≥1)

Comment: Four test animals were inadvertently treated with the incorrect substance and were not proceeded with. After challenge 8/16 animals exhibited moderate erythema compared to 0/10 in the control group. Corresponding figures for rechallenge were 10/16 and 0/10.

Result: OLOA 224 was sensitising to the skin of guinea pigs.

9.1.6.2 OLOA 2990 (37% OLOA 224) and Oils Containing 16.1% OLOA 2990 (6.0% OLOA 224) (Chevron, 1993)

Species/strain: Guinea pig/Dunkin-Hartley.

Number of animals/Study design: 10 control/ 20 test per group. The test animals were induced and challenged twice with OLOA 2990, oils containing 16.1% OLOA 2990 and oils alone as follows:

Test substance	***Induction%***	***Challenge/ Rechallenge %***
OLOA 2990 in petrolatum	75%	25%
16.1% OLOA 2990 in EXXON Base Oils	100%	25%
16.1% OLOA 2990 in CUSA Base Oils	100%	10%
EXXON Base Oil	100%	10%

CUSA Base Oil	100%	10%

In addition to the above a control group treated solely with petrolatum (100%) was included.

Induction procedure:

test group: Over a 15-day period, each of 3 occluded epicutaneous applications were administered weekly on either Wednesdays or Thursdays. 0.3 mL of the test substance in either petrolatum or Base Oil was placed in a 25 mm Hill Top Chamber applied to the left flank and occluded for 6 hours.

control group: As above but without the test substance and an irritation control in which no induction occurred or the test substance in vehicle was applied solely for challenge or rechallenge.

Challenge procedure:

2 weeks after last induction exposure: Same exposure procedure as for induction phase but the test substance applied to the right anterior flank.

Rechallenge procedure: Same procedure as for challenge conducted 7 days later with the test substance applied to the right posterior flank.

Test method: OECD TG 406

Fraction of animals exhibiting a response at designated time after patch removal

	Challenge						**Rechallenge**					
Test Substance	**24 hour**			**48 hour**			**24 hour**			**48 hour**		
	0±*	**1**	**2**	**0 ±**	**1**	**2**	**0 ±**	**1**	**2**	**0 ±**	**1**	**2**
OLOA 2990	0.35	0.55	0.10	0.50	0.50		0.35	0.60	0.05	0.30	0.65	0.05
Irritation control	0	0.77	0.23	0	0.40	0.60	0.80	0.20	0	0.80	0.20	0
Vehicle control	0	1.0	0	0.90	0.10	0	0.90	0.10	0	0.80	0.20	0
OLOA 2990/ Exxon Base Oil	0.55	0.35	0.10	0.70	0.15	0.15	0.05	0.95	0	0.50	0.45	0.05
Irritation control	0.90	0.10	0	0.80	0.20	0	0.60	0.40	0	1.0	0	0
Vehicle control (with induction)	0.55	0.45	0	0.95	0.05	0	0.25	0.75	0	0.75	0.20	0.05
Vehicle control (no induction)	0.90	0.10	0	0.90	0.10	0	0.60	0.40	0	1.0	0	0

OLOA 2990/ CUSA Base Oil	0.70	0.30	0	0.70	0.30	0	0.80	0.20	0	0.95	0.05	0
Irritation control	0.60	0.40	0	0.90	0.10	0	0.20	0.80	0	0.70	0.30	0
Vehicle control (with induction)	0.90	0.10	0	0.95	0.05	0	0.45	0.55	0	0.75	0.25	0
Vehicle control (no induction)	0.80	0.20	0	1.0	0	0	0.40	0.50	0.10	0.90	0.10	0

* Scores: 0 or ±, no reaction or slight patchy erythema; 1, slight but confluent or moderate patchy erythema; 2, moderate erythema.

Fraction of animals exhibiting a positive response at designated time after patch removal

	Challenge		**Rechallenge**	
	24 hr	**48 hr**	**24 hr**	**48 hr**
OLOA 2990	0.65	0.50	0.55	0.65
Irritation control	1.0	1.0	0.20	0.20
Vehicle control	1.0	0.10	0.10	0.20
OLOA 2990/ Exxon Base Oil	0.45	0.30	0.95	0.50
Irritation control	0.10	0.20	0.40	0
Vehicle control (with induction)	0.45	0.05	0.75	0.25
Vehicle control (no induction)	0.10	0.10	0.40	0
OLOA 2990/ CUSA Base Oil	0.30	0.30	0.20	0.05
Irritation control	0.40	0.10	0.80	0.30
Vehicle control (with induction)	0.10	0.05	0.55	0.25
Vehicle control (no induction)	0.20	0	0.60	0.10

Comment: Sensitisation was observed at rechallenge in animals induced with OLOA 2990, 16.1% OLOA 2990 in EXXON Base Oil and EXXON Base Oil. Sensitisation also was observed in challenge animals induced with EXXON Base Oil. No other responses exceeded relevant controls.

