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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

NEW OLOA 2508N

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FULL PUBLIC REPORT**NEW OLOA 2508N****1. APPLICANT**

Chevron Oronite Australia of Level 22, 385 Bourke Street, MELBOURNE VIC 3000 (ARBN 001 010 037) has submitted a standard notification statement in support of their application for an assessment certificate for NEW OLOA 2508N.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, and details of the notified polymer composition and manufacture have been exempted from publication in the Full Public Report and the Summary Report.

Other Names: NEW POBA; POBA; OLOA Capped polybutylene oxide (RS 4999); XU-10348.00.

Marketing Name: NEW OLOA 2508N

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa: Clear & bright viscous liquid with slight polyether odour

Boiling Point: Decomposes before boiling

Specific Gravity at 15°C: 0.9700

Vapour Pressure: $<1.3 \times 10^{-8}$ kPa at 25°C

Water Solubility: Expected to be very low

Partition Co-efficient (n-octanol/water): $\log P_{ow} > 7.6$ – see comments below

Hydrolysis as a Function of pH: Expected to be stable - see comments below

Adsorption/Desorption:	No data provided - see comments below
Dissociation Constant:	Will not dissociate - see comments below
Flash Point:	> 185°C
Flammability Limits:	Not determined. Will burn in presence of heat and oxygen
Autoignition Temperature:	>200°C
Explosive Properties:	Not known to be explosive
Reactivity/Stability:	Will react in the presence of strong oxidizing agents
Particle Size:	Viscous liquid, does not form particles under normal circumstances

3.1 Comments on Physico-Chemical Properties

The notifier has submitted a study report for the partition coefficient only. However, the notifier has provided acceptable study information in notification NA839.

No attempt has been made to estimate the water solubility of the notified polymer, however, it is accepted it will be low given its chemical nature.

The notified polymer contains no functionalities which will be susceptible to hydrolysis in the usual environmental pH region where $4 < \text{pH} < 9$.

The n-octanol/water partition coefficient was determined using reverse phase HPLC method. The retention time of the notified polymer on a standard C18 column was compared with those for a series of polycyclic aromatic hydrocarbons of known P_{ow} and using this technique, the value of $\log P_{ow}$ for the notified polymer was determined to be greater than 7.6. The relatively high value of $\log P_{ow}$ reflects the high hydrocarbon content of the molecules.

Although no data on adsorption/desorption was provided, the high hydrocarbon content, high n-octanol/water partition coefficient and expected low water solubility indicate the notified polymer would adsorb strongly onto the organic component of soils and sediments, and would be unlikely to be appreciably mobile in these media.

The notified polymer does not contain any acidic or basic functionalities, and would not dissociate or become protonated under usual environmental conditions.

4. PURITY OF THE CHEMICAL

Degree of Purity:	~100%
Hazardous Impurities:	Chemical identity is exempt information. Hazardous impurities are each present at less than 1%.
Non-hazardous Impurities (> 1% by weight):	Chemical identity is exempt information. Non hazardous impurities are each present at less than 6%.
Additives/Adjuvants:	None

5. USE, VOLUME AND FORMULATION

NEW OLOA 2508N is intended to be used as a carrier fluid for detergent/dispersant additives in unleaded petrol to control the formation of port fuel injector deposits and intake valve deposits. The notified polymer will be present in imported additive packages at a concentration of 15 to 40% w/w and it will be present in aftermarket concentrates at concentrations of 5 to 15%. The final concentrations of the notified polymer in finished petrol will be 50 to 150 ppm or 1200 to 5000 ppm in some aftermarket applications.

Approximately 10 to 20 tonnes per annum of the notified polymer will be imported in 5200 L isotanks or 200 L steel drums, increasing up to 250 tonnes over an unspecified time period.

NEW OLOA 2508N is blended in a completely enclosed and fully automated process. Blending of the fuel additive package into petrol will occur at approximately 24 sites and blending into aftermarket concentrates will occur at up to three sites across Australia. Using an automatic computer controlled in-line blender, the components for the aftermarket blends are drawn directly from their storage tanks, blended then packaged into plastic bottles of 500 mL or less. Plastic bottles of the aftermarket concentrates will be distributed to service stations, convenience stores and automotive supply stores, probably by road.

For direct addition to unleaded petrol, the components for the petrol blends are similarly drawn directly from their storage tanks, blended and then sent to another product storage tank or directly to petrol delivery trucks. Some petrol may be drummed off. The final blended petrol will be distributed to service stations and convenience stores by tank truck.

6. OCCUPATIONAL EXPOSURE

6.1 Exposure

The table identifies the nature of work done where occupational exposure to the notified polymer (in additive package) may occur at either the petrol blending terminal (petrol) or at the aftermarket blending plant (aftermarket).

<i>Nature of Activity & Number of Workers</i>	<i>% NEW OLOA 2508N in formulation</i>	<i>Maximum Potential Exposure Duration</i>
Unloading (2)	15-40 (petrol) 20 (aftermarket)	8 hours/day; 5 days/year.
Sampling (2)	≤40 (petrol) 20 (aftermarket)	8 hours/day; 220 days/year.
Analysis (1 to 2)	≤40 (petrol) 20 (aftermarket)	1 hour/day; 3 days/year.
Packaging- Drumming & Bottling (2)	<1 (petrol) 5-15 (aftermarket)	8 hours/day; 150 days/year.
Loading tanker trucks (2)	<1 (petrol)	8 hours/day; 220 days/year.
Equipment Cleaning (1)	<1 (petrol & aftermarket)	2 hours/day; 1 day/year.
ISO tank & Drum Cleaning (2)	<1	8 hours/day; 2 days/year.

Marine Terminals

The additive packages containing the notified polymer will be imported in drums and 5 200 L isotanks. Occupational exposure is not likely except in the event of a spill.

Petrol Blending Plant

During unloading workers will fasten a four inch hose to the bottom of the iso-container, to enable the additive package to be pumped to a storage tank. Fastening takes about 10 minutes. A special air back flush system is used to prevent spillage during transfer. The notifier estimates that by adhering to ISO 9001 procedures spills and leaks are less than 50 grams of additive package per unloading operation. For unloading of drums workers will connect a pump line to the drum. For unloading of both iso-containers and drums incidental skin contact to splashes, drips and spills may occur as pump line are connected or disconnected.

Blending of the additive package into petrol occurs in-line and is computer controlled, thereby excluding the potential for occupational exposure. The majority of the blended petrol is transferred automatically to petrol tanker trucks. Some, however, may be sent to a storage tank for blended petrol for later filling into drums for special deliveries. Drumming is an automated process.

Additive package in storage tanks, and blended petrol will be sampled for laboratory analysis and incidental skin contact from splashes, drips and spills may occur as valves are manipulated to collect samples and during analysis.

Aftermarket

At the blending plant, workers unload the drums by inserting a probe and pumping the additive package through flexible hoses and hard piping to a storage tank. For unloading of drums incidental skin contact to splashes, drips and spills may occur as pump lines are connected or disconnected. Whole body exposure to mist may occur if emptied drums are steam cleaned for re use or disposal.

