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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

OLOA 378

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

OLOA 378

1. APPLICANT

Chevron Chemical Company of 385 Bourke Street MELBOURNE VIC 3000 has submitted a standard notification statement in support of their application for an assessment certificate for OLOA 378

2. IDENTITY OF THE CHEMICAL

OLOA 378 is a multifunctional chemical containing hydrocarbon, polyamine and complex metal sulphide functionalities. OLOA 378 is considered not to be hazardous based on the nature of the chemical and the data provided for analogous chemicals. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the chemical composition and details of customers have been exempted from publication in the Full Public Report and the Summary Report.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	viscous black liquid
Boiling Point:	decomposes before boiling
Specific Density:	0.987 $g.cm^{-3}$ at 15 ^oC
Vapour Pressure:	5×10^{-5} kPa at 25°C (see comments below)
Water Solubility:	< 1 $\mu g.L^{-1}$ at 25°C
Partition Co-efficient (n-octanol/water):	log P_{ow} > 6.7 (see comments below)
Hydrolysis as a Function of pH:	no data provided (see comments below)
Adsorption/Desorption:	no data provided (see comments below)

Dissociation Constant:	no data provided (see comments below)
Flash Point:	> 200°C
Flammability Limits:	will burn in the presence of enough heat and oxygen
Autoignition Temperature:	> 200°C
Explosive Properties:	not known to be explosive
Reactivity/Stability:	will react in the presence of strong oxidising agents; stable to acid and base

Comments on Physico-Chemical Properties

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

The water solubility is stated as less than 100 parts per billion as measured according to OECD Test Guideline 105. This is not unexpected for a compound containing a large saturated hydrocarbon group as does the notified chemical. However, the polar nature of the succinimide and amine groups may confer some affinity for water on these portions of the molecule, and it is possible that the material could be dispersed in water as droplets of emulsion. A supporting test report has been requested from the notifier.

The notifier states that the notified chemical is stable to hydrolytic degradation, but the succinimide group, and possibly the bonds between the amine groups and molybdenum may be susceptible to hydrolysis under extreme pH conditions. However, in the usual environmental pH region between pH 4 and pH 9 the material could be expected to be stable to hydrolysis. The very low water solubility also would not favour hydrolysis reactions due to the limited contact between susceptible groups and the aqueous environment.

The n-octanol/water partition coefficient was determined using a high performance liquid chromatography method. The high value of greater than 6.7 reflects the high hydrocarbon content of the substance. No adsorption/desorption data were provided, but the high Log P_{ow} and high hydrocarbon content indicates that the material would adsorb strongly to the organic component of soils and sediments.

No dissociation constant data were provided, and although the ethylenediamine portion of the molecules could be expected to exhibit basic properties if not complexed to the molybdenum atom centres, as the bonding to these metal atoms destroys the potential basicity. Consequently, the material will not exhibit appreciable acidic or basic properties, and the non-provision of dissociation constant data is acceptable for this chemical.

4. PURITY OF THE CHEMICAL

Degree of Purity:	87%
Toxic or Hazardous Impurities:	3%
Non-hazardous Impurities (> 1% by weight):	10 %
Maximum Content of Residual Monomers:	13 %
Additives/Adjuvants:	none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia, but will be imported in marine isotanks (20,000 L) or 200 L drums as a component of an additive package of which it will comprise less than 6% by weight. Some 15 different additive packages containing the new chemical may be imported, and these will then be used in the blending of automotive lubricants in Australia. Total import volumes for the notified chemical are anticipated to be 300 tonnes per annum over the next five years.

It is anticipated that the notified chemical will be blended with oils and other additives (eg viscosity modifiers, foam inhibitors, pour point depressants and lubricant oils) into completed lubricants (approximately 15 different products are anticipated) for both petrol and diesel engines at around 10 facilities throughout Australia. The notified chemical is an inhibitor used to reduce deposits on pistons and in the engine crankcase and to control oxidation of the lubricant at high engine operating temperatures. The lubricant products will contain less than 1.5 % of the new chemical, and will be packed into 1 L and 4 L containers, and into 200 L steel drums for distribution to customers. It is expected that transport of the finished lubricant between the blending facilities and the customers will be primarily by truck.

6. OCCUPATIONAL EXPOSURE

Worker exposure to the notified chemical during handling and transport of the imported oil additive is only likely to occur in the event of an accidental spill. Hence the potential for exposure is low, and the notified chemical is present at levels less than 10 %.

Isotanks or drums containing the oil additive will be transported to the blending facilities, where the additive will be pumped through computer controlled valves to a blending tank. After blending, worker exposure (1 to 2 workers for 30 minutes, 50

days per year) may occur during sample removal for laboratory analysis and during the actual analysis (1 to 2 workers for 30 mins, 50 days per year). Worker exposure (1 worker for 1hour, 50 days per year) may also occur during steam cleaning of the empty oil additive drums and disconnection of transfer lines.

