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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical C in OLOA 289M

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Oronite Australia, (ABN: 16 101 548 716)
Level 8, 520 Collins Street,
MELBOURNE, VICTORIA 3000

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical name,
Other names,
CAS number,
Structure formula,
Molecular formula,
Molecular weight,
Spectral data,
Purity,
Identity toxic/hazardous impurities
Percent weight toxic/hazardous impurities,
Identity non-hazardous impurities,
Percent weight non-hazardous impurities,
Import volumes,
Manufacture process,
Manufacturing sites.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Acute Inhalation Study,
Melting Point/Boiling Point,
Hydrolysis as a function of pH,
Adsorption/desorption,
Dissociation constant,
Particle size,
Flammability limits,
Autoignition temperature,
Water solubility,
Vapour pressure,
Water - octanol partition coefficient;
In addition the notifier requested to be permitted to supply measured data on the product OLOA 289M (physico-chemical properties, toxicology and ecotoxicology) in place of data for the notified chemical itself.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
CEC Permit 562

NOTIFICATION IN OTHER COUNTRIES
Canada, USA and EU

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
XA 289M

MARKETING NAME(S)
OLOA 289M

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Infrared spectroscopy and ^{31}P NMR spectroscopy
Remarks	Reference spectra for the product OLOA 289M were provided.

3. COMPOSITION

DEGREE OF PURITY
<60%

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as part of the product OLOA 289M (containing <60% notified chemical) as a component of an oil additive package, which will be blended in Australia into oil products.

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

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

USE **Non-Confidential**
The notified chemical will be used as a gear oil additive.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS **Non-Confidential**
Several lubricant oil manufacturers

TRANSPORTATION AND PACKAGING
The notified chemical will be transported to Australia by ship in bulk, marine isotanks and 200 L drums. Drums are 16 gauge steel and isotanks are rigid steel containers. The finished oil products will be packaged in 1 or 4 L plastic bottles, 200 L drums, 8000 L isotanks or in bulk shipments.

5.2. Operation Description

Reformulation
At reformulation sites, the notified chemical will be transferred from drums and isotanks into a 10,000 L in-line blend tank by automated dosing systems. The notified chemical can also transferred from storage tanks to the blend tank using computer-controlled valves.

The blending process occurs in a closed system at 60°C and is computer controlled. Laboratory staff will take samples of the blended oil products for testing. The blended lubricant is transferred automatically to a storage tank. From there it can either be dispensed directly into tanker trucks via pump lines or packaged into 200 L drums. Drum filling is an automated process and the tankers are filled by transfer hose.

End Users
The finish product will be used in motor manufacturing and repair facilities throughout Australia. The blended oil products will be added to and drained from systems during these operations.

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 handling the oil additive package in drum or isotanks are not expected to be exposed to the notified chemical during transport except in the case of an accidental spill.

When imported in bulk, transfer from the ship to a holding tank, then to road tankers will occur. During this process exposure of the waterfront and transport workers to spills OLOA 289M is possible during the connection and disconnection of the transfer hoses. The notified chemical has a very low vapour pressure and high viscosity, minimising the possibility of vapour and aerosol formation.

The finished lubricant, containing less than 0.3% of the notified chemical, will be transported to numerous sites since the oil products will have widespread use. The notified chemical will be used by professional motor mechanics and will not be sold into the DIY consumer market.

Dermal exposure will be main route of exposure for transport and storage workers. These workers will wear overalls, safety boots, and gloves when handling containers.

Reformulation
At reformulation sites, the notified chemical will be transferred from drums and isotanks into the in-line blend tank (10,000 L capacity) by automated dosing systems. When the product containing the notified chemical arrives in drum, workers transfer drum contents to the blending tanks using drum pumps. The transfer process takes approximately 10 minutes. During the connection and disconnection of lines, incidental skin contact from splashes, drips, and spills is possible. When the notified chemical arrives in either isotanks or by road tanker it will be unloaded and transferred to storage tanks via 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. Transfer from storage tanks to the blend tank will be automated, using computer-controlled valves.

The blending process occurs in a closed system at 60°C and is computer controlled, thereby excluding the potential for occupational exposure. The blended lubricant is transferred automatically to a storage tank. From there it can either be dispensed directly into tanker trucks via 10 cm pump lines or packaged into 200 L drums. Drum filling is an automated process and worker intervention is not required unless the filling line operation requires adjustment. However, workers are required to insert bungs and label the drums and skin contact with contaminated drum surfaces may occur.

Bulk road tanker filling is performed by a transfer hose. Dermal exposure to drips and spills of blended lubricant is possible during the connection and disconnection of transfer hoses during the filling of bulk tankers.

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 will take samples of the notified chemical in the additive package as well as the blended oil products for testing. During sampling and analysis of the additive package there may be skin contact. The laboratory testing will take a few minutes per batch.

End Users
Occupational exposure to the products containing the notified chemical will also occur at motor manufacturing and repair facilities throughout Australia. End users may be exposed to the blended oil products containing less than 0.3% 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 and while handling automotive components that have been in contact with the oil.

A large number of motor mechanics (>1000) may be exposed to the products under a wide range of conditions. However, it is anticipated that these workers have been trained in the proper handling of lubricants and oil products, the risk to worker health is minimal.

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 notifier estimated 1.5% of the OLOA formulation is lost and released to the environment due to spills and leaks during importation of the active package containing OLOA 289M, transfer of the additive package to the lubricant manufacturers blend plants, blending of the finished oils at the customer's lube blending plant, packaging of fresh oil into containers for sale (1 L, 5 L and 200L) at the lubricant blend plant, transportation of the finished oils to market users, losses on transfer of fresh oil to vehicles and oil left in waste containers that are disposed of in solid waste to landfill. Estimated routes of environmental release are listed below:

Activity	Percentage	Amount of OLOA 289M (kg per annum)	Amount of notified substance (kg per annum;
To wastewater	0.125	18.75	11.25
To waste oil	0.375	56.25	33.75
To landfill	1.0	150	90

RELEASE OF CHEMICAL FROM USE
The notifier indicates that environmental release of the notified chemical to the environment may potentially occur through leakage from equipment.