Result: OLOA 2990 and EXXON Base Oil are skin sensitisers in guinea pigs; 16.1% OLOA 2990 is not sensitising when tested in CUSA Base Oil.

9.1.6.3 OLOA 2000 (15% OLOA 224) (Hill Top Research, 1996)

Species/strain: Guinea pig/Dunkin-Hartley.

Number of animals: 10 control/ 20 test.

Induction procedure:

test group: 3 treatments at intervals of 7 days	0.3 mL of the undiluted test substance placed in a 25 mm Hill Top Chamber applied to the left shoulder and occluded for 6 hours.
control group:	As for test group using mineral oil.

Challenge procedure:

Approximately 2 weeks after last induction exposure	Same exposure procedure as for induction phase but at a different skin site; 1% in mineral oil.

Test method: OECD TG 406

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
1%	**0/20	2/20	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response (ie Draize score ≥1)

Result: OLOA 2000 was sensitising to the skin of guinea pigs.

9.1.6.4 XA 14328 (5.9% OLOA 224) (Hill Top Biolabs, 1995)

Species/strain: Guinea pig/Dunkin-Hartley.

Number of animals: 10 control/ 20 test.

Induction procedure:

test group: 3 treatments at intervals of 7 days	0.3 mL of the undiluted test substance placed in a 25 mm Hill Top Chamber applied to the left shoulder and occluded for 6 hours.
control group:	As for test group using mineral oil.

Challenge procedure:

Approximately 2 weeks after last induction exposure	Same exposure procedure as for induction phase but at a different skin site

Test method: OECD TG 406

Challenge outcome:

	Test animals		*Control animals*	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
undiluted	**15/20	12/20	5/10	5/10

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

Comment: A total of 15 of 20 test animals and 6 of 10 control animals (at either 24 or 48 hours after patch removal) exhibited clear erythema following challenge. One control animal responded only at 24 hours and one control animal responded only at 48 hours.

Result: XA 14328 was sensitising to the skin of guinea pigs.

9.1.6.5 Human Repeat Insult Patch Test with OLOA 2990 (37% OLOA 224) (TKL Research, 1992)

No. of Subjects 106

Study Duration: 7 weeks

Treatment Regime: A pilot study was conducted with 20 subjects for 1 week to determine irritant response. The 20 subjects and 86 additional subjects were treated 3 times per week for 3 weeks with 0.2 mL of the undiluted test substance or mineral oil control under occlusive dressing to the infrascapular area of the back for 24 hours. Patches were applied on Monday, Wednesday and Friday of each week. The Challenge phase was initiated during the sixth week of the study with patches applied to previously unexposed sites. The patches were removed after 24 hours and the sites scored 24 and 48 hours following patch removal.

Result: No irritation or sensitisation to OLOA 2990 was observed in any subject during the study.

9.2 Repeated Dose Toxicity

9.2.1 Repeated Dose Oral Toxicity, Reproduction and Neurotoxicity with 100% OLOA 224 (WIL Research, 1994)

Species/strain:	Rat/Sprague-Dawley
Number/sex of animals:	6/sex/group with an extra 6/sex in the control and high dose groups (subchronic toxicity); 6 males/group (neurotoxicity); 12/sex/group (reproduction).
Method of administration:	Oral (gavage); vehicle: peanut oil.
Dose/Study duration:	*Subchronic toxicity* Test substance administered for 28 consecutive days at 0, 100, 500 or 1 000 mg/kg/day with extra control and high dose groups (6 animals each) allowed 14 days recovery prior to termination. *Neurotoxicity* As for subchronic toxicity but only the control and high doses were administered. *Reproduction* Test substance was administered for 28 consecutive days prior to mating at 0, 100, 500 or 1 000 mg/kg/day. Dosing was continued for a total minimum of 70 days in the F_o males. F_o females continued to receive the test substance through day 4 of lactation for females that delivered a litter and to post-mating day 25 for those that did not.
Test method:	US EPA Test Guidelines for a Neurotoxicity Screening Battery (Pesticide Assessment Guidelines, Subdivision F, Hazard Evaluation: Human and Domestic Animals, Addendum 10, Neurotoxicity: Series 82-7, excluding motor activity). OECD TG 422.

Results

Common to all studies were the observations that no mortalities were observed at any dose level, no consistent changes in body weight or body weight gain could be related to treatment and similar clinical observations in control and treated groups were noted. Other results are listed separately as follows:

Subchronic Toxicity

Clinical chemistry/Haematology/Plasma Cholinesterase/Urinalysis:

Clinical chemistry and haematology parameters were measured for subchronic toxicity only.

