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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Component 2 of XC6170

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Director
NICNAS

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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 using EPI Suite (US EPA): melting point, boiling point, density, vapour pressure, water solubility, log Pow, adsorption/desorption.

Tests on analogous chemicals: 90-day repeat dose toxicity, 28-day repeat dose toxicity, Ames test, chromosomal aberrations in vitro, mouse micronucleus in vivo, eye irritation, dermal irritation, acute oral toxicity, acute dermal toxicity, toxicity to a freshwater alga, toxicity to daphnids, toxicity to rainbow trout, activated sludge respiration inhibition, aerobic aquatic biodegradation, flash point, delayed contact hypersensitivity.

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)
XC6170 (contains <70% notified chemical)

METHODS OF DETECTION AND DETERMINATION

METHOD Infrared Spectroscopy
REMARKS A reference spectrum was provided

3. COMPOSITION

DEGREE OF PURITY
High.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

ADDITIVES/ADJUVANTS

Chemical Name Mineral oil
Weight % 20-50%
Hazardous Properties Not hazardous.

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 chemical is part of a lubricant additive package that will be used as a detergent additive at 1-5% concentration in lubricants 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 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 additive package XC6170 (containing <70% notified chemical) will be transferred from drums, rail cars and tank trucks into storage tanks. The transfer process from the tank truck occurs by the use of 10 cm hosing.

Transfer from storage tanks to blend tanks will be automated, using computer controlled valves. The additive package is blended with other components to form the finished lubricant, which contains the notified chemical at 1-5%. The blending process occurs in a closed system 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, with a worker watching to ensure the drum filling mechanism properly enters the drum before the drum is filled. The bungs and labels are manually applied by the operators. Bulk tank truck or rail car filling is performed by a transfer hose. The small container packaging machine is fully automated and will fill 1-4L containers.

The finished lubricants will then be transported for use commercially (70%) or to service stations and consumer users (30%). The lubricants will likely be transported in the following manner: 50% in drums, 40% in 1-4L containers and 10% in tank trucks. These lubricants will be used as automotive and diesel engine crankcase oils, air and water-cooled two-cycle engine oils, industrial oils, hydraulic fluids and gear oils.

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	<10000	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 transfer from drums, and 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 diameter hose. Connection of the hose takes 10 minutes. An 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 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 blending facilities are well ventilated, with control systems for accidental spills and wastewater treatment.

Workers may be exposed to the finished lubricant (containing the notified chemical at 1-5%) during the drum filling operations. However, exposure will be minimised by the use of PPE such as gloves, eye protection, protective clothing and hard hats.

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. Exposure may also occur when 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 from storage tanks to bulk containers is necessary, it is performed as described above for the reverse process. 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.

End Users:

The drums (50% of the total notified chemical) and some of the 1-4 L containers (10% of the total notified chemical) will be sold to commercial automotive engine service outlets (i.e. auto repair shops). A pneumatic pump will be inserted into the drum and used to transfer the lubricant. 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 professional mechanics, who are likely to wear appropriate PPE and 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.

The remaining 30% of the notified chemical in lubricants will be sold to service stations and consumer users. Exposure to these products is described in the Public Exposure section below.

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 20ºC and 101.3 kPa Dark brown viscous liquid

Melting Point Not measured.
Remarks Estimated using EPI Suite to be 278 – 332ºC

Boiling Point Not measured.
Remarks Estimated using EPI Suite to be 640 – 756ºC 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 25ºC

Water Solubility Not measured.

Remarks Estimated using EPI Suite to be $<10^{-6}$ mg/L at 25ºC

Hydrolysis as a Function of pH Not measured.

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

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

Remarks Log Pow was estimated using EPI Suite to be 9.5-14.4 and indicates strong preference for the octanol phase.

Adsorption/Desorption Not measured.

Remarks Log K_{oc} was estimated using EPI Suite to be 6.3 – 10.1 and indicates a preference for adsorption to soils.

Dissociation Constant Not measured.