Activity	Percentage	Amount of OLOA 289M (kg per annum)	Amount of notified substance (kg per annum)
Equipment leaks	1	150	90

5.5. Disposal

Each year, about 581 million litres of lubricating oil is sold in Australia, and about 303 million litres of waste oil is generated. The remainder is consumed during engine operation, unrecoverable or unaccounted for (Meinhardt (NSW) Pty Ltd, 2002). Between 50-66% of the waste oil generated is currently recycled, with the remainder (34-50%) unaccounted for, probably released a range of disposal routes including landfill and sewer disposal, and stored on farms and in mines underground. Of the amount recycled, the majority is used as low and high grade burner fuel. The notified chemical contained in the oil formulation is expected to broadly follow this disposal pattern, but is more likely to be disposed of responsibly since there is no DIY use. Negligible release of the notified chemical should result from professional mechanical activities.

Emptied containers (1 L & 5 L) containing an estimated 1% of OLOA 289M formulation will be sent to landfill for disposal. Emptied imported 205 L drums will be sent to drum recyclers for steam cleaning prior to re-use, with wastewater treated and the oil component concentrated prior to recycling or incineration.

A fraction of the formulation (<0.125%) may potentially be collected in formulation site wastewaters as a result of spills/leaks and various activities. Treated effluent is discharged to sewer where it will be treated further. With on-site wastewater treatment processes established, release to the sewerage system is likely to be negligible. Following blending, blending tanks will be cleaned with lube oil, which will typically be recycled during subsequent blending or incinerated

5.6. Public exposure

The notified chemical will not be available to public. The final oil additive will only be available to professional mechanics. Exposure of the public is only likely while working on automotive components which have been in contact with the oil, and this is expected to be confined to very few members of the public.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Pale yellow liquid (OLOA289M)

Boiling Point

Remarks Not determined.

Density 949 kg/m^3 at 15.6°C (OLOA289M)

Remarks Test report not available

Viscosity 700 cSt at 40°C (OLOA289M)

Remarks Test report not provided.

Vapour Pressure Negligible at 20°C (OLOA289M)

Remarks Saturated vapour pressure concentration of a typical lubricating base oil is calculated to be 0.015ppm at 20°C. The notified chemical is not expected to be volatile based on its molecular weight and ionic nature. A test report was not provided.

Water Solubility 0.001 g/L at 25°C (OLOA289M)

METHOD Column elution method
Remarks The test result refers to the OLOA 289M formulation rather than the notified chemical.

Water soluble components of the eluent were collected using a pre-conditioned C18 sep-pak cartridge, eluted with methanol, the solvent evaporated before addition of acetonitrile to the residue. This sample was analysed by HPLC.

TEST FACILITY ILT/Lab Services, ERTC, Chevron Texaco (2003a)

Hydrolysis as a Function of pH Not determined.

Remarks Hydrolysis is unlikely to occur at environmentally relevant pH range.

Partition Coefficient (n-octanol/water) log Pow of OLOA 289M formulation at 20ºC = 4.64

METHOD Dialysis Method.

Remarks The test value refers to the OLOA 289M formulation.
The water phase was back-extracted with methylene chloride, the solvent evaporated and the residue dissolved in methanol. The octanol phase was diluted with methanol and the methanol solutions were analysed by HPLC.

TEST FACILITY ILT/Lab Services, ERTC, Chevron Texaco (2003b)

Adsorption/Desorption log K_{oc} = 4.44-4.56 at 25°C (OLOA 289M formulation).

METHOD Estimated by methods of Karickhoff et al (1979) and Di Toro (1985).

Remarks Based on Log K_{ow} of 4.64.

Dissociation Constant not determined

Remarks The notified chemical has low water solubility.

Flash Point 180ºC

METHOD ASTM D93-98

Flammability Limits Not flammable

Remarks Estimated.

Autoignition Temperature Not determined.

Remarks The notified chemical is not isolated from the liquid OLOA 289M formulation.

Explosive Properties Not explosive

Remarks Estimated.

Reactivity

Remarks The notified chemical is not expected to be highly reactive. It is expected to be stable under ambient conditions. Hydrogen sulphide may be formed from OLOA 289M at temperatures greater than 66ºC.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion of OLOA 298M*
Rat, acute oral LD50 Male = 4600 mg/kg bw Female = 3800 mg/kg bw	low toxicity
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity
Rabbit, skin irritation	moderately irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - non-adjuvant test.	no evidence of sensitisation.
Rat, oral gavage repeated dose toxicity - 5 days range finding study.	NOAEL= 100 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration	non genotoxic

Genotoxicity – in vivo mammalian erythrocyte micronucleus test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE	XA 289M
METHOD	In house
Species/Strain	Rat/Sprague-Dawley Crl:CD (SD) BR
Vehicle	None
Remarks - Method	Method similar to OECD TG 401 Acute Oral Toxicity

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 males	1000	0/5
2	5 males	1700	0/5
3	5 males	2900	0/5
4	5 males	3600	1/5
5	5 males	5000	5/5
6	5 females	1000	0/5
7	5 females	1800	0/5
8	5 females	3200	2/5
9	5 females	5000	4/5
10	5 females	5800	3/5

LD50	Male = 4600 mg/kg bw (95% CI=1250-16770 mg/kg bw) Female = 3800 mg/kg bw (95% CI=1670-8500 mg/kg bw)
Signs of Toxicity	Salivation, diarrhoea, reduced food intake, reduced food intake/ no faeces, decreased motor activity, ocular and nasal discharges, lacrimation, anogenital discharge and stain, discoloured fur around the nose and mouth, elevated hindquarters with abnormal gait were observed in both the survivors and animals that died. Signs of toxicity only observed in animals that died were weakness, tremors, thinness, oral discharge, piloerection, hunched posture, and bloody diarrhoea. The time to death ranged from Day 4 to Day 12. A dose related increase in incidence of anogenital and/or abdominal depilation was observed in survivors of both sexes. Sporadic observations of discoloured or scabbed forepaws, scabbed tails and unkempt appearance were also observed in survivors.
	Body weight Males dosed at 1700 mg/kg bw and 2900 mg/kg bw showed a statistically significant ($p \leq 0.01$) lower mean body weight than controls on Day 7. Males dosed at 5000 mg/kg bw showed a statistically significant ($p \leq 0.01$) lower mean body weight than controls on both Day 2 and Day 7. Females dosed at 1800 mg/kg bw and 3200 mg/kg bw showed a statistically significant ($p<0.05$) lower mean body weight than controls on Day 7 and Day 2, and Day 7, respectively. Females dosed at 5000 mg/kg bw and 5800 mg/kg bw showed a statistically significant ($p<0.01$) lower mean body weight than controls on Day 7 and on Day 2 and Day 7, respectively.
Effects in Organs	*Pathology* At necroscopy, the gross pathological changes observed in animals dosed with 5000 mg/kg bw and 5800 mg/kg bw consisted of thin gastric walls with either enlargement of the stomach or haemorrhage, broken blood

vessels, or discolouration of the gastric mucosa. Thickened or blanched intestinal walls, enlarged and darkened adrenal glands, mottled lungs, reddened pancreas, hollow kidneys, and/or alopecia were observed in animals at several dose levels.

