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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Component 2 of OLOA 249S

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Director
NICNAS

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Component 2 of OLOA 249S

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Chevron Oronite Australia (ABN: 16 101 548 716)
Level 8, 520 Collins St
Melbourne, Victoria, 3000

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical name
CAS number
Molecular formula
Structural formula
Molecular weight
Spectral data
Purity
Identity of toxic impurities
Non-hazardous impurities
Identity and percentage of additives
Manufacture or import volumes
Identity of manufacturing sites

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

Estimates: log Kow, boiling point, melting point, vapour pressure, water solubility, soil adsorption, ready biodegradation.

Tests on analogous chemical: Water solubility, all toxicology and environmental tests.

Not supplied: hydrolysis as a function of pH, dissociation constant, particle size, flammability limits, autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
Canadian New Substances Notification (2004)
Korean New Substances Notification (2004)
U.S. Pre-Manufacture Notification (2004)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
The notified chemical is found at 50-80% concentration in OLOA 249S, OLOA 247S, OLOA 247Z and OLOA 246S.

METHODS OF DETECTION AND DETERMINATION

METHODS Infrared Spectroscopy

3. COMPOSITION

DEGREE OF PURITY
>80%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia as part of a lubricant additive package.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-100	10-100	10-100	10-100	10-100

USE
The notified substance will be used as a detergent additive at 1-5% concentration in formulations for automotive and diesel engine crankcase oils, air and water-cooled two-cycle engine oils, industrial oils, hydraulic fluids, and gear oils.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The notified chemical will be transported either: by ship and offloaded to tank trucks or rail cars for distribution to a blending facility; or by drum which will be shipped directly to the customer. After blending, the finished lubricant will be shipped in drums or 1-4L containers.

5.2. Operation description

At blending sites, the notified chemical will the transferred from drums, rail cars and tank trucks into storage tanks. The transfer process from the tank truck occurs by use of flexible 10 cm hosing.

Transfer from storage tanks to blend tanks will be automated, using computer controlled valves. The additive package containing 7-70% of the notified substance is blended into the finished lubricant, which contains the notified chemical at 1-5% concentration. The blending process occurs in a closed system at 60°C and is computer controlled. The blended lubricant is transferred automatically to a storage tank. The finished lubricants are then packaged for shipment in drums, 1-4L containers, or bulk tank trucks.

The drumming facility uses automated weight scales to fill the drums, and worker exposure may occur as the operator watches (from about 1-2 meters away) to ensure the drum filling mechanism properly enters the drum before the drum is filled. The bungs and labels are put on by the operators. Bulk tank truck or rail car filling is performed by a transfer hose. The small container packaging machine is a fully-automated machine and will fill 1-4L containers.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Analysing additive package on arrival	1	10 mins	30 d/yr
Unloading tanks trucks and drums	1-2	30 mins	30 d/yr
Sampling finished oil	1-2	10 mins	220 d/yr
Loading finished oil into tank trucks	1-2	30 mins	220 d/yr
Commercial end users	>1000	8 hours	220 d/yr

Exposure Details

Warehousing and transport:

These workers would only be exposed to the notified chemical in the case of accidental rupture of the containers.

Formulation:

At blending sites, the notified chemical will be transferred from drums, rail cars and tank trucks into storage tanks. During connection and disconnection of lines, incidental skin contact from splashes, drips and spills is possible. The transfer process from the tank truck occurs by use of a 10 cm hose. Connection of the hose takes 10 minutes. A special air back flush system is used to prevent spillage during transfer.

Transfer from storage tanks to blend tanks will be automated, using computer controlled valves. The blending process occurs in a closed system at 60°C and is computer controlled, and thus there should be no exposure at this stage. The blended lubricant is then transferred automatically to a storage tank, and then packaged for transport. The finished oil will likely be transported in the following manner: 50% in drums, 40% in 1-4L containers and 10% in tank trucks.

Workers may be exposed to the finished lubricant (containing the notified chemical at 1-5%) during the drum filling operations. The drumming facility uses automated weight scales to fill the drums, and worker exposure may occur as the operator watches (from about 1-2 meters away) to ensure the drum filling mechanism properly enters the drum before the drum is filled. The bungs and labels are put on by the operators.

The 1-4L container packaging machine is a fully-automated process. Again, worker exposure may occur as the operator watches (from about 1-2 meters away) to ensure the filling mechanism properly enters the container before it is filled.

If any transfer to bulk containers is necessary, it is performed as described above for transport from bulk containers into storage tanks. Dermal exposure to drips and spills of blended lubricant is possible during the connection and disconnection of transfer hoses during the filling of bulk containers.

Laboratory staff will take samples of the notified chemical in the additive package as well as the blended oil products for testing. During sampling and analysis of the additive package there may be skin contact. However, minimal exposure will occur during the laboratory testing since it will occupy only a few minutes per batch.

The blending facilities are well ventilated, with control systems for accidental spills and wastewater treatment. Workers involved in the blending activities receive training in the handling of active packages, and wear personal protective equipment (PPE) such as gloves, eye protection, protective clothing and hard hats.

End Users:

The drums (50% of the total notified chemical) and some of the small containers (10% of the total notified chemical) will be sold to commercial automotive engine service outlets (i.e. auto repair shops). A pneumatic pump, which will pump the finished lubricant, will be inserted into the drum. It is estimated that it will take one worker 10 minutes to insert the pump. In many cases, stationary engines

will be routinely lubricated using dedicated lubricating oil reservoirs and piping to add fluids directly without human intervention. For non-stationary automotive applications, workers will check lubricant levels in the engine manually and top-off as needed using fluids added via pneumatic delivery systems. Most of the commercial end users will recycle their used oil obtained from engine oil drains occurring during routine maintenance and repair work.