Remarks The notified chemical is an anionic chemical which 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 an analogous chemical to be 150°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 >5000 mg/kg bw	low toxicity
Rat, acute inhalation toxicity	not performed
Rabbit, skin irritation	severely irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test.	evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	no NOEL established
Rat, repeat dose oral toxicity – 90 days.	no NOEL established
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – In vitro Mammalian Chromosome Aberration Test	non genotoxic
Genotoxicity – in vivo mouse micronucleus assay	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Analogous chemical

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain Rat/Crl:CD(SD)BR
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 Five males and one female exhibited dark-stained urogenital area and/or nonformed faeces/soft stool within 3 days of exposure. No signs of toxicity were observed 4 days after treatment.
Effects in Organs No abnormal findings observed at gross necroscopy examination at termination.
Remarks - Results None.

CONCLUSION The analogue chemical is of low toxicity via the oral route.

TEST FACILITY Covance Laboratories Inc (1998a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Analogous chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rat/Crl:CD(SD)BR
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	5000	0

LD50	>5000 mg/kg bw
Signs of Toxicity - Local	Dermal irritation was observed in all animals, consisting of moderate to severe erythema, slight to moderate oedema, and slight atonia, desquamation, coriaceousness, fissuring, and subcutaneous hemorrhaging. This irritation was still present in three female animals at day 14.
Signs of Toxicity - Systemic	Four females exhibited weight loss of 4-9 g during the first week.
Effects in Organs	No significant findings.
Remarks - Results	None.
CONCLUSION	The analogue chemical is of low toxicity via the dermal route.
TEST FACILITY	Covance Laboratories Inc (1998b)

7.3. Acute toxicity – inhalation

Not performed.

7.4. Irritation – skin

TEST SUBSTANCE	Analogous chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6 per study
Vehicle	None.
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	Two studies were conducted, using 6 animals each. In the first study the test substance was washed off using soap/water following the 4-hour exposure period, and some residue remained. In the second study the test substance was washed off with mineral oil and soap/water, which removed more of the test material. Data from both tests are presented here.

RESULTS

Study 1 – washed with soap/water

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	3.1	4	14 days	1
Oedema	3.3	4	7 days	0

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

Study 2 - washed with mineral oil and soap/water

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	2.6	3	7 days	0
Oedema	3.3	4	7 days	0

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

Remarks - Results: The majority of animals in both studies showed blanching for 72 hours. Desquamation and/or fissuring was seen in all animals in both groups at day 7, and in three animals in Study 1 on day 14. Five animals in study 1 had areas of possible necrosis after 96 hours.

CONCLUSION: The analogue chemical is severely irritating to the skin.

TEST FACILITY: Covance Laboratories Inc (1998c)

7.5. Irritation – eye

TEST SUBSTANCE: Analogous chemical

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain: Rabbit/New Zealand White
Number of Animals: 9
Observation Period: 72 hours
Remarks - Method: The eyes of 3 rabbits were flushed with water for 1 minute starting 30 seconds after test material instillation.

The eyes of the other 6 rabbits remained unflushed.

RESULTS

Flushed

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.44	2	48 hours	0
Conjunctiva: chemosis	0.33	1	24 hours	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.

Unflushed

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.39	2	48 hours	0
Conjunctiva: chemosis	0.33	2	24 hours	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: Positive irritation reactions were seen in all six animals with unwashed eyes, including: diffuse, deep crimson conjunctival redness, with individual vessels not easily discernable; obvious conjunctival swelling with partial eversion of the lids; and discharge with moistening of the lids and hairs just adjacent to the lids (at 1 hour). By the 24-hour observation, the discharge had cleared, and only mild conjunctival redness and chemosis were observed. All effects had cleared by 48 hours, except for one animal that presented mild conjunctival redness.

Flushing of the eye is not consistent with the test guidelines, and thus these results have not been analysed in detail but the flushing appeared to have little effect.

CONCLUSION The analogue chemical is slightly irritating to the eye.

TEST FACILITY Covance Laboratories Inc (1998d)

7.6. Skin sensitisation

TEST SUBSTANCE Analogous chemical

METHOD OECD TG 406 Skin Sensitisation - Buehler test.

Species/Strain Guinea pig/Dunkin Hartley

PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: None found.

MAIN STUDY

Number of Animals Test Group: 10/sex Control Group: 10/sex

INDUCTION PHASE Induction Concentration:
topical: 100%

Signs of Irritation Erythema scores of 1-2 were seen in all animals.