Histopathology
Severe gastric necrosis and ulceration, and severe gastric hyperkeratosis were observed in one male and on female, both dosed at 5000 mg/kg bw. These lesions may have been compound-related. Other findings of gastritis, congestion of the adrenal glands, lungs, pancreas, and caecum hydronephrosis and acute dermatitis were considered agonal or related to spontaneous disease.

Remarks - Results: Macroscopic and microscopic necropsy findings together with clinical observations on food consumption indicated that gastrointestinal effects were major contributors to the observed toxicity.

CONCLUSION: The test substance is of low toxicity via the oral route.

TEST FACILITY: Chevron Environmental Health Centre (1985a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE: XA 289M (APD 3729)

METHOD: In house.
Species/Strain: Rat/Sprague-Dawley Crl:CD (SD) BR
Vehicle: None
Type of dressing: Occlusive
Remarks - Method: Method similar to OCED TG402 Acute Dermal Toxicity

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 males	2000	0/5
2	5 females	2000	0/5

LD50: >2000 mg/kg bw
Signs of Toxicity - Local: At 24 hours, severe erythema with well-defined oedema was observed in males and no to slight erythema with no oedema was observed in females. By Day 5 all treated sites had thickened, hardened, and scabbed skin. The necrotic skin sloughed in some animals to reveal scabbed, relatively smooth skin.
Seven days after dosing, all treated skin was thickened, hardened, and/or scabbed. Oedema could not be determined in most animals.
By Day 14, all treated males showed relatively smooth skin with scabs, While several treated females showed areas of smooth but scabbed skin all treated female also had flaky, dry, brown, sloughing, thickened, hard, and/or leatherlike skin.
Signs of Toxicity - Systemic: During the first week after dosing red ocular and nasal discharges were observed in several treated animals. Mean body weight of the treated males was statistically significantly ($p \leq 0.01$) less than those of controls at 2, 7, and 14 days after dosing. The mean body weight of the treated females was statistically significantly ($p \leq 0.01$) less than that of the controls two days after dosing.
Effects in Organs: *Pathology*
Gross pathological changes were observed only in the skin.
Histopathology
Skin sections showed acanthosis, necrosis, and ulceration scab formation

and surface exudate.

Remarks - Results: The results indicate that the test substance is severely irritating to skin.

CONCLUSION: The test substance is of low toxicity via the dermal route.

TEST FACILITY: Chevron Environmental Health Centre (1985b)

7.4. Irritation – skin

TEST SUBSTANCE: OLOA 289M

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: 3 males
Vehicle: None
Observation Period: 21 days
Type of Dressing: Semi-occlusive.
Remarks – Method: No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	3.33	4.0	4.0	4	7 days	0
Oedema	2.33	4.0[#]	4.0[#]	4	7 days	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
[#]No scoring for oedema was possible for two animals at 48 and 72 hours during the recording period due to the fissuring of the skin.

Remarks - Results: Severe erythema and severe oedema in treated skin areas of the three rabbits. In all animals the erythema and oedema were also noted outside the application area. Grey-yellowish discolouration of the skin (signs of necrosis) reduced flexibility and fissuring of skin was noted among the animals between 24 hours and 7 days after exposure. Scaliness and bald skin were noted in all animals after 14 days. No skin abnormalities were noted in the animals after 21 days.

CONCLUSION: The test substance is severely irritating to skin.

TEST FACILITY: NOTOX (2002a)

7.5. Irritation – eye

TEST SUBSTANCE: OLOA 289M

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain: Rabbit/New Zealand White
Number of Animals: 3 males
Observation Period: 14 days
Remarks - Method: No significant protocol deviation.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2.66	2.33	2.33	3	7 days	0
Conjunctiva: chemosis	1.66	2	1.33	3	72 hours	0
Conjunctiva: discharge	1.33	1.33	1	2	72 hours	0
Corneal opacity	0.66	0.66	0.33	1	48 hours	0
Iridial inflammation	0.66	0.66	1	1	72 hours	0

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

Remarks - Results: The cornea, iris, and conjunctivae were affected by the test substance. Corneal injury was seen as opacity and epithelial damage. The corneal injury had resolved with 72 hours in two animals and within 7 days in the other animal. Iridial irritation resolved in all animals within 7 days. Irritation of the conjunctivae was seen as redness, chemosis, and discharge which had completely resolved with 14 days in all animals.

CONCLUSION: The test substance is slightly irritating to the eye.

TEST FACILITY: NOTOX (2000b)

7.6 1. Skin sensitisation

TEST SUBSTANCE: OLOA 289M

METHOD: In house method – similar to OECD TG 406 Skin Sensitisation – Modified Buehler Method

Species/Strain: Guinea pig/Hartley albino

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
topical: 10% w/w in mineral oil USP

MAIN STUDY

Number of Animals: Test Group: 15 males per induction concentration Control Group: 10 males

INDUCTION PHASE: Induction Concentration:
topical application: 0.1 and 0.5% w/w in 80% ethanol/water.

Signs of Irritation:
At 0.5% w/w in 80% ethanol/water
Twenty four hours following initial induction application, slight erythema with no oedema was observed in one animal. No skin irritation was observed 48 hours after initial application.
At the fifth induction five animals displayed severe erythema characterised by scabbing with slight to severe oedema 24 hours after application. No skin irritation was observed in the remaining animals. At the tenth induction, skin irritation in three animals ranged from well defined to severe erythema with slight to well-defined oedema 24 hours after application. The 12 remaining animals displayed no erythema or oedema.
At 0.1%w/w in 80% ethanol/water
No skin irritation was observed in any animal during the induction period.

CHALLENGE PHASE

1st challenge: topical application: 0.1% w/w in acetone

Remarks – Method: The test substance was applied using an occlusive chamber.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*		
		24 h	*48 h*	*72 h*

Test Group				
0.5% w/w	0.1% w/w	4/15	1/15	1/15
0.1% w/w	0.1% w/w	0/15	0/15	0/15
Control Group	0.1% w/w	3/10	3/10	0/10

Remarks - Results

Four of the fifteen animals induced with 0.5% w/w of the test substance and challenged with 0.1% w/w of the test substance displayed slight erythema with no oedema twenty fours after challenge. At 48 and 72 hours after challenge only one animal continues to display slight erythema and no oedema.

