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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

OLOA 11004

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Director
Chemicals Notification and Assessment

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OLOA 11004

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Chevron Oronite Australia of Level 8, 520 Collins Street MELBOURNE VIC 3000

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Chevron Oronite applied to claim exempt information for the following data requirements: chemical name, CAS number, structure, molecular formula, structural formula, molecular weight, spectral data, purity, identity and percent hazardous and non-hazardous impurities, import volumes, manufacture process, and manufacturing sites.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Chevron Oronite applied for variations of the schedule requirements for the following data elements: melting point; boiling point; vapour pressure; water solubility; hydrolysis as a function of pH; partition coefficient; adsorption/desorption; dissociation constant; autoignition temperature; toxicity and ecotoxicity data.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES

US:	Premanufacture Notice (PMN) in July 2000.
Canada:	New Substance Notification in October 2001.
Korea:	Notification in July 2003.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
OLOA 11004,
OLOA 11009,
CEA 610.

MOLECULAR WEIGHT
>1000

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD
Analytical methods used to detect these products include FTIR. Detection down to one ppm is possible.

Infrared can be used for routine detection in the workplace. Total Acid Number titration may also be useful in certain circumstances.

3. COMPOSITION

DEGREE OF PURITY
>60%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-30	10-30	10-30	10-30	10-30

USE
Engine oil additive.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Lubricant oil manufacturers.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported into Australia by ship in marine isotanks and 200 L drums. The finished oil products containing OLOA 11004 will be packaged in 1 or 4 litre plastic bottles, 200 L drums or in 8000 L isotanks..

5.2. Operation description

After importation, these lubricating oil packages containing approximately 30% notified chemical are supplied to the lubricating oil manufacturers in Australia. These manufacturers will blend the lubricating oil packages with other substances to produce finished lubricants. Typically, the finished lubricant contains <10% of the notified chemical.

The finished products are used as a lubricant for diesel, petroleum and natural gas engines.

5.3. Occupational Exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Storage	10-20	1-2 hours	50 days/year
Reformulation/Blending	2-3/site	0.5 – 1 hour	200 days/year
Laboratory Staff	1-2/site	0.25 hours	200 days/year
End Users	>1000	1-8 hours	200 days/year

Exposure Details

Transport and Storage
Transport and storage workers are not expected to be exposed to the notified chemical during transport except in the case of an accidental spill.

When imported in bulk, the additive package is transferred from the ship to a holding tank, then to road tankers. During this process, exposure of the waterfront and transport workers to spills of the additive package containing the notified chemical is possible while connecting and disconnecting the transfer hoses. The main route of exposure for transport and storage workers will be dermal. These workers will wear overalls, safety boots and gloves when handling containers.

Reformulation / Blending
When the notified chemical arrives in either isotanks or by road tankers, it will be unloaded and transferred to storage tanks via a 10 cm hosing. The connection of the hose line takes about 10 minutes for a worker. A special air back flush system is used to prevent spillage during transfer. By adhering to ISO 9001 procedures, spills and leaks will be minimised.

When the notified chemical arrives in drums, the transfer process takes 10 minutes for a worker to place a drum pump and transfer drum contents. During the connection and disconnection of lines, incidental skin contact from splashes, drips and spills is possible.

Transfer from storage tanks to the blend tank (10000 L capacity) will be automated, using computer-controlled valves. The blending process occurs in a closed system at 60°C and is also computer controlled, thereby excluding the potential for occupational exposure. The blended lubricant containing <10% notified chemical is transferred automatically to a storage tank.

The finished lubricants are packaged in 1 L bottles, 4 L bottles, 200 L drums, tank trucks or rail cars. Workers may be exposed to the finished lubricant containing notified chemical during the filling operations. The filling of the 1 L and 4 L bottles is highly automated, with little occupational exposure. The drumming facility uses automated weight scales to fill the drums, and worker exposure may occur as the operator watches from about 1-2 meters away to ensure the drum filling mechanism properly enters the drum before the drum is filled. The operators then put on the bungs and labels. The filling of bulk-tank truck or rail-car filling is performed via a transfer hose. Dermal exposure to drips and spills of blended lubricant is possible during the connection and disconnection of transfer hoses while filling the bulk containers.

The blending tank and the transfer lines are cleaned by rinsing with clean lubricating oil. Maintenance workers handling the equipment used for blending and filling may also come into dermal contact with residues containing the notified chemical. Empty drums are sent to drum recyclers where they are steam cleaned.

The blending facilities are well ventilated, with control systems for accidental spills and wastewater treatment. Workers involved in the blending activities receive training in the handling of additive packages, and wear personal protective equipment such as gloves, eye protection, protective clothing and hard hats.

Laboratory Staff
Laboratory staff at the blending facility will take samples of the additive package containing the notified chemical and the blended products for testing. During sampling and analysis, there may be skin contact. However, only minimal exposure would occur during the laboratory testing since the sample size is small and testing will only take a few minutes per batch.

End Users
Occupational exposure to the products containing the notified chemical will occur at railway manufacturing and repair facilities and automotive workshops throughout Australia. End users may be exposed to the blended oil products containing <10% of the notified chemical. Exposure may occur during the transfer the blended oil products from the storage containers into the vehicle being serviced and during cleaning of equipment. There is potential for exposure when oils are added to and drained from systems.

A large number of railway mechanics (>1000) may be exposed to the products under a wide range of conditions. However, these workers are professionals and would be expected to have been trained in the proper handling of lubricants and oil products. Workers will wear overalls, cotton hat and safety boots when using products containing the notified chemical.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured in Australia. Local operation will include transport and storage, blending, filling and packaging.

The additive package will be imported into Australia in isotanks and drums. Using ISO 9001 procedures, spills and leaks are expected to be <50 g (12.5-17.5 g notified substance) per unloading, or 45 g/y, before waste water treatment. The hose end is kept in an oily drain when not in use. Any spills or leaks are sent to the on-site chemical/storm waste water system that includes an American Petroleum Industry (API) water and oil separator which removes approximately 90% of the notified substance from the waste water. The waste oil containing the notified substance is sent to a used oil recycler who re-refines the waste oil into fresh lubricant base stock using hydrocracking technology. The bottoms product containing the notified substance from the re-refining process becomes asphalt. The waste water is sent to a pond where it is further treated by induced air flotation and biological treatment with waste sludge incinerated off site. After biological treatment, the waste water is filtered through a biodisk and sand before being released. This additional process removes a further 8% of the spilled notified substance. Altogether about 0.9 g/y (about 2% of the imported amount) will be released to the environment from spills during unloading.

The isotanks and drums are generally cleaned after use with oil, which is sent for used oil recycling. About 0.1% of the notified substance would remain in the drum or isotank after emptying. Therefore, a maximum of 20 kg/y of the notified substance would be sent to recycling, resulting in 400 g/y to be released due to cleaning (based on 98% removal efficiency).

The blending operations will take place at specially constructed sites owned and operated by the major lubricant manufacturers. It is anticipated that there will be minimal release of the notified chemical during transfer from the storage containers to the blending tanks, as a special air back flush system prevents any spillage. Blending occurs in fully enclosed automated systems. Blending tanks will be cleaned with lube oil, which will typically be recycled during subsequent blending, or incinerated. Any spills incurred in the blending operations will be contained within concrete bunds and either reclaimed or sent to on-site waste-water treatment facilities where residual hydrocarbon based products will be separated from the aqueous stream by the API process.