The finished lubricant products containing the notified chemical are packaged into 1or 4 litre containers or 200 litre drums. Drums are filled automatically, with workers watching from 1 to 2 metres away to ensure that the drum filling mechanism properly enters the drum before it is filled. Hence worker exposure during this process is expected to be minimal. Likewise the packaging of 1 and 4 litre jugs is highly automated and there is minimal worker exposure expected. There is however some potential for worker exposure (1 worker for 1hour, 50 days per year) during disconnection of packaging lines for cleaning.

Finally, worker exposure may occur through mechanics and/or technicians who may come into contact with lubricants containing the notified chemical while working on, or repairing equipment. The most likely route of exposure to the notified chemical is through skin and eye contact. However, poor hygiene (ie eating with contaminated hands) may lead to some ingestion of the notified chemical.

7. PUBLIC EXPOSURE

There is negligible potential for public exposure to the notified chemical arising from the blending process. The cleaning of the additive drums and blending equipment is done with steam, and the resulting waste is sent to on-site waste water treatment facilities which include Australian Petroleum Iindustry oil-water separation, pond aeration and sand filtration. Hence the waste water reaching municipal sewers, and then watercourse, is unlikely to pose any hazard to the public due to contamination with the notified chemical.

Accidental spills during transportation of the additive or finished oils or improper disposal of used oil by the general public could result in public exposure, however the spill is likely to be contained, and therefore the risk of exposure low. Small spills are likely to be cleaned up using sorbent materials or techniques such as pumping.

A moderate level of public contact with the notified chemical could occur through automotive passenger vehicle owner operators who change their own oil or undertake their own engine repair work. However, the potential for exposure is low because contact is likely to be brief and intermittent, and the concentration of the notified chemical in the finished oil is less than 2%.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier indicates that the blending operations are performed at specially constructed sites (around 10 in Australia, all owned and operated by petroleum companies). The additive packages containing the notified chemical will be delivered to, and stored at the blending facilities in isotanks or drums, and it is anticipated that very little of the additive package will be released during transfer from the storage containers to the blending tanks. All transfer operations are controlled automatically, and the blending tanks are cleaned with lube oil which is recycled for use in preparing subsequent batches of product. Any spills incurred in the blending operations are contained within concrete bunds and are either reclaimed or sent to on-site waste water treatment facilities. Similarly, the empty drums of additive package are cleaned with steam, and the resultant waste water is sent to the water treatment facilities where the residual hydrocarbon based products are comprehensively separated from the aqueous stream using techniques which include oil/water separation, induced air flotation and sand filtration. The hydrocarbon based waste is then either incinerated or is removed by oil recycling contractors, while the aqueous stream, now containing very little hydrocarbon based material, is discharged to the sewer. The notifier states that treatment of the wastewater would remove around 95% of any of the new chemical present in the influent wastewater stream.

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

Some release is likely during transfer of the lubricants from containers to engine blocks. If it is assumed that each transfer involves 4 litres of lubricant, then a calculation based on an annual import of 300 tonnes and a typical content of 1% of the new product in the oil indicates around 7 500 000 engine oil changes (using the notified product) take place throughout Australia each year. It is anticipated that on average 20 mL of lubricant, containing 1% of the notified substance, is likely to be either spilt or left as residuals in containers as a result of transfer operations, and consequently around 1 500 kg (0.5% of import quantity) of the notified material could be released annually via this route. Most spills are likely to be adsorbed onto sawdust and incinerated or disposed of to landfill, while residuals left in containers would be disposed of in similar fashion. Irresponsible work practices could lead to spilt oil being washed down driveways and entering stormwater systems, but this is expected to be a minor occurrence.

A recent survey by the Australian Institute of Petroleum (1) indicates that of the annual sales of automotive engine oils (around 182 megalitres) in Australia, some 60% is 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. The remaining 14% (15 megalitres) is removed by do it yourself (DIY) enthusiasts, and in these cases some of the old oil would be either incinerated, left at transfer

stations where it is again likely to be recycled, or deposited into landfill. However, recent survey data tracing the fate of used lubricating oil in Australia (2) indicates that only around 20% of old oil removed by enthusiasts is collected for recycling, while about 25% is buried or tipped into landfill, 5% is disposed of into stormwater drains and the remaining 40% is used in treating fence posts, killing grass and weeds or disposed of in other ways.

Consequently, if it is assumed that oil removed by professional mechanics is disposed of appropriately (ie burning as workshop heating oil or sent for recycling), negligible release of the notified chemical should result from these professional activities. However, assuming a 14% market share, 60% recovery (ie unburnt) of oil and 80% disposal through dumping, burying, fence maintenance etc, then the DIY proportion of oil changes could potentially lead to release of up to 7% of the total import volume of the new chemical, ie an annual release of up to 21 tonnes. Most of this is likely to become associated with soils or sediments.