Blending of the additive package into petrol or a solvent carrier is done in-line between the storage tanks thereby excluding the potential for occupational exposure. Additive package in drums, and final product containing the additive package will be sampled for laboratory analysis and incidental skin contact from splashes, drips and spills may occur during sampling and analytical procedures. The packaging operation is enclosed and automated and worker intervention is not required unless the filling line operation requires adjustment. Extensive skin contact may occur on the rare occasions where it may be necessary to clean, enter and repair equipment containing the additive package.

Service Stations

Mechanics and service station personnel may be exposed to the very low concentration of notified polymer in the final fuel, during routine work procedures. It is inevitable that mechanics will receive skin contact given the nature of the job and that personal protective equipment is not widely used by this trade group. Accidental eye contact may occur, particularly while mechanics are working under vehicles.

Control Measures and Worker Education and Training

Workers at petrol blending and aftermarket blending sites will wear coveralls, gloves & eye protection. The notifier states that inspections of their customers sites have found that their blending facilities are well ventilated, with control systems for accidental spills and wastewater treatment. The notified polymer will be handled by employees of major Australian aftermarket blenders or lubricant manufacturers. Workers involved in the blending activities are reported to have received training in the handling of additive packages.

7. PUBLIC EXPOSURE

There is negligible potential for public exposure to NEW OLOA 2508N arising from blending in Australia as the process is completely enclosed and fully automated.

Accidental spills during transportation of the fuel additive package, the petrol containing the notified polymer or aftermarket concentrates containing the notified polymer or spills of petrol or aftermarket concentrates by the general public could result in contamination of soil or streams.

Finished petrol and aftermarket concentrates containing the notified polymer will be sold to the public through service stations or convenience stores. Some public contact may occur while pumping petrol into vehicle fuel tanks, or small engines used for home and garden activity, or pouring the aftermarket concentrates into petrol tanks of cars and trucks. The most likely route of exposure to the notified polymer will be through the skin. However, the potential for exposure is low, brief and intermittent, and at a low concentration of the notified polymer.

8. ENVIRONMENTAL EXPOSURE

8.1 Function of Notified Polymer in Fuel

In addition to the notified polymer, the additive packages will contain polybutene amine surfactants, polyether amines, polybutene succinimides and other substances which mitigate the build up of deposits in fuel injectors and inlet manifolds of internal combustion engines. The notified polymer (comprising 15% to 40% of the imported additive packages), is described as a “carrier fluid” to assist in the effective transfer of the active additives (amine surfactants and aromatic solvents) to sensitive engine components such as the surfaces of valves and valve ports¹.

Papers by Gibbs (1990) Lewis et al (1983) Taniguchi et al (1986), together with other published reports indicate that the mitigation of injector and intake valve deposits helps promote free flow of fuel/air mixture into the engine cylinders and this in turn allows for cleaner and more uniform (and economic) burning of the fuel and to lower exhaust emissions of particulate material, carbon monoxide, hydrocarbons and nitrogen oxides (Gibbs, 1990). The negative effects of flow restrictions in fuel injectors and air intake ports on engine exhaust emissions has been well documented (Houser and Crosby, 1992) and is discussed further below.

The deposits which form around intake valves and on the pintels of fuel injection assemblies are apparently due primarily to the presence of olefinic hydrocarbons and nitrogen containing molecules in the petrol which form polymeric gums on the surfaces of the hot engine

¹ In the past certain mineral oils were used as carrier fluids however, rather than helping to alleviate the deposit problems, these materials were found to contribute to combustion chamber and valve deposits in newer engine designs which operate at higher temperatures. Accordingly, mineral oil carrier fluids are being replaced with polyethers such as the notified polymer which are less thermally stable and apparently not susceptible to high temperature polymerisation which contributes to deposit formation (Lewis *et al*, 1983).

components (Taniguchi et al, 1986; Tupa and Koehler, 1986). This occurs after the motor has been turned off and fuel/air flow into the cylinders stops and the low molecular weight (MW) fuel hydrocarbons from the residual fuel evaporate leaving olefins and higher MW fuel components. The olefins then polymerise under the influence of the residual heat, and the resultant gums adhere strongly to the metal surfaces. The situation is exacerbated on restarting the motor when small amounts of very fine dust drawn in with the air are attracted and agglomerated by the gum. This cycle repeats on each starting and stopping of the engine until finally large masses of such deposits have built up on and around the metal fuel intake components. There is also ample evidence that different vehicle and engine designs have different propensities for the build up of such deposits and these differences may be correlated with different engine operating temperatures (Taniguchi et al, 1986; Tupa, 1987).

The presence of certain surfactant (detergent) compounds including carrier fluids such as the notified polymer in fuel around 100 ppm apparently break up the polymeric film on the metal surfaces and prevent the unregulated build up of the accretion deposits. Further, even when such deposits have been allowed to form, the use of fuel containing surfactants may break up the agglomerated masses and clean the engine components (Taniguchi et al, 1986; Tupa and Koehler, 1986).

Effects of new fuel additive on vehicle exhaust emissions

Future Commonwealth fuel quality legislation which will require motor fuels to meet certain standards in respect of vehicle exhaust emissions, and the notifier was asked to provide documentation of the effects of the notified polymer on exhaust emissions. A number of papers were provided in which the positive effects of deposit control additives (not necessarily containing the notified polymer) on aspects of vehicle exhaust emissions were examined (Gibbs, 1990; Taniguchi et al, 1986; Houser and Crosby, 1992; Lewis et al, 1983). However, as the notified polymer is one component of a particular additive formulation, the effects observed and described can not be attributed to the notified polymer or other “carrier fluids” alone.

The studies of Houser and Crosby (1992), Tupa and co-workers and certain observational data summarised by Taniguchi (1986) and Gibbs (1990) are relevant to the assessment and provide representative descriptions of the effects of build up of deposits on intake valves and fuel injector deposits on exhaust emissions, and mitigation of this problem through the use of deposit control additives. The pertinent information is briefly described below.

Although these papers do not specifically address the effects of polyether “carrier fluid” additives on the vehicle exhaust emissions, they provide information on the deleterious effects of intake valve deposits on the emissions. Restrictions on the flow of air/fuel mixture into the cylinders leads to uneven and incomplete fuel combustion.

In a 20 vehicle study conducted by Houser (1992) average NO_x emissions increased by up to 20% in the vehicles running with dirty input valves compared with those without input deposits, with similar results for CO and hydrocarbon emissions. Taniguchi (1986) demonstrated that the use of deposit control additives in fuel could prevent build up of deposits and, in most cases after a period of time could remove deposits on fuel injectors and valves which had already formed. By inference this would improve exhaust emission levels of CO, NO_x and hydrocarbons (HC). More explicitly, Gibbs (1990) presented comparative summarised data on exhaust emissions HC, CO and NO_x between vehicles using fuel

containing a deposit control additive and those using same “base” fuel. For the three emission parameters, HC, CO and NO_x, there was significantly increased emissions (20-30%) for the cars using the base fuel without deposit control additive² after running the vehicles for 50 000 miles (80 000 km).