The notified substance will be blended into finished lubricant at <10% by weight. The filling processes are computer automated, so minimal spills due to loading are expected. Therefore, losses from spills and leaks are expected to be <50 g of the finished lubricant, or 1-2 g of the notified chemical per year.

Activity	*Estimated release to environment (g/y)*
Unloading isotanks and drums	0.9
Isotank and drum cleaning	400
Filling finished lubricant containers	2

RELEASE OF CHEMICAL FROM USE

The finished lubricants for use in engine oils will be sold in 1 and 4 L plastic containers, 200 L drums and 8,000 L isotanks to industrial and commercial customers. The notified chemical is not substantially altered during use in natural gas and railroad engines. There may be some accidental losses when lubricant is added to or changed in vehicle engines which may be about every 5,000-10,000 kilometres for light duty trucks and passenger car diesel and petrol engines. In the closed system of an engine, there is no expected release of the chemical to the environment under normal conditions of use, except for oil leaks.

Since the use of the lubricating oils will occur throughout Australia, any releases from use of old oil would be diffuse.

5.5. Disposal

Isotanks and drums used to receive the additive packages

The isotanks and drums are generally cleaned with oil and reused. This oil is used in subsequent blending operations.

Drums used to distribute finished products

The drums are sent to recyclers where they are steam cleaned with water sent to wastewater treatment. Assuming 0.1% remains in the drum after use, 20 kg/y will be disposed of to wastewater based on a total import volume of 20,000 kg/y of the notified chemical. With a wastewater treatment efficiency of

98%, about 400 g/y of the notified substance would be released to the environment.

Small containers
An estimated 10-20% of the finished lubricants are sold to consumers in small containers which are likely to be sent to landfill for disposal. Assuming 0.1% remains in the containers after use and 20% of the total import volume is sold in small containers, about 4,000 g/y would be sent to landfills.

Used oils
The greatest potential for environmental exposure is through disposal of oil product wastes containing the notified chemical. A survey by the Australian Institute of Petroleum (AIP 1995) indicates that of the annual sales of automotive engine oils in Australia, some 60% are potentially recoverable (ie. not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases could be expected to be disposed of responsibly either to oil recycling or incineration. Assuming this is the case, negligible release of the notified chemical should result from these professional activities. The remaining 14% (2,800 kg of the estimated maximum 20 tonnes imported) are removed by "do it yourself" (DIY) enthusiasts, and in these cases some of the used oil would be either incinerated, left at transfer stations where it is again likely to be recycled, or deposited into landfill. Meinhardt (2002) estimated that DIY activities account for 7-10% of the unaccounted used oil. However, changing of heavy duty engine oils is likely to be carried out by specialists with less irresponsible disposal practices.

According to a survey tracing the fate of used lubricating oil in Australia (Snow 1997), only around 20% of used oil removed by enthusiasts is collected for recycling, approximately 25% is buried or disposed of in landfill, 5% is disposed of into stormwater drains and the remaining 50% is used in treating fence posts, killing grass and weeds or disposed of in other ways. In a worst case scenario of 14% of the used oil removed by DIY enthusiasts, the notified chemical could be collected for recycling (≤560 kg), buried or disposed of in landfill (up to 700 kg), disposed of in stormwater drains (≤140 kg) and used in treating fence posts, to kill weeds or disposed of in other ways (≤1,400 kg).

Therefore, about 0.7% (140 kg) of the total import volume of the notified substance could be expected to enter the aquatic environment via disposal into the stormwater system. Since the use of the lubricating oils will occur throughout Australia, all releases resulting from use or disposal of used oil will be very diffuse, and release of the notified material in high concentrations is very unlikely except as a result of transport accidents.

Residues in empty containers from garages and DIY consumers would be disposed of in municipal landfills.

5.6. Public exposure
The public who will use the products containing the notified chemical will include automotive do-it-yourself persons, farmers, or anyone who changes oil of their engines. It is estimated that 10-20% of the finished lubricants will be sold into the consumer market.

The maximum concentration of the notified chemical in the combustion engine lubricant is <10%. Changing lubricant is not a routine practice for the public users; however, they are not expected to wear personal protective equipment when handling the products containing the notified chemical.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Dark brown liquid

Melting Point/Freezing Point Not applicable

Remarks Pour point is approximately -10ºC (Concawe, 1997).

Boiling Point 300-600ºC

Remarks Initial boiling point of highly refined lubricant base oil. Decomposes at > 400ºC (Concawe, 1997).

Density	912 kg/m^3 at 15 °C
METHOD	ASTM D4053/OPM448
Vapour Pressure	< 1.7 x 10^{-7} kPa at 25°C
Remarks	Based on partial pressure of the highly refined lubricant base oil (Concawe, 1997).
Water Solubility	0.125 mg/L at 20°C
METHOD	Removal of diluent oil by Soxhlet extraction followed by a generator column method.
Remarks	The test was presumably performed on the polyolefin polyamine succinimide parent (OLOA 371) used to make the notified chemical, but the identity of the chemical could not be confirmed by DEH from the report provided. Although the parent compound is neutral and the notified chemical is cationic and potentially more soluble, the large hydrophobic chain is expected to dominate and render the chemical relatively insoluble in water. The water solubility of OLOA 371 is 0.54 µg/L based on the QSAR estimated log K_{OW} of 6.07.
TEST FACILITY	Rausina et al. 1996
Hydrolysis as a Function of pH	Not expected to hydrolyse in strong acid or base due to low water solubility and lack of hydrolysable functional groups.
Partition Coefficient (n-octanol/water)	log K_{OW} at 20°C estimated to be >4
Remarks	Estimated based on the low water solubility and QSAR modelling on the parent OLOA 371 using EPIWIN parent models A, B and C indicating a range of 6.07-8.20.
Adsorption/Desorption	K_{oc} estimated to be ~3000
Remarks	Based on the low water solubility of the parent OLOA 371 and QSAR modelling (as above log K_{OW} of 6.07-8.20), the notified chemical is expected to adsorb strongly to soil and sediment.
Dissociation Constant	Not provided.
Remarks	The notified chemical is a salt which is expected to become neutralised at high pH.
Particle Size	Not determined for liquid.
Flash Point	203-204°C
METHOD	ASTM D92/OPM530-1
Flammability Limits	Not flammable
Autoignition Temperature	Not tested due to the high flash point.
Explosive Properties	Not explosive
Remarks	This chemical will not detonate as a result of heat, shock or friction
Reactivity	May react with strong oxidizing agents, such as chlorates, nitrates, and peroxides. Hazardous polymerisation will not occur.

Viscosity	900 cSt at 40°C and 65 cSt at 100°C
METHOD	ASTM D445/OPM 521

7. TOXICOLOGICAL INVESTIGATIONS

The notified chemical, OLOA 11004, is the reaction product of OLOA 371 and terephthalic acid (TPA). The notifier provided toxicological studies on OLOA 232E, a chemical with a very close chemical structure, and the two starting materials, OLA 371 and TPA.