Since the use of the lubricating oils will be occur throughout Australia, all releases resulting from use or disposal of old oil will be very diffuse, and release of the notified material in high concentrations is very unlikely except as a result of transport accidents.

Fate

The notified material is not expected to be readily biodegradable in aerobic environments, and a CO_2 evolution test [EEC method C. 4-C/1992] performed on the parent polyamine known as OLOA 371 (see structures of analogues in Environmental Effects section below) indicated only 23% degradation after 28 days. However, despite the low apparent rate for biodegradation, it is expected that if placed into landfill (if for example adsorbed into sawdust after accidental spills, or dumped irresponsibly) the material would be slowly degraded through the slow biological and abiotic processes operative in these facilities. Apart from some carbon dioxide, these processes could be expected to produce methane, ammonia and water together with some hydrogen sulphide and (solid) molybdenum compounds.

Leaching from a landfill would be slow, and the high anticipated K_{oc} (see notes on physico-chemical properties above) indicates that the material would not be mobile, but would adsorb onto and become associated with the organic component of soils and sediments. Similarly, in the event of accidental release into the water compartment, it is likely to become associated with suspended organic material, and eventually be incorporated into sediments.

Although the chemical has a high Log P_{ow}, the high molecular weight will preclude easy transfer across cell membranes, and hence the material is unlikely to bioaccumulate. A bioaccumulation test on Japanese carp performed using a close analogue of the notified material (ie OLOA 378 (TEPA), “OLD” OLOA 378, see further in Environmental Effects section below) is said to have provided a first division bioaccumulation factor of less than 5.1, but no report on this test was included with the notification statement.

Incineration of waste oil containing the notified material would destroy the substance with evolution of water vapour and oxides of carbon and nitrogen, together with some sulphur dioxide and the production of molybdenum compounds which would be assimilated with the ash. Sludges from waste treatment plants or oil recycling facilities could also be incinerated.

Relatively large quantities of material placed into landfill as a result of irresponsible disposal practices, or for example, used in the preparation of wooden fences, would be adsorbed into and become associated with soil material and eventually be slowly degraded as described above.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

The notifier has not supplied actual toxicology data for the new substance OLOA 378. Rather, toxicological properties are derived from three similar substances, "old" OLOA 378 called OLOA 378 (TEPA), OLOA 370 (the starting material for OLOA 378 TEPA) and OLOA 371 the starting dispersant material for new OLOA 378. In comparison to the old OLOA 378 (TEPA) the new substance has the same proportion of polyamine and of heavy metal sulphide. The notifier effectively argues that if there is no difference in the toxicological properties of OLOA 378(TEPA) and the starting dispersant material from which it is formed, then it should follow that the toxicological properties of the starting dispersant (as provided by the notifier) act as a substitute for the notified chemical. The logic in this argument is acceptable, especially since old OLOA 378 is of low toxicological concern. For completeness, the toxicological properties of the starting dispersant for the notified chemical, the starting dispersant (ie OLOA 371) for old OLOA 378 TEPA (ie OLOA 370) and for the old OLOA 378 (TEPA) will be reported here in full.

Summary of the acute toxicity of OLOA 371, the starting dispersant for OLOA 378

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 $mg.kg^{-1}$	(3)
acute dermal toxicity	rat	LD_{50} > 2 000 $mg.kg_{-1}$	(4)
skin irritation	rabbit	slight irritant	(5)
eye irritation	rabbit	slight irritant	(6)
skin sensitisation	guinea pig	not sensitising	(7)

9.1.1aOral Toxicity (3)

Species/strain:	rat/Crl:CD®(SD)BR
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	oral gavage
Clinical observations:	three males exhibited a dark-stained anal area on days 1 to 5; all animals had normal appearance by day 6
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines (8)
LD_{50}:	> 5 000 $mg.kg^{-1}$
Result:	the test chemical was of low acute oral toxicity in rats

9.1.2aDermal Toxicity (4)

Species/strain:	rat/Crl:CD®(SD)BR
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	single topical application of test chemical at a level of 2 000 $mg.kg^{-1}$ for a 24-hour exposure period
Clinical observations:	none
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines (8)
LD_{50}:	> 2 000 $mg.kg^{-1}$
Result:	the test chemical was of low toxicity to rats when administered dermally

9.1.3aInhalation Toxicity

not determined

9.1.4aSkin Irritation (5)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	6
Observation period:	7 days
Method of administration:	0.5 mL of the test chemical was applied to two intact and two abraded sites on the back of each rabbit for 24 hours using a semi-occlusive wrap
Comments:	five out of six animals showed slight erythema (Draize (9) score =1) at the 4-hour observation period; all but one of these animals had no symptoms after 24 hours, and the erythema of this animal had disappeared by the 48-hour observation period only one animal displayed oedema, but this had disappeared by the 24-hour observation period
Test method:	similar to OECD guidelines (8)
Result:	the test chemical was a slight irritant to rabbit skin