The bulk product (10% of the total notified chemical) will be sold to high volume commercial end users, such as truck and taxi fleets, where it will be used to lubricate gasoline and diesel engines. In the industrial and commercial environment, engines are maintained by highly trained professional mechanics, who are likely to have access to engineering controls. In many cases, stationary engines will be routinely lubricated using dedicated lubricating oil reservoirs and piping to add fluids directly without human intervention. For non-stationary automotive applications, workers will check lubricant levels in the engine manually and top-off as needed using fluids added via pneumatic delivery equipment. It is likely that all of these end users will recycle their used oil.

Some small containers (30% of the total notified chemical) will be sold to service stations and consumer users.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical is not manufactured in Australia. During blending, release to the environment may occur in the unlikely event of an accident during transport or an accidental leak. An air back flush system is used to prevent spillage during transfer from rail, cars or tank trucks into storage tanks at the blending facilities. The formulation processes occur in a closed system and are highly automated therefore losses are not expected. The isotanks, drums and blending equipment will be rinsed with clean lubricating oil, which will be used in the future blends or incinerated. In the unlikely event of an accident, the spillage will be contained within concrete bunds and either reclaimed or sent to on-site wastewater treatment facilities where residual hydrocarbon based products will be separated from the aqueous stream by the Australian Petroleum Industry (API) process, with a claimed removal of greater than 95%. The aqueous waste undergoes further treatment involving pond aeration and biological treatment before being released to the sewage system. The remaining oily waste will be incinerated. As a result of these processes, the accidental release from transport of the additive package and finished oils is unlikely to be significant.

Empty drums are steam cleaned with the resultant aqueous waste sent to on-site wastewater facilities. It is estimated that 7 kg of the notified chemical will be sent to the wastewater treatment per year, based on the maximum import of notified chemical.

RELEASE OF CHEMICAL FROM USE

Some minor and diffuse exposure will result from spills during addition of oil to vehicles. However, the greatest potential for exposure is through disposal of waste oil containing the additive.

A survey by the Australian Institute of Petroleum (AIP, 1995) indicates that of the annual sales of automotive engine oils in Australia, some 60% are potentially recoverable (ie not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases could be expected to be disposed of responsibly - either to oil recycling or incineration. The remaining 14% are removed by “do it yourself” (DIY) enthusiasts, and in these cases some of the used oil would be either incinerated, left at transfer stations where it is again likely to be recycled, or deposited into landfill. A recent report estimated that DIY activities account for between 7 to 10% of the unaccounted for used oil (Meinhardt, 2002).

According to a survey tracing the fate of used lubricating oil in Australia (Snow, 1997) only around 20% of used oil removed by enthusiasts is collected for recycling, approximately 25% is buried or disposed of in landfill, 5% is disposed of into stormwater drains and the remaining 50% is used in treating fence posts, killing grass and weeds or disposed of in other ways.

Consequently, assuming that oil removed by professional mechanics is disposed of appropriately (ie burning as workshop heating oil or sent for recycling), negligible release of the notified chemical

should result from these professional activities. Assuming a worst case scenario of 14% of the used oil removed by the DIY enthusiasts, this oil will have the following fates: oil to be collected for recycling (up to 2.8 tonnes), buried or disposed of in landfill (up to 3.5 tonnes), disposed into stormwater drains (up to 700 kg) and used in treating fence posts, to kill weeds or disposed of in other ways (up to 7 tonnes), respectively.

Since gear oil and hydraulic fluid changes are likely to be carried out by specialists, and will be disposed of more appropriately, an amount less than 1% of the total import volume of the notified substance could be expected to enter the aquatic environment via disposal into the storm water system. Since the use of the lubricating oils will occur throughout Australia, all releases resulting from use or disposal of used oil will be very diffuse, and release of the notified material in high concentrations is very unlikely except as a result of transport accidents.

5.5. Disposal

Drums are sent to drum recyclers where they are steam cleaned and the water sent to wastewater treatment. It is assumed 0.1% of the chemical remains after use. Small containers sold to consumers are likely to be sent to landfill.

5.6. Public exposure

It is expected that during transport and storage, and replenishment of lubricant oil at service garages, exposure of the general public to the notified chemical will be low, except in the event of an accidental spill.

Up to 30% of the notified chemical will be reformulated and packaged in small containers for sale to service stations and the general public. Public exposure to the notified chemical may occur during do-it-yourself replenishment of lubricant, through spills, splashes and contact with runs or drips on the outside of the container after filling. Exposure is also possible while handling automotive components that have been in contact with the lubricant. Exposure is likely to be by the dermal route, with the possibility of ocular and inadvertent oral exposure. It is unlikely that PPE will be worn.

6. PHYSICAL AND CHEMICAL PROPERTIES

No experimental data on the notified chemical have been provided, with all the values given here estimated using EPI Suite (US EPA) or using analogue chemicals.

Appearance at 20°C and 101.3 kPa Dark brown viscous liquid

Melting Point/Freezing Point Not measured.
METHOD Estimated using EPI Suite to be 278 – 332°C

Boiling Point Not measured.
METHOD Estimated using EPI Suite to be 640 – 756°C at 101.3 kPa

Density Not measured.
Remarks Estimated using EPI Suite to be <1000 kg/m^3

Vapour Pressure Not measured.
Remarks Estimated using EPI Suite to be <10^{-15} kPa at 25°C

Water Solubility 4.79 x 10^{-4} g/L

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks
Flask Method.
TEST FACILITY SPL (2004)

Hydrolysis as a Function of pH Not determined

Remarks The notified chemical is unlikely to hydrolyse as there are no hydrolysable groups present.

Partition Coefficient (n-octanol/water) Not measured.

Remarks Estimated using EPI Suite to be 9.50-12.45.

Adsorption/Desorption Not measured.