No skin irritation was observed in animals induced and challenged with 0.1% w/w of the test substance.

At 48 and 72 hours after challenge with 0.1% w/w test substance three of ten animals exhibited slight erythema with no oedema. Seventy-two hours after challenge, no skin irritation was observed in any animal.

CONCLUSION

There is no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.

TEST FACILITY

Chevron Environmental Health Centre (1985c)

7.6.2 Skin sensitisation

TEST SUBSTANCE

OLOA 289M

METHOD

OECD TG 406 Skin Sensitisation – Modified Buehler Method

Species/Strain

Guinea pig/Hartley derived albino

PRELIMINARY STUDY

Maximum Non-irritating Concentration:
topical: 10% w/w in mineral oil USP

MAIN STUDY

Number of Animals

Test Group: 10 animals/sex Control Group: 5 animals/sex

INDUCTION PHASE

Induction Concentration:
topical application: 25% w/w

Signs of Irritation

No erythema to moderate confluent erythema was observed, the oedema when observed was very slight. Dermal irritation outside the test site, superficial lightening and desquamation were also observed.

CHALLENGE PHASE

1st challenge

topical application: 10% w/w

2nd challenge

topical application: 10% w/w

Remarks - Method

Test substance was applied using an occlusive chamber. An additional control group (5/sex) was used during rechallenge.

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	10% w/w	5/20	5/20	2/20	2/20
Control Group	10% w/w	0/20	0/20	0/20	0/20

Remarks - Results

At challenge, slight but confluent or moderate patchy erythema was observed in 5/20 test animals at both 24 and 48 hour scoring intervals.

	Dermal reactions in the remaining 15/20 test animals and 10/10 control animals were scored at no reaction or slight patchy erythema. At rechallenge, slight but confluent or moderate patchy erythema was observed in 2/20 test animals at both 24 and 48 hour scoring intervals. Dermal reactions in the remaining 15/20 test animals and 10/10 control animals were scored at no reaction or slight patchy erythema.
CONCLUSION	There is limited evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.
TEST FACILITY	Springborn Laboratories (2003)

7.7. Repeat dose toxicity (5 day range finding study)

TEST SUBSTANCE	OLOA 289M
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral). (Range finding study)
Species/Strain	Rats/Wistar Crl: (WI) BR
Route of Administration	Oral – gavage.
Exposure Information	Total exposure days: 5 days; Dose regimen: Daily Post-exposure observation period: None
Vehicle	Propylene glycol
Remarks - Method	The range finding study includes a limited range of observations (clinical observations, body weight, food consumption, gross pathology, and limited histopathology). This was a range finding study for a 28 or 90 day study which has not yet been completed.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	3/sex	0	0
II	3/sex	30	0
III	3/sex	100	0
IV	3/sex	300	0
V	3/sex	1000	0

Mortality and Time to Death

No mortality occurred during the study period.

Clinical Observations

All females treated at 1000 mg/kg showed hunched posture. At 1000 mg/kg, alopecia (neck) was noted in one female and one female showed rales, piloerection and brown staining of the abdomen during treatment.

Body weight

Body weight and body weight gains were depressed at 300 and 1000 mg/kg bw/day when compared to the controls. The reduced body weights were statistically significant ($p<0.01$) for males treated at 300 mg/kg bw/day and 1000 mg/kg bw/day. The body weight gains were statistically significantly lower for males treated at 1000 mg/kg bw/day ($p<0.01$) and 300 mg/kg bw/day ($p<0.05$). Body weight gain changes were statistically significant ($p<0.05$) for females treated at 1000 mg/kg bw/day. This finding was considered to be caused by the higher body weight of these animals at the start of treatment, which is generally related to lower body weight gain.

Food consumption

Food consumption (absolute and relative) of animals treated at 300 and 1000 mg/kg bw/day showed a dose-related decrease.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Tests not conducted.

Effects in Organs
Pathology
Irregular stomach surface was noted in all males and females at 1000 mg/kg bw/day and in one female at 300 mg/kg bw/day. Discolouration of the ileum, caecum and colon in males treated at 1000 mg/kg bw/day. Distension of the small and large intestine with gas was found in one female treated at 1000 mg/kg bw/day.

Incidental findings among control females and females treated at 300 mg/kg bw/day included discolouration of the ileum (control), pelvic dilation, watery fluid in the uterus (control) adrenal glands grown together with kidneys, and kidney and thymus discolouration. Historically these findings are occasionally seen among rats and in the absence of correlated microscopic findings they were considered of no toxicological significance.

Among both males and females, effects on the brain, thymus, adrenal and spleen weight were noted at 1000 and/or 300 mg/kg bw/day.

Slight to severe hyperplasia of the squamous epithelium of the forestomach was observed in one male and two females at 300 mg/kg bw/day and in all males and two females at 1000 mg/kg bw/day.

Remarks – Results
The range-finding study indicated that effects in the forestomach should be expected at and above 300 mg/kg bw/day in a 28 or 90 day .

CONCLUSION
The No Observed Effect Level (NOEL) was established as 100 mg/kg bw/day in this study, based on presence of clinical effects, effects on body weight, food consumption, gross gastrointestinal effects, organ weight and hyperplasia of the squamous epithelium of the forestomach at higher doses.

TEST FACILITY	NOTOX (2003)

7.8. Genotoxicity - bacteria

TEST SUBSTANCE	OLOA 289M
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, TA100 *E. coli*: WP2 uvrA,
Metabolic Activation System	Phenobarbitone/β-naphthoflavone induced rat liver S9 fraction
Concentration Range	*S. typhimurium* tester strains a) With metabolic activation: 0.5, 1.5, 5, 15, 50, 150 µg/plate. b) Without metabolic activation: 0.15, 0.5, 1.5, 5, 15, 50 µg/plate. *E. coli* tester strain a) With metabolic activation: 1.5, 5, 15, 50, 150, 500 µg/plate. b) Without metabolic activation: 0.5, 1.5, 5, 15, 50, 150 µg/plate.
Vehicle	Ethanol
Remarks - Method	TA100 and WP2uvrA$^-$ were used in a preliminary toxicity study. The dose range of the test material used in the preliminary toxicity study was 0, 0.15, 0.5, 1.5, 5, 15, 50, 150, 500, 1500 and 5000 µg/plate. An oil precipitate was observed at 5000 µg/plate only, which did not prevent the scoring of revertant colonies. The test material caused a visible reduction in the growth of the bacterial background lawn to all of the *Salmonella* tester strain initially at 50 and 150 µg/plate without and with S9 respectively. Toxicity was observed in the *Escherichia coli* strain

WP2uvrA$^-$, initially at 150 and 500 µg/plate without and with S9 respectively.

