File No: NA/754

March 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Di-μ-thio-bis[{bis(2-ethylhexyl)dithiocarbamato}oxo molybdenum (V)]
(SAKURALUBE 500)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Di-μ-thio-bis[{bis(2-ethylhexyl)dithiocarbamato}oxo molybdenum (V)]
(SAKURALUBE 500)

1. APPLICANT

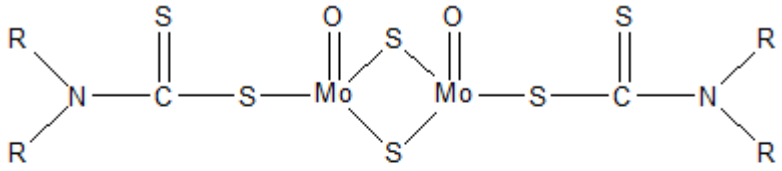
Niissho Iwai Australia Ltd of 459 Collins Street MELBOURNE VIC 3000 has submitted a standard notification statement in support of their application for an assessment certificate for Di-μ-thio-bis[{bis(2-ethylhexyl)dithiocarbamato}oxo molybdenum (V)].

No claims were made for exempt information.

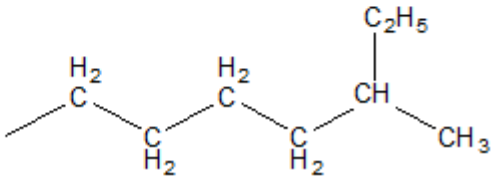
2. IDENTITY OF THE CHEMICAL

Chemical Name:	Di-μ-thio-bis[{bis(2-ethylhexyl)dithiocarbamato}oxo molybdenum (V)]
Chemical Abstracts Service (CAS) Registry No.:	90901-24-9
Other Names:	None
Marketing Name:	SAKURALUBE 500
Product Name:	SAKURALUBE 100 (25% notified chemical in di(2-ethylhexyl) phthalate solvent)
Molecular Formula:	$C_{34}H_{68}N_2S_{6.028}O_{1.972}Mo_2$

Structural Formula:



Where R is the 2-ethylhexyl group -



Molecular Weight:	921.20
Method of Detection and Determination:	Infrared (IR) Analysis; Nuclear magnetic resonance (NMR); High performance liquid chromatography (HPLC).
Spectral Data:	IR spectra: 2 958, 2 928 2 857 cm^{-1} C-H stretch; 1 526 cm^{-1} C-N stretch; 970 cm^{-1} Mo=O stretch. NMR spectra: The spectrum contains four groups of multiplets with chemical shifts and intergration values which are consistent with the presence of 2-ethylhexyl groups.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Odourless, yellow powder
Boiling Point:	Decomposes at 200°C
Melting Point:	92-93°C at 101.3 kPa
Specific Gravity:	1.2846
Vapour Pressure:	2 x 10^{-8} kPa at 25°C

Particle Size (distribution):	Size μm:	%
	≤2.006	3.98
	2.006 – 202.0	84.07
	≥202.0	11.95
	<10 (respirable)	9.1
Water Solubility:	5.45 x 10 $^{-4}$g/L at 20°C	
Partition Co-efficient (n-octanol/water):	log P_{ow} = > 7.1 at 20°C	
Fat Solubility:	1 103 mg/100 g Standard fat at 37°C	
Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0, 7.0, 9.0 = 1 day to 1 year	
Adsorption/Desorption:	K_{oc} = > 28 800 at 21°C	
Dissociation Constant:	Not measured (see comments below)	
Flash Point:	Not determined – substance is a solid	
Flammability Limits:	Not flammable	
Autoignition Temperature:	>450°C	
Explosive Properties:	None	
Reactivity/Stability:	Not oxidising	

Comments on Physico-Chemical Properties

Tests were performed according to corresponding EEC and OECD test guidelines (TG) (European Commission, 1992, OECD, 1995-1996) at Huntingdon Life Sciences Testing Facilities, UK (Huntingdon Life Sciences Ltd, 1998j), (Huntingdon Life Sciences Ltd, 1998i). These facilities comply with the OECD principles of good laboratory practice and full test reports were submitted. All tests were performed on the notified chemical.

The notified chemical melts initially between 92 and 93ºC, but this entails some irreversible changes, and on reheating no broad endotherm was observed. This observation indicates that the chemical undergoes some chemical change between 78 and 100ºC, although the nature of this transformation is apparently not known. At temperatures above 200ºC, the material decomposes.

The vapour pressure was determined by chromatography. Nitrogen gas at the specified temperature was passed over the notified chemical heated to the specified temperature in such a manner that it becomes saturated with vapours of the test substance. The gas stream was passed through a column containing adsorbing material for a specified time, where the nonpolar chemical was removed from the stream. The adsorbed material was eluted and

analysed by gas chromatography, and the quantity of material removed in the N_2 gas stream at a given temperature over a specified time used to calculate the vapour pressure. The vapour pressures determined at 21, 37 and 50ºC (each determined in triplicate) were respectively 4.99×10^{-3}, 1.12×10^{-2} and 2.78×10^{-2} Pa.