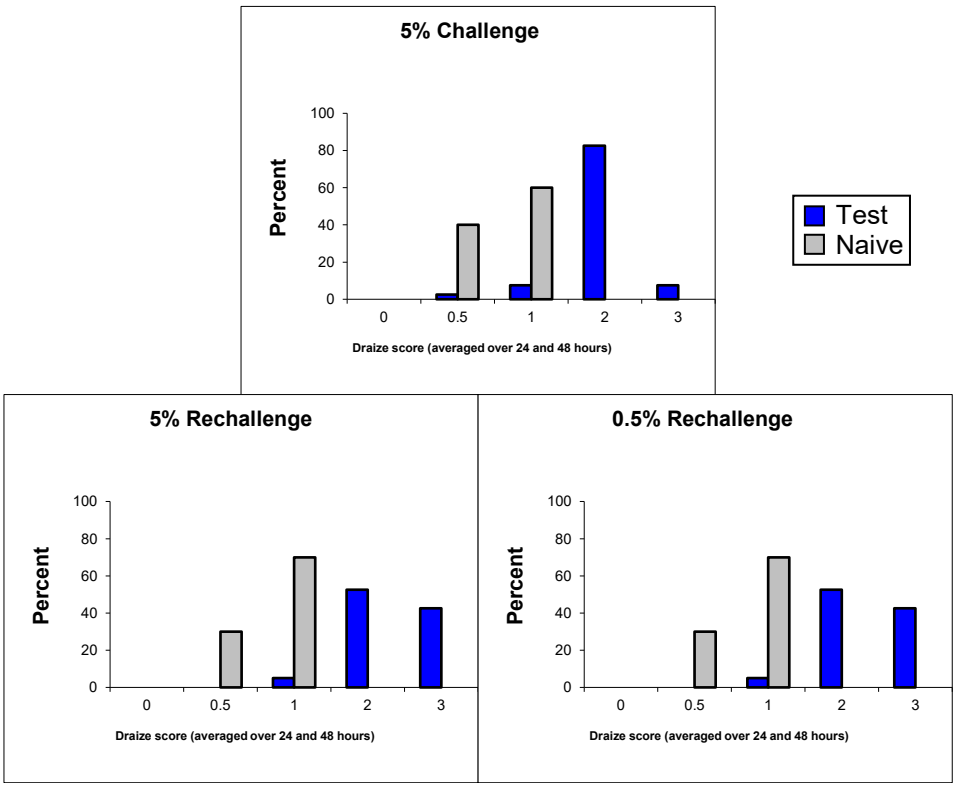
CHALLENGE PHASE

1st challenge topical: 5% in mineral oil

2nd challenge topical: 5%, 0.5%

Remarks - Method No significant protocol deviations.

RESULTS



Remarks - Results Results are presented as a bar graph for each challenge. The scores for each group were averaged over the 24 and 48 hours. The results clearly show that there were higher responses in the test animals than the naïve control.

CONCLUSION	There was evidence of reactions indicative of skin sensitisation to 0.5% analogue chemical under the conditions of the test.
TEST FACILITY	Hill Top Biolabs (1994)

7.7. Repeat dose toxicity – 90 day

TEST SUBSTANCE	Analogous chemical
METHOD	OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents. EC Directive 88/302/EEC B.26 Subchronic Oral Toxicity Test: 90-Day Repeated Oral Dose Study using Rodent Species.
Species/Strain	Rat/Crl:CD BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 90 days Dose regimen: 7 days per week Post-exposure observation period: 28 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	1
II (low dose)	10/sex	10	1
III (mid dose)	10/sex	100	0
IV (high dose)	10/sex	500	1
V (control recovery)	10/sex	0	0
VI (high dose recovery)	10/sex	500	0

Mortality and Time to Death

Three animals were sacrificed due to a damaged eye, following the blood sampling procedures in week 13. These deaths were not related to the treatment.

Clinical Observations

Salivating after dosing was noted intermittently primarily among high-dose rats of either sex from week 5 onwards.