A range finding study was undertaken using a dose range determined by the preliminary toxicity assay and was allocated as follows:

All tester strains (without S9): 0.5, 1.5, 5, 15, 50, 150 µg/plate.
All tester strains (with S9): 1.5, 5, 15, 50, 500 µg/plate.

The test material caused a visible reduction in the growth of the bacterial background lawn to all of the *Salmonella* tester strain initially at 50 and 150 µg/plate without and with S9 respectively. Toxicity was observed in the *Escherichia coli* strain WP2uvrA$^-$, initially at 50 and at 500 µg/plate without and with S9 respectively.

Two independent tests were conducted in triplicate.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Salmonella strains	50 µg/plate	50 µg/plate	5000 µg/plate	-
Escherichia strain	150 µg/plate	50 µg/plate	5000 µg/plate	-
Present				
Salmonella strains	150 µg/plate	150 µg/plate	5000 µg/plate	-
Escherichia strain	500 µg/plate	500 µg/plate	5000 µg/plate	-

Remarks - Results

The test material caused a visible reduction in the growth of the bacterial background lawn to all of the *Salmonella* tester strains, at 150 and 50 µg/plate with and without S9, respectively. Toxicity was observed in the *Escherichia coli* strain WP2uvrA$^-$, initially at 500 and at 50 µg/plate with and without S9, respectively. The material was therefore tested up to the toxic limit. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation.
Appropriate positive controls were used and gave the expected results confirming the sensitivity of the system.

CONCLUSION

The test substance was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

SafePharm Laboratories (2002a)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE

OLOA 289M Lot No TS01026

METHOD

OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line: Cultured human lymphocytes
Metabolic Activation System: Aroclor 1254 induced rat liver S9 fraction.
Vehicle: Ethanol
Remarks - Method: No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			

Test 1	10.2*, 14.5*, 20.7*, 29.8, 42.6, 60.8, 86.8, 124, 177, 253, 361, 515, 735, 1050, 1500 µg/mL	3	22
Test 2	0.625, 1.25, 2.50, 5.00, 7.50*, 10.0*, 15.0*, 20.0*, 25.0, 30.0 µg/mL	21.8	21.8
Present			
Test 1	10.2, 14.5, 20.7*, 29.8*, 42.6*, 60.8, 86.8, 124, 177, 253, 361, 515, 735, 1050, 1500 µg/mL	3	22
Test 2	5.00, 10.0, 20.0, 30.0*, 40.0*, 45.0*, 50.0, 60.0 µg/mL	3	21.8

*Cultures selected for metaphase analysis.

RESULTS

Remarks - Results

Test One:
In absence of metabolic activation, haemolysis was observed in cultures treated at and above 253 µg/mL, prior to end of the exposure period. Reductions in the mitotic index of approximately 50% were observed in cultures treated with 10.2, 14.5, 20.7 µg/mL. Higher concentrations showed 100% reduction in mitotic index when compared to vehicle controls.

In presence of metabolic activation, haemolysis was observed in cultures treated at and above 253 µg/mL, prior to end of the exposure period. A reduction in the mitotic index of 51%, was observed in the culture treated with 42.6 µg/mL, when compared to vehicle controls. Higher concentrations showed 100% reduction in mitotic index when compared to vehicle controls.

Test Two:
In absence of metabolic activation, a reduction in the mitotic index of up to 86% was observed in when compared to vehicle controls.

In presence of metabolic activation, slight haemolysis was observed in cultures treated with 60.0 µg/mL, prior to end of the exposure period. A reduction in the mitotic index of up 86% was observed in cultures when compared to vehicle controls.

No significant increase in chromosomal aberrations, polyploidy or endoreduplication was observed in any of the cultures, either in the presence or absence of metabolic activation.

Appropriate positive controls were used and resulted in large increases in structural aberrations, confirming the sensitivity of the test system.

CONCLUSION

The test substance was not clastogenic to cultured human peripheral blood lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY

Covance (2002)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE

OLOA 289M

METHOD

OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC B.12 Mutagenicity Mammalian Erythrocyte Micronucleus Test.

Species/Strain: Mice/ Cr1:CD-1
Route of Administration: Intraperitoneal
Vehicle: Arachis oil
Remarks - Method: No significant protocol deviations

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I – Vehicle control	7+7 males	0	24, 48
II	7 males	4.5	24
III	7 males	9	24
IV	7+7 males	18	24, 48
V- Positive control, CP	5 males	50	24

CP=cyclophosphamide..

RESULTS

Doses Producing Toxicity	No premature deaths were observed in any of the dose groups. Hunched posture was observed in animals in the 18 mg/kg bw - 48 hours dose group. Statistically significant decreases in PCE/NCE ratio were observed the 4.5 and 9 mg/kg bw dose groups when compared to their concurrent control group. In both 18 mg/kg bw dose groups, a small but not statistically significant decrease in PCE/NCE ratio was observed when compared to their concurrent vehicle controls. Overall, the decreases in ratios indicate that exposure to the bone marrow had been achieved.
Genotoxic Effects	The test substance was considered negative in this micronucleus assay. There was no evidence of a significant increase in the incidence of micronucleated polychromatic erythrocytes in animals dosed with the test material when compared to concurrent controls. The decreases in PCE/NCE ratio indicate exposure to the bone marrow had been achieved.
Remarks - Results	

CONCLUSION — The test substance was not clastogenic in this in vivo mouse erythrocyte micronucleus assay under the conditions of the test.

TEST FACILITY — SafePharm Laboratories (2004)

8. ENVIRONMENT

8.1. Environmental fate

All testing was conducted with the OLOA 289M formulation, which contained <30% of the notified chemical.

8.1.1. Ready biodegradability

TEST SUBSTANCE — OLOA 289M

METHOD

	OECD Guideline 301F Ready Biodegradability (Manometric Respirometry Test), EEC Commission Directive C.4-D and USEPA OPPT 835.3110 (Q).
Inoculum	Sewage sludge micro-organisms
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	No dissolved organic carbon measurements were made due to the insoluble nature of the test material. pH was measured on days 0 and 28.
Remarks - Method	Degradation of the test material was assessed by monitoring of daily oxygen consumption values on Days 0 and 28. Test concentration 20 mg/L, with culture medium in sealed containers tested in the dark at 21±0.9°C.