The water solubility is stated as 0.54 mg/L as by the flask method described in OECD TG 105. An excess of the test material was added to each of six flasks containing distilled water and stirred at 30ºC for periods of 24, 48 and 72 hours respectively (two flasks used for each time period). Each flask was then equilibrated to 20ºC for at least 24 hours, and the solid and aqueous phases separated by centrifugation. The aqueous phase was then analysed for the test substance notified chemical using High Performance Liquid Chromatography (HPLC). Water solubility of the test compound in each of the six samples was between 0.395 and 0.678 mg/L, but this variation was random and was not correlated with stirring time. The mean result of the six measurements gave the water solubility at 20ºC as 0.54 mg/L. The pH of the final solutions was always around 7.5.

Hydrolytic degradation as a function of pH was determined at 50ºC in buffers at pH 4, 7 and 9. The solutions were made up in the buffers at a nominal concentration of 0.2559 mg/L, which was always within 3% of the actual measured concentration (HPLC). The concentration of the test substance in each of the buffers was determined after 5 days, and indicated 49.4% hydrolytic degradation at pH 4, 17.5% degradation at pH 7 and 22.7% at pH 9 – all at 50ºC. The test report indicated that the half-life of the notified chemical at ambient environmental temperatures and pH would be between one day and one year. However, it is often accepted that reaction rates approximately double for every 10 degree rise in temperature (Atkins, 1986). Accordingly, the relative extent of hydrolytic degradation of the new compound after 5 days at 25ºC may be estimated by reducing the above data by a factor of 5.65 ($=2^{2.5}$). This procedure gives 8.7%, 3.1% and 4.0% degradation at pH 4, 7 and 9 respectively. These data indicate that even at pH 7 where the degradation rate is slowest, the half life of the notified chemical in the environment would be significantly less than one year.

The n-octanol/water partition coefficient was determined by HPLC according to OECD TG 117. The elution time for the test substance is used to derive P_{ow} from a calibration curve prepared by plotting the elution time of a series of reference compounds of known P_{ow}. The reference compounds used ranged from aniline with Log P_{ow} of 0.9 to dioctylphthalate with Log P_{ow} = 7.1. The retention time for the test substance on C_{18} columns was significantly longer (around 21 minutes) than for all six of the reference compounds, (longest for dioctylphthalate with a retention time of 6.6 min). This result indicates that Log P_{ow} is significantly greater than 7.1, and that the notified chemical would partition strongly into the oil phase.

The adsorption/desorption data was determined using a draft OECD method using HPLC. The retention time of the test substance on a specially prepared chromatography column is compared to retention times for a range of reference compounds of known Log K_{oc}. The relatively large value of Log K_{oc} determined indicates that the material would adsorb to, and become associated with the organic component of soils and sediments. This is in general accord with the high hydrocarbon content of the notified chemical and the high value for the n-octanol/water partition coefficient.

A spectroscopic test to determine the dissociation constant data was attempted, but the low

water solubility precluded definitive measurement of this parameter. However, it is unlikely that any of the functionalities within the molecule will exhibit acidic or basic properties.

The fat solubility of the notified chemical was measured by stirring an excess of the test substance with melted fat (at 37ºC) for 120 hours, filtering the undissolved solid and analysing the fat solution for dissolved compound using HPLC. The notified chemical has a very large value for Log P_{ow} (>7.1) which indicates high affinity for oil and lipid (fat), although the fat solubility was determined as 11 g/kg at 37ºC which is considered modest.

4. PURITY OF THE CHEMICAL

Degree of Purity: 97%

Hazardous Impurities: None

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

Chemical name: di-μ-thio-bis[{bis(2-ethylhexyl)dithiocarbamato} oxo thio dimolybdenum (V)]

Weight percentage: 2.0%

Chemical name: Unidentified (non-volatile)

Weight percentage: 1.0%

Additives/Adjuvants: None

Formulation details:	SAKURALUBE 100 (import preparation containing notified chemical at 25%)
Chemical name:	di(2-ethylhexyl) phthalate (DEHP)
Weight %	75
CAS No.:	117-81-7
Toxic Properties:	IARC carcinogen - Class 2B (IARC, 1982). Hepatic, reproductive and developmental toxicant in animals. Mild eye and skin irritant in rabbits (Gangolli, 1999).
Regulatory Control:	National Exposure Standard (NOHSC, 1995): 5 mg/m^3 TWA, 10 mg/m^3 STEL.

5. USE, VOLUME AND FORMULATION

The notified chemical is an inhibitor used to reduce deposits on pistons and in the engine crankcase and to control oxidation of the lubricant at the high engine operating temperatures. The notified chemical will not be manufactured in Australia, but will be imported as a 25% solution (Sakuralube 100) in DEHP solvent in 200L steel drums. Total import volumes for the notified chemical are expected to be up to 10 tonnes per annum over the next five years, which equates to total annual imports of around 40 tonnes (200 drums) of the Sakuralube 100 package.

Sakuralube 100 will be transferred from the dockside to oil companies, who would then use it for formulating finished engine oils. The notified chemical will be blended with oils and other additives (eg viscosity modifiers, foam inhibitors, pour point depressants and lubricant oils) into completed lubricants for both petrol and diesel engines.