Remarks Estimated using EPI Suite to be 7.46-9.05.

Dissociation Constant Not measured

Remarks The notified chemical is an anionic chemical that is expected to be fully dissociated under normal environmental conditions.

Particle Size Not measured.

Remarks Not applicable, as the notified chemical is a liquid.

Flash Point Not measured.

Remarks Estimated from analogous chemicals to be 150-160°C

Flammability Limits Not measured.

Autoignition Temperature Not measured.

Explosive Properties Not expected to be explosive.

Reactivity

Remarks May react with strong oxidising agents, such as chlorates, nitrates and peroxides. Hazardous polymerisation will not occur.

7. TOXICOLOGICAL INVESTIGATIONS

The following data have been provided for analogous chemicals (at 50% weight in a highly refined mineral oil) that are considered to be acceptable analogues of the notified chemical.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >5000 mg/kg bw	low toxicity
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity
Rat, acute inhalation toxicity	not performed
Rabbit, skin irritation	moderately irritating
Rabbit, eye irritation	slightly irritating
Skin sensitisation (human patch test)	non-irritating and no evidence of sensitisation
Guinea pig, skin sensitisation non-adjuvant test.	evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL 150 mg/kg bw/day
Reproductive toxicity – one generation study.	NOEL >500 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vivo Mammalian Erythrocyte Micronucleus Test.	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Analogous chemical
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/Sprague-Dawley
Vehicle	None.
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	5000	0

LD50	>5000 mg/kg bw
Signs of Toxicity	None.
Effects in Organs	None.
Remarks - Results	None.

CONCLUSION	The analogous chemical is of low toxicity via the oral route.
TEST FACILITY	Pharmakon (1997a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Analogous chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Sprague-Dawley
Vehicle	None.
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	None.
Signs of Toxicity - Systemic	One treated female showed low body weight gain, however this is likely incidental.
Effects in Organs	None.
Remarks - Results	None.
CONCLUSION	The analogous chemical is of low toxicity via the dermal route.
TEST FACILITY	Pharmakon (1997b)

7.3. Acute toxicity – inhalation

Not performed.

7.4. Irritation – skin

TEST SUBSTANCE	Analogous chemical
METHOD	0.5 mL of test substance was applied to three clipped, intact areas on the back of each of six rabbits for four hours under occlusive dressings. After exposure, the exposed areas were wiped with mineral oil. Irritation was scored at 1, 24, 48 and 72 hours and 7 and 14 days, using a modified Draize scoring method.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Vehicle	None.
Observation Period	14 days.
Type of Dressing	Occlusive.
Remarks - Method	None.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	1.93	4	7 days	0
Oedema	0.15	2	72 hours	0

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

Remarks - Results	After 1 hour, all animals exhibited well defined to moderate erythema. Over the next 48 hours, the severity of the irritation was reduced in only one animal, and progressed to severe erythema and eschar in one animal. At 72 hours, two animals exhibited severe erythema and eschar, with the other animals exhibiting slight to moderate erythema. At seven days the worst-affected animal still displayed well-defined erythema, which cleared after 14 days.

All animals had dry/flaky skin at 72 hours and/or 7 days.

The individual mean values over 72 hours for the six animals are: 3.7, 2.4, 1.7, 1.7, 1.4, 0.7.

CONCLUSION The analogous chemical is moderately irritating to the skin.

TEST FACILITY CEHC (1989a)

7.5. Irritation – eye

TEST SUBSTANCE Analogous chemical

METHOD 0.1 mL of test substance was applied to the conjunctival sac of one eye of each of nine rabbits. After a 30-second exposure, the eyes of three rabbits were washed with water for one minute. Irritation was scored at 1, 24, 48 and 72 hours, using a modified Draize scoring method.

Species/Strain	Rabbit/New Zealand White
Number of Animals	9
Observation Period	72 hours
Remarks - Method	No significant protocol deviations.

RESULTS

Treated-unrinsed

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0	3	1 hour	0
Conjunctiva: chemosis	0	1	1 hour	0
Conjunctiva: discharge	0	3	1 hour	0
Corneal opacity	0	0	0	0
Iridial inflammation	0	0	0	0

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

Treated-rinsed

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0	3	1 hour	0
Conjunctiva: chemosis	0	1	1 hour	0
Conjunctiva: discharge	0	2	1 hour	0
Corneal opacity	0	0	0	0
Iridial inflammation	0	0	0	0

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

Remarks - Results All effects had a maximum duration of 1 hour.

CONCLUSION The analogous chemical is slightly irritating to the eye.

TEST FACILITY CEHC (1989b)

7.6. Skin sensitisation – 5% challenge

TEST SUBSTANCE Analogous chemical

METHOD OECD TG 406 Skin Sensitisation – Buehler test
EC Directive 96/54/EC B.6 Skin Sensitisation - Buehler test

Species/Strain Guinea pig/Hartley

Vehicle	Mineral oil	
PRELIMINARY STUDY	Maximum Non-irritating Concentration: None determined. Maximum score at 0.5% (w/v) was 1.	
MAIN STUDY		
Number of Animals	Test Group: 10/sex	Control Group: 10/sex
INDUCTION PHASE	Induction Concentration: Topical: 100%	
Signs of Irritation	Erythema, up to score 2.	
CHALLENGE PHASE		
1st challenge	Topical: 5%	
2nd challenge	Topical: 5%	
3rd challenge	Topical: 0.5%	
Remarks - Method	No significant protocol deviations.	

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions* after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	5%	17/20	19/20	19/20	19/20
	0.5%			8/20	15/20
Control Group	5%	0/10	0/10	0/10	0/10
	0.5%			0/10	0/10

*Animals with a response of 2 or more.