RESULTS

Test substance		*Aniline Control*	
Day	*% degradation*	*Day*	*% degradation*
7	0	7	52
14	0	14	67
28	0	28	73

Remarks - Results	The toxic control, aniline control and control satisfied validation criteria.
CONCLUSION	The test substance was not readily biodegradable.
TEST FACILITY	SafePharm Laboratories (2002f)

8.1.2. Bioaccumulation

Remarks	No bioaccumulation test data or comments were provided in the notification dossier. With a low water solubility and high Log Kow of 4.64 indicating an affinity for lipids, the notified chemical has the potential to bioaccumulate in exposed organisms. However, limited aquatic exposure will reduce this potential.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	OLOA 289M (Water Accommodated Fraction - WAF)
METHOD	OECD TG 203 Fish, Acute Toxicity Test – semi-static.
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	Notified chemical concentrations were not determined analytically. Total organic carbon (TOC) analyses were performed at 0 and 24 h, with no significant change compared to control. Physico-chemical parameters monitored at 0, 24, 48 and 96 h. Temperature 14-15°C, pH 7.6-7.8, dissolved oxygen 7.3-10 mg O_2/L. Light:dark 16:8 h. No auxiliary aeration was provided to the test containers.
Remarks – Method	Range finding and definitive tests were performed. WAFs were prepared by adding weighed amounts of test substance to dechlorinated tap water, stirring for 48 h and standing for 4 h, then mid-depth siphoning (first 75-100 mL discarded). Micro-inspection of WAFs showed no micro-dispersions or undissolved test material, therefore a glass wool plug was not used to filter the WAFs.

RESULTS

Concentration mg/L WAF		*Number of Fish*	*Cumulative Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0 (control)	0	10	0	0	0	0	0
1.0	Not determined	10	0	0	0	0	0
1.8	"	10	0	0	0	0	0
3.2	"	10	0	0	0	0	0
5.6	"	10	0	0	0	0	1
10	"	10	0	0	10	10	10

LL50 (lethal loading rate)	<7.3 mg/L at 96 hours (95% CI 6.9-7.7)
NOEC	1.8 mg/L at 96 hours.
Remarks – Results	Significant sub-lethal effects, such as swimming at the bottom and coughing, were noted in trout exposed to concentrations of 3.2 mg/L or greater after 96 h exposure and to 10 mg/L after 6 h exposure.
CONCLUSION	The test substance is at least toxic to fish. As nominal concentrations were used, accurate values cannot be determined in this instance.
TEST FACILITY	SafePharm Laboratories (2002b)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	OLOA 289M (Water accommodated fraction - WAF)
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test and Reproduction Test – static test.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	274 mg $CaCO_3$/L
Analytical Monitoring	Notified chemical concentrations were not determined analytically. Total organic carbon (TOC) analyses were performed at 0 and 24 h, with no significant change compared to control. Physico-chemical parameters monitored at 0 and 48 h. Temperature 21°C, pH 7.9-8.0, dissolved oxygen 7.8-8.3 mg O_2/L. Light:dark 16:8 h. No auxiliary aeration was provided to the test containers.
Remarks - Method	Range finding and definitive tests were performed. WAFs were prepared by adding weighed amounts of test substance to reconstituted water, stirring for 48 h and standing for 4 h, then mid-depth siphoning (first 75-100 mL discarded). Micro-inspection of WAFs showed no micro-dispersions or undissolved test material, therefore a glass wool plug was not used to filter the WAFs.

RESULTS

Concentration mg/L		*Number of D. magna*	*Cumulative Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0 (control)	0	20	0	0
0.05	Not determined	20	0	0
0.09	"	20	0	0
0.16	"	20	0	11
0.28	"	20	0	20
0.50	"	20	6	20
0.90	"	20	20	20
1.6	"	20	20	20
2.8	"	20	20	20
5.0	"	20	20	20

EL50 (effective loading)	0.15 mg/L loading rate WAF at 48 hours (95% CI 0.14-0.18)
NOEC	0.09 mg/L loading rate WAF at 48 hours
CONCLUSION	The test substance is very toxic to freshwater waterfleas (*D. magna*)
TEST FACILITY	SafePharm Laboratories (2002c)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	OLOA 289M (Water accommodated fraction - WAF)
METHOD	OECD TG 201 Alga, Growth Inhibition Test
Species	*Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*)
Exposure Period	96 hours
Concentration Range	
Nominal	0, 0.05, 0.1, 0.2, 0.4, 0.8 mg/L
Auxiliary Solvent	None
Water Hardness	Not determined
Analytical Monitoring	Temperature 21°C. pH 7.4 to 10.4 at 96 hours (not considered significant).
Remarks - Method	WAFs were prepared by adding weighed amounts of test

substance to culture medium, stirring for 48 h and standing for 4 h, then mid-depth siphoning (first 75-100 mL discarded) and filtering through glass wool plugs. 3 replicate flasks per treatment concentration. Constant illumination. Samples of cells were removed daily for counting using a Coulter Multisizer II Particle Counter. At the end of the tests, small globules of test material were observed to be floating on the test media.
Mean cell density of controls at 0, 72 and 96 h was $1.28x10^4$, $1.18x10^6$, and $3.17x10^6$ cells per mL, respectively.

RESULTS

Biomass		*Growth*
E_bL50 (Effective Loading rate) mg/L loading rate WAF at 96 h	*96 h NOEL (loading rate WAF)*	*E_rL50 (Effective Loading rate) mg/L loading rate WAF at 96 h*
0.13	0.050	0.17

Remarks - Results: At the three highest test concentrations of 0.2, 0.4 and 0.8 mg/L loading rate WAF, no intact algal cells were present.

CONCLUSION: The test substance is very toxic to freshwater algae

TEST FACILITY: SafePharm Laboratories (2002d)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE: OLOA 289M

METHOD: OECD TG 209 Activated Sludge, Respiration Inhibition Test and
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test

Inoculum: Activated sewage sludge and synthetic sewage, Severn Trent Water Plc domestic sewage treatment plant, Loughborough, UK.

Exposure Period: 3 hours

Concentration Range Nominal: 100, 180, 320, 560 and 1000 mg/L

Remarks – Method: Range finding and definitive tests were performed. The test material was dispersed directly in water. Amounts of test material were each separately dispersed in ~250 mL water and subjected to ultrasonication (~30 mins). Synthetic sewage (16 mL), activated sewage sludge (200 mL) and water were added to a final volume of 500 mL to give the required test concentrations. Test temperature 21°C and pH 8.0.