Clinical Chemistry: Triglyceride levels in low dose females were elevated and sodium in mid dose females were decreased at the week 4 evaluation. As the effects were limited to a single sex and were not observed in the high dose group they were considered to be chance effects. In high dose females increased urea nitrogen and B/C ratio (blood urea nitrogen/ creatinine) and decreased glucose were observed at the 4 week evaluation. Again these changes were considered to be of no toxicological significance as they were limited to a single sex and the differences were slight. At the 6 week evaluation sodium was decreased and urea nitrogen increased in males and calcium was increased in females. As these changes were limited to a single sex and did not occur at the 4 week evaluation they were considered to be of no toxicological significance.

Haematology: The mean absolute lymphocyte count in low dose males was increased as was the MCV in mid dose females at the 4 week evaluation. As the effects were limited to a single sex and were not observed in the corresponding high dose group they are considered to be of no toxicological significance.

Plasma Cholinesterase: No changes in plasma cholinesterase levels were observed.

Urinalysis: In high dose males at the 6 week evaluation urine volume was lower and specific gravity higher than controls. As these effects were limited to a single sex and were not observed at the 4 week evaluation they are considered not to be of toxicological significance.

Organ weights:
Absolute and relative spleen and lung weights in low dose females were elevated; liver weight relative to body weight was elevated in mid dose females and spleen weight relative to brain weight was elevated in low dose females. As these effects were not reflected at the high dose and were confined to one sex they are not considered to be toxicologically significant. Absolute and relative thymus weights were lower in high dose males at the 6 week evaluation. As these effects were not seen in high dose females or males at the 4 week evaluation, they are not considered to be toxicologically significant.

Macroscopic examination:
No significant findings.

Histopathology:
No significant findings.

Comment:
All of the effects observed following administration of the test substance at up to 1 000 mg/kg/day for 28 consecutive days were considered to be chance effects and not toxicologically significant. The NOAEL was 1 000 mg/kg/day.

Neurotoxicity

Functional observation battery, brain pathology, histopathology:

The functional observation battery consisted of home cage, handling, open field, sensory, neuromuscular and physiological observations at weeks –1, 2 4 and 6 for control and treated groups. The only apparent difference was a consistently lower (4 – 9%) body weight on weeks 2, 4 and 6. Brain weight and dimensions were not affected by treatment and no treatment-related microscopic lesions were observed in any central or peripheral nervous system tissues.

Reproductive Effects

Reproductive performance:
Mating, fertility and fecundity indices were similar in the treated and control groups.

Gestation length:
Gestation lengths in the mid and high dose groups were slightly lower than in the control group but were within the historical control range.

F_0 Pathology
No treatment-related macroscopic findings were noted in males or females which delivered or in 3 females which did not deliver.

Some slight changes in organ weights were a decrease in epididymides weight relative to brain weight in low dose males, an increased kidney weight relative to body weight in high dose males and an increased adrenal gland weight relative to final body weight in high dose females. These differences were attributed to slight changes in body or brain weight.

Histopathology
No treatment-related microscopic findings were noted in any group.

F_1 Litter data
No treatment-related effects on mean live litter size, number of stillborn pups, pup viability indices, general physical condition, pup body weights or sex ratios were observed.

Pup necropsies
No significant findings.

Conclusion:
The NOAEL for the test substance in a 28-day repeated dose study in rats was 1000mg/kg/day. The test substance exhibited no neurotoxicity when administered to rats at 1000 mg/kg/day for 28 days and had no effect on reproductive parameters at doses up to 1000 mg/kg/day.

9.2.2 Repeated Dose Dermal Toxicity (OLOA 224) (Chevron, 1988)

Species/strain:	Rat/Sprague-Dawley
Number/sex of animals:	6/sex/group.
Method of administration:	The test substance was applied to the dorsal area of the trunk by an automatic 1.0 mL pipette or plastic syringe and left on the site for 6 hours, 5 days per week for 4 weeks.

Dose/Study duration: Doses were 0, 100, 400 or 1000 mg/kg/day for 21 applications over 28 days; applied in mineral oil.

Test method: OECD 410

Mortality:
No mortality was observed during the study.

Clinical observations:
No treatment-related signs. Body weights for the male high dose group were significantly lower on days 5 and 7 and body weight gain for mid and high dose males was lower during the first week of dosing. These effects appeared to be related to treatment.

Skin irritation did not occur in a consistent dose related fashion. A slightly higher incidence and severity occurred throughout the observation period in mid dose males.

Clinical chemistry/Haematology
Haematology: Mean cell haemoglobin was reduced in females for all dose groups but the reductions were slight and within the historical control range.

Clinical chemistry: Glucose levels in males were lower than control values in the mid and high dose groups and the control value was lower and outside the historical control range. Glucose levels in the female mid and high dose groups also were lower than the control but the differences were not significant.