Toxicological studies on OLOA 232E

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	LD50>5000 mg/kg bw, low toxicity
Rat, acute dermal	LD50>5000 mg/kg bw, low toxicity
Rabbit, skin irritation	slightly to moderately irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation-non-adjuvant test (1).	inadequate evidence of sensitisation.
Guinea pig, skin sensitisation-non-adjuvant test (2).	limited evidence
Rat, repeat dose.	Not study provided
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mouse lymphoma cells	non mutagenic
Genotoxicity – in vivo	Not study provided

7.1. Acute toxicity – oral

TEST SUBSTANCE	OLOA 232E
METHOD	Similar to OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Sprague Dawleys
Vehicle	None
Remarks - Method	None

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	10 males	5000	0

LD50	>5000 mg/kg bw
Signs of Toxicity	None.
Effects in Organs	None.
Remarks - Results	None
CONCLUSION	OLOA 232E is of low toxicity via the oral route.
TEST FACILITY	Chevron Chemical Company (1972).

7.2. Acute toxicity - dermal

TEST SUBSTANCE	OLOA 232E
METHOD	Similar to OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rabbit/New Zealand White
Vehicle	None
Type of dressing	Occlusive.

Remarks - Method None

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	6 males	5000	0

LD50 >5000 mg/kg bw
Signs of Toxicity - Local Moderate skin irritation was observed.
Signs of Toxicity - Systemic None.
Effects in Organs None except staining of the applied areas on 2 rabbits.
Remarks - Results None

CONCLUSION OLOA 232E is of low toxicity via the dermal route.

TEST FACILITY Chevron Chemical Company (1972).

7.3. Irritation – skin

TEST SUBSTANCE OLOA 232E

METHOD Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 6
Vehicle None
Observation Period 72 hours
Type of Dressing Occlusive.
Remarks - Method 24-hour exposure study.

RESULTS

Intact skin

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	1.8	2	72 hours	2
Oedema	1.1	3	72 hours	2

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Abraded skin

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	1.8	2	72 hours	2
Oedema	1.0	3	72 hours	2

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results Draize scores were recorded at 24 and 72 hours after treatment.

The primary irritation index (PII) for both intact skin and abraded skin was 1.42.

CONCLUSION OLOA 232E is slightly to moderate irritating to skin.

TEST FACILITY Chevron Chemical Company (1972).

7.4 Irritation - eye

TEST SUBSTANCE OLOA 232E

METHOD Similar to OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 6
Observation Period 7 days
Remarks - Method None

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.9	2	7 days	1
Conjunctiva: chemosis	0.1	1	1 day	0
Conjunctiva: discharge	0.3	2	1 day	0
Corneal opacity	0	-	-	0
Iridial inflammation	0	-	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results The mean Draize scores for redness, chemosis and discharge at 1 hour were 1.8, 1 and 1.5, respectively.

CONCLUSION OLOA 232E is slightly irritating to the eye.

TEST FACILITY Chevron Chemical Company (1972).

7.5. Skin sensitisation (1)

TEST SUBSTANCE OLOA 232E

METHOD OECD TG 406 Skin Sensitisation – Buehler method
Species/Strain Guinea pig/Hartley
PRELIMINARY STUDY Not reported.

MAIN STUDY
Number of Animals Test Group: 15 (low-dose), 15 (high-dose); Control Group: 10 (first challenge control), 10 (second challenge control), 10 (irritation control)
INDUCTION PHASE Induction Concentration:
topical: 5% in mineral oil (low dose group)
25% in mineral oil (high dose group)
Signs of Irritation Number of animals showing skin reactions (Draize score ≥1) after inductions were listed below:

Animal	*Number of Animals Showing Skin Reactions*			
	after 1st induction		*after 5th induction*	*after 10th induction*
	24 h	*48 h*	*24 h*	*24 h*
Test Group				
Low-dose	0/15	1/15	9/15	1/15
High-dose	0/15	2/15	7/15	3/15
Control Group				
1st challenge control	0/10	2/10	4/10	1/10
2nd challenge control	0/10	2/10	4/10	1/10
irritation	0/10	0/10	7/10	1/10

CHALLENGE PHASE
1st challenge topical: 25% in mineral oil
2nd challenge topical: 25% in mineral oil

Remarks - Method GLP & QA

The induction course included 10 occluded dermal applications, which were administered on alternate days. The animals were challenged 14 days and 21 days after the last induction.

RESULTS

Animal	*Challenge Concentration*		*Number of Animals Showing Skin Reactions*					
	1st challenge	*2nd challenge*	*1st challenge*			*2nd challenge*		
			24 h	*48 h*	*72 h*	*24 h*	*48 h*	*72 h*
Test Group								
Low-dose	25%	25%	5/15	13/15	12/15	3/15	3/15	1/15
High-dose	25%	25%	8/15	13/15	12/15	7/15	4/15	7/15
Control Group								
1st challenge	25%	vehicle	3/10	8/10	8/10	4/10	4/10	4/10
2nd challenge	vehicle	25%	3/10	6/10	6/10	8/10	5/10	3/10
Irritation	vehicle	-	1/10	5/10	7/10	-	-	-

Remarks - Results After challenges, the challenge control groups, which inducted with mineral oil showed skin irritation greater than or equal to that in both test groups.

CONCLUSION OLOA 232E may have skin sensitising ability but the test conditions employed are inadequate or not sufficiently documented. Therefore, on the basis of inadequate evidence, no conclusion is made.

TEST FACILITY Chevron Environmental Health Center Inc (1986).

7.6. Skin sensitisation (2)

TEST SUBSTANCE OLOA 232E

METHOD OECD TG 406 Skin Sensitisation – Buehler method
Species/Strain Guinea pig/Hartley
PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: <0.5%
MAIN STUDY
Number of Animals Test Group: 10/sex; Control Group: 5/sex (first challenge control), 5/sex (second challenge control)
INDUCTION PHASE Induction Concentration:
topical: 100%
Signs of Irritation Not reported
CHALLENGE PHASE
1st challenge topical: 100%
2nd challenge topical: 100%

Remarks - Method GLP & QA

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*

		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100%	9/19	3/19	4/19	2/19
Control Group (1st challenge control)	100%	6/10	0/10	-	-
Control Group (2nd challenge control)	100%	-	-	1/10	0/10

Remarks - Results: Limited evidence of skin sensitisation was observed in the test group.

CONCLUSION: Limited evidence of reactions indicative of skin sensitisation to OLOA 232E under the conditions of the test.

TEST FACILITY: Hill Top Biolabs Inc (1991).

7.7. Genotoxicity - bacteria

TEST SUBSTANCE: OLOA 232E

METHOD: OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA98, TA100 and TA102 *E. coli*: WP2 uvrA
Metabolic Activation System	S9 mix
Concentration Range in Main Test	a) With metabolic activation: 0-10000 µg/plate. b) Without metabolic activation: 0-10000 µg/plate.
Vehicle	25% Pluronic F127 in ethanol
Remarks - Method	GLP & QA.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1		>10000	Not reported	Not observed
Present				
Test 1		>10000	Not reported	Not observed

Remarks - Results: OLOA 232E showed a weak mutagenic potency, $\leq 2 \times 10^{-2}$ revertants per µg OLOA 232E, to TA100 with metabolic activation and to TA102 with and without metabolic activation.