RESULTS

EC50: 540 mg/L

NOEC: 100 mg/L

Remarks – Results: Oil globules were evident dispersed in test media containing test concentrations of 100 mg/L or greater, indicating poor solubility of the test material. Validation criteria from tests conducted using a control and 3,5-dichlorophenol, a test reference material, were satisfactory.
In a ready biodegradability test conducted over 20 days, SafePharm Laboratories (2002e) indicated that at test concentration of 100 mg/L over a 20 day exposure period resulted in inhibitory effects. The rate of inhibition is greater over extended exposure periods.

CONCLUSION: The test material is unlikely to inhibit microbial activity at environmentally relevant concentrations.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notifier estimates that a small fraction (≤0.125 %) of the total annual import volume of the formulation containing the notified chemical may potentially enter the wastewater compartment during formulation due to spills/leaks and various activities. However, the notifier indicates that all customer formulation facilities have on-site wastewater treatment plants (WWTPs) where residual hydrocarbon-based products will be separated from the aqueous stream by the American Petroleum Industry (API) process, with a removal efficiency of ≥95% (ie. ≤0.0063% in on-site treated effluent), followed by further treatment involving pond aeration and sand filtration, before discharge of this treated effluent to the sewer for further treatment. Negligible environmental release to the aquatic environment is expected following these treatment processes. The remaining oily waste is incinerated. As a worst case scenario assuming only 95% removal of the notified chemical from wastewaters at the formulation sites, the predicted environmental concentration (PEC) in the treated effluent, and downstream waterways, has been estimated with a sewage treatment plant (STP) model developed by the Department of the Environment and Heritage (DEH, 2003). The model assumes that the notified chemical is discharged into the sewerage system and none is attenuated or biodegraded within this system. As customer facilities are located in capital cities, the sewerage system involved would comprise the majority of the sewerage system in Australia (estimated at 75%). Australia has a population of ~20.1 million people, and an average value for water consumption of 200 L/person/day has been adopted for this national-level assessment (4020 ML/day for total population). Therefore the concentration of OLOA 289M formulation containing the notified chemical in the Australian sewage network may be calculated on the basis of a maximum annual volume of ≤20 tonnes of OLOA 289M. The approximate sewerage effluent concentration under these assumptions is 0.0011 μg/L (20 $x10^{12}$ μg per annum x 0.125% x 5% ÷ 365 days/ year ÷ 4020 x 10^6L/day x 1.333). Based on dilution factors of 1 and 10 for inland and ocean discharges of STP-treated effluents, respectively, PECs of the formulation containing notified chemical in freshwater and marine surface waters may, under these assumptions, approximate 0.0011 μg/L ($PEC_{freshwater}$) and 0.00011 μg/L (PEC_{marine}), respectively.

Less than 150 kg of the formulation containing the notified chemical (<90 kg) is expected to be sent to landfill for disposal. The use pattern would indicate that this disposal pattern would be widespread.

Practically all of the notified chemical in waste oil will be generated from professional workshops and waste oil containing the notified chemical will most likely be managed in a responsible manner and recycled or incinerated as fuel oil, resulting in destruction of the notified chemical with emission of combustion products to the atmosphere.

The notifier estimates that ≤1% of the total import volume of the notified chemical formulation may potentially be released to the environment due to drips/leaks from equipment containing formulation, where is may enter the soil and stormwater compartments over a diffuse area based on the widespread use pattern. A worst case may involve all of this estimated quantity (≤200 kg/annum) being discharged into the stormwater drains in a single metropolitan area with a geographical footprint of 500 square kilometres, and an average annual rainfall of 500 mm. With a maximum annual release into this localised stormwater system of ≤200 X 10^9 μg/y and the annual volume of water drained from this region estimated to be approximately 250 X 10^9 L, the resultant predicted environmental concentration (PEC) in the receiving environment is ≤0.8 μg/L, with dilution, dispersion and sedimentation also likely to occur in the receiving environment.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests available indicate that the lowest available acute L(E)C50 is for algae, with an E_bL50 (WAF) of 0.13 mg/L (for the OLOA 289M formulation). Similar results were reported in *Daphnia magna*, with an EL50 of 0.15 mg/L. A predicted no effect concentration for aquatic organisms ($PNEC_{aquatic}$) of <0.0013 mg/L (<1.3 µg/L) has been derived by dividing the lowest acute EL50 value by a safety factor of 100, used to account for interspecies sensitivity, acute to chronic effects ratio and other adverse factors that may potentially arise in the environment if organisms are exposed to the substance. In the absence of ecotoxicity data for marine species, the freshwater PNEC has been adopted as a marine species PNEC. No sediment toxicity data were available for the notified substance. No soil toxicity data are available for the notified substance or formulation; however, environmental release to the terrestrial compartment is unlikely to be significant.

9.1.3. Environment – risk characterisation

he submission did not include ecotoxicity data for the notified chemical, but did include ecotoxicity data for the formulation containing the substance. Hence, the ecological risk assessment has only been performed on the formulation. The notified chemical will not be manufactured in Australia, or isolated from the formulation.

A risk quotient value (PEC/PNEC) for freshwater receiving environments of 0.0009 (ie. 0.0011 µg/L ÷ 1.3µg/L) has been estimated based on a sewer disposal scenario described in Section 9.1.1 (less for marine waters). Likely biodegradation in on-site wastewater treatment plant pondages and filtration, in the sewerage system and the aquatic compartment further reduces the risk. A risk quotient value (PEC/PNEC) for receiving environments of <0.6 (ie. 0.8 µg/L ÷ 1.3µg/L) has been estimated based on a stormwater disposal scenario described in Section 9.1.1; however, the risk quotient is likely to be lower based on the widespread and diffuse use pattern, natural attenuation processes in the environment and release to the terrestrial environment. Therefore, the proposed use of the notified chemical is unlikely to pose an unacceptable risk to the aquatic life.

Although the formulation containing the notified chemical is not readily biodegradable over a 28 day test period, it is expected that it would biodegraded over time to simpler products within a landfill environment. With a low water solubility (0.001 g/L), moderate Log Kow of 4.64 and Log Koc of 4.44-4.56 (estimated), the formulation is likely to partition to soil particles and is likely to have low mobility in soil.The submission did not include ecotoxicity data for the notified substance, but did include ecotoxicity data for the formulation containing the substance. Hence the ecological risk assessment has only been performed on the formulation. As the notified substance will not be manufactured in Australia, or isolated from the formulation.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and Storage

Dermal exposure to drips and spills of blended lubricant is possible during the connection and disconnection of transfer hoses during the filling of bulk tankers. The notified chemical has a very low vapour pressure and is present in a high viscosity formulation, minimising the possibility of vapour and aerosol formation. Worker exposure will be minimised by the user of overalls, safety boots and gloves.

