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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in OLOA 777R

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polymer in OLOA 777R

1. APPLICANT

Chevron Chemical Australia of 385 Bourke Street, Level 22, MELBOURNE VIC 3000 has submitted a standard notification statement in support of their application for an assessment certificate for Polymer in OLOA 777R.

2. IDENTITY OF THE CHEMICAL

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

Trade Name:	OLOA 777R
Other Names:	SP 1236, CP 1236, XC 1238, R-Series
Number-Average Molecular Weight (NAMW):	26000
Weight-Average Molecular Weight:	89500
Polydispersity:	3.44
Maximum Percentage of Low Molecular Weight Species	
Molecular Weight < 500:	0.0 %
Molecular Weight < 1 000:	0.31 %
Method of Detection and Determination:	can be detected at 10 ppb by HPLC **Characterisation methods:** UV/Visible spectroscopy; Infrared (IR) spectroscopy; ^{13}C nmr spectroscopy
Spectral Data:	UV/Vis 326.5(sh), 272, 261.5, 220.5 nm
	IR 2955, 2924, 2854, 1600, 1462, 1378, 1364,

		1203, 1142, 1054, 1012, 832, 762, 722, 698, 661, 605, 588 cm^{-1}
	^{13}C nmr	128, 126.8, 126.4, 126, 79, 78.7, 78, 37.1, 36.7 32.6, 31.6, 30, 29.4, 29.1, 27.8, 26.9, 26.5, 24.5, 22.8, 20.2, 19.5, 19.1, 13.9, 11.3 ppm

3. PHYSICAL AND CHEMICAL PROPERTIES

OLOA 777R contains 50 % notified polymer in lubricating oil solvent. The notified polymer is never isolated. The physical and chemical properties below are generally those of the product OLOA 777R rather than of the notified polymer.

Appearance at 20°C and 101.3 kPa:	dark brown viscous liquid
Boiling Point:	decomposes before boiling
Specific Gravity:	0.987 at 15°C
Vapour Pressure:	notified polymer not expected to be volatile; vapour pressure of OLOA 777R 4.9×10^{-5} kPa at 25°C (lubricating oil)
Water Solubility:	< 100 ppb at 25°C (see comments below)
Particle Size:	not applicable as OLOA 777R is a viscous liquid
Partition Co-efficient (n-octanol/water):	log K_{ow} > 7
Hydrolysis as a Function of pH:	not determined (see comments below)
Adsorption/Desorption:	expected to adsorb strongly (see comments below)
Dissociation Constant:	not determined (see comments below)
Flash Point:	> 200°C
Autoignition Temperature:	> 200°C
Flammability Limits:	combustible liquid (see comments below)
Explosive Properties:	not expected to be explosive
Reactivity/Stability:	expected to be stable under normal conditions

Comments on Physico-Chemical Properties

The vapour pressure is stated to be that of the refined lube oil in which the notified polymer is dissolved.

The water solubility is stated as <100 parts per billion (ppb) as measured according to OECD Test Guideline 105, and this is not unexpected for a compound containing large saturated hydrocarbon groups as does the notified polymer. 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.

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

The n-octanol/water partition coefficient was determined by a HPLC method. The high value of > 7.0 reflects the high hydrocarbon content of the notified polymer and a strong preference for the organic phase.

No adsorption/desorption data was provided, but the high Log K_{ow} and high hydrocarbon content indicates that the notified polymer would adsorb strongly to, or be associated with, the organic component of soils and sediments.

No dissociation constant data was provided. The notifier states that the notified polymer will not dissociate. However, it could potentially show cationic properties due to protonation of the amines, but due to the very low water solubility this is unlikely to occur to a significant extent.

Due to the low volatility of the notified polymer, flammability limits in air could not be determined. The oil will burn if preheated, and is a Class C2 combustible liquid.

4. PURITY OF THE CHEMICAL

Degree of Purity: 50 % in lubricating oil

Hazardous Impurities:

Chemical name:	polyethylenepolyamines
CAS No.:	68131-73-7
Weight percentage:	0.8 %
Toxic properties:	R 21/22 Harmful in contact with skin and if swallowed R34 Causes burns R43 May cause sensitisation by skin contact

(NOHSC, 1999b)

Non-hazardous Impurities (> 1% by weight):

Chemical name:	polyisobutylene
Weight percentage:	13 %
CAS No.:	9003-27-4

Additives/Adjuvants:

Chemical name:	distillates, hydrotreated heavy paraffinic
Synonyms:	lubricating oil
CAS No.:	64742-54-7
Weight percentage:	up to 50 %
Toxic properties:	classified as a carcinogen, R45(2) unless the DMSO extract under the procedure as defined by IP 346 is shown to be less than 3 % (NOHSC, 1999b)

Chemical name:	distillates, solvent refined heavy paraffinic
Synonyms:	lubricating oil
CAS No.:	64741-88-4
Weight percentage:	up to 50 %
Toxic properties:	classified as a carcinogen, R45(2) unless the DMSO extract under the procedure as defined by IP 346 is shown to be less than 3 % (NOHSC, 1999b)

The notifier has indicated that the mineral oils are not classified as carcinogens on the basis of the IP 346 results.