Remarks - Results	Controls exhibited scores of 1, at most. Animals scored as positive at challenge or rechallenge had scores of 2 or more.
CONCLUSION	There was evidence indicative of skin sensitisation to the analogue chemical under the conditions of the test.
TEST FACILITY	HTR (1995)

7.7. Skin sensitisation – 50% challenge

TEST SUBSTANCE	Analogous chemical	
METHOD	OECD TG 406 Skin Sensitisation – Buehler test EC Directive 96/54/EC B.6 Skin Sensitisation - Buehler test	
Species/Strain	Guinea pig/Hartley	
Vehicle	Mineral oil	
PRELIMINARY STUDY	Maximum Non-irritating Concentration: None determined. Maximum score at 0.5% (w/v) was 1.	
MAIN STUDY		
Number of Animals	Test Group: 10/sex	Control Group: 5/sex
INDUCTION PHASE	Induction Concentration: Topical: 100%	
Signs of Irritation	Erythema, up to score 2.	
CHALLENGE PHASE		
1st challenge	Topical: 50%	
Remarks - Method	No significant protocol deviations.	

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions* after: 1st challenge*	
		24 h	*48 h*
Test Group	50%	4/20	7/20
Control Group	50%	0/10	0/10

*Animals with a response of 2 or more.

Remarks - Results: Controls exhibited scores of 1, at most. Animals scored as positive at challenge or rechallenge had scores of 2 or more.

CONCLUSION: There was evidence indicative of skin sensitisation to the analogue chemical under the conditions of the test.

TEST FACILITY: HTR (1991)

7.8. Skin sensitisation – human volunteers

TEST SUBSTANCE: Analogous chemical

METHOD

Study Design: Pilot phase: Test substance was applied undiluted, and at 50%, 25% and 10% in mineral oil. 0.2 mL was applied under occlusive dressing, for 24 hours.

Induction Procedure: Nine consecutive applications of 0.2 mL undiluted test substance under occlusive dressing for 24 hours each.

Rest Period: 14 days.

Challenge Procedure: Application of 0.2 mL of test substance to a naïve location under occlusive dressing for 24 hours.

Study Group: 101 subjects between 21 and 60 years old.

Vehicle: None.

Remarks - Method: Nineteen subjects completed a one week pilot phase to determine the appropriate concentration to be used in the main study and continued on with the main study.

RESULTS

Remarks - Results: One subject was discontinued from the test due to pruritis on the left arm, which was regarded by the consulting dermatologist as unrelated to exposure to the test product.

No other significant irritation was observed.

There was no evidence of sensitisation in the test.

CONCLUSION: A repeat insult patch test was conducted using undiluted analogous chemical under occlusive dressing. The analogous chemical was non-irritating and non-sensitising under the conditions of the test.

TEST FACILITY: CRTC (1991)

7.9. Repeat dose toxicity

TEST SUBSTANCE: Analogous chemical

METHOD: OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain	Rat/Sprague Dawley Crl:CD(SD)IGS BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Corn oil
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	10/sex	0	0
II	10/sex	50	0
III	10/sex	150	0
IV	10/sex	500	0
V	10/sex	1000	0
VI (control recovery)	10/sex	0	0
VII	10/sex	1000	0

Mortality and Time to Death

None.

Clinical Observations

Significantly lower body weight gain was noted in males receiving 500 and 1000 mg/kg bw/day, with overall weight gain being 9% and 6% lower than controls at the end of treatment. Food consumption was also significantly decreased in group 4 males during week 3.

The differences seen between groups in the functional observation battery were not dose related and were not considered to be treatment related.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Platelet counts were significantly increased on day 28 in males receiving 500 and 1000 mg/kg bw/day. This is unlikely to be toxicologically relevant as abnormalities in platelet count generally manifest as decreases.

Gamma-glutamyl transferase (GGT) was significantly increased in males in all treated groups, however this was thought to be the result of an abnormally low concentration observed in the control group.

Serum alanine amino transferase (ALT) was significantly increased on day 28 in high-dose males (52%) and females receiving 500 and 1000 mg/kg bw/day (108% and 144%), and increased (not significantly) by 42% in 500 mg/kg bw/day males and 36% in 150 mg/kg bw/day females. These changes were not supported by changes to other indicators of hepatic injury.

Phosphorus was significantly increased by 9% in 1000 mg/kg bw/day males. This was considered incidental in the absence of any related findings.

Other changes to hematology and blood chemistry did not show a dose response, or occurred in the recovery period only, and were not considered to be treatment related.

Effects in Organs

The most notable findings at the day 28 necroscopy involved the stomach:

Group	*50 mg/kg bw/day*	*150 mg/kg bw/day*	*500 mg/kg bw/day*	*1000 mg/kg bw/day*
Males	-	-	(2/5) Thickening (2/5) Minimal oedema of submucosa	(4/5) Thickening (2/5) Minimal/mild oedema of submucosa (3/5) Minimal epithelial hyperplasia
Females	(1/5) Thickening	(1/5) Thickening (1/5) Foci (2/5) Minimal oedema	(1/5) Thickening (1/5) Foci (1/5) Ulcer, mild	(1/5) Thickening (1/5) Minimal oedema of submucosa

		of submucosa	oedema of submucosa, minimal haemorrhage, minimal epithelial hyperplasia, mild inflammation	(2/5) Minimal epithelial hyperplasia

There were no notable findings in the stomachs of animals after the recovery period, or in control animals.

The liver-to-body weight ratio were significantly increased in 1000 mg/kg bw/day males (19%) and 500 and 1000 mg/kg bw/day females (11% and 20% respectively). There were no unusual microscopic findings in the livers of any animals.

Thymus weights were decreased in 1000 mg/kg bw/day males. This was considered to be incidental in the absence of any related findings.