Reformulation

During the reformulation process, there is expected to be minimal worker exposure. The transfer of the imported lubricant additive package from bulk tankers into storage tanks and charging of blending tanks are highly automated processes. Incidental dermal exposure to splashes, drips and spills may occur during the connection and disconnection of the lines. The blending process is automated and occurs in closed system. The blending is transferred automatically to storage tanks

Drum filling is again an automated process and worker intervention is not required unless the filling line operation requires adjustment. However, workers are required to insert bungs and label the drums and dermal contact with contaminated drum surfaces may occur. Bulk road tanker filling is performed by a transfer hose. Dermal exposure to drips and spills of blended lubricant is possible during the connection and disconnection of transfer hoses.

Maintenance workers involved in cleaning blending and filling equipment may be dermally exposed to residues containing the notified chemical.

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 are expected to have minimal exposure due to the brief sampling periods and the small quantities involved. Dermal exposure due to drips may occur during sampling. It would be expected that gloves, lab coats and safety glasses would be used by laboratory personnel during testing.

End Users
End users of the finished product may be exposed to notified chemical when the blended oil products are added and drained from systems, handling automotive components that have come into contact with the oil and during cleaning of equipment. Workers will wear overalls, cotton hat and safety boots when using products containing the notified chemical.

9.2.2. Public health – exposure assessment

The public will not be directly exposed to the notified chemical, as it will not be sold to the DIY consumer market. Very limited numbers of the public may have occasional exposure while doing specialised automotive repair work.

9.2.3. Human health - effects assessment

The toxicological studies provided in this notification were undertaken using the formulation containing the notified chemical. The studies indicate that the product has low acute oral and dermal toxicity, and the observed effects are dominated by the irritant nature of the product.

The product containing the notified chemical is a skin irritant, causing severe erythema and oedema, grey-yellowish discolouration of the skin, reduced flexibility, fissuring of the skin, bald skin and scaliness. All effects were reversible, with no abnormalities being observed at the end of the observation period.

The product containing the notified chemical is slightly irritating to the eyes. The test substance affected the cornea, iris, and conjunctivae. The corneal injury (opacity and epithelial damage) and iridial inflammation were resolved by 7 days in all animals. The observed conjunctivae redness, chemosis, and discharge were completely resolved by 14 days. The product containing the notified chemical is not classified as a skin sensitiser, with a response of 25% at challenge and 10% at rechallenge and 6.67% at challenge, respectively, in two experiments using the modified Buehler method.

The NOEL for the product containing the notified chemical established in a range finding 5 day repeated dose study in rats was 100 mg/kg bw/day, based on presence of clinical effects, effects on body weight, food consumption, gross organ pathology, organ weight and hyperplasia of the squamous epithelium of the forestomach at higher doses.

The mutagenicity of the test substance examined in two *in vitro* tests and one *in vivo* test. The test substance was not mutagenic to bacterial cells with and without metabolic activation. The test substance was not genotoxic to cultured human peripheral blood lymphocytes with and without metabolic activation. The test substance was found not be clastogenic in mouse micronucleus assay.

The product containing the notified chemical is classified as a hazardous substance. Based on the reversible severe erythema and oedema observed the product containing the notified chemical can be classified as skin irritant (R38 - Irritating to skin).

9.2.4. Occupational health and safety – risk characterisation

The main route of exposure to the notified chemical will be dermal exposure.

During transport, storage and formulation workers may be exposed to the notified chemical as result of drips and spills during the connection and disconnection of transfer hoses, drum filling, labelling, and bung insertion. Maintenance workers and laboratory staff may also be exposed to the notified chemical during the cleaning and testing activities, respectively. These workers may be exposed either to the imported additive package or to finished lubricants containing <0.3% notified chemical. The finished lubricant will not pose a high risk on dermal contact due to the low concentration of notified chemical, but precautions are required while handling the imported additive package, which is classified as R38 –irritating to the skin. Workers handling the notified chemical in the imported product should wear, gloves, overalls, and safety boots to minimise dermal exposure.

Motor mechanics using the products containing notified chemical or handling the automotive components that have been in contact with the oil will be dermally exposed to the notified chemical. The concentration of the notified chemical in the oil will be low (<0.3%).

9.2.5. Public health – risk characterisation

The risk to public will be very low as the final product containing the notified chemical will not be available to public. While there may be occasional exposure for a very few members of the public, the oil residues involved will contain low levels of the notified chemical.

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

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:
R38 Irritating to the skin

and

As a comparison only, the classification of the formulation containing the 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.

- Oral acute Category 5
- Skin irritant Category 2
- Eye irritant Category 2A
- Chronic Hazard Category 1: Very Toxic to Aquatic Life with Long lasting Effects

The formulation containing the notified chemical is not readily biodegradable and very toxic to aquatic organisms (ie. L(E)C50 <1 mg/L). This system is not mandated in Australia and carries no legal status but is presented for information purposes.

10.2. Environmental risk assessment

On the basis of the reported use pattern, aquatic PEC/PNEC ratios and ecotoxicity data, the formulation containing the notified chemical is not considered to pose an unacceptable risk to the environment.

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 Negligible Concern to public health when used as described in the notification.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing the 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 products containing the 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

REGULATORY CONTROLS

Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the product containing the notified chemical:
  - R38-Irritating to skin
  - S37/38/39-Wear suitable protective clothing, gloves, and eye/face protection.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced and the formulated product:
  - Minimise spills and drips

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Chemical resistant gloves
  - Protective clothing
  - Safety goggles

  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 will be a component of waste oil generated from professional operations. It should be disposed of by recycling as waste oil or incinerated in accordance with approved State or Territory waste management regulations. Emptied containers (1-4 L) should be sent to landfill for disposal. Emptied drums should be reconditioned by steam cleaning prior to re-use, with wastewater treated and the oily concentrate either recycled or incinerated.

Emergency procedures

- Spills/release of the notified chemical should be handled in accordance with procedures described in the Material Safety Data Sheet. Report spills to local authorities as appropriate or required. Spills of heated oil containing the notified chemical should be allowed to cool before proceeding with cleanup methods. Stop source of spill. Contain spill to prevent further contamination of soil, surface water or groundwater. Clean up spill as soon as possible by applying non-combustible, absorbent materials or by pumping to recovery tanks. Remove contaminated soil. Place contaminated materials in disposable containers and dispose of in accordance with State or Territory waste disposal regulations.

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 Section 64(1) of the Act; if
  - If any proposed uses lead to a more significant release to water.

or

(2) Under Section 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.

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