5. USE, VOLUME AND FORMULATION

The notified polymer will be used in the blending of automotive diesel and petrol crankcase engine oils. The purpose of the additive is as an inhibitor to reduce deposits on pistons and in the engine crankcase and to control oxidation of the lubricant at the high engine operating temperatures.

The notified polymer will be imported in lubricating oil additive packages containing 10 – 50 % OLOA 777R and will be reformulated in Australia to produce the finished lubricants, where the concentration will be 0.5 - 3 % notified polymer (1 – 6 % OLOA 777R). The notifier indicates that approximately five additive package formulations will contain the notified polymer. The additive packages will be imported in 200 L drums, isotanks or bulk shipments.

The import volume for the notified polymer is expected to be 1500 tonnes in the first year, increasing to 2500 tonnes per annum after three years.

6. OCCUPATIONAL EXPOSURE

Transport and Storage

Transport and storage workers are not expected to be exposed to the additive packages containing the notified polymer during shipment in isotanks or drums except in the case of an accident involving spillage. The additive package will also be imported in bulk, and transferred from the ship to a holding tank, then to road tankers. Dermal exposure of the waterfront and transport workers to drips and spills of the additive package is possible during the connection and disconnection of the transfer hoses during these procedures. No details of the exposure control measures or personal protective equipment to be employed at these facilities was provided by the notifier.

Additive package delivered to the customer site in bulk tankers or in isotanks will be transferred to holding tanks. The delivery system will be equipped with an air back-flush system to minimise any spillage on disconnection. The tanker or isotank will then be steam cleaned. Dermal exposure to drips and spills of the additive package containing the notified polymer (at up to 25 %) is possible during these operations. Workers involved in the hose transfer are stated by the notifier to wear gloves, coveralls and eye protection.

Reformulation

The additive package containing the notified polymer will be reformulated by blending with oils and other additives, such as viscosity index improvers, foam inhibitors and pour point depressants, to produce the finished lubricants. The blending will be mostly an automated in-line process in an enclosed system. Additive packages shipped in drums will be transferred into the blend tank by drum pump. The notifier states that one worker will be involved for 10 minutes per drum placing the drum pump and transferring the drum contents. During the connection and disconnection of drums, dermal contact with the notified polymer in the additive package (up to 25 % notified polymer) is possible. Transfer from drums may also be carried out by heating the drum contents to approximately 55°C and pouring the contents into a storage tank through a grille.

Transfer from storage tanks will be automated, using computer controlled valves. The finished lubricant will be sampled by one or two workers, and analysed in a laboratory by one or two workers. The notifier states that minimal exposure will occur during the laboratory testing, which will occupy several minutes per blend. The total exposure time for these workers is estimated by the notifier to be 30 minutes per day, 50 days per year. Dermal exposure to the notified polymer as part of the blended lubricant (up to 3 % notified polymer) is possible during the sampling. Workers involved in the drum pump transfers and sampling the finished lubricant are stated by the notifier to wear gloves, coveralls and eye protection. Where sampling requires exposure to heated oil during the blending process, respiratory protection will be used.

OLOA 777R has a very low vapour pressure and, as a mineral oil based product, a high viscosity, minimising the possibility of vapour and aerosol formation. Inhalation is therefore

not expected to be an important exposure route.

The blend tank will be cleaned by rinsing with clean lubricating oil. The finished lubricants will be packaged into 1 L and 4 L containers and 200 L drums, or transferred to road tankers for bulk delivery to customers. The filling of the 1 L and 4 L containers is stated to be highly automated with little human involvement. The drum filling is stated to be automated, with an operator watching from about 1 – 2 metres distance to ensure that the drum filling mechanism enters the drum properly before filling, and also manually installing the drum bung and affixing the label. The packaging lines are cleaned with lubricating oil. Dermal exposure to drips and spills of blended lubricant (up to 3 % notified polymer) is possible in the event of a mishap during drum filling, and during installation of drum bungs. Workers are stated to be involved in this process for 1 hour per day, 50 days per year. The notifier states that the workers will wear gloves and coveralls.

Bulk road tanker filling is performed by transfer hose. Workers will be involved in this process for 1 hour per day, 50 days per year. Dermal exposure to drips and spills of blended lubricant (up to 3 % notified polymer) is possible during the connection and disconnection of transfer hoses during the filling of bulk tankers. Workers involved in loading of road tankers are stated to wear gloves and overalls.

Maintenance workers handling the equipment used for blending and filling may also come into dermal contact with residues containing the notified polymer, should maintenance be required prior to flushing the equipment.

Distribution

The finished lubricant will have very widespread use, and will be used by both professional and home motor mechanics. The transport, storage and retail sale of the lubricants will involve a large number of workers, but should involve little risk of exposure to the notified polymer, except in the case of an accidental spill.