During week 1 of the treatment period, there was an unusually high bodyweight gain for mid-dose females, but in isolation this is not considered to be of toxicological importance. During the recovery period, a statistically significant higher bodyweight gain and higher food consumption was seen in males.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

A number of statistically significant changes were observed in mid- and high-dose animals. A number of these changes were indicated at the lowest dose, but did not obtain statistical significance. The following table summarises these observations:

	Low dose	*Mid dose*	*High dose*	*High dose recovery*
Potassium	(m) 7% increase, p<0.05 (f) no significant change.	(m) 7% increase, p<0.05 (f) no significant change.	(m) 7% increase, p<0.01 (f) no significant change.	No observed change
Glucose	(m) 7% increase, not significant (f) 2% increase, not significant	(m) 11% increase, not significant (f) 9% increase, not significant	(m) 15% increase, p<0.05 (f) 14% increase, p<0.01	(m) 6% increase, not significant (f) 12% increase, P<0.05
Cholesterol	(m) No observed change (f) 11% decrease, not significant	(m) 15% decrease, p<0.05 (f) 9% decrease, not significant	(m) 25% decrease, p<0.01 (f) 30% decrease, p<0.01	(m) 5% decrease, not significant (f) 7% decrease, not significant
Sodium	No observed change	(m) 2% increase, p<0.01 (f) 1% increase, p<0.05	(m) 2% increase, p<0.01 (f) 1% increase, p<0.01	No observed change
Chlorine	No observed change	(m) 1% increase, p<0.01 (f) 1% increase, p<0.05	(m) 3% increase, p<0.01 (f) 3% increase, p<0.01	No observed change
Calcium	No observed change	(m) 4% decrease, p<0.01 (f) 2% decrease, p<0.05	(m) 6% decrease, p<0.01 (f) 3% decrease, p<0.01	No observed change
Alkaline phosphatase	No observed change.	No observed change	(m) 24% increase, p<0.05 (f) 17% increase, not significant	No observed change
Alanine amino transferase	No observed change	No observed change.	(m) 67% increase, p<0.01 (f) 32% increase, p<0.01	No observed change
Total protein	No observed change	No observed change	(m) 6% decrease, p<0.05 (f) 4% decrease, p<0.05	No observed change

Creatine was significantly reduced in high-dose males only.
A/G ratio was significantly increased in high dose males only.

Minor variations in haematology were either not dosage related or influenced by outlier animals and are not thought to be toxicologically significant.

Effects in Organs

Upon necroscopy, there were a number of effects observed in the stomach. These are summarised below:

	Low dose	*Mid dose*	*High dose*	*High dose recovery*
Thickened forestomach	(m) 0/10 (f) 0/10	(m) 0/10 (f) 0/10	(m) 5/10 (f) 0/10	(m) 0/10 (f) 0/10
Roughened forestomach	(m) 0/10 (f) 0/10	(m) 3/10 (f) 5/10	(m) 9/10 (f) 7/10	(m) 0/10 (f) 0/10
Epithelial hyperplasia and hyperkeratosis	(m) 1/10 (f) 0/10	(m) 7/10 (f) 8/10	(m) 9/10 (f) 9/10	(m) 1/10 (f) 2/10
Epithelial erosion	(m) 0/10 (f) 0/10	(m) 0/10 (f) 2/10	(m) 1/10 (f) 2/10	(m) 0/10 (f) 0/10
Subepithelial inflammation	(m) 0/10 (f) 0/10	(m) 2/10 (f) 3/10	(m) 8/10 (f) 10/10	(m) 0/10 (f) 0/10
Submucosal inflammation	(m) 0/10 (f) 0/10	(m) 3/10 (f) 3/10	(m) 8/10 (f) 10/10	(m) 0/10 (f) 0/10

A dosage related and statistically significant increase in kidney weight was noted for all male groups in comparison with the controls. This finding was not correlated with any microscopic changes.

At termination, raised liver weights were noted for high-dose males in comparison with the control, and minimal centrilobular hepatocyte hypertrophy was also seen in the livers of this group. This finding was not noted in any other groups, or following the recovery period.

A statistically significant higher spleen weight was noted for high-dose males and mid- and high-dose females in comparison with the controls. This finding was not correlated with any microscopic changes.

Other inter-group differences in organ weights were not considered to be toxicologically important, due to the absence of statistical significance, consistent dose response relationships or supporting histological lesions.

Aggregations of vacuolated histiocytes were recorded in the mesenteric lymph nodes of all animals of both sexes in the high-dose group, and in 3 females given in the mid-dose group, and this finding persisted following the recovery period.