High dose males exhibited elevated aspartate aminotransferase, creatine phosphokinase and alanine aminotransferase. Low and mid dose males exhibited elevated globulin and all treated males exhibited a lower A:G ratio. Low and mid dose males also exhibited elevated total protein. All of these changes were within the historical control range, affected one sex only and were not correlated with any microscopic changes. Therefore, they are considered to be chance effects.

Organ weights:
Elevated brain to body weight was observed in mid and high dose males resulting from slightly decreased body weights in these groups.

Macroscopic findings:
A number of macroscopic changes in individual animals were considered to be spontaneous in origin and not treatment-related. Dryness, flakiness and scabbing of the skin was observed in mainly the mid dose males.

Histopathology:
No treatment-related microscopic lesions noted in organs other than the skin.

Microscopic observations corresponding to skin irritation were acanthosis and escharotic exudate (scab).

Result:

Target organ toxicity was limited to effects on the skin although no consistent dose-related changes were observed. Decreased glucose levels in mid and high dose males were not correlated with any microscopic effects. The NOEL was 100 mg/kg/day.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (OLOA 224) (Chevron, 1985e)

Strains: TA 1535, TA 1537, TA 1538, TA 98, TA 100.

Metabolic activation: Aroclor-induced Sprague-Dawley rat liver S9 fraction.

Concentration range: 0.1, 0.33, 1.0, 3.33 or 10 mg/plate.

Test method: OECD TG 471

Comment: The test substance was not completely miscible in the top agar above 0.1 mg/plate. It was cytotoxic at 10 mg/plate to strains TA 100, TA 1535 and TA 1537 without S9. The test substance was weakly mutagenic in strains TA 98 (3×10^{-3} mutants per mcg), TA 1538 (3×10^{-3} mutants per mcg) and TA 100 (2×10^{-2} mutants per mcg) with S9. Positive controls gave the expected results and negative controls were within historical limits.

Result: The notified chemical was weakly mutagenic under the conditions of the test in strains TA 98, TA 100 and TA 1538 in the presence of S9.

9.3.2 Chromosomal Aberration Assay in Chinese Hamster Ovary (CHO) Cells (OLOA 224) (Microbiological Associates, 1987)

Cells: $CHO\text{-}K_1$

Metabolic activation system: Aroclor 1254-induced Sprague-Dawley rat liver S9 fraction.

Dosing schedule:

Metabolic Activation	Experiment/ Study Number	Test concentration (μg/mL)	Controls
-S9	1 Harvest time of 16 hours	treatment time = 14 hours 0, 25, 50, 100 or 200 μg/mL	Positive: triethylene melamine (1 μg/mL)

			Negative: untreated and ethylene glycol diethyl ether at the same concentration as for cells treated with test substance.
+S9	2 Harvest times of 8 or 12 hours	treatment time = 2 hours 0, 125, 250, 500 or 1 000 μg/mL	Positive: cyclophosphosphamide (100 μg/mL) Negative: untreated and ethylene glycol diethyl ether at the same concentration as for cells treated with test substance.

Test method: OECD TG 473

Comment: Partial precipitation was observed for the test substance at concentrations of 50μg/mL and above.

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

9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Hazelton, 1993)

Species/strain: Mouse/ICR.

Number and sex of animals: 5/sex/group.

Doses: 0, 1250, 2500 and 5000 mg/kg.

Method of administration: Intraperitoneal in peanut oil. Bone marrow was harvested at 24, 48 and 72 hours after administration.

Test method: OECD TG 474

Comment: The test substance did not induce a significant increase in micronucleated polychromatic erythrocytes (PCE) over the levels in the vehicle controls in either sex. The test substance had no effect on the ratio of PCE to normochromatic erythrocytes. The positive control substance, cyclophosphamide, induced the expected increases in micronucleated PCE. The maximum tolerated dose was not reached in this study.

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

9.4 Overall Assessment of Toxicological Data

OLOA 224 was of very low acute oral toxicity in rats (LD_{50} > 5000 mg/kg) and low acute dermal toxicity in rats (LD_{50} > 5000 mg/kg). It was a slight skin irritant in rabbits and a slight eye irritant in rabbits.

Non adjuvant type skin sensitisation studies in guinea pigs revealed that old OLOA 224, OLOA 2990 (37% old OLOA 224), OLOA 2000 (15% old OLOA 224), XA 14328 (5.9% old OLOA 224) and Exxon base oil were sensitising and 16.1% OLOA 2990 was not sensitising to the skin of guinea pigs. The observation that XA 14328 (5.9% OLOA 224) was more strongly sensitising than OLOA 2000 (15% OLOA 224) may be ascribed to fact that at least a slight response (patchy erythema) was observed in most animals in the control and test groups in both studies. Apparent sensitisation as evidenced by an excess of animals in the test group exhibiting slight, confluent erythema or moderate patchy erythema (grade 1 score) may be an irritant response with the excess of grade 1 scores occurring by chance. Alternatively, the discrepancy may be due to the fact that 1% OLOA 2000 was used for challenge but the XA 14328 used for challenge was undiluted. A human repeat insult patch test with OLOA 2990 (37% old OLOA 224) was negative for sensitisation.