Similar results were reported in a series of papers by Tupa and Koehler (1986, 1988). Tupa (1987) indicated that in comparison with engines with clean intake ports a 30% flow reduction in the intake ports could lead to approximately 40% increase in NO_x, around 100% increase in CO and several hundred percent increase in HC in the exhaust emissions (ie around 1.2 g per mile with dirty injection ports as compared with around 0.2 g per mile in the case of clean ports).

However, the papers made no specific reference to the notified polymer, and the benefits accruing from mitigation of inlet valve deposits should be generic and not confined to the notified polymer alone. Nevertheless, the available evidence suggests that use of the notified polymer as an additive for preventing/cleaning inlet port deposits and fuel injectors would be beneficial to exhaust emissions of HC, CO and NO_x. It is also relevant that mitigation of these engine deposits also has significant positive impact on engine efficiency (see for example Tupa and Koehler 1988).

8.2 Release

Formulation into petrol and aftermarket concentrates

The notifier indicates that the blending operations are to be performed at specially constructed sites (around 24 in Australia), all owned and operated by petroleum companies. The additive packages containing the notified polymer will be delivered to the blending facilities in 5200 L ISO tanks or 200 L drums and pumped to on-site storage tanks. As the pumping and transfer equipment is automated and self contained it is anticipated that very little of the additive package (containing 15% to 40% of the notified polymer) will be released during transfer to the storage containers. All transfer operations from the storage facility to the closed blending equipment are automated, and any spills incurred in the blending operations would be contained within concrete bunds and reclaimed or sent with other waste material to the on-site waste water treatment facilities at the refineries. These facilities employ technologies such as oil/water separation, induced air flotation, sand filtration and biological treatment. Treated water is discharged to either municipal sewage or receiving waters while most of the hydrocarbon material including the notified polymer would be recovered into waste sludge. Sludge is usually incinerated or placed into landfill. The notifier has estimated that the total amount of waste notified polymer generated from all of the blending terminals would be approximately 2000 kg per year. This includes spills, leaks and cleaning effluent.

No estimates of the quantity of material left in the emptied ISO tanks and drums were provided, but the residue remaining in the ISO containers is estimated to be 1%. Assuming a maximum importation of 20 tonnes per annum, this equates to a total maximum release of 200 kg of the polymer each year as residues. The empty containers are steam cleaned at a reconditioning facility, and the waste condensate containing the residual material is treated to remove the hydrophobic material in equipment similar to that used at refineries, and the

² However, it is of some interest to note that in the early stages of this test (ie. up to 15 000 miles running) the exhaust NO_x and CO emissions were slightly larger in the vehicles using fuel supplemented with deposit control additive than for those using on the base fuel.

waste sludge containing notified polymer release would be either placed into landfill or incinerated.

Some of the notified polymer will be formulated into aftermarket concentrates for use by the general public. Very small release is anticipated from blending and bottle filling activities and any spills at the facilities would be treated in the same way as described for waste handling at refineries.

End use release

Finished petrol is transported to service stations by bulk rail or road tankers, and distributed to the general public from bowzers. It is estimated that total losses of petrol through transport and transfer operations would be a maximum of 1%. If it is assumed all this is spilt onto the concrete driveways of service stations, followed by evaporation of the volatile hydrocarbons, then up to 200 kg of the notified polymer could be left on the service station driveways per annum. It is likely that this would be washed into stormwater systems, or possibly sewers where it would be expected to rapidly become associated with sediments because of the anticipated high affinity of the notified polymer for organic material.

Residue of notified polymer would remain in aftermarket concentrates used by individuals. Empty bottles would be placed into landfill with domestic and industrial garbage. The notifier estimated that more than 325 kg of the notified polymer could be placed into landfill each year with empty concentrate bottles.

The vapour pressure of the material is low, so any release to the atmosphere during all transfer operations, or from spilt materials would be low.

8.3 Fate

The majority of the material will be burnt with the petrol with evolution of water vapour and oxides of carbon. Similarly, any material lost as a result of spills at refineries or blending facilities will be recovered into waste sludge and likely to be incinerated. The notifier indicates that use of the notified polymer as an additive for non-leaded fuels will not increase levels of HC, CO, CO₂ or NO_x emissions in exhaust emissions, and claims that use of the notified polymer will reduce emissions through improved engine performance.

No biodegradation studies were provided with this notification. The following information comes from a biodegradation study supplied for the assessment of NEW OLOA 2509H under NA839. The test substance was not readily biodegradable under aerobic conditions, and a standard biodegradation screening test conducted according to OECD TG 301A indicated 46% degradation after 28 days (Environmental Chemistry Research Laboratory 1996). However, any notified polymer released to the soil or water compartments through accidental spills or leaks from storage tanks would rapidly become associated with the organic component of soils and sediments, and could be expected to undergo slow degradation through bacterial action with production of water, oxides of carbon and under anaerobic conditions, methane. It is likely that the notified polymer, NEW OLOA 2508N will behave similarly.

The notified polymer is not expected to cross biological membranes, due to the low water solubility and high molecular weight (Connell DW 1990)

9. EVALUATION OF TOXICOLOGICAL DATA

Test data on the notified polymer, NEW OLOA 2508N, are not available. In support of claims for Variation to the Schedule Requirements, acute toxicity data for OLOA 200 Capped Polybutylene Oxide RS 4999, were submitted by the notifier as read across data for the assessment of the potential acute health effects of the notified chemical. OLOA 200 Capped Polybutylene Oxide RS 4999 differs from the notified chemical by the carbon number of the olefin oligomer; the notified carbon has higher carbon number in this respect. Although the studies conducted on OLOA 200 Capped Polybutylene Oxide RS 4999 predate the protocols described in OECD Test Guidelines and OECD Principles of Good Laboratory Practice, the data reported are considered satisfactory for conclusions to be reached and are therefore acceptable for this assessment.

Data on OLOA 2509H previously assessed by NICNAS under NA585 is also used for the assessment of the notified polymer. The data on OLOA 2509H covers acute and repeat toxicity and genotoxicity. OLOA 2509H is structurally and compositionally similar to the notified chemical, but is of lower molecular weight. OLOA 2509H is also known as CP 2532 and Experimental Polyglycol XU-13481.01.