Granulomatous inflammation was recorded in the paracortex of 9 male and 7 female rats in the high dose group at the end of the main study, and was seen at a reduced level following the recovery period.

Remarks – Results

A No Observed Effect Level (NOEL) could not be determined. The following statistically significant changes were seen in low-dose animals, and are believed to be treatment related: lesions in the stomach, reduction in kidney weight and reduced mean potassium. In addition to these findings, a number of other biochemical values displayed sub-significant dose-response relationships.

Adverse effects to the stomach were the most pronounced findings, and were severe and widespread in mid- and high-dose animals. These effects were most likely due to local irritation caused by the analogue chemical, and are consistent with the skin irritation study.

The changes to the liver, kidney and the altered blood chemistry were likely adaptive.

The causes of the changes to the mesenteric lymph node are difficult to identify, but may indicate toxicity to histiocytes and/or macrophages. The aggregations of vacuolated histiocytes may be due to histiocytes/macrophages ingesting the substance and subsequently accumulating in the mesenteric lymph node, or alternatively the substance may have been absorbed into the lacteals and only ingested by histiocytes on arrival at the draining lymph node. The granulomatous inflammation may be due direct inflammation caused by the substance, or by toxicity to macrophages and a subsequent inflammatory reaction. These effects are not considered to provide evidence of serious systemic toxicity.

CONCLUSION

The No Observed Effect Level (NOEL) could not be established in this study.

TEST FACILITY Huntington Life Sciences Ltd. (2000)

7.7. Repeat dose toxicity – 28 day

TEST SUBSTANCE	Analogous chemical
METHOD	EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Crl:CD BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week
Vehicle	Corn oil
Remarks - Method	No recovery period was used.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	200	0
III (mid dose)	5/sex	1000	0
IV (high dose)	5/sex	2000	0

Clinical Observations

Transient salivation after dosing was noted intermittently throughout the study among high-dose rats of both sexes. Bodyweight gain was variable and did not reveal any treatment related trends. Increased food consumption was observed for mid- and high-dose females, which reflected the increased bodyweight gain for these groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Increased white blood cell parameters were noted among high-dose females. Increased alanine aminotransferase, aspartate aminotransferase, glucose, phosphorous, and reduced cholesterol were noted for both sexes in the mid- and high-dose groups compared with control. There was some evidence of increased urea nitrogen for males, especially in the high-dose group.

Effects in Organs

Liver weight was increased in all treated female groups.

In the stomach, roughening of the epithelial aspect was observed in 2/5 high-dose rats and 3/5 mid-dose rats of either sex. Yellow staining of the epithelial aspect was seen in 1/5 high-dose rats of either sex, and 1/5 mid-dose rats of either sex. Epithelial hyperplasia and hyperkeratosis in the nonglandular stomach, sometimes with associated inflammatory changes, was reported for all rats of either sex in the mid- and high-dose groups, and in 1/5 low-dose female rats.

Remarks – Results

Elevated white blood cell parameters may have been due to the inflammatory responses seen in the stomach. The changes to blood chemistry and increased liver weight suggest a perturbation in liver function.

CONCLUSION

The No Observed Effect Level could not be established from this study, based on the epithelial hyperplasia and hyperkeratosis in the nonglandular stomach seen in one female receiving a dose of 200 mg/kg/day.

TEST FACILITY Huntington Life Sciences Ltd. (1999)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Analogous chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. 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: 33.3-10,000 µg/plate b) Without metabolic activation: 33.3-10,000 µg/plate
Vehicle	DMSO
Remarks - Method	The tester strain WP2*uvr*A was retested as the positive control in the initial test did not reach an acceptable (3-fold greater than the vehicle) level of revertant colonies.

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	At ≥ 3,300 µg/plate	Negative
Test 2	None	None	At ≥3,300 µg/plate	Negative
Present				
Test 1	None	None	At ≥ 2,500 µg/plate	Negative
Test 2	None	None	At ≥ 2,500 µg/plate	Negative