The lubricant products may contain up to 1% of the notified chemical (the exact range was not specified in the notification), and will be packed into drums of 4 L and 200 L capacity. The notifier indicated that at this stage the relative percentages of lubricants containing the new chemical which will be sold into the general retail market, and into the industrial sector is unknown. However, they did indicate that it is likely that most would be used within the automotive industry (ie mechanical workshops and garages), rather than in the general retail sector.

Assuming a typical lubricant contains 0.5% of the notified chemical, then an annual import of 10 tonnes of the chemical equates to an annual production of approximately 2 000 000 L of finished lubricant containing the notified chemical[1].

[1] Annual usage of engine lubricants in Australia is estimated at around 182 000 000 L (AIP, 1995), so the new chemical would be used in approximately 1% of lubricant products.

6. OCCUPATIONAL EXPOSURE

Exposure

Dockside and Transport

The notified chemical in Sakuralube 100 will be imported in 200 L steel drums. Occupational exposure is not expected except in the event of a spill.

Blending Facility

The import drums are opened and the contents are automatically removed and transferred into a mixer (steel tank of 5 to 30 tonne capacity). Between 50 to 300 kg of substance is added to the mixer taking approximately one hour to fill. Mineral or synthetic oil is then added automatically to the mixer tanks. The blending operation occurs at 70°C. The notifier estimates two batches per annum of 12 hours duration each. After blending, the finished oil is automatically discharged into steel drums. Drum filling takes 2 hours to complete. The mixing vessel, automatic filler and pipes are cleaned afterwards by an automatic steam cleaning system. Local exhaust systems are in place to control inhalation exposure.

Worker exposure (two production workers) is expected to be minimal during addition of the additive package to the oil because of the use of closed automated processes and dedicated delivery lines and equipment. Exposure is expected to be confined to incidental skin contact to drips and spills that may occur during the connection/disconnection of pump lines between the import drum (25% notified chemical) and blending system, the handling of empty import containers (<0.075% notified chemical) and contact with washings. Incidental skin contact may also occur during quality control procedures, which is expected to occupy one person for one hour per day.

Service Stations

As the notified chemical is present at very low concentration (<1%) in the finished oil, exposure to the notified chemical for mechanics and service station personnel is expected to be negligible.

Control Measures

The notifier indicates that during routine handling, workers wear industrial canister gas mask, chemical safety goggles, cuffed butyl rubber or PVC gloves and anti static work clothes and boots. Engineering controls, that is, automated delivery systems already in place at the repackaging site and refineries, will minimise the potential for exposure during repackaging and blending.

Worker Education and Training.

The notifier states that the additive product containing the notified chemical will be handled by trained workers knowledgeable of safe handling procedures for fuels and fuel additives.

Occupational Health

The notifier indicates that there have been no records of injury or disease to workers during the fifteen years that the substance has been on the market overseas.

7. PUBLIC EXPOSURE

The product containing the notified chemical will be formulated into engine oils at large oil companies. The majority of the lubricants would be used within the automotive industry (eg mechanics and garages), however, some may be available for general retail sale. Home mechanics could therefore be exposed to the notified chemical while changing the engine oil of their automobile.

It is expected that during transport, storage and use, exposure of the general public to the notified chemical will be minimal, except in the event of an accidental spill. Spillages should be cleaned up using appropriate technology such as sorbent materials before being transferred to suitable containers for recovery or disposal in accordance with local, state and federal regulations. Prompt attention to spillages will be needed to prevent spill and clean up material from entering waterways. The Material Safety Data Sheet (MSDS) supplied for the notified chemical has instructions for spillage containment and disposal.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier indicates that the blending operations are performed at specially constructed sites by petroleum companies. The Sakuralube 100 product (containing 25% of the new chemical) will be delivered to, and stored at the blending facilities in 200 L steel drums. It is anticipated that very little of the additive package will be released during transport operations or in 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 in subsequent batches. Any spills incurred during blending are contained within concrete bunds, to be soaked up with absorbant material and incinerated at approved facilities. In some cases spilt material may be sent to onsite waste water treatment facilities. The notifier indicated that 0.075% of the chemical may remain in the drums after emptying, while a further 0.075% may be lost in other process related activities. Together these losses amount to 0.15% (maximum) of total imports, or up to 15 kg of the notified chemical each year. Chemical released in this manner is expected to be combined with other residual material and placed into landfill or incinerated. Empty drums are to be cleaned out, and sent for drum recycling.

The vapour pressure of the material is low, so release to the atmosphere during formulation of the lubricants when using or removing the lubricant from crankcases would be negligible.

Some release is likely during transfer of the lubricants from containers to engine blocks. If it is assumed that each transfer involves 4 litres of lubricant, then with an annual import of 10 tonnes and a typical content of 0.5 % of the notified chemical in the oil around 500 000 engine oil changes using the notified chemical would take place throughout Australia each year. It is anticipated that on average 20 mL of lubricant - containing 0.5 % of the notified substance would be spilt or left as residues in containers as a result of transfer operations. Consequently, around 500 kg (5% of import quantity) of the notified material could be released annually via this route. Most spills are likely to be adsorbed onto sawdust and incinerated or disposed of to landfill, while residuals left in containers would be disposed of

in similar fashion. Irresponsible work practices could lead to spilt oil being washed down driveways and entering stormwater systems, but this is expected to be a minor occurrence.