End Use

The products containing the notified polymer will be sold in drums or bulk to customers for maintenance of fleet vehicles and for commercial automobile maintenance operations. A significant proportion will also be sold in smaller commercial packages through hardware, automotive and chain stores to home users. Occupational exposure to the products containing the notified polymer will occur at a large number of motor repair facilities throughout Australia. A large number of motor mechanics will be exposed to the products under a wide range of conditions, and dermal and ocular exposure to the notified polymer at a concentration of up to 3 % is possible.

7. PUBLIC EXPOSURE

The public will be exposed to the notified polymer when individuals carry out engine oil changes at home. Exposure is likely to be by dermal, inhalation and possibly ocular routes. Public exposure may also occur where used oil is used in the environment, such as for killing grass and weeds (see Environmental Exposure, below). Minimal public exposure is expected from transport, storage and blending operations.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier indicates that the blending operations are performed at approximately 10 major lubricant oil blending facilities sites around Australia by approximately 5 different customers. The additive packages containing OLOA 777R will be delivered to, and stored at, the blending facilities in 250 to 1000 tonne storage tanks, and it is anticipated that very little of the additive package will be released during transfer from the storage containers to the blending tanks. All transfer operations are controlled automatically, and the blending tanks are cleaned with lube oil, which is recycled for use in preparing subsequent batches of product. Any spills incurred in the blending operations are contained within concrete bunds and are either reclaimed or sent to onsite wastewater treatment facilities. Similarly, the empty drums of additive package are cleaned with steam, and the resultant wastewater is sent to the water treatment facilities where the residual hydrocarbon based products are comprehensively separated from the aqueous stream using techniques which include American Petroleum Institute (API) oil/water separation, induced air flotation and sand filtration. The hydrocarbon based waste is then either incinerated or is removed by oil recycling contractors, and the aqueous stream is discharged to the sewer. The notifier states that treatment of the wastewater would remove around 95 % of any of the notified polymer present in the influent wastewater stream.

Some release is likely during transfer of the lubricants from containers to engine blocks. The notifier estimates that < 10 g (approximately 1 %) of oil will remain as residue from each 1 litre container of oil used and will most likely be disposed of to landfill. The approximate import volume of the notified polymer is up to 2500 tonnes per annum, therefore approximately 25 tonnes of OLOA 777R could be released to the environment via this route as container residues. Most spills are likely to be adsorbed onto sawdust and incinerated or disposed of to landfill. However, 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 (Australian Institute of Petroleum Ltd, 1995) indicates that of the annual sales of automotive engine oils in Australia, some 60 % are potentially recoverable (ie not burnt in the engines during use). The survey 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 % are 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 (Snow, 1997) 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 burnt as workshop heating oil or sent for recycling), negligible release of the

notified polymer 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, the DIY proportion of oil changes could potentially lead to release of up to 7 % of the total import volume of the notified polymer - ie an annual release of up to 175 tonnes from improper disposal of used oil. Most of this is likely to become associated with soils or sediments, as will the 25 tonnes released to landfill as container residues.

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 polymer in high concentrations is very unlikely except as a result of transport accidents.

Of the 14 % of waste oil produced by DIY enthusiasts, approximately 5 % will be disposed to waterways via the stormwater system. This equates to < 1 % of the total import volume of the notified polymer or < 25 tonnes that could be expected to enter the aquatic environment. It would be expected to then become associated with the sediments.

Fate

The notified polymer is not readily biodegradable in aerobic environments, although a CO_2 evolution test [EEC method C. 4-C/1992] (Mead, 1998b) performed on OLOA 777R indicated 63 % degradation after 28 days. Under the conditions of OECD Guideline 301B the substance cannot be considered to be readily biodegradable as it failed to satisfy the 10 day window criterion whereby 60 % degradation must be attained within 10 days of the degradation exceeding 10 %. 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. These processes could be expected to produce carbon dioxide, methane, water and nitrogen oxides.

Leaching from a landfill would be slow, and the high anticipated K_{oc} (see notes on physico-chemical properties above) indicates that the notified polymer 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 polymer has a high Log K_{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 polymer (OLOA 374A) is said to have provided a result to support this claim, but no report on this test was included with the notification.

Incineration of waste oil containing the notified polymer would destroy the substance with evolution of water vapour and oxides of carbon and nitrogen. Sludges from waste treatment plants or oil recycling facilities could also be incinerated.

Relatively large quantities of notified polymer 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

Reports on acute toxicity testing using OLOA 777R, containing 50 % notified polymer in mineral oil, were provided by the notifier. Genotoxicity testing was also carried out using OLOA 777R, and reports have been provided. Analogue toxicity data was provided for 28 day repeat dose exposure by both oral and dermal routes, using the product OLOA 374A. The analogue chemical is chemically similar to the notified polymer, but has a lower molecular weight. Additional toxicological studies on the analogue chemical provided by the notifier indicate that the analogue has a similar toxicity profile to the notified polymer.