Remarks - Results	Positive control substances had the appropriate response, except for WP2*uvr*A in the presence of S9, which was retested and an acceptable positive control value obtained. Negative controls were within historical limits.
CONCLUSION	The analogue chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Covance Laboratories Inc (1998e)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Analogous chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	Human lymphocytes
Metabolic Activation System	Aroclor 1254 induced rat liver S9fraction.
Vehicle	DMSO
Remarks - Method	No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	34.7, 49.5, 70.7, 101, 144*, 205*, 293*, 419, 598, 854, 1220, 1740, 2480, 3540, 5050 µg/mL	3 hours	22 hours
Test 2A	12.5, 25, 50, 100, 150*, 200*, 250*, 300, 350, 400 µg/mL	19.3 hours	22 hours
Test 2B	12.5, 25*, 50*, 100*, 150, 200, 250, 300, 350, 400 µg/mL	43.3 hours	46 hours
Present			
Test 1	34.7, 49.5, 70.7, 101*, 144*, 205*, 293, 419, 598, 854, 1220, 1740, 2480, 3540, 5050 µg/mL	3 hours	22 hours
Test 2A	25*, 50*, 100*, 150, 200*, 250*, 300* µg/mL	3 hours	22 hours
Test 2B	25*, 50*, 100*, 150, 200, 250, 300 µg/mL	3 hours	46 hours

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	≥419 µg/mL	≥854 µg/mL	Negative
Test 2A	≥250 µg/mL	-	Negative
Test 2B	≥200 µg/mL	-	Negative
Present			
Test 1	≥419 µg/mL	≥854 µg/mL	Negative
Test 2A	≥250 µg/mL	-	Negative
Test 2B	≥250 µg/mL	-	Negative

Remarks - Results: Mitomycin C and Cyclophosphamide were used as positive controls and showed distinct increases in cells with structural chromosomal aberrations. Negative controls were within historical limits.

CONCLUSION: The analogue chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY: Covance Laboratories Inc (1998f)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE: Analogous chemical

METHOD: OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain: Mouse/Crl:CD-I(ICR)BR
Route of Administration: Intraperitoneal injection
Vehicle: Peanut oil
Remarks - Method: No significant protocol deviations.
The doses were determined based on 2 preliminary toxicity experiments.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	6/sex	-	48
IIm (low dose)	6/m	47	24
IIIm (mid dose)	6/m	94	24
IVm (high dose)	6/m	188	24
Vm (high dose 48 hour)	6/m	188	48
IIf (low dose)	6/f	63	24
IIIf (mid dose)	6/f	125	24
IVf (high dose)	6/f	250	24
Vf (high dose 48 hour)	6/f	250	48
VI (positive control, CP)	6/sex	20	24

CP=cyclophosphamide.

RESULTS
Doses Producing Toxicity: Males: 2 animals receiving 94 mg/kg exhibited rough haircoat 24 hours after dosing. All animals dosed with 188 mg/kg were hypoactive and had rough haircoat at 24 hours. Three males in this group were found dead at 48 hours.
Females: 3 animals receiving 125 mg/kg exhibited rough haircoat 24 hours after dosing. All animals dosed with 250 mg/kg were slightly hypoactive, with hunched position and rough haircoat at 24 hours. Three females in this group were found dead at 48 hours.

Genotoxic Effects	The test article was not cytotoxic to the bone marrow.
Remarks - Results	The positive control group induced statistically significantly increases in micronucleated polychromatic erythrocytes. Negative controls were within historical limits.
CONCLUSION	The notified chemical was not clastogenic under the conditions of this in vivo mouse micronucleus assay.
TEST FACILITY	Covance Laboratories Inc (1998g)

8. ENVIRONMENT

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

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Analogous chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test. US EPA Method 796.3260
Inoculum	Activated sludge.
Exposure Period	28 days
Auxiliary Solvent	None.
Analytical Monitoring	Carbon analyser
Remarks - Method	The CO_2 produced was measured using a carbon analyser.

RESULTS

Test substance		*Canola oil*	
Day	*Cumulative % of theoretical CO_2 evolved*	*Day*	*Cumulative % of theoretical CO_2 evolved*
2	0	2	1
6	2	6	30
13	8	13	66
19	10	19	78
23	12	23	80
29	14	29	83

Remarks - Results	The reference substance yielded >60% of theoretical maximum CO_2 prior to day 14 of the test thereby fulfilling the criteria for a valid test. The amount of CO_2 evolved was within the acceptable limit for CO_2 evolution tests. The temperature and pH measured during the test were within acceptable limits.
CONCLUSION	The test substance is considered not readily biodegradable.
TEST FACILITY	Wildlife International Ltd (1998).