CONCLUSION: OLOA 232E was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY: Chevron Environmental Health Center (1985).

7.8. Genotoxicity – in vitro

TEST SUBSTANCE: OLOA 232E

METHOD: OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.

Cell Type/Cell Line	L5178Y TK+/- Mouse Lymphoma cells
Metabolic Activation System	S9 mix
Vehicle	Ethylene glycol diethyl ether

Remarks - Method GLP & QA.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 7.5, 10, 13, 18, 24, 32, 42, 56, 75, and 100	4 hours	52 hours
Present			
Test 1	0, 7.5, 10, 13, 18, 24, 32, 42, 56, 75, and 100	4 hours	52 hours

RESULTS

Remarks - Results

The concentrations of OLOA 232E produced a range in suspension growth of 19% to 51% for the culture without activation, and from 23% to 74% for the S9 activated cultures.

After cloning, 3 cultures without activation (100, 56 and 32 μL/mL) exhibited higher mutant frequencies, which were 4.9, 4.9 and 2.3 times, respectively, of the solvent controls. The total growth of these cultures was 2%, 4% and 14%, respectively. The remaining cultures without activation did not exhibit mutant frequencies, which were significantly greater than the solvent controls. The total growth of these cultures ranged from 12-35%. A dose dependent response was not evident in the treated cultures.

After cloning, one culture with S9 activation (75 μL/mL) exhibited a mutant frequency that was 4.8 times than the solvent control. The total growth of this culture was 2%. The remaining cultures with S9 activation did not exhibit mutant frequencies significantly greater than the solvent controls. The total growth of these cultures ranged from 2-62%. A dose dependent response was not evident in the treated cultures.

The results indicate that, under the conditions of this test, OLOA 232E produced a negative response in the presence and absence of exogenous metabolic activation.

CONCLUSION OLOA 232E was not mutagenic to L5178Y TK+/- mouse lymphoma cells treated in vitro under the conditions of the test.

TEST FACILITY Microbiological Associates Inc (1986).

Toxicological studies on OLOA 371

Rat, acute oral	LD50>5000 mg/kg bw, low toxicity
Rat, acute dermal	LD50>2000 mg/kg bw, low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - non-adjuvant test.	limited evidence
Rat, repeat dose oral toxicity - 29 days.	NOAEL=1000 mg/kg/day
Neurotoxicity, oral – 29 days	NOAEL=1000 mg/kg/day
Reproductive toxicity	NOAEL=1000 mg/kg/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vivo mammalian bone marrow chromosomal aberration	non genotoxic

7.9. Acute toxicity – oral

TEST SUBSTANCE OLOA 371

METHOD | OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain | Rat/Crl:CD (SD)BR
Vehicle | None
Remarks - Method | GLP & QA.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	5000	0

LD50 | >5000 mg/kg bw
Signs of Toxicity | All animals appeared normal except 3 males exhibited a dark-stained anal area on day 1-5.
Effects in Organs | No lesions related to the treatment were observed.
Remarks - Results | None

CONCLUSION | OLOA 371 is of low toxicity via the oral route.

TEST FACILITY | Corning Hazleton Inc (1997a).

7.10. Acute toxicity - dermal

TEST SUBSTANCE | OLOA 371

METHOD | OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain | Rat/Crl:CD (SD)BR
Vehicle | None
Type of dressing | Semi-occlusive.
Remarks - Method | GLP & QA.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0

LD50 | >2000 mg/kg bw
Signs of Toxicity - Local | The Draize scores were all zero during the observation period (up to 14 days).
Signs of Toxicity - Systemic | None.
Effects in Organs | No lesions related to the treatment were observed.
Remarks - Results | None.

CONCLUSION | OLOA 371 is of low toxicity via the dermal route.

TEST FACILITY | Corning Hazleton Inc (1997b).

7.11. Irritation – skin

TEST SUBSTANCE | OLOA 371

METHOD | OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain | Rabbit/New Zealand White
Number of Animals | 6

Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	GLP & QA.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.1	1	24 hours	0
Oedema	0	1	4 hours	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results	The primary irritation index (PII) was calculated as 0.3.

CONCLUSION OLOA 371 is slightly irritating to skin.

TEST FACILITY Corning Hazleton Inc (1997c).

7.12. Irritation - eye

TEST SUBSTANCE OLOA 371

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	Unrinsed eye group: 6 Rinsed eye group: 3
Observation Period	72 hours
Remarks - Method	GLP & QA.

RESULTS

Rinsed eye group

Lesion	*Mean Score** *Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.7	0.3	0.3	2	48 hours	0
Conjunctiva: chemosis	0	0	0	-	-	0
Conjunctiva: discharge	0	0	0	-	-	0
Corneal opacity	0	0	0	-	-	0
Iridial inflammation	0	0	0	-	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Unrinsed eye group

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.6	2	48 hours	0
Conjunctiva: chemosis	0	-	-	0
Conjunctiva: discharge	0	-	-	0
Corneal opacity	0	-	-	0
Iridial inflammation	0	-	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results	The mean Draize scores for redness, chemosis and discharge at 1 hour for the rinsed group were 2, 1 and 0.3 respectively, and for the unrinsed groups were 2, o.3 and 0.8 respectively.

CONCLUSION	OLOA 371 is slightly irritating to the eye.
TEST FACILITY	Corning Hazleton Inc (1997d).

7.13. Skin sensitisation

TEST SUBSTANCE	OLOA 371
METHOD	OECD TG 406 Skin Sensitisation – Buehler method
Species/Strain	Guinea pig/Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: <0.5%
MAIN STUDY	
Number of Animals	Test Group: 10/sex Control Group: 5/sex
INDUCTION PHASE	Induction Concentration: topical: 100%
Signs of Irritation	Not reported.
CHALLENGE PHASE	
1st challenge	topical: 2.5% in mineral oil
Remarks - Method	GLP & QA
RESULTS	There were 3 topical inductions in test animals with 7-day interval.

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after 1st challenge*	
		24 h	*48 h*
Test Group	2.5%	1/20	0/20
Control Group	2.5%	0/10	0/10

Remarks - Results	None
CONCLUSION	There was limited evidence of reactions indicative of skin sensitisation to OLOA 371 under the conditions of the test.
TEST FACILITY	Hill Top Research Inc (1997).

7.14. Subchronic Toxicity, Neurotoxicity and Reproduction Study

TEST SUBSTANCE	OLOA 371
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage.
Vehicle	Corn oil
Remarks - Method	GLP & QA

Subchronic Toxicity Phase

METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Exposure Information	Total exposure days: 29-30 days; Dose regimen: 7 days per week; Post-exposure observation period: 14 days

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*

I (control)	6/sex	0	0
II (low dose)	6/sex	100	0
III (mid dose)	6/sex	500	0
IV (high dose)	6/sex	1000	0
V (control recovery)	6/sex	0	0
VI (high dose recovery)	6/sex	1000	0

Mortality and Time to Death
None.

Clinical Observations
No treatment-related effects were seen in the clinical observation.