9.1 Acute Toxicity

Summary of the acute toxicity of OLOA 777R

Test	*Species*	*Outcome*	*Reference*
Acute oral toxicity	Rat	LD50>5000 mg/kg	(Driscoll, 1998c)
Acute dermal toxicity	Rat	LD50>2000 mg/kg	(Driscoll, 1998b)
Skin irritation	Rabbit	moderate irritant	(Driscoll, 1998a)
Eye irritation	Rabbit	slight irritant	(Driscoll, 1998d)
Skin sensitisation	Guinea pig	non-sensitising	(Morris, 1998)

9.1.1 Oral Toxicity (Driscoll, 1998c)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage, 5000 mg/kg bodyweight test substance in arachis oil (dose volume 10 mL/kg)
Test method:	OECD TG 401; EC Directive 92/69/EEC
Mortality:	no deaths occurred during the study
Clinical observations:	no clinical signs of toxicity were noted during the study; all animals showed expected gain in bodyweight during the study
Morphological findings:	no abnormalities were noted at necropsy
LD_{50}:	> 5000 mg/kg

Result:	OLOA 777R was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Driscoll, 1998b)

Species/strain:	rat/Sprague-Dawley CD
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	single, 24-hour semi-occluded application to intact skin; dose level 2000 mg/kg bodyweight
Test method:	OECD TG 402; EC directive 92/69/EEC
Mortality:	no deaths occurred during the study
Clinical observations:	no clinical signs of toxicity were noted during the study; all animals showed expected gain in bodyweight during the study
Morphological findings:	no abnormalities were noted at necropsy
Dermal observations:	no signs of skin irritation were noted during the study
LD_{50}:	> 2000 mg/kg bodyweight
Result:	OLOA 777R was of low acute dermal toxicity in rats

9.1.3 Inhalation Toxicity

No inhalation toxicity data were presented by the notifier, with the argument that because the notified polymer has a very low vapour pressure (less than 4.9×10^{-5} kPa at 25°C) and a viscosity of 520 cSt at 100°C, it is unlikely to present an inhalation hazard either as a vapour or as an aerosol. This argument was accepted for the purposes of this assessment.

9.1.4 Skin Irritation (Driscoll, 1998a)

Species/strain:	rabbit/New Zealand white
Number/sex of animals:	6/male
Observation period:	4 days
Method of administration:	a single 4 hour semi-occluded application of 0.5 mL test material to intact skin; residual test material removed by

gentle swabbing with cotton wool soaked in diethyl ether.

Test method: OECD TG 404; EC Directive 92/69/EEC

Draize scores (Draize, 1959):

Time after treatment (days)	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6***
Erythema						
30 min	[a]1	1	1	1	1	1
1	2	2	2	2	2	2
2	2	2	2	1	1	1
3	1	1	1	1	0	1
4	0	0	0	0	0	0
Oedema						
30 min	1	1	1	1	0	1
1	1	2	2	1	1	2
2	1	2	1	1	1	1
3	0	0	0	0	0	0
4	0	0	0	0	0	0

[a] see Attachment 1 for Draize scales

Mean Scores (24, 48 and 72 hour observations): erythema/eschar formation – 1.4
oedema – 0.9

Comment: well-defined erythema and very slight or slight oedema had cleared by the 96 hour observation

Result: OLOA 777R was moderately irritating to rabbit skin

9.1.5 Eye Irritation (Driscoll, 1998d)

Species/strain: rabbit/New Zealand white

Number/sex of animals: 9/male (6 non-irrigated, 3 irrigated 30 secs after application)

Observation period: 3 days

Method of administration: single instillation of 0.1 mL into conjunctival sac of one eye

Test method: OECD TG 405; EC Directive 92/69/EEC

Draize scores (Draize, 1959) of non-irrigated eyes:

	Time after instillation							
Animal	***1 hour***		***1 day***		***2 days***		***3 days***	
Cornea	all individual scores were zero							
Iris	all individual scores were zero							
Conjunctiva	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***
1	1	1	0	0	0	0	0	0
2	2	1	1	0	0	0	0	0
3	2	1	1	0	0	0	0	0
4	1	1	0	0	0	0	0	0
5	2	1	1	0	0	0	0	0
6	1	0	0	0	0	0	0	0

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

Mean scores:
(non-irrigated eyes, 24, 48, 72 hour observation)

redness of conjunctiva - 0.2
all other scores - 0

Comment:

non-irrigated eyes:

no corneal or iridial effects were noted during the study; conjunctival redness, chemosis and discharge (grade 2) were noted at the 1-hour observation

conjunctival redness was noted in three treated eyes at the 24-hour observation but had cleared by the 48 hour observation

irrigated eyes:

residual test material was noted in and around the treated eye of all animals throughout the study

no corneal or iridial effects were noted during the study; conjunctival redness (grade 1) was noted in two treated eyes with discharge (grade 1) in one treated eye at the 1-hour observation; no ocular effects were noted in all treated eyes at the 24-hour observation.

Result:

OLOA 777R produced transitory irritation to the eyes of rabbits

9.1.6 Skin Sensitisation (Buehler method) (Morris, 1998)

Species/strain:

guinea pig/Hartley

Number of animals: 10/sex for test; 5/sex for naïve controls; 4/sex for pilot animals

Induction procedure: the left shoulder was clipped of hair and a 0.3 mL quantity of undiluted test material was applied; the procedure was repeated at the same site once a week for the next two weeks for a total of three approximate six-hour exposures (the interval between induction exposures varied from 6 to 7 days)

Challenge procedure: treated animals were again exposed in the challenge phase approximately two weeks after the last induction exposure; ten naïve animals, which had never been exposed to the test material, were also concurrently treated with the same test material concentration

the same exposure procedure as for induction was used, the skin site chosen for challenge (left posterior flank) had not been exposed previously.