Summary of the acute toxicity of OLOA 200 Capped Polybutylene Oxide RS 4999

<i>Test</i>	<i>Species</i>	<i>Outcome</i>
acute oral toxicity	rat	LD ₅₀ > 5000 mg/kg
acute dermal toxicity	rabbit	LD ₅₀ > 5000 mg/kg
acute inhalation toxicity	rat	LC ₅₀ > 0.67mg/L/1-hour.
skin irritation	rabbit	Slight to moderate irritant
eye irritation	rabbit	Slight irritant
skin sensitisation	guinea pig	Non sensitiser

Summary of the toxicity of OLOA 2509H

<i>Test</i>	<i>Species</i>	<i>Outcome</i>
Acute oral toxicity – limit test	Rat	LD ₅₀ > 5000 mg/kg
Acute dermal toxicity	Rabbit	LD ₅₀ > 5000 mg/kg
Skin irritation	Rabbit	Non-irritant
Eye irritation	Rabbit	Slight irritant
Skin sensitisation	Guinea pig	Non sensitiser
Repeat Dose Toxicity (oral)	Rat	NOAEL = 1000 mg/kg/day
Bacterial Reverse Mutation	<i>S. typhimurium</i> ; <i>E. coli</i> :	Non mutagenic
Chromosome aberration	CHO cells <i>in vitro</i>	Non clastogenic
Induction of micronuclei	Mouse <i>in vivo</i>	Non clastogenic

9.1 Acute Toxicity

9.1.1 Oral Toxicity (Chevron Environmental Health and Toxicology 1978c)

<i>Test Substance:</i>	OLOA 200 Capped Polybutylene Oxide RS 4999
<i>Species/strain:</i>	Rat/Sprague-Dawley
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	A single dose of 5 000 mg/kg of neat test substance by gavage
<i>Test method:</i>	Not stated but protocol is similar to the fixed dose procedure of OECD TG 401
<i>Mortality:</i>	Nil
<i>Clinical observations:</i>	No clinical signs of toxicity were observed. Transient soft stool was observed in one male after dosing.
<i>Morphological findings:</i>	No gross pathological changes were observed.
<i>LD₅₀:</i>	> 5000 mg/kg
<i>Result:</i>	OLOA 200 Capped Polybutylene Oxide RS 4999 was of very low acute oral toxicity to the rat.

9.1.2 Oral Toxicity (The Toxicology Research Laboratory 1997f)

<i>Test Substance:</i>	OLOA 2509H
<i>Species/strain:</i>	Rat/Fischer 344
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	A single-dose, by gavage, of neat test substance at 5000 mg/kg bw
<i>Clinical observations:</i>	One male had faecal soiling of the perineum on the day of dosing which had resolved by day 2
<i>Mortality:</i>	Nil
<i>Morphological findings:</i>	No treatment related abnormalities observed
<i>Test method:</i>	OECD TG 401 - Limit Test
<i>LD₅₀:</i>	> 5000 mg/kg
<i>Result:</i>	OLOA 2509H was of very low acute oral toxicity to the rat.

9.1.2.1 Dermal Toxicity (Chevron Environmental Health and Toxicology 1978a)

<i>Test Substance:</i>	OLOA 200 Capped Polybutylene Oxide RS 4999
<i>Species/strain:</i>	Rabbits/New Zealand White
<i>Number/sex of animals:</i>	Males, 6/treatment group; 6/control group.
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	A single, 24 hour occlusive application of neat test substance (viscous yellow liquid) at 5000 mg/kg to intact skin (3 rabbits) or abraded skin (3 rabbits).
<i>Test method:</i>	Not stated.
<i>Mortality:</i>	Nil
<i>Clinical observations:</i>	One treated rabbit with abraded skin had reduced food consumption with weight loss during the first week of study but returned to normal during the second week.
<i>Dermal responses:</i>	Mild to moderate skin irritation was observed following the

24 hour exposure period. (No Draize scores were reported).

Morphological findings: No gross pathological changes were observed.

LD₅₀: > 5000 mg/kg

Result: OLOA 200 Capped Polybutylene Oxide RS 4999 was of very low acute dermal toxicity to the rabbit

9.1.2.2 Dermal Toxicity (The Toxicology Research Laboratory 1997c)

Test Substance: OLOA 2509H

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: A single, 24-hour semi occluded application of neat test substance to intact skin at a dose of 5 000 mg/kg bw

Clinical observations: Faecal soiling was observed for one rabbit on day 1 and for another on Day 2;
Erythema and oedema were noted in two rabbits on Day 2.
Erythema or oedema was noted in two rabbits on Day 3.
Scaling was observed at the application site of 4 rabbits up to Day 9; all observations had resolved by Day 14.
Faecal soiling was observed in one rabbit on the day of dosing and in another on Day 2.

Test method: OECD TG 402 - Limit Test

LD₅₀: > 5000 mg/kg

Result: OLOA 2509H was of very low dermal toxicity to the rabbit.

9.1.3 Inhalation Toxicity (Chevron Environmental Health and Toxicology 1978b)

<i>Test Substance:</i>	OLOA 200 Capped Polybutylene Oxide RS 4999
<i>Species/strain:</i>	Rats/Sprague Dawley
<i>Number/sex of animals:</i>	5/sex/treatment group; 5/sex/control group.
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	A single, one-hour whole body exposure to the test substance. The test substance was heated to 40°C to generate a vapour. During the one hour exposure, 0.2 g of test substance was introduced into 300 L of air.
<i>Test method:</i>	OECD TG 403
<i>Mortality:</i>	Nil
<i>Clinical observations:</i>	No clinical signs of toxicity were observed.
<i>Morphological findings:</i>	No gross pathological changes were observed.
<i>LC₅₀:</i>	> 0.67mg/L/1-hour.
<i>Result:</i>	OLOA 200 Capped Polybutylene Oxide RS 4999 was of low acute inhalation toxicity in rats

9.1.4 Skin Irritation (Chevron Environmental Health and Toxicology 1978e)

<i>Test Substance:</i>	OLOA 200 Capped Polybutylene Oxide RS 4999
<i>Species/strain:</i>	Rabbit/New Zealand White
<i>Number/sex of animals:</i>	6 females
<i>Observation period:</i>	7 days
<i>Method of administration:</i>	A single, 24 hour occlusive application of 0.1 mL of neat test substance to intact and abraded skin of each rabbit.
<i>Test method:</i>	OECD TG 404

Draize scores:

<i>Time after treatment (days)</i>	<i>Animal #</i>											
	<i>1</i>		<i>2</i>		<i>3</i>		<i>4</i>		<i>5</i>		<i>6</i>	
<i>Erythema</i>	<i>i</i>	<i>a</i>	<i>i</i>	<i>a</i>	<i>i</i>	<i>a</i>	<i>i</i>	<i>a</i>	<i>i</i>	<i>a</i>	<i>i</i>	<i>a</i>
1	2	2	3	3	2	2	1	1	2	2	2	2
2	2	2	2	1	1	1	1	1	1	1	2	2
3	1	1	1	1	0	0	0	0	0	0	1	1
7	0	0	0	0	0	0	0	0	0	0	0	0
<i>Oedema</i>	<i>i</i>	<i>a</i>	<i>i</i>	<i>a</i>	<i>i</i>	<i>a</i>	<i>i</i>	<i>a</i>	<i>i</i>	<i>a</i>	<i>i</i>	<i>a</i>
1	2	2	2	2	1	1	1	1	0	0	2	1
2 to 7	0	0	0	0	0	0	0	0	0	0	0	0

^a see Attachment 1 for Draize scales

Comment: Well defined erythema and very slight to slight oedema were observed in most treated areas at 24 hours. By 72 hours, very slight erythema was observed in 3 animals which had cleared by day 7.