9.1.5aEye Irritation (6)

Species/strain:	rabbit/New Zealand White
Number:	6 unirrigated, 3 irrigated
Observation period:	7 days
Method of administration:	0.1 mL of the test chemical was placed in the conjunctival sac of one eye in each animal; the untreated eye served as a control
Comments:	no corneal or iridal effects were noted for the animals in both the irrigated and non-irrigated ocular groups; the test chemical

was slightly irritating to the conjunctiva of both the irrigated and unirrigated eyes of rabbits; irrigation diminished the severity of conjunctival irritation

Draize scores (9)

	Time after instillation											
Animal	**1 hour**			**1 day**			**2 days**			**3 days**		
Conjunctiva	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**
unirrigated												
1	2	0	1	1	0	0	0	0	0	0	0	0
2	2	0	0	2	0	0	0	0	0	0	0	0
3	2	1	1	2	0	0	0	0	0	0	0	0
4	2	1	1	1	0	0	0	0	0	0	0	0
5	2	0	1	1	0	0	0	0	0	0	0	0
6	2	0	1	2	0	0	1	0	0	0	0	0
irrigated eye												
1	2	1	0	1	0	0	1	0	0	0	0	0
2	2	1	0	1	0	0	0	0	0	0	0	0
3	2	1	1	1	0	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
[c] redness [d] chemosis [e] discharge

Test method: similar to OECD guidelines (8)

Result: the test chemical was a slight irritant to the rabbit eye

9.1.6aSkin Sensitisation (7)

Species/strain: guinea pig/Dunkin Hartley

Number of animals: 20 test, 10 control animals

Induction procedure: undiluted test chemical was applied to the exposed skin of each test animal and held in place using a semi-occlusive wrap; the wrap was removed 6 hours after exposure and excess chemical removed by rinsing; the procedure was repeated at the same site

	once a week for the next 2 weeks for a total of three approximate 6-hour exposures
Challenge procedure:	test animals were challenged with a 50% (w/v) solution of the test chemical in light mineral oil 2 weeks after the last induction dose; challenge site was different to the induction site

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
50%	1/20**	0/20	0/10	0/10

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

Test method:	similar to OECD guidelines (8)
Result:	the test chemical was not sensitising to the skin of guinea pigs

9.2a Repeated Dose Toxicity

not determined

9.3a Genotoxicity

9.3.1a *Salmonella typhimurium*/*Escherichia coli* Reverse Mutation Assays (10)

Strains:	*Salmonella typhimurium* TA 98, TA100, TA 1535, TA 1537 *Escherichia coli* WP2*uvr*A
Concentration range:	100, 250, 500, 1 000, 5 000 and 10 000 μg per plate in the presence or absence of S9 mix; pluoronic F127 25% w/w in ethanol was used as a vehicle
Comments:	no cytotoxicity was observed up to 10 000 μg per plate with the salmonella tester strains or with WP2*uvr*A in either the presence or absence of S9 mix; precipitate of the test chemical was observed on the plates at concentrations ≥ 500 μg per plate
Test method:	similar to OECD guidelines (8)

Result:	the test chemical did not induce mutations in either Salmonella or Escherichia strains both in the presence or absence of S9 mix

9.3.2aMicronucleus Assay in the Bone Marrow Cells of the Mouse (11)

Species/Strain:	mouse/Crl:CD-1 (ICR) Br
Number and sex of animals:	6 animals per dose group (3/sex)
Doses:	1 625, 2 750, 3 875 and 5 000 $mg.kg^{-1}$
Method of administration:	the test chemical was solubilised in peanut oil and dosed by intraperitoneal injection
Test method:	similar to OECD guidelines (8)
Result:	the test chemical did not induce a statistically significant increase in micronuclei in the bone marrow polychromatic erythrocytes of the mouse under the conditions of the test

Summary of the acute toxicity of OLOA 370, the starting dispersant for OLOA 378 (TEPA)

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 $mg.kg^{-1}$	(12)
acute dermal toxicity	rat	LD_{50} > 5 000 $mg.kg_{-1}$	(13)
skin irritation	rabbit	slight irritant	(14)
eye irritation	rabbit	slight irritant	(15)
skin sensitisation	guinea pig	non-sensitising	(16)

9.1.1bOral Toxicity (12)

Species/strain:	rat/Crl:CD®(SD)BR
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	oral gavage
Clinical observations:	diarrhoea was observed in two treated males and two treated females on the day of dosing and the following day

Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines (8)
LD_{50}:	> 5 000 $mg.kg^{-1}$
Result:	the test chemical was of low acute oral toxicity in rats