Minimal to mild pulmonary irritation was seen at day 28 in one male and two females receiving 1000 mg/kg bw/day, and in three males and one female after the recovery period. This irritation most likely arises from a foreign body response to incidentally aspirated test article.

Other changes to organs did not show a dose response relationship, and were not considered to be treatment related.

Remarks – Results

The main toxicologically relevant findings were related to irritation of the stomach. One female receiving 500 mg/kg bw/day had severe stomach irritation, including an ulcer.

There was also some evidence of test-substance-related changes to the liver (increased liver weight, increased serum ALT). These were statistically significant in both sexes at 500 mg/kg bw/day and above, with non significant trends in serum ALT at 150 mg/kg bw/day. However there were no microscopic findings or supporting blood chemistry findings, and there was full recovery, indicating that these were most likely adaptive changes.

Body weight gain and food intake was slightly decreased in high dose males.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 150 mg/kg bw/day in this study, based on a stomach ulcer and related findings in one female treated with 500 mg/kg bw/day.

TEST FACILITY SLI(2002)

7.10. Toxicity to reproduction – one generation study

TEST SUBSTANCE Analogous chemical

METHOD OECD TG 415 Reproductive toxicity test

Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Exposure period - female: At least 14 days prior to mating through lactation day 20. Exposure period - male: At least 70 days prior to mating
Vehicle	Corn oil
Remarks – Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
1	28/sex	50	0
2	28/sex	167	0
3	28/sex	500	0

Mortality and Time to Death
None.

Effects on Parental (P) animals:
Slightly decreased mean absolute weight and mean relative to body weight for the epididymides at 500 mg/kg bw/day. In the absence of any other findings, this was not considered toxicologically relevant.

Other changes did not show any dose response relationship and thus were not considered to be treatment related.

Effects on 1st Filial Generation (F1)
Any changes did not show any dose response relationship and thus were not considered to be treatment related.

Remarks - Results
None.

CONCLUSION
The No Observed Effect Level (NOEL) for reproductive effects was established as 500 mg/kg bw/day in this study, based on no significant findings at any dose level.

TEST FACILITY SLI (2004)

7.11. Genotoxicity – bacteria

TEST SUBSTANCE Analogous chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 97/69/EC Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2*uvr*A
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction
Concentration Range in Main Test	a) With metabolic activation: 100, 250, 500, 1000, 5000, 10000 µg/plate b) Without metabolic activation: 100, 250, 500, 1000, 5000, 10000 µg/plate
Vehicle	None.
Remarks - Method	No significant protocol deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	None.	None.	≥1000µg/plate	None.
Test 2		None.	≥1000µg/plate	None.
Present				
Test 1	None.	None.	≥1000µg/plate	None.
Test 2		None.	≥1000µg/plate	None.

Remarks - Results Positive control substances had the appropriate response. Negative controls were within historical limits.

CONCLUSION The analogous chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Corning (1997)

7.12. Genotoxicity – in vivo

TEST SUBSTANCE Analogous chemical

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

Species/Strain Mouse/Crl:CD-1(ICR)BR
Route of Administration Intraperitoneal injection
Vehicle Peanut oil
Remarks - Method No significant protocol deviations.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5/sex	0	24, 48, 72 hours
II (low dose)	5/sex	625	24, 48, 72 hours
III (mid dose)	5/sex	1250	24, 48, 72 hours
IV (high dose)	5/sex	2500	24, 48, 72 hours
V (positive control, CP)	5/sex	60	24 hours

CP=cyclophosphamide. M=mitomycin C.

RESULTS

Doses Producing Toxicity Animals receiving 625 mg/kg bw were slightly hypoactive at 72 hours.

Animals receiving 1250 mg/kg bw were slightly hypoactive with rough haircoats at 48 hours (males only) and 72 hours (all animals).

Animals receiving 2500 mg/kg bw were slightly hypoactive at 24 hours, hypoactive with rough haircoats at 48 hours, and very hypoactive with rough haircoats, laboured breathing and distended abdomens at 72 hours.

Two animals receiving 2500 mg/kg bw died during the test.

Bone marrow cytotoxicity was pronounced in animals receiving 2500 mg/kg bw and there was some evidence of bone marrow toxicity in animals receiving 1250 and 625 mg/kg bw.

Genotoxic Effects None.
Remarks - Results The positive control group induced statistically significantly increases in micronucleated polychromatic erythrocytes. Negative controls were within historical limits.

CONCLUSION The analogous chemical was not clastogenic under the conditions of this in vivo mouse micronucleus test.

TEST FACILITY CHV (1996)

8.1. Environmental fate

The following data have been provided for an analogous chemical (at 50% weight in a highly refined mineral oil) that is considered to be an acceptable analogue of the notified chemical.

8.1.1. Ready biodegradability

TEST SUBSTANCE	Analogous chemical
METHOD	OECD TG 301D Ready Biodegradability: Closed Bottle Test. EEC Directive 79/831 and EEC Directive 67/548 Annex V C6.
Inoculum	Activated sludge from the HRC Limited sewage treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	COD
Remarks - Method	Dissolved oxygen concentrations for each test medium were determined by means of a Yellow Springs BOD probe and COD were measured by using a semi-micro sample digestion method.