Bodyweight and bodyweight gains, and food consumption in the test groups were comparable to the controls.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No treatment-related effects from the test groups were observed in haematological studies and urinalysis.

In clinical chemistry studies, higher AST levels in high-dose males recovery group, and a statistically significant difference in creatine levels between high-dose female recovery group and the controls were observed. However, these changes are not considered to be toxicologically significant.

Pathology
No treatment-related effects were observed. Organ weights, macro- and microscopic evaluations in the test groups were comparable to that of the controls.

Remarks – Results
As no treatment-related effects were observed in the study, the No Observed Averse Effect Level (NOAEL) would be the high dose administered in the study.

CONCLUSION FOR THE SUBCHRONIC STUDY
The NOAEL for systemic effects was established as 1000 mg/kg bw/day (the highest dose) in this study.

Neurotoxicity Phase

METHOD	OECD TG 424 Neurotoxicity Study in Rodents
Exposure Information	Total exposure days: 29 days; Dose regimen: 7 days per week; Post-exposure observation period: 14 days
Remarks - Method	At the end of study, the animals were perfused in situ for collection and preservation of selected central nervous system (CNS) and peripheral nerve tissues for microscopical examinations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	6 males	0	0
II (high dose)	6 males	1000	0
III (control recovery)	6 males	0	0
IV (high dose recovery)	6 males	1000	0

Mortality and Time to Death
None.

Clinical Observations
No treatment-related effects were observed.

Bodyweight and bodyweight gains, and food consumption in the test groups were comparable to the controls.

Functional Observational Battery Data

No treatment-related effects were observed except the landing foot splay distance for the high-dose group was shorter than the controls during the study and at completion of the recovery period. However, the levels of landing foot splay distance for the high-dose group were similar to their pre-test data. Thus, it is not considered to be toxicologically significant or treatment-related.

Effects in Organs

Brain weight, length and width data in the test groups were comparable to the controls.

No treatment-related effects were observed in the neuropathologic examinations.

Remarks – Results

As no treatment-related effects were observed in the study, the No Observed Effect Level (NOEL) would be the high dose administered in the study.

CONCLUSION FOR NEUROTOXICITY STUDY

The NOAEL for neurotoxicity was established as 1000 mg/kg bw/day (the highest dose) in this study.

Reproduction Study Phase

METHOD — OECD TG 415 One-Generation Reproduction Toxicity Study

Exposure Information — Total exposure days: from 29 days prior to mating to lactation day 4 for females, and 70 days for males.

Dose regimen: 7 days per week.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	12/sex	0	0
II (low dose)	12/sex	100	0
III (mid dose)	12/sex	500	0
IV (high dose)	12/sex	1000	0

Mortality and Time to Death

None.

Clinical Observations

No treatment-related effects were seen in the clinical observations.

During the pre-mating period, the bodyweight gain for the mid-dose females was significantly lower than the controls from week 1 to week 2.

During the mating and post-mating period, the mid- and high-dose males had lower bodyweight gains between weeks 9 to 10.

During gestation and lactation period, the mid- and high-dose females had higher bodyweight gains over days 7-14. The gestation length and parturition data in the test groups were comparable to the control data.

Mating, Pregnancy and Male Fertility Indices

	Group			
	I (control)	***II (low dose)***	***III (mid dose)***	***IV (high dose)***
Male mating index	100%	100%	100%	83.3%
Male fertility index	91.7%	91.7%	91.7%	100%
Female mating index	100%	100%	100%	91.7%
Pregnancy rate	91.7%	91.7%	91.7%	100%

Effects on Dams

The numbers of live pups at birth and at day 4 of lactation, pup body weight, pup viability indices, and pup sex distribution in the test groups were comparable to the controls.

No malformations were seen in stillborn pups from the control or OLOA 371 treated groups.

Effects in Organs
No treatment-related effects in organs were observed in the reproduction study.

Remarks – Results
As no treatment-related effects were observed in the study, the No Observed Adverse Effect Level (NOAEL) would be the high dose administered in the study.

CONCLUSION FOR REPRODUCTION STUDY
The NOAEL for reproductive effects was established as 1000 mg/kg bw/day (the highest dose) in this study.

TEST FACILITY Huntingdon Life Science (1998).

7.15. Genotoxicity - bacteria

TEST SUBSTANCE OLOA 371

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, and TA100
E. coli: WP2 uvrA

Metabolic Activation System S9 mix

Concentration Range in Main Test
a) With metabolic activation: 0-10000 µg/plate.
b) Without metabolic activation: 0-10000 µg/plate.

Vehicle 25% Pluronic F127 in ethanol

Remarks - Method GLP & QA.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	>10000		3300	
Test 1		>10000	≥500	Not observed
Test 2		>10000	≥500	Not observed
Test 3		>10000	≥500	Not observed
Present	>1000		3300	
Test 1		>10000	≥500	Not observed
Test 2		>10000	≥500	Not observed
Test 3		>10000	≥500	Not observed

Remarks - Results Test 3 was carried out with TA98, TA1535 and TA1537 only.

CONCLUSION OLOA 371 was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Corning Hazleton Inc (1997e).

7.16. Genotoxicity – in vivo

TEST SUBSTANCE OLOA 371

METHOD — OECD TG 475 Mammalian Bone Marrow Chromosomal Aberration Test.

Species/Strain	Mouse/Cr1:CD-1(ICR)BR
Route of Administration	Intraperitoneal injection
Vehicle	Peanut oil
Remarks - Method	GLP & QA.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
1	5/sex/group	1250	24, 48, 72
2	5/sex/group	2500	24, 48, 72
3	5/sex/group	5000	24, 48, 72
4 (vehicle control)	5/sex/group	Peanut oil, 10 mL/kg	24, 48, 72
5 (positive control)	5/sex	CP, 60 mg/kg	24

CP=cyclophosphamide.

RESULTS

Remarks - Results

Animals showed slight hypoactive, rough haircoats after i.p. treatment.

Some evidence of bone marrow toxicity was observed, as OLOA 371 induced statistically significant decreases in the PCE:NCE ratio in the 2500 mg/kg males at the 72 hour harvest time, in the 5000 mg/kg males at the 48 and 72 hour harvest times, and in the 5000 mg/kg females at the 72 hour harvest time.

A statistically significant increase in micronucleated PCEs was observed in the 5000 mg/kg males at the 24 hour harvest time. This increase was considered not to be the result of OLOA 371 treatment, but was due to the low number of micronucleated PCEs in the concurrent control group. In addition, there was no observable dose response, and the value was within the historical control range for the test laboratory.

No other statistically significant increases in micronucleated polychromatic erythrocytes over the levels observed in the vehicle controls occurred at any of the other harvest times.

The positive control induced statistically significant increases in micronucleated PCEs in both sexes as compared to the vehicle controls.

In this study, OLOA 371 induced a statistically significant increase in micronuclei in bone marrow polychromatic erythrocytes in one sex at one harvest time. However, the response was not dose responsive and was within the historical control range for the lab. Thus, under the conditions of this assay, OLOA 371 is considered negative in this mouse micronucleus assay.

CONCLUSION — OLOA 371 was not clastogenic in this in vivo mammalian bone marrow chromosomal aberration test under the conditions of the test.