Four-week repeated dose oral and dermal toxicity studies did not reveal organ toxicity at doses of 1000 mg/kg/day except for some non-dose related skin irritation in the dermal toxicity study. The oral study did not reveal any neurotoxic or reproductive effects.

The notified chemical was a weak mutagen in bacteria but was not clastogenic in CHO cells *in vitro* or in bone marrow cells of mice *in vivo*.

OLOA 224 is determined to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999) in terms of skin sensitisation and is assigned the risk phrase R43: May cause sensitisation by skin contact.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided the following ecotoxicity data for OLOA 224. The tests were conducted according to OECD protocols, and the data is summarised in the table and discussed below.

Test	***Species***	***Results (Nominal)***
Acute Toxicity [OECD 203]	Rainbow Trout *Oncorhynchus mykiss*	LC_{50} (96 h) > 1000 mg/L WAF NOEC (96 h) > 1000 mg/LWAF
Acute Toxicity [OECD 203]	Sheepshead minnow *Cyprinodon variegatus*	LC_{50} (96 h) > 10000 mg/L WSF NOEC (96 h) > 1000 mg/LWSF (see notes below)
Acute Toxicity [OECD 203]	Zebra fish *Brachydanio rerio*	LC_{50} (96 h) > 4 mg/L WAF NOEC (96 h) > 4 mg/LWAF
Acute Immobilisation [OECD 202]	Water Flea *Daphnia magna*	EC_{50} (48 h) > 4 mg/L WAF NOEC (48 h) > 4 mg/L WAF

Acute Immobilisation [OECD 202]	Water Flea *Daphnia magna*	LC_{50} (96 h) > 1000 mg/L WAF NOEC (96 h) > 1000 mg/LWAF
Acute Toxicity	Mysid Shrimp *Mysidopsis bahia*	LC_{50} (96 h) > 1000 mg/L WAF NOEC (96 h) = 63 mg/LWAF
Growth Inhibition [OECD 201]	Algae *Selenastrum capricornutum*	EbC_{50} (72 h) = 174 mg/L (WAF) NOEC (72 h) = 15.6 mg/L (WAF)
Growth Inhibition [OECD 201]	Algae *Selenastrum capricornutum*	EbC_{50} (72 h) = 17 mg/L (WAF) NOEC (72 h) = 12 mg/L (WAF)
Growth Inhibition [OECD 201]	Algae *Selenastrum capricornutum*	EbC_{50} (72 h) > 4 mg/L NOEC (72 h) >4 mg/L

WSF = Water Soluble Fraction; WAF = Water Accommodation Fraction

ACUTE TOXICITY AGAINST FISH

Rainbow trout (Madsen, 1997a)

This test was performed using a static limit methodology with 80% renewal at 24, 48 and 72 hours. The test was performed in triplicate over a 96-hour period using five specimen fish per replicate at 16 ± 1ºC. The tests were conducted using a water accommodation fraction (WAF) of the test substance made up at a nominal concentration of 1000 mg/L together with controls containing no test material. The WAF was prepared by stirring approximately 18 g of OLOA 224 into 18 L of water at 23 - 24ºC for 24 hours, and cooling to the test temperature of 15ºC prior to siphoning off the water for use in the test. No film or undissolved test material was observed in the test media. Water hardness was around 145 mg/L as $CaCO_3$, while the pH and dissolved oxygen levels were always 7.8 - 8.2 and 7.4 - 8.9 mg/L, respectively. The Total Organic Carbon (TOC) content in the test media was determined after 24 hours as < 1 mg/L, in both the test medium and a sample of unused WAF preparation.

No fish mortality, or abnormalities in the test system or fish behaviour, were observed over the 96 hour test duration. The LC50 and No Observed Effect Concentration (NOEC) were taken as > 1000 mg/L WAF. These results indicate that the notified chemical is not toxic to this species of fish up to the limit of its water solubility.

Sheepshead minnow (Rausina, 1987)

The tests on this saltwater species were conducted over 96 hours at 20 - 23ºC using Water Soluble Fractions (WSF) of the test material made up in sea water at nominal concentrations of 0 (control), 0.1, 1 and 10 g/L. The WSFs were prepared by stirring requisite amounts of the test material into the sterilised water for 20 hours, and allowing them to settle for 2 hours. The WSF was then siphoned away from the remaining insoluble material and used in the tests. The WSFs prepared as described were clear and apparently free of insoluble material.

Each test was conducted in duplicate using 10 fish in each test vessel. The pH and dissolved oxygen levels were always 7.8 – 8.6 and 6.8 - 7.5 mg/L, respectively. The water used was sea water diluted to a salinity of 20 parts per thousand.