RESULTS

Test substance		*Sodium benzoate*		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*	*Day*	*% Degradation*
5	5	5	87	5	57
15	3	15	85	15	59
28	8	28	97	28	61

Remarks - Results	The degradation of the reference substances fulfils the criteria for a valid test. Oxygen depletion in the inoculated and non-inoculated control series were within the acceptable limits.
CONCLUSION	The test substance is not considered to be readily biodegradable.
TEST FACILITY	Huntingdon Research Centre (1989)

8.1.2. Bioaccumulation

Based on the high calculated logKow of 9.5-14.4, the notified chemical has the potential to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogous chemical
METHOD	40 CFR 797.1400: Subpart B-Aquatic Guidelines, Fish Acute Toxicity Test (EPA 1985)
Species	Rainbow trout (*Oncorhyricus mykiss*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	36-38 mg $CaCO_3$/L
Analytical Monitoring	Carbon analyser
Remarks – Method	Due to the low solubility of the test material, a Water Soluble Fraction was prepared by stirring mixtures containing the nominal concentrations at room temperature for 20 hours and removing the soluble fraction. Throughout the test period, a film of undissolved test material was observed on the surface of all test solutions. Total organic carbon (TOC) analyses were performed at 0 and 24 h, with

control ranging from 6.2-7.7 mg/L and treatment groups ranging from 40-92 mg/L. The pHs and dissolved oxygen concentrations were within acceptable levels during the test.

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*Mortality*					
		3 h	*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
1000[a]	20	0	0	0	0	0	0[b]
600	20	0	0	0	0	0	0
360	20	0	0	0[c]	0	0	0
220	20	0	0	0	0	0	0
130	20	0	0	0	0	0	0
Control	20	0	0	0	0	0[d]	0[d]

a Test solutions were noted to have a heavy layer of film present on the surface at 48, 72 and 96 h of exposure
b One of the surviving fish exhibited darkened pigmentation
c Several of the surviving fish exhibited darkened pigmentation
d A total of 19 fish were observed in the control vessels

LC50	>1000 mg/L nominal WSF at 96 h
NOEC	1000 mg/L nominal WSF at 96 h
Remarks – Results	All organisms of the control and the treatment groups survived the 96 h toxicity test. Sub lethal effects of darkened pigmentation were noted at nominal concentrations of 360 and 1000 mg/L at 24 and 96 h, respectively.

CONCLUSION The test substance is considered to be non-toxic to fish up to the limit of its water solubility.

TEST FACILITY Springborn Laboratories Inc (1989)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Analogous chemical

METHOD

	40 CFR 797.1300: Subpart B-Aquatic Guidelines, Daphnid Acute Toxicity Test (EPA 1985)
Species	*Daphnia magna*
Exposure Period	48 h
Auxiliary Solvent	None
Water Hardness	180 mg $CaCO_3$/L
Analytical Monitoring	Carbon analyser
Remarks - Method	The WSFs were prepared according to the procedures in the fish test. Total organic carbon (TOC) analyses were performed at 0 and 24 h, with no significant change compared to control (7.3-11.5 mg C/L). The pHs and dissolved oxygen concentrations were within acceptable levels.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*Immobilization (%)*			
		3 h	*6 h*	*24 h*	*48 h*
1000	20	0[abc]	25[bcde]	60[ab]	75[ch]
500	20	0	0	0	0[c]
250	20	0	0	25	30[ci]
125	20	0	0	0[bf]	0[cg]
63	20	0	0	0	0[cg]
Control	20	0	0	0	0

a All of the surviving daphnia were lethargic
b A film was present on the surface of the test solution
c Test solutions were cloudy
d All of the surviving daphnids were lethargic and caught on particulate matter
e A precipitate was observed at the surface of the test solution
f One of the surviving daphnids was lethargic
g Several of the surviving daphnids were observed at the surface of the test solution
h All of the surviving daphnids were caught on particulate matter
i One of the surviving daphnids was observed at the surface of the test solution

LC50	830 mg/L nominal WSF at 48 h (CI: 130-1000 mg/L)
NOEC	<63 mg/L nominal WSF at 48 h
Remarks - Results	75% immobilisation was observed at nominal concentration of 1000 mg/L WSF. Immobilisation of 30% was observed at 250 mg/L WSF while no immobilised organisms were observed in the remaining concentrations tested. All surviving daphnids at 1000 mg/L WSF were observed to be caught on particulate matter. Several surviving daphnids at concentrations ≤250 mg/L WSF were observed at the surface of the test solution. Test solutions at test termination, except for control, were all observed to be cloudy. The 48 h EC50 of 830 mg/L WSF was estimated by non-linear interpolation.

CONCLUSION The test substance is considered to show some toxicity to *Daphnia magna* below the limit of its water solubility. However, these results should be treated with caution, as it appears the toxic effects observed are a result of physical effects.

TEST FACILITY Springborn Laboratories Inc. (1990)

8.2.3. Inhibition of microbial activity

TEST SUBSTANCE Analogous chemical

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.

Inoculum	Activated sludge was obtained from the wastewater treatment plant
Exposure Period	3 h
Concentration Range	Nominal: 100, 300 and 1000 mg/L
Remarks – Method	The test was conducted under static conditions. Nominal concentrations were prepared by the addition of the test substance directly to the dilution water. After 3 h incubation period the concentrations of the dissolved oxygen was measured. The test was also performed using 3,5-dichlorophenol as the reference.

RESULTS

IC50	>1000 mg/L (nominal)
NOEC	1000 mg/L (nominal)
Remarks – Results	Insoluble material was observed on the bottom and on the surface of non-control test vessels. The EC50 for the reference was 9.0 mg/L and within the acceptable range of 5-30 mg/L. The test substance did not inhibit respiration of the activated sludge for the concentration range tested. The 3 h EC50 could not be calculated by standard statistical techniques as the % inhibition was <50% of the control at all concentrations tested.

CONCLUSION	The test substance is not inhibitory to the activated sludge micro-organisms.
TEST FACILITY	Wilbury Laboratories Inc. (1994)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be imported and reformulated into lubricant oils at blending facilities. The used oil and the sludge collected from the on-site wastewater treatment facilities may be incinerated. The main environmental exposure is expected to result from inappropriate disposal of waste lubricant product, assuming that about 14% of oil changes in Australia are performed by DIY enthusiasts.