Test method: adaptation of the method of Ritz and Buehler (Buehler, 1994)

Challenge outcome:

	Test animals		***Control animals***	
Response grade	***24 hours****	***48 hours****	***24 hours***	***48 hours***
0	**0	1	0	0
±	16	18	8	10
1	4	1	2	0

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

skin responses were graded using the following scale
no reaction
± slight, patchy erythema
1 slight but confluent, or moderate patchy erythema
2 moderate erythema
3 severe erythema with or without oedema

Comment: following primary challenge using undiluted test material the incidence of grade 1 responses in the test group (4 of 20) was compared to that of the naïve control group (2 of 10); the incidence and severity of responses in the test group were comparable to those produced in the naïve control

	group
Result:	OLOA 777R was not considered to be a sensitiser to the skin of guinea pigs

9.2 Repeated Dose Toxicity

No reports on repeated dose toxicity using the notified polymer were provided by the notifier. Reports on two 28 day repeated dose studies (oral and dermal) using the analogue chemical OLOA 374A were provided. The analogue chemical is chemically similar to the notified polymer, but has a lower molecular weight. Additional toxicological studies on the analogue chemical provided by the notifier indicate that the analogue has a similar toxicity profile to the notified polymer.

9.2.1 28 Day Oral Study in Rats (Blackwell & Brooks, 1988)

Species/strain:	rat/Sprague-Dawley CFY
Number/sex of animals:	5/sex/group
Method of administration:	gavage
Dose/Study duration:	0, 50, 250, 1000 mg/kg once daily for 28 consecutive days; satellite control and high dose groups were maintained for a further 14-day treatment-free period following the 28th and final day of treatment
Test method:	OECD TG 407

Clinical observations:

No clinically significant signs of toxicity were noted in any of the test or control animals during the study period. One animal in the 50 mg/kg/day group died on day 17. This animal had prior signs of ill-health and its death was considered to be unrelated to treatment with the test material

Bodyweight

Both test and control animals showed normal bodyweight gain throughout the study period. Food and water consumption was also similar in both groups

Clinical chemistry/Haematology

No treatment-related effects were detected. Statistically significant differences in some haematological parameters were noted between test and control animals but these were confined to low and intermediate groups. Thus, these effects were deemed to be unrelated to treatment.

Biochemistry

Total bilirubin levels were increased in high dose animals of both sexes but direct (conjugated) bilirubin levels remained consistent between groups. Some statistically significant differences between test and control animals in levels of aspartate aminotransferase (for males in the 250 and 1000 mg/kg/day groups), alkaline phosphatase (for all treated females) and calcium (for males in the 250 and 1000 mg/kg/day groups and all treated females) were also noted but because of the absence of a dose response, these differences were considered to be unrelated to treatment with the test material. A subsequent examination of these parameters in the satellite groups also revealed no significant differences.

No appreciable differences were detected between urine samples from test and control animals

Histopathology:

No treatment-related macroscopic abnormalities were detected in either test or control animals, nor were there any differences with organ weights. No treatment-related histopathological changes were observed.

Result:

Increased total bilirubin levels in the 1000 mg/kg/day group was the only significant effect of treatment with the test material. This observation was considered to be of doubtful biological significance in the absence of any other evidence of liver damage or haemolytic effects. Since there were no other treatment-related changes at any of the lower doses, a No Observed Adverse Effect Level (NOAEL) of 250 mg/kg/day was determined.

9.2.2 28 Day Dermal Study in Rats (Korenaga, 1986)

Species/strain:	rat/Sprague-Dawley Crl:CD
Number/sex of animals:	12/sex/group
Method of administration:	a dose of 1 mL/kg of the appropriately diluted test material was applied by pipette to the clipped dorsal area on the trunk; the dose was applied to either the anterior or posterior half of the prepared area, alternating sites with each application, and gently spread with a metal spatula to cover the site a gauze sponge dressing was placed over the site and secured with tape, and a collar was placed around the neck of each animal to prevent ingestion of the test material; dressings and collars were removed six hours after application, and the skin site was wiped with a sponge moistened with mineral oil

Dose/Study duration: 0, 15, 75 and 250 mg/kg 6 hours/day, 5 days/week for 4 weeks

Test method: OECD TG 410

Clinical observations:

No deaths or signs of toxicity were observed during the study. Pigmented secretions from the eyes and nose were seen from virtually every animal and this was attributed to stress induced from the plastic collars. Six animals, representing all groups, developed sores or scabs on the skin over the throat during the third and fourth weeks of dosing and this was also reported to be collar-related. Swelling of the head or face was seen at the end of the exposure period in 10 animals of both sexes and several dose levels during the study, and all recovered overnight after removal of the collar. Nine animals, at all dose levels and of both sexes, had swollen eyes lasting for one or two days. This occurred usually only on weekends, in the absence of other signs.