Result: OLOA 200 Capped Polybutylene Oxide RS 4999 is a slight to moderate irritant to rabbit skin.

9.1.5 Skin Irritation (The Toxicology Research Laboratory 1997e)

Test Substance: OLOA 2509H

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 3/sex

Observation period: 72-hours

Method of administration: A single, 4-hour occlusive application of 0.5 mL of neat test substance to intact skin

Test method: OECD TG 404

Dermal response: No oedema, erythema or eschar was observed. All individual Draize scores were zero. No evidence of skin irritation was noted.

Result: OLOA 2509H was non irritating to rabbit skin.

9.1.6.1 Eye Irritation (Chevron Environmental Health and Toxicology 1978d)

Test Substance: OLOA 200 Capped Polybutylene Oxide RS 4999

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 6 females

Observation period: 72 hours

Method of administration: A single 0.1 mL instillation of neat test substance into the conjunctival sac of one eye. The untreated eye served as the control.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

<i>Animal</i>	<i>Time after instillation</i>											
	<i>1 hour</i>			<i>24 hours</i>			<i>48 hours</i>			<i>72 hours</i>		
<i>Conjunctiva</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>
1	2	0	2	1	0	1	0	0	0	0	0	0
2	1	0	2	1	0	1	0	0	0	0	0	0
3	1	0	2	1	0	1	0	0	0	0	0	0
4	2	0	2	1	0	1	0	0	0	0	0	0
5	2	0	2	1	0	1	0	0	0	0	0	0
6	1	0	2	0	0	1	0	0	0	0	0	0
<i>Cornea</i>	<i>No corneal effects noted</i>											
<i>Iris</i>	<i>No iridial effects noted</i>											

¹ see Attachment 1 for Draize scales. r = redness c = chemosis d = discharge

Mean group score at 24, 48 & 72 hours, for unirrigated eyes: Corneal opacity: 0.0;
Iridial lesion: 0.0;
Redness of conjunctivae: ;
Chemosis of conjunctivae: 0.0

Comment: No corneal opacity or iridial effects were observed. Slight conjunctival redness and discharge were observed at 24 hours which had cleared by 48 hours.

Result: OLOA 200 Capped Polybutylene Oxide RS 4999 is a slight irritant to rabbit eye.

9.1.6.2 Eye Irritation (The Toxicology Research Laboratory 1997d)

Test Substance: OLOA 2509H

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 3/sex

Observation period: 72-hours

Method of administration: A single instillation of 0.1 mL of neat test substance into the conjunctival sac of the left eye of each animal. The right eye served as the control.

Test method: OECD TG 405

Ocular Response of irrigated eyes (Draize scores):

<i>Animal</i>	<i>Time After Instillation</i>											
	<i>1 hour</i>			<i>24 hours</i>			<i>48 hours</i>			<i>72 hours</i>		
<i>Conjunctiva</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>
1F	1	0	0	1	0	0	0	0	0	0	0	0
2F	1	0	0	1	0	0	0	0	0	0	0	0
3F	1	0	0	1	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0
5	1	0	0	0	0	0	0	0	0	0	0	0
6	1	0	0	1	0	0	0	0	0	0	0	0
Cornea	<i>No corneal effects noted</i>											
Iris	<i>No iridial effects noted</i>											

¹ see Attachment 1 for Draize scales. r = redness c = chemosis d = discharge. F = female.

Ocular response - comments: Slight conjunctival redness was observed which had resolved by 48-hour observation time.
No corneal or iridial effects were noted.

Result: OLOA 2509H was a slight irritant to rabbit eye.

9.1.7.1 Skin Sensitisation (Chevron Environmental Health and Toxicology 1978f)

Test Substance: OLOA 200 Capped Polybutylene Oxide RS 4999

Species/strain: Guineapig/albino

Number of animals: 20 males in treatment group; 20 males in positive control group.

Induction procedure: Day 1:
An occlusive, 6 hour application of 0.5 mL of either the test substance (50% w/w in acetone) or the positive control, dinitrochlorobenzene (DNCB) (0.03% in acetone) to slightly abraded skin every Monday, Wednesday and Friday (a total of 10 applications) over a period of 22 days.

Challenge procedure: Day 36:
An occlusive, 6 hour application of 0.5 mL of either the test substance (50% w/w in acetone) or DNCB (0.03% in acetone) to slightly abraded skin not previously treated.

Test method: Modified Buehler test

Challenge outcome:

<i>Test Animals</i> <i>Test substance 50%</i> <i>24 hours*</i>	<i>Positive Control Animals</i> <i>DNCB 0.03%</i> <i>24 hours</i>
**3/20	17/18

* time after patch removal

** number of animals exhibiting positive response ie Grade 1 or more.

Comment: Two animals of the positive control died during the induction phase. Their deaths were not attributed to treatment.

Result: OLOA 200 Capped Polybutylene Oxide RS 4999 was non sensitising to guineapig skin.

9.1.7.2 Skin Sensitisation (The Toxicology Research Laboratory 1997g)

<i>Test Substance:</i>	OLOA 2509H
<i>Species/strain:</i>	Guineapig/Hartley albino
<i>Number of animals:</i>	20 test and 10 naïve control males
<i>Induction procedure:</i>	Test Animals: Days 1, 7 and 14: a single, 6-hour occlusive application of 0.4 mL of neat test substance applied, to the clipped skin of the left side of each animal.
<i>Challenge procedure:</i>	Test and Naïve Control Animals: Day 28: same procedure as induction phase, except test substance was applied to a previously non-treated site. Grading of dermal responses occurred 24 and 48 hours post exposure.
<i>Test method:</i>	OECD TG 406 – Buehler Method
<i>Challenge outcome:</i>	No oedema or erythema was observed in any test animal. No evidence of skin irritation was noted in control animals.
<i>Result:</i>	OLOA 2509H was non-sensitising to guinea pig skin.

9.2 Combined Repeat Dose Oral, Reproductive and Neurotoxicity Study (WIL Research Laboratories Inc. 1997)

Species/strain: Rat/Sprague-Dawley Crl:CD BR

Study Design:

The test substance was administered by the oral route (gavage) daily for 28 consecutive days to animals in the:

Subchronic toxicity phase - 12/sex in the control and 1 000 mg/kg/day groups;
6/sex in the 100 and 300 mg/kg/day groups.

Neurotoxicity phase - 6 males in the control and the 1 000 mg/kg/day groups.

The treatment period was followed by a 14-day recovery period in the control and 1 000 mg/kg/day groups, [6/sex/group (subchronic toxicity) and 6 males/group neurotoxicity)].

In the reproduction phase, the test substance was administered to 12 animals/sex/group for 28-days prior to mating; dosing was continued for a total of 71 or 72 days in the parental (F₀) males, while F₀ females continued to receive test article until Day 4 of lactation. Dose levels were 100, 300 or 1 000 mg/kg/day.