TEST FACILITY — Corning Hazleton Inc (1997f).

Toxicological studies on Terephthalic acid (TPA)

The notifier provided two study reports on TPA. However, only parts of the reports were submitted. The two reports are summarised below.

7.17. A Ninety-Day Study of Terephthalic Acid Induced Urolithiasis and Reproductive Performance in Wistar and CD Rats (Research Triangle Institute, 1982)

Dose-related decreases in food consumption, bodyweight and bodyweight weight gain were observed in male and female rats during 90-days of feeding of 0, 0.03, 0.125, 0.5, 2.0 or 5% TPA in the diet. Diarrhea was observed in some of the rats ingesting high concentration of dietary TPA. Five unscheduled deaths occurred between 4 and 13 weeks in animals at 5% TPA.

TPA, at the dietary levels investigated, did not adversely affect reproductive performance in adult male and female rats. However, TPA ingestion by the dams caused adverse effects in the foetuses and neonates. Of pups found dead at birth, 76% of the Wistar and 96% of the CD animals were clustered in the groups of parents at 2 and 5% TPA diets. In addition, there were 50% reductions in viable Wistar male newborn at day 1 and in survivability to day 21 of male and female CD pup in the 5% TPA groups.

Weanling Fl rats were maintained on the same TPA diets as their parents until sacrifice. Unscheduled deaths during the post-weaning period were confined to the 5% TPA diets for both Wistar and CD offspring and were associated with a high incidence of renal and bladder calculi. Similarly renal and bladder stones were frequently observed at necropsy in those groups of offspring at 5% TPA diet. Other findings at necropsy included enlarged caecums, enlarged or distended ureters, enlarged kidneys, and bladder wall thickening.

7.18. Chronic Dietary Administration of Terephthalic Acid (IIT Research Institute, 1983)

TPA was evaluated for toxicological and carcinogenic effects in male and female Fischer 344 rat following dietary administration at levels of 0, 20, 142 and 1000 mg/kg/day for two years.

The number of survival animals in females may be affected by the treatment of TPA. However, the difference was not evidenced in the final period of the study (18-24 months), and there was no evidence of a dose-response relationship.

Clinical observations did not reveal any signs that could be directly attributable to treatment. Based on the bodyweight data, animal growth was retarded in a dose-related manner for female rats. This effect at the low-dose was of shorter duration with recovery evident after 6 months. The high-dose of TPA also retarded growth in male rats.

Neither the neurological nor the ophthalmologic evaluations provided evidence of toxicological effects of TPA.

At both 6 and 12 months, the high-dose females had higher relative liver weight. At study termination, heart and kidney weights were reduced in the mid- and high-dose females and there was an increase in relative brain weight at this period as well as at 18 months. For high-dose males, the weight of the lung, heart, liver and kidney were reduced at study termination. These reductions were consistent with an overall reduction in bodyweights of these animals.

Urolithiasis was induced in high-dose females, but not in male rats or in low-dose females. The high-dose of TPA also induced transitional cell tumours and squamous metaplasia in the bladder of females and may have increased the incidence of bladder hyperplasia.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	OLOA 371
METHOD	European Communities CO_2 Evolution Test (Method C. 4-C) 1992
Inoculum	Activated sludge from the Downingtown Regional Water Pollution Control Center
Exposure Period	29 d
Auxiliary Solvent	Tap water
Analytical Monitoring	Total and soluble organic carbon (TOC/SOC), pH and standard plate counts (SPC) for microorganisms.

Remarks - Method	OLOA 371 was added by direct weight at 10 mg C/L to duplicate inoculated flasks with positive and negative controls. Flasks were shaken at 110 rpm for 29 d at 21.6-23.4°C with CO_2 measured regularly in $Ba(OH)_2$ traps.

RESULTS

Test substance		*Sodium benzoate reference substance*	
Day	*% degradation*	*Day*	*% degradation*
14	5.9-14.9	14	85.1
29	8.6-23.3	29	88.1

Remarks - Results	No explanation was provided for the large variability in results between the two replicates of the treatment. The reference substance achieved a satisfactory level of biodegradation thus validating the test.
CONCLUSION	The test substance did not achieve 60% biodegradation within 28 d and is therefore not considered readily biodegradable.
TEST FACILITY	Roy F Weston (1997), Weston Fate and Effect Laboratory, Lionville, Pennsylvania, USA

8.1.2. Bioaccumulation

While the low water solubility and high log K_{OW} indicated a potential for bioaccumulation, this is discounted by the high MW. The company performed QSAR modelling for the bioconcentration factor (BCF) for three likely protonated lower MW homologs as their ionic hydrochloride salts. The BCFs were ~70 indicating they were not expected to bioconcentrate in organisms.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	OLOA 371
METHOD	OECD TG 203 Fish, Acute Toxicity Test – static renewal, US EPA (1993).
Species	Juvenile rainbow trout (*Oncorhynchus mykiss*), mean wet weight 1.3 g, mean total length 46.4 mm.
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	40-44 mg $CaCO_3$/L
Analytical Monitoring	Total organic carbon (TOC) analyses, 5.8-9.9 mg/L dissolved oxygen, temperature 11.6-13.1°C and pH 7.0-7.7 were satisfactory.
Remarks – Method	Water accommodated fractions (WAF) of the relatively insoluble chemical were prepared every 24 h for renewal of the exposure medium by stirring a mixture for about 20 h and allowing it to settle for 4 h. The water phase was siphoned off for use without any centrifuging or filtering to remove possible micelles or fine emulsions. However, when the TOC analysis is corrected for the organic carbon added to the water by the fish themselves, the mean measured concentration in water was 0.87-2.4 mg/L for the nominal concentration of 1,000 mg/L. It is reasonable to assume the actual concentration was limited by the water solubility of the chemical.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual (TOC)*		*2 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	30	0	0	0	0	0
1000	0.87-2.4	30	0	0	0	1	1

EC50	>2.4 mg/L at 24-96 h
Remarks – Results	Only one of 30 fish (3%) died in the nominal treatment 1,000 mg/L water accommodated fraction (2.4 mg/L measured concentration by TOC) indicating the EC50 was >2.4 mg/L. No sublethal effects were noted during the test. A thin film of insoluble material was observed on the surface of all treated vessels throughout the test.
CONCLUSION	At the limit of water solubility (2.4 mg/L in this test) of OLOA 371, no adverse effects were noted in 96 h.
TEST FACILITY	TR Wilbury Laboratories Inc (1997a)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	OLOA 371
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test and Reproduction Test – static, US EPA (1993).
Species	Neonate *Daphnia magna* (<24 h old)
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	168 mg $CaCO_3$/L
Analytical Monitoring	Total organic carbon (TOC) analyses, 7.8-8.8 mg/L dissolved oxygen, temperature 19.4-21.0°C and pH 7.4-8.8 were satisfactory.
Remarks - Method	The method of producing WAFs was the same as for the rainbow trout test. After correcting the TOC analysis for the organic carbon added to the water by the daphnids themselves, the mean measured concentration in water was 0.22-0.3 mg/L for the two reported nominal concentrations of 130 and 1,000 mg/L, which were the lowest and highest treatments respectively. It is reasonable to assume the actual concentrations of all treatments (regardless of their nominal concentration) was limited by the water solubility of the chemical and was in this range. No insoluble material was noted during the test.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual (TOC)*		*24 h [acute]*	*48 h [acute]*
0	0	20	0	0
130	0.22-0.30	20	0	1
220	Not reported	20	0	1
360	Not reported	20	1	3
600	Not reported	20	1	4
1000	0.22-0.30	20	3	11

EC50	>0.3 mg/L at 24 h based on measured concentrations >0.3 mg/L at 48 h based on measured concentrations
Remarks - Results	The higher mortality of daphnids at the highest nominal concentration is anomalous given the TOC analysis of the measured concentrations for this and the lowest treatments to be in the 0.22-0.30 mg/L range. Assuming the actual concentration of all treatments was in this range, the mean 48-h mortality in the five treatments is 20% indicating the 48-h EC50 is >0.30 mg/L. However this result must be treated with caution

given the anomalies of this test. It appears that the higher deaths at nominal concentration 1,000 mg/L may have been a physical effect as a thin, clear oily surface film was observed throughout the test.