8.1.2. Bioaccumulation

Based on the high calculated logKow of 10.0-12.9, the notified chemical has the potential to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogous chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test –Semic-static.
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	None.
Water Hardness	44 mg $CaCO_3$/L
Analytical Monitoring	TOC analysis
Remarks – Method	The test material was prepared as a Water Accommodated Fraction

(WAF) due to its expected low water solubility. The mixtures were stirred at room temperature for 24 h and allowed to settle for 4 h. Following the settling period the water phase containing the WAF was removed with a siphon. The 1,000 mg/L test solutions were slightly cloudy at the start of each 24 h period and they were clear with a thin film on the surface at the end of each 24 h. No other insoluble material was noted in any test vessels.

The WAF was prepared at the beginning of the test and three additional times during the test to allow media renewal at approximately 24, 48 and 72 h. A range-finding test was conducted at the WAF concentrations of 10, 100 and 1000 mg/L. The definitive test was conducted under static renewal conditions only at the highest concentration.

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*Mortality*				
		2 h	*24 h*	*48 h*	*72 h*	*96 h*
1000*	10	0	0	0	0	0
Control	10	0	0	0	0	0

*Tests were performed in triplicates each containing 10 fish.

LC50	>1000 mg/L nominal WAF at 96 hours.
NOEC	1000 mg/L nominal WAF at 96 hours.
Remarks – Results	The 1000 mg/L test solutions were slightly cloudy at the start of each 24 h period and they were clear with a thin film on the surface at the end of each 24 h. No other insoluble material was noted in any test vessels. All organisms at 1000 mg/L survived the 96 h toxicity test. No sublethal effects were noted at 96 h. Total organic carbon (TOC) analyses were performed at 0 and 24 h, with no significant change compared to control, though levels were low (2.7-5.5 mg C/L). The pH, temperature, conductivity and dissolved oxygen concentration measurements were within acceptable levels.
CONCLUSION	The test substance is considered to be non-toxic to fish up to the limit of its water solubility.
TEST FACILITY	Wilbury T. R. Laboratories Inc (1998a)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Analogous chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None.
Water Hardness	164-168 mg $CaCO_3$/L
Analytical Monitoring	TOC analysis
Remarks - Method	The WAFs were prepared according to the procedures in the fish test (see 8.2.1). A range-finding test was conducted at the WAF concentrations of 1, 10, 100 and 1000 mg/L. The definitive test was conducted under static conditions at the WAF of 1000 mg/L.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*Number Dead*	
		24 h	*48 h*
1000*	10	1	1
1000	10	1	1
1000	10	0	0
Control	10	0	0

* Three replicates each containing 10 daphnia

LC50	>1000 mg/L at 48 hours (nominal WAF)
NOEC	1000 mg/L at 48 hours (nominal WAF)
Remarks - Results	No insoluble material was noted during the test. 97% survival with no sublethal effects occurred in the control. Total organic carbon (TOC) analyses were performed at 0 and 24 h, with no significant change compared to control, though levels were low (1.8-2.1 mg C/L). The pH, temperature, conductivity and dissolved oxygen concentration measurements were within acceptable limitss.
CONCLUSION	The test substance is considered to be non-toxic to *Daphnia magna* up to the limit of its water solubility.
TEST FACILITY	Wilbury T. R. Laboratories Inc (1998b)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Analogous chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	Freshwater alga (*Selenastrum capricornutum*)
Exposure Period	96 hours
Concentration Range	1000 mg/L
Auxiliary Solvent	None.
Water Hardness	Not given
Remarks - Method	The WAF was prepared in a similar manner as the fish test (see 8.2.1). Based on the range-finding test, the definitive test was conducted for 96 h under static conditions using dilution water control and the WAF of 1000 mg/L. Approximately 10000 algal cells/mL were allocated into each of three replicates of the treatment and control. The number of algal cells/mL in each test vessel and the occurrence of relative size differences, unusual cell shapes, colours, flocculations, adherence of cells to test containers, or aggregation of cells was determined visually using a haemocytometer. Cell counts were made and recorded daily during the 96 h duration.