Control animals received, the vehicle, peanut oil. A dose volume of 10 mL/kg was used for all groups.

Test Method: similar to OECD TG 407

Clinical observations:

No mortality. No adverse clinical effects were noted in the subchronic toxicity, neurotoxicity (functional observational battery data) or reproductive toxicity (F₀ reproductive performance, gestation length and parturition were normal) studies.

No obvious treatment-related effects were seen in body weight gain or food consumption.

No significant adverse effects were noted on F₁ live litter size, mortality, viability and sex ratios.

Clinical chemistry/Haematology:

No significant treatment related effects on haematological indices or clinical chemistry parameters at end of treatment or at recovery. Minor changes in clotting (activated partial thromboplastin time (APTT) males at 300 and 1 000 mg/kg/day) and serum chemistry parameters (urea, nitrogen and cholesterol at 1 000 mg/kg/day in males and females, respectively) were noted, however, the changes were within historical control values.

Pathology:

No treatment-related macroscopic, microscopic or neuropathological lesions or dose related effects on organ weights were noted at any dose level at end of treatment or at recovery.

Reproduction:

In F1 litter data, 6 dead pups were noted on lactation day 0 and 300 mg/kg/day, however, in the absence of mortality at 1 000 mg/kg/day, the incidence was not regarded as being treatment related. Similarly, minor malformations were observed in 2 pups at 300 mg/kg/day at the lactation day 4 necroscopy, but only one pup at 1 000 mg/kg/day.

Comment:

No adverse effects related to treatment were observed in the subchronic, reproduction or neurotoxicity phases of this study on any recorded parameter.

Result:

Based on the absence of treatment related organ or systemic toxicity, neurotoxicity or reproductive toxicity at any dose, the No Observed Adverse Effect Level (NOAEL) was determined at 1 000 mg/kg/day, the highest dose tested.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Corning Hazelton Inc. 1997)

Test Substance: OLOA 2509H

Strains: *Salmonella typhimurium*: TA100, TA1535, TA98, TA1537;
Escherichia coli: WP2uvrA.

Auxillary metabolic activation system: Liver S9 fraction from rats induced with Aroclor 1254

Concentration range: 0, 100, 250, 500, 1 000, 5 000 10 000 µg/plate of test substance in ethanol.
Each concentration was tested in triplicate, with or without metabolic activation, in two independent experiments.
Appropriate strain specific positive control reference substances were used.

Test method: OECD TG 471

Comment: Precipitation was noted at and above 500 µg/plate.
Toxicity characterised by growth inhibition was not observed at up to 10 000 µg/plate.
There was no increase in the number of revertant colonies above the control, or demonstration of a dose response relationship, either in the presence or absence of metabolic activation at any test concentration.
Concurrent positive controls used in the test induced marked increases in the frequency of revertant colonies and the activity of the S9 fraction was found to be satisfactory.

Result: OLOA 2509H was non mutagenic under the conditions of the test.

9.3.2 Mammalian Cell Chromosomal Aberration Assay (Corning Hazleton Inc. 1997)

Cells: Chinese Hamster Ovary (CHO) cells

Metabolic activation system: Liver fraction (S9) from rats pretreated with Aroclor 1254

Dosing schedule: Each concentration was tested in duplicate, with or without metabolic activation (S9), in two independent experiments,

Test method: OECD TG 473

Experiment 1:

-S9 0*, 5.0*, 12.5*, 25.0c, 37.5, 50.0*, 100*, 200 or 400 µg/mL;
treatment/harvest time = 17.7/20 hours;
positive control: mitomycin C 0.1 µg/mL;

+S9 0*, 50, 125, 250*, 375c, 500*, 1000p*, 1500p*, 2000p µg/mL
treatment/harvest time = 3/20 hours,
positive control: cyclophosphamide 5µg/mL;

Experiment 2:

-S9 0*, 5.0, 12.5, 25.0, 37.5, 50c*, 100*, 200* or 400* µg/mL;
treatment/harvest time = 17.8/20 hours;

0*, 2.5, 5.0, 12.5, 25.0c*, 37.5*, 50*, 100*, 200, 400 µg/mL
treatment/harvest time = 41.8/44 hours;

positive control: mitomycin C 0.1 µg/mL;

+S9 0*, 50, 125, 250, 375, 500*, 1 000*, 1 500c*, 2 000* µg/mL;
treatment/harvest time: 3/20 hours,

0*, 250, 375, 500c*, 1 000p, 1 500p*, 2 000p*, 2 500p*
3 000p µg/mL;
treatment/harvest time: 3/44 hours,

positive control: cyclophosphamide, 5 µg/mL.

Metaphase analysis:

Cultures selected for metaphase analysis are annotated with (*).

Cytotoxicity was observed in cultures annotated with (c). Underlined concentrations indicates cultures (chromosome aberrations) not analysed due to excessive toxicity.

Precipitate was observed in concentrations annotated with (p).

Experiment 1 (+S9)

A statistically significant, dose-related increase in endoreduplication was observed in cultures at 1 000 and 1 500 µg/mL in the 20-hour assay.

Experiment 2 (+S9)

A statistically significant increase (dose related, but nonmonotonic) in endoreduplication was observed in cultures at 1 000, 1 500 and 2 000 µg/mL in the 20-hour assay.

In all other cultures the test substance did not cause any significant increases in the incidence of cells with chromosomal aberrations, polyploidy or endoreduplication, at the concentrations analysed in the presence or absence of metabolic activation.

Positive controls used in the test caused marked increases in the incidence of aberrant cells and the activity of the S9 fraction was found to be satisfactory.

A statistically significant increase in endoreduplication was observed in the 20-hour assay, but not in the 44-hour assays. The study authors were not able to provide an interpretation of this finding. However, it was suggested that the induction of endoreduplication was not biochemical but rather a physical effect.

Result:

OLOA 2509H was considered non clastogenic under the conditions of the test.

9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Corning Hazleton Inc 1996)

<i>Species/strain:</i>	Mouse/Crl:CD-1
<i>Number and sex of animals:</i>	5/sex/dose/harvest time
<i>Dosing scheme:</i>	<p>A single intraperitoneal (ip) injection of 0, 1045, 2070 or 4 180 mg/kg neat test substance dissolved in peanut oil. Positive control, cyclophosphamide, 60 mg/kg was administered by ip injection.</p> <p>Bone marrow was extracted from test animals at harvest times of 24, 48 or 72 hours post injection and from control animals at 24 hours post injection.</p>
<i>Test method:</i>	OECD TG 474
<i>Clinical observations:</i>	No mortality. No clinical signs of toxicity although animals were noted to have slightly distended abdomens.
<i>Micronuclei score:</i>	<p>No significant increase in micronucleated polychromatic erythrocytes (PCE) due to treatment with test substance at either sampling time above the control animals. The test substance did not induce a change in the PCE: NCE (normochromatic erythrocyte) ratio.</p> <p>The positive control caused a significant increase in micronucleated PCE.</p>

Result: OLOA 2509H did not induce a significant increase in micronucleated PCE in bone marrow cells of the mouse *in vivo*.