9.1.2bDermal Toxicity (13)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	single topical application at a level of 5 000 $mg.kg^{-1}$ for a 24-hour exposure period
Clinical observations:	slight erythema was observed in the treated skin of all animals one hour after exposure; three animals had well defined erythema six days later, but all had normal skin by day 14;
Mortality:	none
Morphological findings:	possible treatment-related lesions of the skin for males but not females; flaky and pinpoint scabs observed
Test method:	similar to OECD guidelines (8)
LD_{50}:	> 5 000 $mg.kg^{-1}$
Result:	the test chemical was of low dermal toxicity to rats

9.1.3bInhalation Toxicity

not determined

9.1.4bSkin Irritation (14)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	12

Observation period:	14 days
Method of administration:	0.5 mL of the test chemical was applied to an unabraded site on the shaved back of each rabbit for 4 hours using a semi-occlusive wrap
Comments:	slight erythema or oedema was observed in seven animals one hour after exposure; slight erythema was observed in three animals at 24 hours and in one animal at 48 hours; no further irritation was observed
Test method:	similar to OECD guidelines (8)
Result:	the test chemical was a slight irritant to the rabbit skin

9.1.5bEye Irritation (15)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	9
Observation period:	72 hours
Method of administration:	0.1 mL of the test chemical was placed into the conjunctival sac of one eye; the untreated eye of each animal served as the control; three of the animals were treated further by rinsing the control and treated eye for one minute at a rate of 250 mL per minute with distilled water 30 seconds after exposure
Comments:	all animals experienced redness of the conjunctivae 1 hour after treatment; at 24 hours this redness persisted in all but one animal; at 48 hours only one animal had this effect; at 72 hours all animals were normal; no iridal or corneal effects were noted
Test method:	similar to OECD guidelines (8)
Result:	the test chemical was a slight irritant to the rabbit eye

9.1.6bSkin Sensitisation (16)

Species/strain: guinea pig/Dunkin Hartley

Number of animals: 20 test, 10 control animals

Induction procedure: undiluted test chemical was applied to the exposed skin of each test animal and held in place using a semi-occlusive wrap; the wrap was removed 6 hours after exposure and excess chemical removed by rinsing; the procedure was repeated at the same site once a week for the next 2 weeks for a total of three approximate 6-hour exposures

Challenge procedure: test animals were challenged with undiluted chemical 2 weeks after the last induction dose; challenge site was different to the induction site

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
100%	2/20**	1/20	1/10	0/10

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

Test method: similar to OECD guidelines (8)

Result: the test chemical was not a sensitiser in guinea pigs

9.2b Repeated Dose Dermal Toxicity (17)

Species/strain: rat/Sprague -Dawley

Number/sex of animals: 12/sex

Method of administration: the test chemical was applied daily to the shaved dorsal surface of the trunk for a 6-hour period; a plastic collar prevented the animal ingesting the test chemical

Dose/Study duration: 1 $ml.kg^{-1}day^{-1}$ of 10%, 40% and 80% of the test chemical in mineral oil for 28 days

Clinical observations:	no deaths occurred and no treatment-related signs of toxicity were observed
Clinical chemistry/Haematology	no treatment-related effects
Histopathology:	no treatment-related effects
Test method:	similar to OECD guidelines (8)
Result:	no specific organ toxicity was noted in rats when an 80% solution of the test chemical in mineral oil was administered dermally at 1 $ml.kg^{-1}.day^{-1}$

9.3b Genotoxicity

9.3.1b *Mouse Lymphoma* Mutagenicity Assay (18)

Strains:	L5178Y mouse lymphoma cells
Concentration range:	333 - 6 670 $\mu g.mL^{-1}$ of test chemical in 5% pluoronic F68 (w/w in distilled water); with metabolic activation 500 - 2 000 $\mu g.mL^{-1}$ of test chemical in 5% pluoronic F68 (w/w in distilled water); without metabolic activation
Test method:	similar to OECD guidelines (8)
Result:	the test chemical was not mutagenic to mouse lymphoma cells with or without metabolic actitvation under the conditions of the test

9.3.2b *Salmonella typhimurium* Reverse Mutation Assay (19)

Strain:	TA98, TA 100, TA 1535, TA 1537
Doses:	333 - 3 333 μg of the test chemical per plate; the test chemical was first diluted with tetrahydrofuran (THF) to obtain the highest dose; subsequent dilutions were carried out using dimethylsulphoxide (DMSO)
Comments:	the test chemical was miscible in THF and partially miscible in subsequent dilutions

	with DMSO, but was not completely miscible with the top agar (3 333 μg)
Test method:	similar to OECD guidelines (8)
Result:	the test chemical was not mutagenic to any of the Salmonella strains with or without metabolic activation under conditions of the test

Summary of the acute toxicity of OLOA 378 (TEPA)