A recent survey by the Australian Institute of Petroleum (AIP, 1995) indicates that of the total annual sales of automotive engine oils in Australia (182 ML), some 60% (109 ML) are not burnt in the engines during use, and are potentially recoverable. This survey also indicates that around 86% of oil changes take place in specialised automotive service centres, where spent oil drained from crankcases could be expected to be disposed of responsibly - either to oil recycling or incineration. The remaining 14% (approximately 25 megalitres) are removed by "do it yourself (DIY)" enthusiasts, and in these cases some of the spent 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 (Snow, 1997) tracing the fate of spent lubricating oil in Australia indicates that only around 20% of spent 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 50% is used in treating fence posts, killing grass and weeds or is disposed of in other ways. The total amount of spent oil which is disposed of into stormwater systems is estimated at 5% of 14%, or 0.7% of all engine lubricants.

Consequently, if it is assumed that oil removed by professional mechanics is disposed of appropriately (ie burning as workshop heating oil or sent for recycling), negligible release of the notified chemical should result from professional activities.

However, assuming that the lubricants containing 0.5% of the notified chemical attain 1% total market share, or that 60% is unburnt in engines and that 14% is disposed through dumping, burying, or fence maintenance the DIY proportion of oil changes could potentially lead to an annual release of up to 150 000 L of spent oil. This amounts to around 750 kg of notified chemical (7.5% of the total import volume), and of this 35 kg (around 5%) may enter stormwater drains. In any case, almost all the released notified chemical is expected to become associated with soils and sediments.

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

Fate

A closed bottle test (Huntingdon Life Sciences Ltd, 1998g) for biodegradation (OECD TG 301 D) was conducted on the notified chemical. The test substance at nominal concentration of 2 mg/L (several times the water solubility) was inoculated with sewage bacteria and incubated at 22±2ºC for 28 days. The dissolved oxygen levels were determined periodically, and when compared with the theoretical oxygen demand the dissolved oxygen results indicated very little degradation. After 28 days, no more than 7% of the theoretical oxygen demand had been removed from the test media, indicating that the notified chemical is not readily biodegradable. Reference tests performed using identical test conditions, but with sodium benzoate as substrate indicated 69% degradation of the benzoate moiety after 5 days, and 72% degradation after 28 days. Further, the notified chemical is not inhibitory to respiration of the sewage bacteria – see Environmental Effects.

Despite the low measured rate of biodegradation, it is expected that the notified chemical would be slowly degraded through biological and abiotic processes if placed into landfill. These processes could be expected to produce carbon dioxide, methane, ammonia, water, hydrogen sulphide and (solid) molybdenum compounds.

Leaching from a landfill would be slow. The relatively large value for Log K_{oc} indicates that the material would not be mobile, but would adsorb into and become associated with the organic component of soils and sediments. Similarly, in the event of accidental release into the water compartment, the notified chemical is likely to become associated with suspended organic material, and eventually incorporated into sediments.

The notified chemical has a very high Log P_{ow} (>7.1) which implies low water solubility. This factor, together with the relatively high molecular weight of the notified chemical will preclude easy transfer across cell membranes, hence the material is unlikely to bioaccumulate (Connell, 1990).

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

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

9. EVALUATION OF TOXICOLOGICAL DATA

Tests were performed according to corresponding EEC and OECD test guidelines (European Commission, 1992, OECD, 1995-1996) at Huntingdon Life Sciences Testing Facilities, UK. These facilities comply with the OECD principles of good laboratory practice and full test reports were submitted. All tests were performed on the notified chemical.

9.1 Acute Toxicity

Summary of the acute toxicity of Sakuralube 500

Test	*Species*	*Outcome*	*Reference*
Acute oral toxicity	Rat	> 2 000 mg/kg	(Huntingdon Life Sciences Ltd, 1998b)
Acute dermal toxicity	Rat	> 2 000 mg/kg	(Huntingdon Life Sciences Ltd, 1998a)
Skin irritation	Rabbit	Non irritating	(Huntingdon Life Sciences Ltd, 1998k)
Eye irritation	Rabbit	Very slightly irritating	(Huntingdon Life Sciences Ltd, 1998h)
Skin sensitisation	Guineapig	Non sensitising	(Huntingdon Life Sciences Ltd, 1998l)

9.1.1 Oral Toxicity (Huntingdon Life Sciences Ltd, 1998b)

Species/strain:	Rat/Sprague-Dawley (Hsd:sprague-Dawley (CD)
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	2 000 mg/kg of test substance in methyl cellulose administered by gavage.
Test method:	OECD TG 420, Fixed dose method.
Mortality:	Nil
Clinical observations:	Piloerection was observed 5 minutes post dosing. There were no other clinical signs and recovery was complete in all instances by Day 4.
Morphological findings:	No abnormalities noted.
LD_{50}:	>2 000 mg/kg

Result:	The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Huntingdon Life Sciences Ltd, 1998a)