9.4 Overall Assessment of Toxicological Data

OLOA 200 Capped Polybutylene Oxide RS 4999 (OLOA 200)

OLOA 200 exhibited very low acute oral and dermal toxicity in rats and rabbits, respectively. In rats there was no mortality following a one hour inhalation exposure to 0.67 mg/L OLOA 200. OLOA 200 is a slight to moderate irritant to rabbit eye and skin. Evidence of skin sensitisation potential was not observed in guineapigs in a non adjuvant study.

OLOA 2509H

OLOA 2509H exhibited very low acute oral and dermal toxicity in rats and rabbits, respectively. Inhalation studies have not been conducted. The substance is viscous and aerosol formation is unlikely under normal circumstances. OLOA 2509H was not irritating to rabbit skin, but caused slight eye irritation in the same species. OLOA 2509H was not a skin sensitiser when tested in guinea pigs using a non adjuvant type method. No signs of toxicity or organ toxicity were observed in a combined oral repeat dose, reproductive and neurotoxicity studies. The NOAEL was 1000 mg/kg/day, the highest dose tested. No mutagenic activity was observed in a bacterial assay. An *in vitro* investigation of the clastogenic potential of the polymer to Chinese Hamster Ovary cells revealed a significant increase in endoreduplication. However, clastogenicity was not observed *in vivo*; the polymer did not induce a significant increase in micronucleated PCE in bone marrow cells of the mouse.

NEW OLOA 2508N

By analogy the toxicity of the notified polymer is not expected to differ substantially from that of OLOA 200 and OLOA 2509H. New OLOA 2509H is expected to have very low acute oral, dermal and inhalation toxicity. It may be irritating to skin and eyes but is not expected to be sensitizing to skin. Upon repeated exposure, organ or systemic effects, neurotoxic effects or reproductive effects are not expected. New OLOA 2509H is not expected to be genotoxic.

On the basis of the data supplied, OLOA 2509H or OLOA 200 Capped Polybutylene Oxide RS 4999 would not be classified as hazardous substances under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999a). By analogy, the same is considered for NEW OLOA 2508N.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Test data on the notified polymer, NEW OLOA 2508N, are not available. In support of claims for Variation to the Schedule Requirements ecotoxicity studies for OLOA 2509H (assessed under NA585) were submitted. Based on chemical similarity, the notified polymer is likely to share similar ecotoxicity as OLOA 2509H. The tests were carried out using OECD Test Methods.

OLOA 2509H is also known as CP 2532 and Experimental Polyglycol XU-13481.01.

10.1 Summary of Effects on Biotic Systems

<i>Test</i>	<i>Species</i>	<i>Results (WAF - Nominal)</i>
Acute Toxicity of OLOA 2509H OECD 203	Rainbow trout <i>Oncorhynchus mykiss</i>	LC ₅₀ (96 hour) = 50 mg/L. NOEC = 26 mg/L.
Acute Toxicity of XU-13481.01 OECD 203	Fathead minnow <i>Pimephales promelas</i>	LC ₅₀ (96 hour) >1000 mg/L.
Acute Immobilisation of XU-13481.01 OECD 202	Water flea <i>Daphnia magna</i>	LL ₅₀ (48 hour) > 1000 mg/L.
Growth Inhibition of XU-13481.01 OECD 201	Alga <i>Scenedesmus subspicatus</i>	34% inhibition at 500 mg/L.

10.2.1 Fish Acute Toxicity Test (T. R. Wilbury Laboratories Inc 1997)

The test was performed over a 96 hour period using a static renewal methodology with 80% renewal at 24, 48 and 72 hours. The test was performed in duplicate with controls using ten Rainbow Trout per replicate at a temperature of 12±1°C. The tests were conducted using water accommodation fractions (WAF) of the test substance made up at nominal concentrations of 26, 43, 72, 120 and 200 mg/L. The individual WAF were prepared by stirring weighed amounts of the test substance with 35 L of water that had been previously aerated, filtered through carbon filters, and sterilised by a 24 hour exposure to UV light, followed by a four hour settling period. Throughout the tests a film of the test substance was apparent on the surface of each test medium, and the vessels containing the four highest concentration WAF were cloudy over the initial 24 hour period. Dissolved oxygen levels (DOL) were always above 7.4 mg/L, and forced aeration of the test vessels was not required for maintenance of these levels. Over the 96 hour test period the solution pH dropped from initial values around 8.1 to around 7.5.

The results indicate the test substance shows some toxicity to the rainbow trout, and that at exposures to sub-lethal WAF, the fish displayed signs of loss of equilibrium, lethargy and darkening of colour.

10.2.2 Fish Acute Toxicity Test (The Toxicology Research Laboratory 1997b)

A series of toxicity tests were performed against fathead minnow, but preliminary studies indicated that this species was far less susceptible to the notified polymer than is rainbow trout. Consequently, WAF were prepared at nominal loadings of 0, 62.5, 125, 250, 500 and 1000 mg/L. The tests were conducted in duplicate using 10 fathead minnow per test vessel with temperature maintained at $22\pm1^{\circ}\text{C}$. Quantities of undissolved test substance were evident in the test vessels. Throughout the test duration DOL and pH were always within acceptable limits.

Some mortality was observed, but this was erratic and did not follow the nominal exposure concentrations (ie no dose response). Thus, after 96 hours exposure (nominal) at 62.5 mg/L of the test substance the mortality rate was 15%, while there was 0% mortality at 125 mg/L, 15% mortality at 250 mg/L, 0% mortality at 500 mg/L, and 5% mortality at 1 000 mg/L. No marked sublethal effects were observed, and given the very erratic nature of the mortality pattern, it is probable that those fish which succumbed either ingested or were otherwise exposed to undissolved droplets of the test substance. However, it may be concluded from the results that the test substance is non-toxic to this species up to the limits of its solubility.

10.3 Daphnia Acute Immobilisation Test (The Toxicology Research Laboratory 1997a)

The immobilisation tests with *Daphnia magna* were performed over a 48 hour period under static conditions using WAF of 0, 15.4, 31.6, 62.7, 125, 250, 500 and 1001 mg/L at a temperature of $20\pm1^{\circ}\text{C}$. The test at each WAF was conducted in triplicate with a control using 10 daphnia per test vessel. Low mortality (maximum of 6.7% at nominal exposure of 62.7 mg/L) among the daphnia were observed in some of the test vessels, but as with the tests on fathead minnow, no dose response was observed. As no mortality occurred at 500 and 1000 mg/L, the No Observed Effect Concentration (NOEC) was determined as $>1\ 000\ \text{mg/L}$.