Test	***Species***	***Outcome***	***Reference***
acute oral toxicity	rat	LD_{50} > 5 000 $mg.kg^{-1}$	(20)
acute dermal toxicity	rat	LD_{50} > 5 000 $mg.kg^{-1}$	(20)
skin irritation	rabbit	slight irritant	(20)
eye irritation	rabbit	slight irritant	(20)
skin sensitisation	guinea pig	non-sensitising	(16)

9.1.1cOral Toxicity (20)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage
Clinical observations:	none
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines (8)
LD_{50}:	> 5 000 $mg.kg^{-1}$
Result:	the test chemical was of low acute oral toxicity in rats

9.1.2cDermal Toxicity (20)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	5/sex

Observation period:	14 days
Method of administration:	single topical application to the abraded skin at a level of 5 000 $mg.kg^{-1}$ for a 24-hour period
Clinical observations:	none
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines (8)
LD_{50}:	> 5 000 $mg.kg^{-1}$
Result:	the test chemical was of low dermal toxicity in rats

9.1.3 Toxicity **cInhalation** not determined

9.1.4cSkin Irritation (20)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	6
Observation period:	7 days
Method of administration:	0.5 mL of the test chemical was applied to two intact and two abraded sites on the back of each rabbit for 24 hours using a semi-occlusive wrap

Draize scores (9):

Time after treatment	***1 day***	***2 days***	***3 days***	***7 days***
Erythema				
1	1,2[a]	1,1	0,0	0,0
2	2,2	1,1	0,0	0,0
3	2,2	1,1	1,1	0*,0
4	1,1	1,0	0,0	0,0
5	1,2	1,1	1,0	0,0
6	1,1	1,1	1,0	0,0
Oedema				
1	0,0	0,0	0,0	0,0
2	1,1	0,0	0,0	0,0
3	1,0	0,0	0,0	0,0
4	0,0	0,0	0,0	0,0
5	0,0	0,0	0,0	0,0
6	0,0	0,0	0,0	0,0

[a] see Attachment 1 for Draize scales

Comments: only the Draize scores for the unabraded skin have been recorded (front and rear applications); results for the abraded skin are similar to these reported here

the test chemical caused very slight to well defined erythema and very slight oedema at 24 hours after treatment; irritation was reduced at 48 hours, and all rabbits had normal skin seven days after treatment, although 2 animals had dry skin at one application site

Test method: similar to OECD guidelines (8)

Result: the test chemical was a slight irritant to the skin of rabbits

9.1.5 cEye Irritation (20)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 6 unirrigated, 3 irrigated

Observation period:	7 days
Method of administration:	0.1 mL of the test chemical was placed in the conjunctival sac of one eye in each animal; the untreated eye served as a control
Comments:	no corneal or iridal effects were noted for the animals in both the irrigated and non-irrigated ocular groups;at 1 hour after treatment, slight to moderate conjunctival irritation (redness and discharge) was observed in treated-unrinsed eyes and slight conjunctival irritation was observed in treated-rinsed eyes; all eyes were normal at 48 hours after treatment
Test method:	similar to OECD guidelines (8)
Result:	the test chemical was a slight irritant to the rabbit eye

9.1.6cSkin Sensitisation (16)

Species/strain:	guinea pig/Dunkin Hartley
Number of animals:	20 test, 10 control animals
Induction procedure:	undiluted test chemical was applied to the exposed skin of each test animal and held in place using a semi-occlusive wrap; the wrap was removed 6 hours after exposure and excess chemical removed by rinsing; the procedure was repeated at the same site once a week for the next 2 weeks for a total of three approximate 6-hour exposures
Challenge procedure:	test animals were challenged with a 50% (w/v) solution of test chemical in light mineral oil 2 weeks after the last induction dose; challenge site was different to the induction site

Challenge outcome:

Challenge concentration	Test animals		Control animals	
	24 hours*	***48 hours****	***24 hours***	***48 hours***
50%	0/20	0/20	0/10	0/10

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

Comments: slight responses noted, but they were not significant enough for allocation of Draize scores

Test method: similar to OECD guidelines (8)

Result: the test chemical was not a skin sensitiser in guinea pigs

9.2c Repeated Dose Toxicity (21)

Species/strain: rat/Sprague-Dawley

Number/sex of animals: control (12/sex/group);
test - (6/sex/group)

Method of administration: oral gavage with peanut oil vehicle; 5 $mL.kg^{-1}$ once each day for 28 consecutive days

Dose/Study duration:: low dose - 50 $mg.kg^{-1}.day^{-1}$;
mid-dose - 500 $mg.kg^{-1}.day^{-1}$
high dose -1 000 $mg.kg^{-1}.day^{-1}$;
duration 28 days

Clinical observations: faecal stains noted in the high dose group; sores were noted most frequently in all groups; alopecia and red penile discharge were also frequently noted, as were occasional occurrences of soft faeces, lacrimation and bloody crust around the eyes