One animal had a slow pupil response which lasted for only the second week of dosing.

Skin irritation

Slight to severe erythema with no to slight oedema was seen in the control, low-, and mid-dose groups. Slight to severe erythema with no to well-defined oedema was observed in the high-dose groups. Higher dose groups showed higher incidences of irritation at Days 2,16 and 23 but there did not appear to be a consistent relationship between dose and irritation. Single or multiple small scabs, apparently due to scratching or biting, were observed on the backs of animals in all dose groups by Day 9. Dry, flaky, abraded, and/or cracking skin was observed in all treatment groups and appeared unrelated to dose level.

Body weights and food consumption

There were no significant differences in mean body weight, body weight gain or food consumption during the study.

Clinical chemistry/Haematology

Mean total bilirubin levels were significantly lower in the low- and high-dose males than in the control males. For the mid-dose females, the mean albumin level was higher and the mean BUN/creatinine ratio lower than the values for the control females. These findings were not considered related to treatment with the test material due to lack of any dose-related trend.

There were no significant differences in any haematological parameter for either sex.

Histopathology:

Both sexes at all dose levels had dilated renal pelves and dry, flaky, red, thickened, and/or scabbed skin. A number of other macroscopic observations were noted, but none were

considered to be dose-related.

Examination of control and high-dose treated skin sites showed acanthosis, epidermal crusting, hyperkeratosis, and dermal inflammation. Dermal ulceration was observed in three high-dose animals. Some dermal changes were attributable to the wrapping method and treatment with mineral oil. The incidence of irritation was greater in the high-dose than in the control group although the severity was slightly less. The authors concluded that this increased incidence was probably attributable to the mild irritating effects of the test material.

All other histopathological findings were considered to be spontaneous or naturally occurring lesions in the strain of rat employed in the study.

Result:

Repeated dermal applications of the test material produced general dermal irritation at all dose levels, including controls. The higher incidence of dermal lesions in the high-dose animals showed that the test material is a mild dermal irritant. There was no evidence of test substance related systemic toxicity, so the NOEL (dermal) for systemic toxicity is 250 mg/kg/day.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Thompson, 1998)

Strains:	*Salmonella typhimurium*: TA98, TA100, TA1535, TA1537 *Escherichia coli*: WP2*uvr*A$^-$
Concentration range:	0, 15, 50, 150, 500, 1500 and 5000 μg/plate
Metabolic Activation System:	10% rat liver S9 fraction (Aroclor 1254-induced) in standard cofactors.
Test method:	OECD TG 471 and TG 472 – plate incorporation method
Positive controls	without metabolic activation: N-ethyl-N'-nitro-N-nitrosoguanidine (ENNG): 2 μg/plate for WP2uvrA$^-$, 3μg/plate for TA100 and 5μg/plate for TA1535 9-aminoacridine (9AA): 80 μg/plate for TA1537 4-nitroquinoline-1-oxide (4NQO): 0.2 μg/plate for TA98 with metabolic activation: 2-aminoanthracine (2AA): 1 μg/plate for TA100; 2 μg/plate for TA1535 and TA1537; 10 μg/plate for WP2uvrA$^-$

	benzo[a]pyrene (PB): 5 μg/plate for TA98
Comment:	the test material was neither soluble nor adequately suspendable in sterile distilled water, dimethyl sulfoxide, acetone, dimethyl formamide, ethanol or acetonitirile; it was, however, soluble in tetrahydrofuran which is an acceptable vehicle for use in the Ames test the test material was observed to form an oily precipitate at 5000 μg/plate, but this did not interfere with the scoring of revertant colonies all positive control chemicals induced marked increases in the frequency of revertant colonies, both in the presence and absence of metabolic activation there was no visible reduction in the growth of the bacterial lawn at any dose level 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
Result:	OLOA 777R was considered to be non-mutagenic under the conditions of the assay

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Durward, 1998)

Species/strain:	mouse/albino Crl:CD-1™ (ICR) BR Strain
Number and sex of animals:	7 males/group
Doses:	0, 500, 1000 and 2000 mg/kg in vehicle (arachis oil); 50 mg/kg cyclophosphamide (positive control)
Method of administration:	intraperitoneal injection for test material and vehicle; oral for positive control
Test method:	OECD TG 474 and EC Directive 92/69/EEC
Mortality:	there were no deaths during the course of the study
Comment:	there was no evidence of a significant increase in the incidence of micronucleated polychromatic erythrocytes in animals dosed with the test material when compared with the concurrent vehicle control groups no evidence of bone marrow toxicity was observed, as

	would have been indicated by a statistically significantly decreased polychromatic/ normochromatic ratio in the dose mean group compared with the concurrent control group the positive control material produced a marked increase in the frequency of micronucleated polychromatic erythrocytes
Result:	OLOA 777R was considered to be non-genotoxic under the conditions of the test

9.4 Overall Assessment of Toxicological Data

Toxicity Summary
OLOA 777R was of very low acute oral toxicity (LD_{50}>5 000 mg/kg) and low acute dermal toxicity (LD_{50}>2 000 mg/kg) in rats. It was a slight eye irritant and a moderate skin irritant in rabbits. Although no acute inhalation studies have been conducted, the notified polymer is not expected to be an inhalation hazard based upon its low vapour pressure and high viscosity. In a non-adjuvant type test, the notified polymer was not sensitising to guinea pig skin.