10.4 Algal Growth Inhibition Test (The Toxicological Research Laboratory 1997)

Tests on algal growth inhibition were performed over a 96 hour period with WAF made up at the nominal concentrations of 0, 30, 70, 150, 260, 500 and 1000 mg/L, and at a temperature of $24.8\pm0.2^{\circ}\text{C}$. The tests were conducted in triplicate, and the effects of the test substance on algal growth ranged from an increase of 8% in growth rate at a nominal loading of 30 mg/L to inhibition of 34.4% at a nominal loading of 500 mg/L. These data indicate that exposure of green algae to between 5 and 10 times the test substance's water solubility will have no adverse effect on growth.

10.5 Conclusion

The ecotoxicity tests for OLOA 2509H (assessed under NA585) indicate that the notified polymer, NEW OLOA 2508N will be non toxic to most fresh water organisms up to the limits of its solubility. However, it may display slight toxicity to sensitive species such as rainbow trout, as does OLOA 2509H.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified polymer is low when it is blended into petrol and used in the manner indicated by the company.

There is little potential for significant release of the notified polymer during the blending operations which will be performed at dedicated petrochemical facilities. A maximum of 0.5 tonne of the material may be released each year as a result of spills, leaks and cleaning during these operations, and most of this is expected to be recovered into waste sludge and would then be either incinerated or placed into landfill.

Some release will inevitably occur as a result of petrol spills during distribution to motorists. This is estimated as a maximum of 2.5 tonne per annum and release will be widespread and very diffuse.

Some of the notified polymer will be formulated into aftermarket concentrates and small quantities of the concentrate will be left in the emptied bottles used after vehicle owners have individually treated their fuel. Empty bottles would be disposed of with domestic and industrial garbage to landfill, and it is estimated that around 350 kg of the notified polymer may be disposed of in this manner, again in a diffuse manner.

It is likely the notified polymer will not be readily biodegradable. The notified polymer has a high octanol/water partition coefficient ($\log P_{ow} > 7.6$) and is expected to be insoluble in water, and consequently if released to the soil or water compartments is expected to bind to, and become associated with the organic component of soils and sediments. Any material released to the soil compartment (eg. from petrol spills) would firstly become associated with the organic component of the soil, and in this situation would be slowly mineralised to water and oxides of carbon through biological processes. The same fate is expected for any polymer placed into landfill with waste sludge from refineries.

The notified polymer will be used as a component of engine deposit control additives for non leaded petrol, and there is considerable evidence that modern motor vehicles using fuel containing such additives show significant improvements in exhaust emission of hydrocarbons, CO and NO_x over those of vehicles using un-supplemented fuel. However, the formation and control of engine deposits, their effects on fuel combustion efficiency and on the composition of exhaust emissions is complex. Factors influencing engine operating parameters may include the composition of the base fuel as well as the presence and concentration of control additives in the fuel. Nevertheless, the available evidence indicates that the use of the notified polymer as a fuel additive has no significant deleterious effects on the quality or quantity of noxious or toxic vehicular exhaust emissions. Overall, use of the

notified polymer as intended is probably beneficial and not considered to pose a hazard to the environment.

The majority of the notified polymer is expected to be completely destroyed by combustion within the engine, resulting in oxides of carbon and hydrogen.

Except in the case of a transport accident, very little of the notified polymer is likely to enter the water compartment, and any polymer released to water would become associated with aquatic sediments and slowly mineralised through biological processes. The notified polymer is not expected to have high potential for bioaccumulation.

No ecotoxicity studies were conducted on the notified polymer but it is likely that it may show some toxicity to sensitive aquatic species such as rainbow trout. However, the high octanol/water partition coefficient indicate that if released to the soil or water compartments the notified polymer is expected to bind to, and become associated with the organic component of soils and sediments. This will mitigate any toxic potential of the notified polymer.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

By analogy, the toxicity of the notified polymer is not expected to differ substantially from that of OLOA 200 Capped Polybutylene Oxide RS 4999 and OLOA 2509H. New OLOA 2509H is expected to have very low acute oral, dermal and inhalation toxicity. It may be irritating to skin and eyes but is not expected to be sensitizing to skin. Upon repeated exposure, organ or systemic effects, neurotoxic effects or reproductive effects are not expected. New OLOA 2509H is not expected to be genotoxic. On the basis of the data supplied, OLOA 2509H or OLOA 200 Capped Polybutylene Oxide RS 4999 would not be classified as hazardous substances under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999a). By analogy, the same is considered for NEW OLOA 2509H.

Occupational Health and Safety

The blending of the additive package, containing the notified polymer at 15 to 40%, into petrol for distribution to service stations or for subsequent packaging into retail products will occur in automated, closed systems. Exposure to the additive package containing the most concentrated forms of the notified polymer is expected to be limited to incidental skin contact to the additive package is most likely during the procedures involved in connection and disconnection of pump lines and during sampling for laboratory analysis. Other scenarios of exposure to the notified polymer are at concentrations of less than 1% and this would be limited to incidental skin contact also. The toxicological profile, mode of use, use of personal protective gear and *in situ* engineering controls, indicate that significant risks to human health through occupational exposure to the notified polymer are unlikely.

Public Health

No significant exposure to the notified polymer is anticipated during transport and product formulation. Members of the public may, however, make skin contact with the notified polymer when using petrol or aftermarket concentrate which contain the notified polymer. The amounts to which the public are likely to be exposed are expected to be minimal and exposure is expected to be brief and intermittent. Inhalation exposure is expected to be minimal, as the notified chemical is not expected to be volatile. Where exposure does occur, the notified chemical is unlikely to pose a significant hazard given its low toxicity, low concentration in final uses by consumers and its high molecular weight. Based on the use pattern and hazard the notified polymer is considered not to pose a significant risk to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to NEW OLOA 2508N the following guidelines and precautions should be observed:

Occupational Health and Safety Matters

To minimise occupational exposure to additive packages that contain the notified polymer the following guidelines and precautions should be observed:

- Workers should receive regular instruction on good occupational hygiene practices in order to minimise personal contact, and contamination of the work environment with additive packages.
- Chemical impervious clothing and gloves are necessary to prevent skin contact - consideration should be given to the ambient environment, physical requirements and other substances present when selecting protective clothing and gloves. Good hygiene practices dictate that eye protection be worn routinely. Workers should be trained in the proper fit, correct use and maintenance of their protective gear. PPE guidance in the selection, personal fit and maintenance of personal protective equipment can be obtained from:

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

- The notified polymer is not determined to be a hazardous substance. The additive package may contain hazardous ingredients making the overall package hazardous. Therefore, workplace practices, control procedures and hazard communication products consistent with provisions of State, Territory and Commonwealth legislation based on the *National Model Regulations for the Control of Workplace Hazardous Substances* (NOHSC 1994b) must be in operation.

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

14. MATERIAL SAFETY DATA SHEET

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

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

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

16. REFERENCES

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Attachment 1

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

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

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

CORNEA

<i>Opacity</i>	<i>Rating</i>	<i>Area of Cornea involved</i>	<i>Rating</i>
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

<i>Redness</i>	<i>Rating</i>	<i>Chemosis</i>	<i>Rating</i>	<i>Discharge</i>	<i>Rating</i>
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

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

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