The results of these tests were unusual in that no fish mortality was observed over the 96 hour test period in the WSF prepared at nominally 10 g/L, while 10% mortality was observed in the nominally 1 g/L preparation, and fish mortality in excess of 50% (80% in one replicate) was observed at nominally 0.1 g/L. It is likely that this trend was a result of incorrect labelling of the test media, and while the report author accepted that the material was not acutely toxic to this species up to a WSF of 10 g/L, it is prudent to interpret the data as indicating some toxicity.

Zebra fish (Wyness, 1996a)

This test was conducted over a 96 hour period using static methodology without renewal of the test media with solutions of OLOA 224 made up at a nominal concentrations of 0 (control[1]), 0.25, 0.5, 1.0, 2.0 and 4.0 mg/L. The test was conducted in soft water (44 mg/L as $CaCO_3$) at 22±0.5 ºC, while the pH and dissolved oxygen were 7.1-7.8 and between 82 and 98 % saturation, respectively. The test was conducted using seven fish in each test vessel, and no fish mortality or sublethal effects were observed at any concentration over the duration of the test.

The results indicate that the test material is not toxic to this species of fish up to the limits of its water solubility, claimed to be 4 mg/L, although no corroborating evidence was included in the report. However, the author stated that while determination of the concentration of test material was attempted this was not successful, and accordingly the stated results should be treated with caution due to uncertainties in test material concentration.

ACUTE TOXICITY AGAINST INVERTEBRATES

***Daphnia magna* (Wyness, 1996b)**

This test was conducted over a 48 hour period using static methodology without renewal of the test media with solutions of OLOA 224 made up as described above for the zebra fish test at nominal concentrations of 0 (control), 0 (solvent control), 0.25, 0.5, 1.0, 2.0 and 4.0 mg/L. The test was conducted at 22 ± 0.5ºC, while the pH and dissolved oxygen were 7.7 - 8.5 and between 92 and 98 % saturation, respectively, and the water hardness was 200 mg/L as $CaCO_3$. Twenty daphnia were used in each test vessel, and no mortality or sublethal effects were observed at any concentration over the duration of the test. The results indicate that the test material is not toxic to this species to the limits of its water solubility (ie. claimed as 4 mg/L – see notes above).

***Daphnia magna* (Madsen, 1997b)**

This test was performed using a static limit methodology with 80% renewal at 24 and 48

[1] The test solutions were made up by firstly dissolving the OLOA 224 in dichloromethane to produce an 80 g/L stock solution. An aliquot of this was added to the test water sufficient to give a nominal concentration of 8 mg/L, stirred for 18 hours, allowed to stand for more than 1 hour.
The "solution" was drawn off to make the dilutions mentioned above. In addition to the water control, a solvent control (containing dichloromethane) was also run in parallel.

hours. The test was performed over a 48 hour period in quadruplicate using five daphnia per replicate at a temperature of 21 ± 1ºC. The tests were conducted using a single WAF of the test substance made up at a nominal concentration of 1000 mg/L together with controls containing no test material. The WAF was prepared as described above for the test on rainbow trout. Water hardness was around 145 mg/L as $CaCO_3$, while the pH and dissolved oxygen levels were always 8.4 – 8.5 and 7.9 - 8.7 mg/L, respectively. The TOC content in the test media was also determined after 24 hours as being around 1.8 mg/L, which was not substantially different from the 1.4 mg/L TOC for unused WAF preparation.

No immobilisation of the daphnia was observed after 24 hours exposure, although after 48 hours 15% (3 Daphnia) were observed to be on the bottom of the test vessels. However, it should be noted that after 48 hours some immobilisation and behavioural abnormalities were also observed in the control vessels (15% of the "control" daphnids). Consequently, since there were no overall statistically significant differences between the fate of the daphnia in the controls and test media, the LC50 and NOEC were estimated as being > 1000 mg/L WAF, indicating the test material is not toxic to this species up to the limit of its water solubility.

Mysid Shrimp (Suprenant, 1988)

The tests on this saltwater invertebrate were conducted over 96 hours at 25 ± 2ºC using WAFs of the test material made up in sea water at nominal concentrations of 0 (control), 31, 63, 130, 250, 500 and 1000 mg/L. The WAFs were prepared by stirring requisite amounts of the test material into the sterilised water for 20 hours. After leaving the solutions to settle for 2-4 hours the WAFs were siphoned away from the remaining insoluble material and used in the tests. Each test was conducted in duplicate using 10 mysids in each test vessel. The pH and dissolved oxygen levels were always 7.8 – 8.1 and 4.8 - 7.2 mg/L, respectively, while the water used was sea water with a salinity of 29 - 32 parts per thousand. The TOC in the control and two of the WAF preparations prepared at nominally 31 and 1000 mg/L, was measured at 0 and at 24 hours after preparation. The mean concentrations were 3.8 (control), 4.3 and 5.8 mg/L, respectively, indicating that very little of the test material entered the aqueous phase.