No reports on repeated dose toxicity using the notified polymer were provided by the notifier. Reports on two 28 day repeated dose studies (oral and dermal) using the analogue chemical OLOA 374A were provided. The analogue chemical is chemically similar to the notified polymer, but has a lower molecular weight. Acute toxicity and genotoxicity study reports for OLOA 374A also provided by the notifier indicate that the analogue has a similar toxicity profile to OLOA 777R. These studies were not reviewed further in this assessment.

In the oral repeated dose study, an increased total bilirubin level in the high dose group (1000 mg/kg/day) was the only significant effect that was test-material-related. Since there were no other significant changes at any of the lower doses, the NOAEL was determined to be 250 mg/kg/day. In the 28 day dermal study, the test material produced dermal irritation at all dose levels. No signs of systemic toxicity were observed, and the dermal NOEL for systemic toxicity was 250 mg/kg/day.

OLOA 777R was not considered mutagenic in a bacterial reverse mutation assay, nor did it induce an increased incidence of micronuclei in mice.

Hazard Classification
None of the toxicity findings for OLOA 777R and OLOA 374 A indicate that OLOA 777R can be determined to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (NOHSC, 1999a)

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Test	***Species***	***Results***
acute toxicity (OECD TG 203)	***rainbow trout*** **Oncorhynchus mykiss**	LLR_{50} (96 h) > 1000 mg/L NOEC (96 h) > 1000 mg/L

acute immobilisation (OECD TG 202)	*Daphnia magna*	ELR_{50} (48 h) > 1000 mg/L NOEC (48 h) > 1000 mg/L
growth inhibition (OECD TG 201)	Algae (*Pseudokirchneriella subcapitata*)	ELR_{50} (96 h) > 1000 mg/L NOEC (96 h) >1000 mg/L
respiration inhibition (OECD TG 209)	activated sewage sludge	EC_{50} (3h) > 1000 mg/L NOEC (3h) > 1000mg/L

* NOEC - no observable effect concentration

The ecotoxicity tests were performed on the Water Accomodated Fraction (WAF) of the notified polymer. The WAF was prepared by adding OLOA 777R to water to give a 1000 mg/L loading rate which was then stirred for 24 hours. The mixture was then allowed to stand for 4 hours prior to siphoning off the aqueous phase, or WAF.

Total Organic Carbon (TOC) measurements were performed on the WAFs to determine the amount of the notified polymer present in the mixture. Results varied but all showed that the test substance was present in concentrations higher than the water solubility value for the notified polymer. This indicates that a small amount of the material was finely dispersed throughout the aqueous fraction.

The tests on fish were performed using a static methodology with observations at 24, 48, 72 and 96 hours (Wetton, 1998b). The test was performed in triplicate using ten specimen fish per replicate at 14±1°C. The tests were conducted using a WAF of the test substance at a nominal concentration of 1000 mg/L. No abnormalities were observed in the test system, or in the behaviour of the fish.

The immobilisation tests with *Daphnia magna* were also performed under static conditions with observations at 24 and 48 hours (Wetton, 1998a). The test was performed on four duplicates using 10 daphnids per flask at 21±1°C. The tests were conducted using a WAF of the test substance at a nominal concentration of 1000 mg/L. No immobilisation or adverse reactions to exposure were observed.

Tests on algal growth inhibition were performed with six replicate WAFs at 1000 mg/L and at 24±1°C (Mead, 1998a). No effect on algal growth was observed.

The respiration inhibition test on activated sewage sludge was performed in triplicate on activated sewage sludge treated with 1000 mg/L OLOA 777R for 3 hours at 21°C with observations at 30 minutes and 3 hours (Mead, 1998c). No significant effect on respiration occurred at either observation time.

The ecotoxicity data for the notified polymer indicate that the new material is unlikely to be toxic to aquatic organisms up to the limits of its solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified polymer is small provided that the material is used as indicated, and that disposal of spent oil takes place via the approved routes indicated

above. As a component of automotive lubricants, the notified polymer 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 up to 50 % (ie 7 % of the total import volume of 2500 tonnes), 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. The material is not readily biodegradable, but in landfill is expected to be slowly degraded through microbiological and abiotic processes. Incineration would produce water vapour and oxides of carbon and nitrogen.

Of the 14 % of waste oil produced by DIY enthusiasts, approximately 5 % will be disposed to waterways via the stormwater system. This equates to < 1 % of the total import volume of the notified polymer or < 25 tonnes that could be expected to enter the aquatic environment. Due to the high Log K_{ow} and high hydrocarbon content, the notified polymer would be expected to associate with suspended organic material which would settle out into the sediments, and eventually to be biodegraded. The notified polymer is not toxic to aquatic species up to the limit of its water solubility.