CONCLUSION

At the limit of water solubility (0.22-0.30 mg/L in this test) of OLOA 371, a mean of 20% mortality was observed giving a 48-h EC50 of >0.30 mg/L. However, given the anomalies in this test, this result must be treated with caution.

TEST FACILITY

TR Wilbury Laboratories Inc (1997b)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE

Two separate experiments were performed on OLOA 371

METHOD

Species	*Pseudokirchneriella subcapitata*	
Exposure Period	96 h	
Concentration Range		
	Experiment 1	Experiment 2
Nominal	0, 13, 23, 36, 60 and 100 mg/L	0, 33, 65, 130, 250, 500, 1,000 mg/L
Actual	0-0.22 mg/L (WAF)	0 mg/L (WAF)
Auxiliary Solvent	None	
Water Hardness	Not reported	
Analytical Monitoring	Total organic carbon (TOC) analyses, temperature 23.2-24.0°C and pH 7.3-10.7.	

Remarks - Method

A similar method of producing water accommodated fractions (WAF) was used as for the fish and daphnid studies. After correcting the TOC for the carbon added to the water by the alga, the mean measured concentrations were 0-0.22 mg/L for the nominal 13 and 100 mg/L treatments in Experiment 1 and <1 mg/L for the lowest and highest nominal concentrations of 33 and 1,000 mg/L in Experiment 2. The actual concentration of dissolved chemical of all treatments was likely limited by the water solubility of the chemical of approximately 0.125 mg/L. No insoluble material was observed in any treatment vessel in either experiment.

Although the method seemed adequate in Experiment 2, the definitive test was conducted four times before a final test resulted in no anomalous or unexpected effects such as poor or variable growth.

RESULTS

Experiment	*Biomass*	*Growth*
1	*96-h E_bC50 = 23 (21, 25) mg/L of the nominal WAF*	*96-h E_rC50 = 47 (29,86) mg/L of the nominal WAF*
2	*96-h E_bC50 = 370 mg/L of the nominal WAF (no confidence limits reported)*	*96-h E_rC50 = 510 (330, 820) mg/L of the nominal WAF*

Remarks - Results

Experiment 1

Given the typical dose dependent response, the TOC analysis is not likely an accurate measurement of the true exposure of the chemical in the WAF to the alga. It is possible that chemical could be adsorbed to algal cells and not measured by TOC analysis. Therefore the actual concentration for all treatments was most likely similar to the water solubility of 0.125 mg/L, making this the LOEC. When cells from the highest treatment were cultured in clean media for 96 h, growth occurred indicating the chemical was algistatic rather than algicidal.

	Experiment 2 The inhibition of growth only at the two highest nominal concentrations of 500 and 1,000 mg/L is anomalous given previous results and the TOC analysis of the measured concentrations of <1 mg/L. As with Experiment 1, the TOC analysis is not likely an accurate measurement of the true exposure which was probably the limit of water solubility of the chemical. The chemical was again found to be algistatic.
CONCLUSION	The most sensitive 96-h E_bC50 of the water accommodated fraction of OLOA 371 was 23 (21, 25) mg/L nominal. However, the limit of water solubility of 0.125 mg/L was likely the true exposure, making this the LOEC. This is considered very toxic to aquatic life (United Nations 2003)
TEST FACILITY	TR Wilbury Laboratories Inc (1997c and 1998a)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	OLOA 371
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge from a municipal wastewater treatment plant receiving predominantly domestic waste.
Exposure Period	3 h
Concentration Range	
Nominal	0, 650, 1,300, 2,500, 5,000, 10,000 mg/L
Remarks – Method	The static test was conducted at 18.0-18.7°C and aerated during the exposure at ambient light. Deionised water of hardness 8 mg/L as $CaCO_3$ was used. Test material was added to treatment vessels and incubated for 3 h. After this time, insoluble material was observed on the surface of all treatment vessels.
RESULTS	
3-h IC50	>10,000 mg/L nominal concentration
Remarks – Results	In the range of concentrations tested, no inhibition of respiration was observed although raw data were not presented to allow confirmation. The reference toxicant test with 3,5-dichlorophenol gave a 3-h EC50 of 19 mg/L which was within the acceptable range of 5-30 mg/L.
CONCLUSION	The 3-h IC50 for activated sludge exposed to OLOA 371 was >10,000 mg/L nominal concentration.
TEST FACILITY	TR Wilbury Laboratories Inc (1998b)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The used oil and the sludge collected from the on-site wastewater treatment facilities may be incinerated. This will generate water vapour and oxides of carbon. The main environmental exposure is expected to result from inappropriate disposal of waste lubricant product, assuming a worst case scenario of about 14% of oil changes in Australia are performed by DIY enthusiast.

This improper disposal is, however, widespread across Australia. Most of the improperly released notified chemical due to DIY activities is likely to become associated with soils or sediments, as will the chemical released to landfill as container residues. The chemical released

into the aquatic environment would be expected to become associated with the sediments.

The amount released to stormwater drains (about 0.7% of the import volume) can enter the aquatic compartment and could be expected to become associated with suspended organic material (due to the estimated high Pow), settle out into the sediments and eventually be biodegraded.

It is difficult to estimate the Predicted Environmental Concentration (PEC) of the notified chemical released into the stormwater drains, which have the potential to directly enter the aquatic environment. However, a worst case PEC may be calculated assuming that all of the 0.7% of the notified substance (i.e. 140 kg) were released into the stormwater drains in a single metropolitan area with a geographical footprint of 500 square kilometres, and an average annual rainfall of 50 cm. With a maximum annual release into this localised stormwater system of 140 kg and the annual volume of water drained from this region estimated to be approximately 250 X 10^6 m^3, the resultant PEC is 0.56 µg/L. This is very much a worst case scenario, and in reality releases of the chemical would be much more diffuse and at significantly reduced levels.

9.1.2. Environment – effects assessment

Based on the data provided and using the most sensitive endpoint of 0.125 mg/L for the 96-h LOEC to algae, a predicted no effect concentration (PNEC) for aquatic ecosystems of 1.25 µg/L was derived by dividing the LOEC by an uncertainty (safety) factor of 100 because toxicity data are available for three trophic levels.