Clinical chemistry/Haematology no treatment-related changes in the haematological parameters noted

increased γ-glutamyltransferase in high dose females at week 4 returning to normal values by week 7

Histopathology: no treatment-related changes

Test method:	similar to OECD guidelines (8)
Result:	no specific organ toxicity was noted in rats when the test substance was administered at a maximum dose of 1 000 $mg.kg^{-1}.day^{-1}$; no significant treatment-related effects

9.3c Genotoxicity

9.3.1c *Salmonella typhimurium* Reverse Mutation Assay (22)

Strains:	*Salmonella typhimurium* TA 98, TA100, TA 1535, TA 1537, TA 1538
Concentration range:	100, 250, 500, 1 000, 5 000 and 10 000 μg per plate in the presence and absence of S9 mix; Tween 80 (8.5%) was used as a vehicle
Test method:	similar to OECD guidelines (8)
Result:	the test chemical did not induce mutations in either Salmonella strains either in the presence or absence of S9 mix under the conditions of the test

9.3.2cChromosome Aberrations in Chinese Hamster Ovary (CHO) Cells (23)

Strain:	CHO cells
Doses:	313, 625, 1 250 and 2 500 $\mu g.mL^{-1}$ with and without; pluoronic F127 in ethanol vehicle
Comments:	the test chemical remained partially insoluble in the aqueous treatment medium at all concentrations tested
Test method:	similar to OECD guidelines (8)
Result:	the test chemical did not induce a statistically significant increase chromosomal aberrations in CHO cells under conditions of the test

9.4 Overall Assessment of Toxicological Data

By analogy to the toxicological properties of OLOA 378(TEPA), OLOA 371 and OLOA 370, the notified chemical is expected to have low acute oral toxicity (LD_{50} > 5 000 $mg.kg^{-1}$), and low acute dermal toxicity (LD_{50} > 2000

mg.kg^{-1}). The notified chemical is also not expected to be orally or dermally toxic following repeated exposures.

The notified chemical is expected to cause slight eye (conjunctival reddening) and skin irritation, but it is not expected to cause skin sensitisation in exposed individuals.

The notified chemical is unlikely to be mutagenic or clastogenic.

The notified chemical, OLOA 378 would not be classified as hazardous according to the *Approved Criteria of the National Occupational Health and Safety Commission* on the basis of the analogue data provided.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Although not a requirement of the Act for chemicals with NAMW greater than 1 000 g.mol^{-1}, the notifier provided fairly extensive ecotoxicity data for two related and closely analogous compounds (OLOA 371 and "OLD" OLOA 378).

Some summary data were also provided for a material known as CMA 610, (or OLOA 370) which is another close analogue of the notified chemical, and is the parent chemical of OLOA 378(TEPA) - "Old" OLOA 378. These test data are summarised below.

DATA FOR OLOA 371

Full test reports on the ecotoxicity studies for the OLOA 371 were provided by the notifier.

Test	Species	Results (Nominal)
Acute Toxicity	Rainbow Trout	LC_{50} (96 h) > 1 000 mg.L^{-1}
[OECD 203]	*Oncorhynchuc mykiss*	NOEC (96 h) > 1 000 mg.L^{-1}
Acute Immobilisation	Water Flea	EC_{50} (48 h) > 1 000 mg.L^{-1}
[OECD 202]	*Daphnia magna*	NOEC (48 h) = 220 mg.L^{-1}
Growth Inhibition	Algae	EC_{50} (72 h) = 19 mg.L^{-1}
[OECD 201]	*Scenedesmus subspicatus*	NOEC (72 h) <13 mg.L^{-1}

The tests on fish were performed using a static methodology with 80% renewal at 24, 48 and 72 hours. The test was performed in triplicate using ten specimen fish per replicate at a temperature of 12Ò1 ^{o}C. The tests were conducted using a water accommodation fraction (WAF) of the test substance made up at a nominal concentration of 1 000 mg.L^{-1}. Although a film of the test material was apparent on the surface of the test medium, no other abnormalities were observed in the test system, or in the behaviour of the fish specimens.

The immobilisation tests with daphnia were also performed under static conditions using WAF's of 130, 220, 360, 600 and 1 000 mg.L^{-1} at a temperature of

20±1 °C. The test at each WAF was conducted in duplicate with a control using ten *daphnia* per test vessel. After 48 hours exposure to the WAF containing 220 $mg.L^{-1}$ of test substance, 10% mortality of the daphnia had occurred, while after 48 hours exposure at the highest WAF of 1 000 $mg.L^{-1}$, the mortality was 60%.

Tests on algal growth inhibition were also performed with WAF's made up at the nominal concentrations of 13, 23, 36, 60 and 100 $mg.L^{-1}$, and at a temperature of 24±1 °C.