This disposal is however, widespread across Australia. Most of the improperly released notified chemical due to DIY activities is likely to become associated with soils or sediments, as will the notified chemical released to landfill as container residues. The notified chemical released into the aquatic environment would be expected to become associated with the sediments due to its estimated low water solubility. While some components of the notified chemical are not readily degradable, these can be expected to slowly degrade due to the biotic and abiotic processes.

The amount released to stormwater drains (less than 1% of the import volume) can enter the aquatic compartment and could be expected to associate with suspended organic material (due to the calculated high log Pow), settle out into the sediments and eventually biodegrade.

It is difficult to estimate the Predicted Environmental Concentration (PEC) of the notified chemical released into stormwater drains, which have the potential to directly enter the aquatic environment. However, a worst case estimated PEC might be calculated if it is assumed that all of the 1% of the notified chemical that is expected to be released into the stormwater (i.e. 1 tonne) drains into a single metropolitan area with a geographical footprint of 500 square kilometres and an average annual rainfall of 50 cm. With a maximum annual release into this localised stormwater system of 1000 kg and the annual volume of water drained from this region estimated to be approximately 250 x 10^6 m^3, the resultant worst-case PEC is approximately 4 µg/L. It should be stressed that this result is very much a worst case scenario, and that in reality releases of the chemical would be very much more diffuse than indicated here, and also at significantly reduced levels.

9.1.2. Environment – effects assessment

Based on the ecotoxicity data for fish and Daphnia provided, the notified chemical is not toxic up to the limit of water solubility where the TOC = 9.1-92 mg/L. A PNEC is not able to be calculated based on the TOC value.

9.1.3. Environment – risk characterisation

The notified chemical is not toxic to the aquatic organisms tested up to the limit of its water solubility where the TOC = 9.1-92 mg/L. This is well above the worst case PEC of 4 µg /L. Further, the notified chemical is expected to become associated with the sediments, and biodegradation will further reduce the risk to the aquatic life.

Overall, the environmental risk from the proposed blending and use of the notified chemical is expected to be low. However, the potential exists for physical fouling of aquatic organisms by undissolved material in the advent of a sizeable release to waterways. For this reason the notified chemical should be prevented from entering waterways.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Warehouse and transportation workers would only be exposed to the notified chemical in the case of accidental rupture of containers.

During formulation of the lubricant additive into the final lubricant product, the main exposure will be from drips and spills during transfer into storage tanks through hoses and lines, and during filling of the finished lubricant into drums. During the rest of the operation there is unlikely to be exposure, as the process is automated and enclosed. Laboratory workers may also be exposed during quality testing.

About 70% of the lubricant products (containing <5% notified chemical) will be sold to commercial users. These users will likely be professional mechanics and engineers, and will use either pneumatic devices to transfer oil, or have access to engineering controls. Exposure to the notified chemical is expected to be low, based on these controls, and the low concentration of the notified chemical in the products.

9.2.2. Public health – exposure assessment

Approximately 30% of the lubricant will be sold to service stations and consumer users; therefore public exposure will be widespread. The lubricant will be used to manually top-up and fill engines in cars, lawn mowers etc. Dermal exposure, and possible ocular, and inadvertent oral exposure to the notified chemical may occur when the blended oil products are added and drained from automobiles and when handling automotive components that have come into contact with the oil, as DIY end users are not likely to wear PPE while using the engine oil. It is expected that exposure to individuals will be intermittent, and the concentration (<5%) of the notified chemical within the oil will limit the total exposure levels.

The public may also be exposed to the notified chemical from spills onto roads, parking areas and soil. However, exposure will be limited by the dispersive use and low concentration of the notified chemical in products.

9.2.3. Human health – effects assessment

In two Buehler skin sensitisation tests, challenges to previously exposed rats resulted in markedly increased skin reactions compared with naïve controls. In a human patch test, the analogous chemical was found to be non sensitising in the population studied. Based on the positive result in the animal test, the notified chemical is classified in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2002) as:

R43 - May cause sensitisation by skin contact.

The analogue chemical is a moderate skin irritant, with mean draize score for erythema of 1.93. Erythema formation was classed as > 2 in 2/6 animals tested. Thus, classification as a hazardous substance is not required according to the NOHSC criteria (an average score above 2.0 or more or 2/3 animals having a score above 2). A human repeat insult occlusive patch test found no evidence of irritation.

Based on analogue data, it is expected that the notified chemical will have low acute toxicity via the oral and dermal routes, and be slightly irritating to the eye.

A repeat-dose oral toxicity study found that the chemical was irritating to the stomach, but no other conclusive signs of systemic toxicity were observed. A NOAEL of 150 mg/kg bw/day was established based on the stomach irritation.

No adverse effects were observed in a one generation reproductive toxicity study, with the NOAEL established as 500 mg/kg bw/day.

An in vivo mammalian erythrocyte micronucleus test and an Ames test did not indicate genotoxocity.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

The lubricant additive package (<70% notified chemical) that is imported into Australia is hazardous; specifically it is classified as a skin sensitiser. However, the risk to workers will be mitigated by the mainly automated transportation and formulation process of the additive package. Exposure is not expected, except via splashes and spills, and it is expected that PPE will minimise exposure.

The formulated lubricant products (containing 1-5% notified chemical) will be sold to commercial users (70%), who are considered here in the OHS section, and automotive service stations and consumer users (30%) who will be discussed in the public health risk characterisation below.

Commercial users are likely to have minimal exposure to the formulated lubricants as they use pneumatic transfer equipment and personal protective equipment, such as gloves, overalls and work boots. The OHS risk presented by the notified chemical is expected to be low in situations where the workers take precautions to reduce dermal exposure. Commercial users are likely to take precautions that are recommended on the label/MSDS.