Overall the hazard to the environment is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

OLOA 777R, containing 50 % of the notified polymer, is of very low acute oral and low dermal toxicity. OLOA 777R was slightly irritating to the eyes of rabbits. It was found to be moderately irritating to rabbit skin, but the irritation was not of sufficient severity to warrant classification according to the Approved Criteria. OLOA 777R was non-sensitising to skin in a non-adjuvant study, and was non-genotoxic in a bacterial reverse mutation assay and a mouse micronucleus test.

The notifier supplied subchronic toxicity studies for the analogue chemical OLOA 374A and indicted that these should be taken as indicative of the subchronic toxicity of the notified polymer. Additional toxicity studies for this chemical were also provided to demonstrate that the toxicity profile was similar to that of the notified polymer. In a 28 day repeat dose oral rat study, a NOEL of 250 mg/kg/day was established for the analogue. Increased bilirubin was observed in both male and female rats given 1000 mg/kg. In a 28 day repeat dose dermal rat study with the analogue, dermal irritation was found at all doses but no systemic toxicity was seen. A NOEL of 250 mg/kg/day for systemic toxicity was established for the analogue in this study.

The paraffinic petroleum distillates listed as adjuvants with the notified polymer are Category 2 carcinogens, with concentration cutoffs of 0.1 %, unless the petroleum distillate is shown to satisfy the condition that it contains less than 3 % DMSO extract as measured by IP 346. The notifier has indicated that this is the case for the petroleum distillates used in OLOA 777R.

Occupational Health and Safety

The notified polymer will be imported in drums, isotanks or in bulk vessels as a component

(10 – 50 % OLOA 777R) of a lubricant additive package. The additive package will be reformulated in Australia, by blending with oils and other additives. The final product is then repackaged into 1 L and 4 L containers and 200 L drums, or transferred to road tankers for bulk delivery to customers.

Dermal exposure would be the predominant route of occupational exposure to the notified polymer. The toxicity reports for OLOA 777R identify the potential for skin irritation. At the concentration of OLOA 777R present in the imported additive package (10 – 50 %) and finished oil (1 – 6 %) the risk of adverse skin effects following acute exposure is expected to be low. However, adverse skin effects may ensue if contact is repeated or prolonged. Inhalation exposure is expected to be minimal because the product containing the notified polymer and the finished oil are viscous and therefore have reduced potential to generate aerosols. In addition, the notified polymer has a very low vapour pressure, so vapour accumulation in the workplace air is not likely. The notified polymer is a skin irritant, and so protective gloves and clothing should be worn when the possibility of exposure to drips and spills exists.

The system for reformulating the additive package to produce finished lubricants is generally enclosed and automated and the possibility of exposure is therefore limited and typically of short duration. Workers involved in transferring the imported oil additive containing the notified polymer, including bulk oil terminal workers and transport workers, and workers involved in blending the additive into oil may be exposed to drips and spills of the additive package, containing 10 – 50 % OLOA 777R (5 – 25 % notified polymer). Occupational exposure to the drips and spills of the final lubricating oil containing 0.5 – 3 % notified polymer is possible for workers handling the finished oil. Workers involved in cleaning and maintenance of tanks and blending equipment may also have general dermal exposure to oil residues. Dermal exposure should be controlled by the use of oil impervious clothing and gloves to minimise the risk of adverse skin effects.

Occupational exposure to the products containing the notified polymer will occur for a range of customers. The customers are expected to include both professional and home motor mechanics. Dermal exposure is likely during filling and top ups, and while handling equipment which has been in contact with the lubricating oils. Dermal and ocular exposure to the notified polymer at a concentration of 0.5 – 3 % is possible. Exposure will be of short duration and intermittent. It is recommended that the workers wear oil impervious protective clothing and gloves to minimise the risk of adverse skin effects from the notified polymer in addition to those of other components of the finished oil product.

Public Health
There will be public exposure during engine oil changes carried out at home. Although the notified polymer is a moderate skin irritant and a slight eye irritant, it is likely to be of minor hazard based on its low concentration in engine oil, low vapour pressure and intermittent use. It is considered that the notified polymer will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to Polymer in OLOA 777R the following guidelines and precautions should be observed:

- Personal protective equipment during blending operations should include industrial clothing conforming to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.2 (Standards Australia, 1990); impermeable gloves conforming to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998); and occupational footwear conforming to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);

- Personal protective equipment during end use should include industrial clothing conforming to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.2 (Standards Australia, 1990); impermeable gloves conforming to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998); and occupational footwear conforming to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);

- Spillage of the notified polymer should be avoided. Spillages should be cleaned up promptly with absorbents which should 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;

- Used oil containing the notified polymer should only be disposed of by approved methods.

If the conditions of use are varied from the notified use, such as if the concentration in engine oil increases, greater exposure of the public may occur. In such circumstances, secondary notification may be required to assess the hazards to public health.

14. MATERIAL SAFETY DATA SHEET

The MSDS for OLOA 777R was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified polymer shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	3 severe	Swelling with lids half-closed to completely closed	4 severe		

IRIS

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