Species/strain:	Rat/Sprague-Dawley (Hsd: Sprague-Dawley (CD)
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	A single, 24 hour, semi occluded application of 2 000 mg/kg of test substance in 1% methylcellulose.
Test method:	OECD TG 402 – Limit test
Mortality:	Nil
Clinical observations:	Local: Transient to well-defined demal irritation (Grade 2 erythema and oedema) was seen in one female on Day 2. Slight dermal irritation (Grade 1 erythema and oedema) was noted for this female on Day 3, resolving by Day 4. There was also some mechanical damage of the treatment side caused by the removal of the dressing in this animal due to the adherence of the test substance. This mechanical damage resolved by Day 5. There was no dermal response to treatment in the remaining nine animals, with the exception that residual test substance staining (yellow) was noted on the treatment sites of all males and two females. Systemic: There were no signs of systemic reaction to treatment.
Morphological findings:	No abnormalities noted.
LD_{50}:	> 2 000 mg/kg
Result:	The notified chemical was of low dermal toxicity in rats.

9.1.3 Inhalation Toxicity

Claims were made and accepted for a waiver to the Schedule requirements for this toxicological end point. To support their claim the notifier states that the particle size distribution study indicates there is some potential for inhalation of the dust of the notified chemical. However, the median particle size of the substance is 44.2 μm in diameter, with less than 10% having a diameter of less than 10 μm. This coupled with the moderate specific gravity (1.28) and negligible vapour pressure of the substance, limits exposure via the inhalation route. Acute dermal and oral toxicity studies also indicate that the substance is unlikely to be harmful.

9.1.4 Skin Irritation (Huntingdon Life Sciences Ltd, 1998k)

Species/strain:	Rabbit/New Zealand white
Number/sex of animals:	3 females
Observation period:	72 hours
Method of administration:	A single, 4 hour, semi occluded application of 0.5 g of test substance to shorn intact skin.
Test method:	OECD TG 404
Dermal responses:	No erythema or oedema noted; all Draize scores were zero.
Result:	The notified chemical was non irritating to the skin of rabbits.

9.1.5 Eye Irritation (Huntingdon Life Sciences Ltd, 1998h)

Species/strain:	Rabbit/New Zealand white
Number/sex of animals:	3 females
Observation period:	72 hours
Method of administration:	A single ocular dose of 0.1 mL (61 mg) of compacted test substance into the conjunctival sac of one eye.
Test method:	OECD TG 405
Ocular response:	No corneal damage or iridial inflammation was observed. One hour after instillation, all animals had transient hyperaemia (Grade 1) of the conjunctivae accompanied in one rabbit by slight swelling. The conjunctival irritation had resolved by Day 1 or 2.
Result:	The notified chemical was transiently, very slightly irritating to the eyes of rabbits.

9.1.6 Skin Sensitisation (Huntingdon Life Sciences Ltd, 1998l)

Species/strain:	Guinea pig: Dunkin/Hartley strain
Number of animals:	10 test animals, 5 control animals
Induction procedure:	Intradermal Induction: Day 1: Three pairs of intradermal injections, prepared as follows, into the scapular region: • 1:1 mixture of Freunds Complete Adjuvant (FCA) and water for irrigation; • test substance 7.5% w/v in 5% acetone in Alembicol D; • test substance, 7.5% w/v in a 1:1 mixture of FCA and 5% acetone in Alembicol D. Topical Induction: Day 7: injection site treated with 10% w/w sodium lauryl sulphate; Day 8: 48 hour occlusive application of 0.4 mL test substance at 70% w/v in acetone; Control animals were treated as above but omitting the test substance.
Challenge procedure:	Day 21: 24 hour occlusive application of test substance at 70% w/v to the anterior flank or 35% w/v in acetone to the posterior flank.
Test method:	OECD TG 406 – Magnusson & Kligman maximisation test
Challenge outcome:	No dermal reactions (erythema or oedema) observed in either test or control animals.
Result:	The notified chemical was non sensitising to the skin of guinea pigs.

9.2 Repeated Dose Toxicity (Huntingdon Life Sciences Ltd, 1998m)

Species/strain:	Rat/Crl:CD BR
Number/sex of animals:	5/sex/dose
Method of administration:	0, 15, 150 or 1 000 mg/kg/day of test substance in corn oil administered daily by gavage for 28 consecutive days
Test method:	OECD TG 407

Clinical observations:
There were no clinical signs or changes in behavioural parameters, bodyweight, food or water consumption that were considered to be related to treatment.

Clinical chemistry/Haematology:
Significantly increased mean cell haemoglobin concentration and mean cell haemoglobin in females at 1 000 mg/kg/day. Activated partial thromboplastin time (APTT) was significantly longer in males at 15 and 150 mg/kg/day but not at 1 000 mg/kg/day. Female rats at 150 or 1 000 mg/kg/day showed significantly lower values for large unstained cells.

Significantly decreased total protein levels in males at 150 and 1 000 mg/kg/day, the highest dose tested.

Pathology:
Organ Weight:
Males at 1 000 mg/kg/day showed significantly decreased liver weight and significantly increased testes weight compared to control animals. Females showed significantly increased liver weights at 150 and 1 000 mg/kg/day and significantly increased spleen weight at 1 000 mg/kg/day.

Macroscopic Pathology:
No changes attributable to treatment.