RESULTS

Biomass		*Growth*	
Nominal (WAF) E_bC50 mg/L at 96 h	*Nominal (WAF) NOE_bC mg/L at 96 h*	*Nominal (WAF) E_rC50 mg/L at 96 h*	*Nominal (WAF) NOE_rC mg/L at 96 h*
>1000	1000	>1000	1000

Remarks - Results	The 24, 48, 72 and 96 h EC50s were >1000 mg/L when calculated using biomass or growth rate. Similarly, the 96 h NOEC was calculated to be 1000 mg/L. No effects were noted during the test. Total organic carbon (TOC) analyses were performed at 0 and 96 h, with no significant change compared to control, though levels were low (1.2-

	2.8 mg C/L). Temperature and pH measurements were within acceptable limits during the test.
CONCLUSION	The test substance is considered to be non-toxic to algae up to the limit of its water solubility.
TEST FACILITY	Wilbury T. R. Laboratories Inc (1998c)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Analogous chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge.
Water Hardness	<4 mg $CaCO_3$/L
Exposure Period	3 hours
Concentration Range	650 - 10000 mg/L
Remarks – Method	Based on the range-finding test performed at concentrations of 10, 100, 500 and 1000 mg/L, the definitive test was conducted under static conditions for 3 hours. Nominal concentrations of 0 (control), 650, 1300, 2500, 5000 and 10000 mg/L were prepared by the addition of the test substance directly to the dilution water. After 3 h incubation period the concentration of the dissolved oxygen was measured. The test was performed using 3 nominal concentrations of the reference substance, 3,5-dichlorophenol at 5, 12 and 30 mg/L.
RESULTS	
IC50	>10000 mg/L
NOEC	10000 mg/L
Remarks – Results	Insoluble material was observed floating on the surface of the test media in all non-control test vessels in the test. The EC50 for the reference was within the acceptable range. 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 percentage inhibition was <50% of the control at all concentrations tested.
CONCLUSION	The test substance is not inhibitory to activated sludge micro-organisms.
TEST FACILITY	Wilbury T. R. Laboratories Inc (1998d)

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 provided, the notified chemical is not toxic up to the limit of water solubility where the TOC = 1.2–5.5 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 = 1.2-5.5 mg/L This value allows for at least 3 orders of magnitude safety factor using a PEC of 4 µg/L. Further, the low water solubility of the notified chemical and its limited release to the aquatic environment (mainly via stormwater drainage) are expected to reduce the amount that may potentially cause toxicity in solution. The notified chemical is expected to become associated with 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 a Buehler skin sensitisation test, challenges to previously exposed rats resulted in markedly increased skin reactions compared with naïve controls. Based on this evidence, 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.

In a dermal irritation test using an analogous chemical, a number of signs of dermal irritation were seen, persisting in all animals for more than 7 days. Based on this evidence, the notified chemical is classified in accordance with the approved criteria as:

R38 - Irritating to skin.

Two repeat dose toxicity studies were conducted, and no NOEL could be determined. The animals receiving 10 and 100 mg/kg bw/day in the 90-day test exhibited changes to blood chemistry, increased liver and kidney weights, lesions in the stomach, and aggregations in the mesenteric lymph node. However, these changes are not considered to be signs of serious systemic toxicity, and thus the classification as 'R48 – Danger of serious damage to health by prolonged exposure' is not required.

The analogue chemical was of low acute toxicity via oral and dermal routes, and was slightly irritating to eyes, although this finding is somewhat surprising given the strong evidence of skin irritation.

There was no evidence of genotoxicity based on the following tests: bacterial reverse mutation, *in vitro* mammalian chromosome aberration test and *in vivo* mouse micronucleus assay.

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 2002).

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 severely irritating to skin and may cause skin sensitisation. 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
R38 – Irritating to skin

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.)
Irritant – Warning. Causes skin irritation. (Category 2.)

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

Note: The MSDSs and labels for any lubricant products containing the notified chemical were not provided.

11.1. Material Safety Data Sheet

The MSDS of the lubricant additive package containing 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 lubricant additive package containing 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
  - R38 Irritating to skin

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - >1% R43 May cause sensitisation by skin contact
  - >20% R38 Irritating to skin

- 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

Covance Laboratories Inc (1998a) Acute Oral Toxicity Study of [Analogous Chemical] in Rats. Covance Laboratories Inc. Vienna, Virginia, USA (unpublished report submitted by notifier).

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