9.1.3. Environment – risk characterisation

The worst-case PEC is significantly below possible toxic levels and the resulting risk quotient (Q = PEC ÷ PNEC = 0.56 µg ÷ 1.25 µg/L = 0.4) is below 1. Further, the limited release to the aquatic environment (mainly via stormwater drainage) and more diffuse national use than modelled is expected to reduce the PEC and the chemical is expected to associate with sediments. The moderate biodegradation will further reduce the exposure to aquatic life. Overall, the chemical is not expected to pose a risk to the environment based on its reported use pattern.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Skin contact is possible during transfer operations (hose coupling/uncoupling) of the additive package and the blended products containing the notified chemical at waterfront, formulation sites, and customers' facilities.

At the formulation sites, inhalation exposure is unlikely as the process is unlikely to generate aerosols and ventilation systems are in place. During the automatic blending, operators will have low exposure by skin contact since they are only required to take samples for quality control purposes. During packaging process, skin contact may occur for operators involved in overseeing the filling process where manual intervention is required and during bunging and labelling of the drums. However, in all instances potential exposure is for brief periods only.

Workers may have repeated skin or eye contamination with the finished products containing the notified chemical during repairing and servicing of engine equipment. However, as the concentration of the notified chemical in the formulated products is low, the potential exposure for these end users is low.

9.2.2. Public health – exposure assessment

Individuals who maintain their engine equipment will handle the products containing the notified chemical. Infrequent dermal exposure (most likely to the hands and forearms), and accidental ocular exposure could occur in these individuals. The notified chemical comprises less than 10% in blended products, thus the public exposure is considered to be low.

The dermal exposure during formulation and end use can be estimated by the EASE (Estimation and Assessment of Substance Exposure) program developed by the Health and Safety Executive,

UK (1997). In the calculation of dermal exposure, the surface area of occupational exposure is selected to be 1000 cm^2 (NICNAS, 1996).

EASE Prediction			
Physical state	Liquid		
Temperature	25°C		
Operation	***Formulation***	***End use (occupational)***	***End use (public)***
Dermal exposure			
Use pattern	- Closed system	- non-dispersive use	- wide dispersive
Pattern of control	- non-direct handling	- direct handling	- direct handling
Contact level		- extensive	- incidental
Predicted exposure (product)	Very low	1-5 mg/cm^2/day or 1000-5000 mg/day	0.1-1 mg/cm^2/day or 100-1000 mg/day
Predict exposure (chemical)	Very low	100-500 mg/day	10-100 mg/day

9.2.3. Human health - effects assessment

Based on data for the analogue OLOA 232E, the notified chemical, OLOA 11004 is considered to be of low acute oral and dermal toxicity in rats. It is a slight skin and eye irritants in rabbits. There is limited evidence of skin sensitisation to OLOA 11004 in guinea pigs based on data from two Buehler studies. Regarding genotoxicity, OLOA 11004 is not expected to be mutagenic in the bacterial reverse mutation test or the in vitro mouse lymphoma cells test.

OLOA 11004 is the reaction product of OLOA 371 and TPA. According to the toxicity data provided by the notifier, OLOA 371 was of low acute oral and dermal toxicity in rats, and was slightly irritating skin and eyes in rabbits. Limited evidence of skin sensitisation was noted in a Buehler study guinea pigs. The NOAEL for OLOA 371 in a combined repeat-dose (280day oral), neurotoxicity and reproductive toxicity study in rats was 1000 mg/kg/day, the highest dose. OLOA 371 was non-mutagenic in an Ames test and non-genotoxic in an in vivo mammalian bone marrow chromosomal aberration test.

Based on the data provided by the notifier and other available information (European Commission, 2000), TPA was of low acute oral and dermal toxicity, and was a slight skin and eye irritant. It was not a skin sensitiser. The NOEL from repeat-dose inhalation studies was approximately 10 mg/m^3/6 hours per day. It showed negative in Ames tests but was positive in an in vivo micronucleus assay.

Based on all available data, the notified chemical is of low acute toxicity, it is a slight irritant and may be a weak skin sensitiser. The notified chemical is unlikely to cause adverse effects after repeated exposure and is most likely not genotoxic.

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is predicted to be a slight irritant. It is unlikely to exhibit irritant effects at the low concentrations. The main concern of occupational health is the possible skin sensitisation effect. Any workers who become sensitised with the notified chemical should avoid further handling of the chemical. Risk from repeated exposure is considered to be low since at 1000 mg/kg/day (the NOAEL), the amount of product equivalent will be large and workers would not be expected to be exposed repeatedly to large amounts.

Dermal contact will be the main route of exposure and the occupational exposure is considered to be low. Pumps are used for transferring processes and automatic equipment is used for formulation. In addition, the engineering controls such as automation and enclosure are in place and workers will wear personal protective equipment. Therefore, the adverse health risk for workers handling the notified chemical is assessed to be low.

9.2.5. Public health – risk characterisation

The main concern of public health in handling products containing the notified chemical is the possibility of skin sensitisation. Consumers who become sensitised to the notified chemical should be advised to avoid any further handling of products containing the chemical.

Formulated products containing the notified chemical are on the market for sale to the general public. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified chemical. However, the health risk for public will be low because of the low concentrations of notified chemical present in the products, and the intermittent use pattern.

The dermal exposure estimated by the EASE can also be used for risk characterisation. Based on the assessment of health effects, the NOAEL of 1000 mg/kg/day is selected in the risk characterisation. An absorption rate from dermal exposure of 10% and a bodyweight of 70 kg are used for estimation. The margins of exposure (MOEs) are calculated for the various scenarios (MOE = NOAEL/internal dose).

Risk characterisation based on EASE Prediction

Operation	***Formulation***	***End use (occupational)***	***End use (public)***
Predict dermal exposure to chemical	Very low	100-500 mg/day	10-100 mg/day
Internal dose (or absorbed dose) NOAEL = 1000 mg/kg/day	Very low	10-50 mg/day	1-10 mg/day
Margin of Exposure (MOE) (NOAEL*70 kg/internal dose)	Very high	1400-7000	7000-70000

The EASE program did not include the scenario of exposure with personal protective equipment (PPE). If PPE such as overalls, gloves and eye protection is worn to reduce the exposure, the MOE is expected to be higher. Taking into account that exposure estimates were worst-case, the risk of adverse health effects in workers or the general public exposed to the notified chemical is considered to be low particularly when industrial control is in place and PPE is worn.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

Based on its toxicity to algae, the notified chemical is considered very toxic to aquatic life (United Nations 2003).

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, the chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Low Concern to public health based on its reported use pattern.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - gloves (nitrile, viton or silver shield) when handling additive packages
  - eye protection
  - overalls, and
  - occupational footwear

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

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

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

Environment

Disposal

- The notified chemical should be disposed of to landfill and not to water.

Emergency procedures

- Spills/release of the notified chemical should be handled by applying non-combustible absorbent materials or pumping. Where feasible and appropriate, remove contaminated soil. Place contaminated materials in disposable containers and dispose of in a manner consistent with applicable regulations. If heated material is spilled, allow it to cool before proceeding with disposal methods.

12.1. Secondary notification

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

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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