Microscopic Pathology:
No treatment related changes were observed. Changes in organ weights noted above were not supported by histological changes.

Comment:
There were no mortalities or clinical signs or differences from control animals for parameters measured, including bodyweight, food consumption, haematology, biochemistry, neurobehavioural screening, organ weights and histopathology that were considered to be related to treatment. Therefore, the no observed adverse effect level (NOAEL) is established at 1 000 mg/kg/day the highest dose tested.

Result:
The NOAEL established for this 28 day oral study is 1 000 mg/kg/day.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Huntingdon Life Sciences Ltd, 1998f)

Strains:	*Salmonella typhimurium* TA98, TA100, TA1535, TA1537; *E.Coli WP2uvrA/pKM101*.
Metabolic activation system:	Liver S9 mix from rats pretreated with Aroclor 1254.
Concentration range:	Test substance tested in triplicate in two independent experiments with and without metabolic activation at concentrations of: Experiment 1: 0, 5, 15, 50, 150, 500, 1 500, or 5 000 μg/plate. Experiment 2: 0, 50, 150, 500, 1 500, or 5 000 μg/plate. Appropriate strain specific positive controls were used. Solvent: acetone.
Test method:	OECD TG 471 & 472 – pre incubation method
Comment:	No toxicity was observed at up to 5 000 μg/plate. No increased incidence of revertant colony numbers were obtained with any of the tester strains at any concentration in either the presence or absence of metabolic activation. It was concluded that the test substance did not exhibit any mutagenic activity under the conditions of the test. Positive controls induced marked increases in revertant colony numbers.
Result:	The notified chemical was non mutagenic under the conditions of the test.

9.3.2 Chromosomal Aberration Assay (Huntingdon Life Sciences Ltd, 1997)

Cells: Human peripheral lymphocytes

Metabolic activation system: Supplemented liver preparation (S9 mix) prepared from animals previously treated with Phenobarbital and 5,6-benzoflavone.

Test method: OECD TG 473

Dosing schedule:

Metabolic Activation	***Test concentration (μg/mL)***	***Controls (μg/mL)***
-S9	Experiment 1: 0, 39.06, 78.13, 156.3, 312.5, 625, 1 250*, 2 500*, 5 000*. treatment/harvest time = 3/19 hours.	+ve: MMC (0.1) -ve: culture medium.
	Experiment 2: 0, 312.5, 625, 1 250*, 2 500*, 5 000*. treatment/harvest time = 3/19 hours.	
+S9	Experiment 1: 0, 39.06, 78.13, 156.3, 312.5, 625, 1 250*, 2 500*, 5 000*. treatment/harvest time = 3/19 hours.	+ve: CP (6) -ve: culture medium.
	Experiment 2: 0, 312.5, 625, 1 250*, 2 500*, 5 000*. treatment/harvest time = 3/19 hours. treatment/harvest time = 19/19 hours.	

MMC – mitomycin C.
CP – cyclophosphamide.
* - cultures selected for metaphase analysis.

Observations: Toxicity was not observed at the highest dose tested in either experiment.
In the absence of S-9 mix, increases in the frequency of metaphases with aberrant chromosomes were observed at all concentrations (including gaps, $p<0.05$) in the first test.
In the presence of S-9 mix, increases in the frequency of metaphases with aberrant chromosomes were observed at all concentrations (including and excluding gaps, $p<0.05$ in the first test, and at 1 250 μg/ml (excluding gaps, $p<0.05$) and 5 000 μg/ml (including gaps, $p<0.05$) in the second test.
The positive control substances induced significant increases in

the frequency of metaphases with aberrant chromosomes compared to the vehicle control.

The study authors considered the increases observed with the test substance as not biologically significant based on the lack of biological relevance (gap type aberrations), reproducibility between experiments and historical control values.

Result: The notified chemical was not considered clastogenic under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity and low acute dermal toxicity. Inhalation studies were not conducted. The notified chemical was a transient, very slight eye irritant but was not irritating or sensitising to skin.

A 28 day repeat oral dose study in rats did not reveal treatment related changes when administered at up to 1 000 mg/kg/day, taken as the NOAEL.

The notified chemical did not display mutagenic activity in bacteria and did not show evidence of clastogenic activity in an *in vitro* human lymphocyte chromosomal aberration study.

Based on the data provided the notified chemical would not be classified as a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Tests were performed according to corresponding EEC and OECD test guidelines (European Commission, 1992, OECD, 1995-1996) at Huntingdon Life Sciences Testing Facilities, UK. These facilities comply with the OECD principles of good laboratory practice and full test reports were submitted. All tests were performed on the notified chemical.