DATA FOR OLOA 378 (TEPA), "OLD" OLOA 378

Test	Species	Results (nominal)
Acute Toxicity	Sheepshead Minnow	LC_{50} (96 h) = 7,700 $mg.L^{-1}$
	Cyprinodon variegatus	NOEC (96 h) = 500 $mg.L^{-1}$
Acute Toxicity	Brown Shrimp	LC_{50} (96 h) > 10,000 $mg.L^{-1}$
	Cragnon cragnon	

Summary reports only were provided for the series of tests with OLOA 378 (TEPA) - "OLD" OLOA 378, but the major observations in regard to the progress of the tests is summarised as follows. The fish tests were performed under semi-static conditions, but no other details were provided, such as whether the tests were conducted with WAF's or using other methodologies. During the tests on brown shrimp, the test substance was observed to adhere to the mouth parts, eye stalks and appendages of the test specimens when the nominal concentration of the test material exceeded 500 $mg.L^{-1}$.

Some summary data were also provided for a material known as CMA 610, which is believed to be another close analogue of the notified material, and probably the parent chemical of OLOA 378 (TEPA) - "OLD" OLOA 378. These test data are summarised below.

DATA FOR OLOA 370 (CMA 610)

Test	Species	Result (nominal)
Acute Toxicity	Fathead Minnow	LC_{50} (96 h) > 1 000 $mg.L^{-1}$
	Pimephales promelas	NOEC (96 h) = 1 000 $mg.L^{-1}$
Acute Toxicity	Fathead Minnow	LC_{50} (96 h) > 1 000 $mg.L^{-1}$
[Dispersion Method]	*Pimephales promelas*	NOEC (96 h) = 1 000 $mg.L^{-1}$
Acute Immobilisation	Water Flea	LC_{50} (48 h) > 1 000 $mg.L^{-1}$
	Daphnia magna	NOEC > 1 000 $mg.L^{-1}$
Respiration Inhibition	Aerobic Waste Water Bacteria	EC_{50} > 1 000 $mg.L^{-1}$

The ecotoxicity data for these analogues of the notified chemical indicate that the notified chemical is unlikely to be toxic to aquatic organisms up to the limits of its solubility. However, the parent chemical OLOA 371 is moderately toxic to algae and consequently the notified material may also be potentially toxic to this species.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical is considered to be small provided that the material is used as indicated, and that disposal of old oil takes place via the routes indicated above. As a component of automotive lubricants, the notified material has the potential to be released to the environment during lubricant change, but losses during lubricant formulation and transfer to engine crankcases would be small. It is expected that around 86% of contained material would be destroyed through incineration and/or oil recycling activities. About 14% of the material will be used by automobile enthusiasts, and it is expected that much of this will be released through disposal into landfill, stormwater drains, and other routes. If deposited into landfill the material will be immobilised through adsorption onto soil particles, while if released into waterways it would become associated with sediments. The material is not readily biodegradable, but in a landfill is expected to be slowly degraded through micro-biological and abiotic processes. Incineration would produce water vapour and oxides of carbon, nitrogen and sulphur. Some solid molybdenum compounds would be produced as a consequence of both incineration and of landfill biodegradation. The material is not toxic to aquatic species up to the limit of its water solubility, except for algae against which it demonstrated some toxicity.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Worker exposure to the notified chemical during reformulation is expected to be minimised by the automated blending facilities used by the oil companies employing the OLOA 378 oil additive package. This combined with the relatively innocuous toxicological profile of the notified chemical (by comparison with analogues), and the low concentration of the notified chemical in OLOA 378 and the final oil products, minimises the risk to worker health should exposure occur.

The notifier states that the notifed chemical contains 3 % of hazardous impurities, but made no comment on the levels of such hazardous impurities in the analogues. However, similar concentrations of hazardous impurities are likely to be present in the analogues based on the nature of the synthetic processes for these compounds. Hence, it is reasonable to assume that the analogues do indeed reflect the toxicological properties of the notified chemical. Therefore, these hazardous impurities are of minimal concern.

Although worker exposure to the notified chemical in finished oil products is expected, the risk of adverse health effects is likely to be low. Again, this is based on the toxicological properties of the notified chemical and its very low concentration in finished oil products.

No significant public exposure to the notified chemical in OLOA 378 is anticipated during transport and oil formulation. Members of the public may, however, make dermal contact with the notified chemical when using automotive oils which contain OLOA 378 oil additive. Where exposure does occur, the notified chemical

is unlikely to pose a significant hazard given its low toxicity and low concentration in automotive oils for consumer use.

13. RECOMMENDATIONS

To minimise occupational exposure to OLOA 378 the following guidelines and precautions should be observed:

- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the oil additive package, containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (24).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

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

16. REFERENCES

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Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

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

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

CORNEA

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

CONJUNCTIVAE

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

IRIS

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