9.2.5. Public health – risk characterisation

Many consumer users of the lubricants containing the notified chemical will not take precautions to minimise exposure. Thus, they will have intermittent dermal exposure, and possibly accidental ocular and oral exposure, to the notified chemical. The risk of adverse effects such as dermal irritation due to acute exposure will be limited by the low concentration of the notified chemical within the lubricants. The low concentration and intermittent exposure will also minimise any effects related to chronic exposure.

However, there is a high risk of dermal sensitisation to consumers who use the formulated lubricant, containing <5% notified chemical, without PPE such as gloves and overalls.

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

10.1. Hazard classification

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

R43 – May cause sensitisation by skin contact

and

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

Skin Sensitisation – Warning. May cause an allergic skin reaction. (Category 1.)

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described, based on the expected low exposure.

10.3.2. Public health

There is High Concern to public health when used as a lubricant additive due to the hazardous nature and proposed use patterns.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R43 May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - >1% R43 May cause sensitisation by skin contact

- The National Drugs and Poisons Standing Committee (NDPSC) should consider the notified chemical for listing on the SUSDP.

- Products containing more than 1% notified chemical and available to the public should carry the following safety phrases on the label:
  - S2 Keep out of reach of children
  - S24 Avoid contact with skin
  - S36 Wear suitable protective clothing
  - S37 Wear suitable gloves

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Minimise spills and drips
  - Where possible, automated processes should be used to reduce worker contact
  - Use closed systems for reformulation

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

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of by landfill or incineration.

Emergency procedures

- Contain release to prevent further contamination of soil, surface water or groundwater. Clean up spillage as soon as possible by applying non-combustible absorbent materials (small spills) or pumping (large spills). Remove contaminated soil and place contaminated material in disposable containers.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

CEHC (1989a) The Four-Hour Skin Irritation Potential of [Analogue Chemical] in Adult Albino Rabbits. CEHC Report number: 3073. Chevron Environmental Health Center, Inc. California, USA (unpublished report supplied by notifier).

CEHC (1989b) The Acute Eye Irritation Potential of [Analogue Chemical] in Adult Albino Rabbits. CEHC Report number: 3072. Chevron Environmental Health Center, Inc. California, USA (unpublished report supplied by notifier).

CHV (1997) Mutagenicity Test on [Analogue Chemical] in the Salmonella – Escherichia coli/Mammalian Microsome Reverse Mutation Assay with a Confirmatory Assay. CHV Study 17869-0-409R. Corning Hazleton Inc, Virginia, USA (unpublished report supplied by notifier).

CHV (1996) Mutagenicity Test on [Analogue Chemical] in an In Vivo Mouse Micronucleus Assay. CHV Study number: 17869-0-455CO. Corning Hazleton Inc, Virginia, USA (unpublished report supplied by notifier).

CRTC (1991) Repeated Insult Patch Test with [Analogue Chemical]. CEHC reference number 91-96. Chevron Environmental Health Center, Inc. California, USA (unpublished report supplied by notifier).

HTR (1995) Delayed Contact Hypersensitivity Study in Guinea Pigs (Buehler Technique) of [Analogue Chemical]. HTB Project 94-8280-21. Hill Top Biolabs Inc, Ohio, USA (unpublished report supplied by notifier).

HTR (1991) Delayed Contact Hypersensitivity Study in Guinea Pigs (Buehler Technique) of [Analogue Chemical]. HTB Project 91-8154-21. Hill Top Biolabs Inc, Ohio, USA (unpublished report supplied by notifier).

Huntingdon Research Centre Ltd (1989) The Ready Biodegradability of [Analogue chemical] in a Closed Bottle Test System. HRC Report No. 30/891706, Huntingdon Research Centre Ltd., Cambridgeshire, England (unpublished report supplied by notifier).

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

Pharmakon (1997a) [Analogue Chemical] – Single Dose Toxicity Study by the Oral Route in the Rat (Limit Test). Report number: 50596. Pharmakon, France (unpublished report supplied by notifier).

Pharmakon (1997b) [Analogue Chemical] – Single Dose Toxicity Study by the Cutaneous Route in the Rat (Limit Test). Report number: 50696. Pharmakon, France (unpublished report supplied by notifier).

SLI(2002) A 28-Day Oral Toxicity Study in Rats with a 14-Day Recovery Phase Using [Analogue Chemical]. SLI Study Number: 3580.1. Springborn Laboratories, Inc., Ohio, USA (unpublished report supplied by notifier).

SLI (2004) An Oral (Gavage) One-Generation Reproduction Study in Sprague Dawley Rats with [Analogue Chemical] SLI Study Number 3626.1. Springborn Laboratories, Inc., Ohio, USA (unpublished report supplied by notifier).

Snow R (1997) Used Oil Management. Paper presented at the Used Oil Management Conference, Brisbane, August 1997, Queensland Dept. Environment.

SPL (2004) Determination of Water Solubility. SPL Project No. 1666/013, SafePharm Laboratories Ltd, Derbyshire, England (unpublished report supplied by notifier).

Springborn Laboratories Inc. (1989) [Analogue Chemical] Acute Toxicity to Rainbow Trout (*Oncorhynchus Mykiss*) Under Static Renewal Conditions. SLI Report No. 89-8-3068, Springborn Laboratories Inc., Massachusetts, USA (unpublished report supplied by notifier).

Springborn Laboratories Inc. (1990) [Analogue Chemical] Acute Toxicity to Daphnids (*Daphnia Magna*) Under Static Renewal Conditions. SLI Report No. 89-8-3084, Springborn Laboratories Inc., Massachusetts, USA (unpublished report supplied by notifier).

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.

Wilbury Laboratories Inc. (1994) Activated Sludge Respiration Inhibition Test With [Analogue Chemical]. Study No. 76-CM-603, Wilbury Laboratories Inc., Massachusetts, USA (unpublished report supplied by notifier).