10.1.1 Summary of Sakuralube 500 Test Results

Test	*Species*	*Results*
Acute Toxicity	Rainbow Trout	LL_{50} (96 h) > 2.11 mg/L
[OECD 203]	*Oncorhynchuc mykiss*	NOEC (96 h) > 2.11 mg/L
Acute Immobilisation	Water Flea	EL_{50} (48 h) > 0.1 mg/L
[OECD 202]	*Daphnia magna*	NOEC (48 h) > 0.1 mg/L
Growth Inhibition	Alga	ELr_{50} (72 h) > 5.8 mg/L
[OECD 201]	*Scenedesmus capricornutum*	NOEC > 5.8 mg/L
Inhibition of Bacterial Respiration	Sewage Bacteria	No inhibition

10.1.2 Fish Acute Toxicity (Huntingdon Life Sciences Ltd, 1998d)

The tests on fish were performed using a static methodology with 80% renewal at 24, 48 and 72 hours. The test was conducted using a single water accommodation fraction (WAF) of the test substance made up in purified water at a nominal concentration of 10 mg/L (water solubility = 0.54 mg/L at 25ºC). The WAF was prepared by adding a suspension of the test substance made up at a nominal loading of 130 mg/L then diluting to 13 L. This mixture was stirred for 3 hours prior to adding the fish. A control test was run in parallel. Ten fish were added to both the test vessel and to the control vessel, and the temperature was maintained 13.9 ± 0.5 ºC, pH between 7.5 and 8.2 and dissolved oxygen levels between 85% and 105% of the saturation value. Water hardness was around 220 mg/L as $CaCO_3$.

No mortality was observed, but some "nervous" behaviour and hyperventilation was observed in one or two fish throughout the test period. However, these effects did not increase with time and it is to be noted that one of the fish in the control also exhibited aggressive behaviour. Since these effects were of low level and did increase with time, it is possible that they were associated with the experimental set up, or the fish population. Consequently, no inferences as to toxic effects of the test substance may be drawn from these observations. The results from this test indicate that the chemical is not toxic to this species of fish up to the limit of its water solubility. However, analysis of the test media for actual concentrations (see further below) indicated possible incomplete solubilisation of the compound, and consequently this conclusion should be qualified in respect of possible low true exposures of the fish to the test substance.

The actual levels of test compound in the (unfiltered) water were measured at 24, 72 and 96 hours after the beginning of the test, and indicated loadings of the test substance between 1.8 and 2.36 mg/L (geometric mean calculated as 2.11 mg/L). This "fall off" may indicate that during the course of the test the chemical had adsorbed to the sides of the test vessel, the fish or to other pieces of test equipment. However, it is also to be noted that analysis of filtered water invariably indicated concentrations < 0.096 mg/L (the detection limit of the analytical system used), which is well below the actual measured water solubility of the substance (ie 0.54 mg/L at 25ºC), and this result indicates that actual exposure of the fish to the substance may have been significantly less than indicated above.

10.1.3 Aquatic Invertebrate Acute Toxicity (Huntingdon Life Sciences Ltd, 1998c)

The immobilisation tests with daphnia were also performed under static conditions using a WAF prepared with a nominal loadings of the test substance of 10 mg/L, in the same manner as described above for the fish test. The temperature, pH and dissolved oxygen levels during the tests were respectively 20.1 ± 0.2ºC, 7.7 ± 0.1 and 90%-98% of saturation, while water hardness was around 234 mg/L as $CaCO_3$. The test and the control was conducted using four replicates with five daphnia per test vessel. None of the daphnia were immobilised over the 48 hour duration of the test, and no other adverse effects were observed. It was concluded that the test substance is not toxic to daphnia up to the limit of its water solubility.

The actual levels of test substance in the (unfiltered) water were measured at 24 and 48 hours after the beginning of the test, and indicated actual loadings of the test substance of 7.8 and 0.1 mg/L respectively. This dramatic "fall off" may indicate that the chemical had adsorbed to the sides of the test vessel, or to other pieces of test equipment. As above, the conclusions on toxicity should be seen in conjunction with possible low true exposures.

10.1.4 Alga Growth Inhibition Test (Huntingdon Life Sciences Ltd, 1998e)

Tests on algal growth inhibition were also performed with a WAF made up at a nominal concentration of 10 mg/L. The mean temperature throughout the test was 22.6ºC. Both growth of algal biomass and the rate of biomass growth were monitored over the 72 hour test period, and no significant reduction in the growth of algal biomass compared with that of the controls was observed. The results indicate that the notified chemical is not toxic to this species of algae up to the limit of its water solubility.

The actual loading of the test substance in the (unfiltered) test medium was measured after 72 hours as 5.78 mg/L.

Microscopic examination of the algal cells after 72 hours exposure to a nominal 100 mg/L of the test substance revealed no cellular abnormalities.

10.1.5 Microorganisms

No definitive test on inhibition of bacterial respiration was conducted, but during the tests for biodegradation a test conducted in bottles containing both the notified chemical substance (at 2 mg/L) and sodium benzoate (at 2 mg/L) indicated the expected biodegradation rate for the sodium benzoate, and that the test substance was not inhibitory to the sewage bacteria.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical is considered to be small provided that the material is used as indicated, and that disposal of spent oil takes place via the routes indicated above. As a component of automotive lubricants, the notified material has the potential to be released to the environment during lubricant change, but losses during lubricant formulation and transfer to engine crankcases would be small. It is expected that around 86% of contained material (a maximum of 8.6 tonnes per annum) would be destroyed through incineration and/or oil recycling activities. About 14% of the material will be used by automobile enthusiasts, and it is expected that much of this will be released through disposal into landfill, used in treating fence posts and released by other routes. Some of the chemical (estimated at around 35 kg per year) may enter stormwater drains as a result of inappropriate disposal of used oil.