No statistically significant differences between the mortality of test animals in the controls and test media were observed over the 96 hour test period for the (nominally) 31 and 63 mg/L preparations, but 15% mortality occurred after 48 hour exposure to the (nominally) 130 mg/L WAF (increasing to 20% after 96 hours). The highest mortality rate was for 96 hours exposure to the (nominally) 1000 mg/L WAF, which was 35%.

Analysis of the observed results provided a 96 hour LC50 > 1,000 mg/L and a corresponding 96 hour NOEC of 63 mg/L. Results indicate some toxic effects of the compound against this species. However, it was noted in the report that in those preparations for which significant mortality was observed, all test media showed evidence of an oily film on the surface. It is possible that the observed toxic effects were physical in origin rather than being due to true chemical toxicity.

ACUTE TOXICITY AGAINST ALGAE

Algae (Madsen, 1998a)

A test on algal growth inhibition was performed under static conditions over 96 hours on

Selenastrum capricornutum with WAFs made up at the nominal concentrations of 0 (control), 15.6, 31.3, 62.4, 125, 250, 500 and 1000 mg/L at a temperature of 24 ± 1°C. Each test, including the control was conducted in triplicate with the cell density determined using a coulter counter. It is to be noted that while the WAFs were prepared at the above nominal concentrations, the actual concentrations in solution were very much lower, and the measured TOC in even the highest concentration WAF was < 1 mg/L.

Significant inhibition of algal growth rate (compared with the controls) was observed at all nominal test concentrations, and the results analysed using acceptable statistical methods (eg. Shapiro-Wilks and Dunnett's tests), to provide an E_bC50 of 174 mg/L WAF and an E_rC50 of 854 mg/L WAF with a 96 hour NOEC of 15.6 mg/L WAF based on the area under the growth curves. The results indicate that the new compound shows some toxicity to this species.

Algae (Ward *et al*, 1994)

A second algal growth inhibition test was conducted against *Selenastrum capricornutum* using WAFs of nominally 0 (control), 6.2, 12, 25, 50 and 100 mg/L over a 96 hour period. The test was conducted in duplicate, and gave a 72 hour E_bC50 of 17 mg/L WAF and a corresponding NOEC of 12 mg/L WAF. These results indicate a lower E_bC50 than the test described above although the NOEC is comparable, and indicates some toxicity to this species of algae.

Algae (Wyness, 1996c)

A third test against *Selenastrum capricornutum* conducted in a similar manner found that both the 72 hour E_bC50 and 72 hour E_rC50 were greater than 4 mg/L which was taken as the limit of water solubility for the compound.

CHRONIC TOXICITY TESTS

***Daphnia magna* (Madsen, 1998b)**

A report on a 21-day study of the chronic toxicity (reproduction) of the compound against *Daphnia magna* was also submitted. This test was conducted according to OECD TG 202 using WAFs with nominal concentrations of 0 (control), 100 and 1000 mg/L. No toxic effects on daphnia reproduction or other adverse effects were observed over the 21-day test period and the Maximum Allowable Toxic Concentration (MATC) was taken as > 1,000 mg/L WAF.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical is considered to be low provided that the material is used as a component of diesel locomotive engine lubricants, where there is little potential for release of the notified material to the environment. Losses during lubricant formulation and transfer to engine crankcases are estimated as a maximum of 50 kg per annum (1% of imports), which would be either incinerated or be placed into landfill.

It is expected that much of the material contained in locomotive engine lubricants would be destroyed through incineration in the engines, since apparently much lubricant oil is burnt during their operation. Some old oil will be removed from engines during routine maintenance at railway workshops, and mostly recycled or used as an extender for diesel fuel. Very little release is anticipated from maintenance activities.

The chemical has a high value for log Pow and if released to the soil compartment would become strongly associated with the organic component of soils and sediments in which it is not expected to be mobile.

The chemical is not readily biodegradable, but if released to landfill or associated with soil it is expected to slowly degrade through various biological and abiotic processes operative in these situations. The compound will mineralise to water and oxides of carbon and nitrogen and the calcium component will associate with soil minerals. Incineration would lead to similar products, although the calcium will assimilate into ash.

Based on a total of 9 tests conducted against a variety of freshwater and marine organisms (fish, invertebrates and green algae), the notified chemical is at worst slightly toxic to the aquatic species (both fresh water and marine) against which it has been tested. However, very little of the chemical is likely to reach the aquatic compartment and damage to aquatic organisms is not considered likely.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

Old OLOA 224 was used to generate the toxicological data. It was of very low acute oral toxicity and low acute dermal toxicity in rats. It was a slight skin irritant and a slight eye irritant in rabbits. It was a skin sensitiser in guinea pigs when applied undiluted and at concentrations of 37%, 15% and 5.9% but was not sensitising at 6.0%. The 37% dilution was not sensitising in a patch test using human volunteers. The test substance containing 15% OLOA 224 (OLOA 2000) would not be classified as a skin sensitiser according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) but the finished oil XA 14328 containing 5.9% OLOA 224 would be so classified. The reason for this may be that a higher concentration of OLOA 224 was used for challenge in the latter case than in the former where a maximal non-irritant concentration was employed. The fact that 37% OLOA 224 was sensitising to guinea pigs but not to humans suggests that XA 14328 also would not be sensitising to humans.