It is difficult to estimate the Predicted Environmental Concentration (PEC) of released lubricant additives because of the diverse disposal routes. However, a worst case PEC may be estimated if it is assumed that all the lubricants using the notified chemical are used in a single metropolitan area of 500 square kilometres, with an average annual rainfall of 50 cm and that 50% of the used oil is eventually washed into the stormwater channels and drained away. If it is further assumed that none of the notified chemical is destroyed during combustion in the engines, then the maximum annual release into this localised stormwater system would be around 5 tonnes. The annual volume of water drained from this region would be approximately 250 x 10^6 m^3, and the resultant PEC is approximately 20 μg/L. The material is not toxic to the fish, invertebrate and algal species against which it has been tested up to the limit of its water solubility, and the PEC is several orders of magnitude below possible toxic levels. However, it should be noted that the actual ecotoxicity results may reflect very low actual exposure levels compared with the nominal 10 mg/L loading at which the tests were conducted – see Environmental Effects.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical was of very low acute oral toxicity and low acute dermal toxicity in rats. Inhalation studies were not conducted: the physiochemical properties of the notified chemical are considered to limit inhalation exposure. The notified chemical was a transient, very slight eye irritant in rabbits but was not irritating or sensitising to skin in rabbits or guinea pigs, respectively. A 28 day repeat oral dose study in rats did not reveal treatment related changes when administered at up to 1 000 mg/kg/day, taken as the NOAEL. The notified chemical did not display mutagenic activity in bacteria and did not show evidence of clastogenic activity in an *in vitro* human lymphocyte chromosomal aberration study. Based on the data provided the notified chemical would not be classified as a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

Sakuralube 100, containing the notified chemical at 25% also contains di(2-ethylhexyl) phthalate (DEHP) solvent. The IARC carcinogen classification for DEHP is Group 2B. DEHP causes hepatic, reproductive and developmental effects in animals. The national exposure standard for DEHP is 5 mg/m^3 TWA, 10 mg/m^3 STEL.

Occupational Health and Safety
The available toxicological data does not reveal any occupational hazards of concern for the notified chemical. However, the solvent base is hazardous and stringent controls are required in the workplace to prevent exposure.

During import and transport of the notified chemical in Sakuralube 100, there is unlikely to be any worker exposure, except in the event of a spill. Exposure after a spill would be controlled by use of the recommended practices for spillage clean up given in the MSDS supplied by the notifier.

At the blending facility, exposure to Sakuralube 100 during transfer operations may occur as delivery lines are connected/disconnected, during equipment maintenance and drum disposal. Dermal exposure is expected to be infrequent and minimal, as these activities will occur infrequently (twice per year), the blending process is highly automated and engineering controls exist. Local exhaust ventilation is in place to control inhalation exposure. Workers also wear personal protective equipment, namely industrial canister gas mask, chemical safety goggles, cuffed butyl rubber or PVC gloves and anti static work clothes and boots. Therefore, the risk of adverse health effects arising from exposure of workers to Sakuralube 100 is low.

Service station workers and mechanics will receive negligible exposure because of the very low concentration (less than 1%) of the notified chemical present in the finished engine oil.

Public Health
Some of the lubricant products containing the notified chemical will be for sale to the general public. Home mechanics could therefore be exposed to the notified chemical while changing the engine oil of their automobile. This is not likely to be a regular activity and public exposure to the notified chemical throughout all phases of its life cycle is considered to be low. Based on the above information, it is considered that the notified chemical will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

Occupational Health and Safety

To minimise occupational exposure to Sakuralube 100 the following guidelines and precautions should be observed:

- The workplace be assessed for health risks in accordance with the *National Model Regulations for the Control of Workplace Hazardous Substances* (NOHSC, 1994b). Exposure to di(2-ethylhexyl) phthalate in the workplace should be controlled to well below the national exposure standard of 5 mg/m^3 TWA, 10 mg/m^3 STEL (NOHSC, 1995).

- Respiratory protection to conform to Australian/New Zealand Standard (AS/NZS) 1715-1994 (Standards Australia/Standards New Zealand, 1994a) and AS/NZS 1716-1991 (Standards Australia/Standards New Zealand, 1994b); Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with AS/NZS 1337 (Standards Australia/Standards New Zealand, 1992); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990); impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994c);

- Spillage of the notified chemical 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.

Public Health

If the conditions of use are varied, then greater exposure of the public may occur. In such circumstances, further information may be required to assess the hazards to public health.

14. MATERIAL SAFETY DATA SHEET

The MSDS for Sakuralube 500 (notified chemical) and Sakuralube 100 (containing the notified chemical) were provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

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

16. REFERENCES

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Standards Australia/Standards New Zealand (1994b) AS/NZS 1716-1994, Australian/New Zealand Standard Respiratory Protective Devices. Sydney/Wellington, Standards Australia and Standards New Zealand.

Standards Australia/Standards New Zealand (1994c) AS/NZS 2210-1994, Australian/New Zealand Standard Occupational Protective Footwear. Sydney/Wellington, Standards Australia and Standards New Zealand.

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