OLOA 224 is determined to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) in terms of skin sensitisation and is assigned the risk phrase R43: May cause sensitisation by skin contact. However, the imported product is not determined to be hazardous according to these criteria and is not assigned this risk phrase R43.

Repeated dose 28-day oral and dermal studies with OLOA 224 did not reveal any systemic toxicity at doses up to 1000 mg/kg/day. In the oral study no neurotoxicity or reproductive effects were noted.

OLOA 224 was weakly mutagenic in bacteria but was not clastogenic in CHO cells (chromosomal aberrations) or mouse bone marrow cells (micronuclei) in vivo.

Occupational Health and Safety

During import and transport of the notified chemical, worker exposure is unlikely except in the event of a spill. Exposure after a spill would be controlled by use of the recommended practices for spillage clean up outlined in the MSDS supplied by the notifier.

Blended oils are produced by pumping the additive package to a blend tank via a drum pump. This operation is of short duration and workers wear gloves, overalls and eye protection to control exposure. Samples are taken for analysis by workers wearing the same personal protective equipment (PPE) and, again, this operation is of short duration. Some exposure may be possible when cleaning the tank with oil. Following blending, the oil is pumped automatically to drums or storage tanks. There is a possibility of worker exposure to drips and spills and workers wear gloves, overalls and eye protection to control exposure. Given that most operations are of short duration on few days per year, the workers wear adequate PPE and the hazard is low, there is negligible risk of adverse health effects from lubricant blending.

Workers transferring lubricant to railroad engines wear PPE as above and exposure should be low. Mechanics working on engines typically wear overalls but not gloves. OLOA 224 is at a maximum concentration of 6% in finished oils and end use product labels will need to warn of skin sensitisation, and provide for PPE, unless tests on the formulation indicate otherwise.

Public Health

Since the notified chemical is used in engines not handled by the public and there is limited potential for exposure during transport and storage of the imported formulation or blended oils, the risk of adverse public health effects is negligible.

13. RECOMMENDATIONS

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

- It is recommended that OLOA 224 be labelled as a Skin Sensitiser with the following R and S phrases :

R43	May cause sensitisation by skin contact
S24	Avoid contact with skin
S27	Wear suitable gloves

- Workers should be advised of the potential for occupational dermatoses following repeated skin exposure to OLOA 224 and to report any skin changes to the occupational health and safety officer at their workplace. When an occupational skin disease occurs, work practices and opportunities for contact with the substance should be reviewed and preventive measures instigated to

ensure other workers do not develop the same condition. Further guidance on preventing the occurrence of occupational skin diseases can be found in the NOHSC guide *Occupational Diseases of the Skin* (NOHSC, 1990).

- Personal protective equipment (PPE) should be used on all occasions where exposure to additive packages containing the notified chemical occurs. The notifier recommends nitrile, viton or silver shield gloves. Chemical impervious clothing is also necessary to prevent skin contact. Consideration should be given to the ambient environment, physical requirements and other substances present when selecting protective clothing and gloves. Workers should be trained in the proper fit, correct use and maintenance of their protective gear. PPE guidance in the selection, personal fit and maintenance of personal protective equipment can be obtained from:

Protective eyewear:	AS 1336 (SAA 1994);
	AS/NZS 1337 (SAA/SNZ 1992).
Chemical impermeable clothing:	AS 3765.2 (SAA 1990).
Impermeable gloves:	AS 2161.2 (SAA/SNZ 1998).
Occupational footwear:	AS/NZS 2210 (SAA/SNZ 1994);

- If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), workplace practices and control procedures consistent with provisions of State, Territory and Commonwealth legislation based on the *National Model Regulations for the Control of Workplace Hazardous Substances* must be in operation.

- OLOA products are identified as a C2 combustible liquid and should be stored, handled and used in accordance with AS 1940 (SAA 1993);

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

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical and the imported additive package were provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, the director must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise, and secondary notification of the notified chemical may be required. No other specific conditions are prescribed.

16. REFERENCES

Chevron (1985a) The Acute Oral Toxicity of OLOA 224 (APD 4784) in Adult Male and Female Rats. Study No. SOCAL 2393. CA, USA, Chevron Environmental Health Center. (Unpublished report submitted by Chevron Chemical Australia).

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Attachment 1

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

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

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

CORNEA

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

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	3 severe	Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

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