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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Z-55

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FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Lubrizol International Inc. (ARBN 002 747 944) of 28 River Street Silverwater NSW 2128.

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, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Spectral Data, Purity, Hazardous and Non-hazardous Impurities, Additives/Adjuvants, Import Volume, and Use Details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Part B: Hydrolysis as Function of pH, Dissociation Constant, Flammability Limits.
Part C: Acute Inhalation Toxicity, Bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
Korea: No. 216 (2003), Canada (submitted)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Z-55

3. COMPOSITION

DEGREE OF PURITY
High

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Import

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-3	1-3	3-10	3-10	10-30

USE
As a lubricant additive.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Lubrizol International Inc.

TRANSPORTATION AND PACKAGING
A concentrate or additive package (containing <30% notified chemical) will be transported by road in ISO containers (208 L or 1250 L drums) to the notifier's warehouse for storage, and then by truck or rail to a number of customer blending facilities in NSW and VIC. The finished lubricant emulsion (<3% notified chemical) will be packaged into consumer size containers (approximately 1 L) and transported to distributors or end users. Storage will be in a covered bunded area and in accordance with state legislation.

5.2. Operation description

The notified chemical will not be manufactured in Australia but will be imported at <30% in a lubricant additive package with approximately 2-4 shipments per year.

At a customer blending plant, this product will be decanted from the shipment containers into a mixing tank for diluting with oil and other additives to make the final lubricant fluids containing <3% notified chemical. The blending process is fully enclosed and automated with exhaust ventilation fitted to capture volatiles at source. Packaging of the finished lubricant into the end use containers using filling lines will also be automated.

When the equipment is cleaned, residues of the chemical will be flushed through containers, blend tank and transfer lines with mineral oil. However, it is indicated that these oils would likely be used in another blend and thus no losses are expected.

The finished lubricant products will be sold and transported to a range of end-users such as commercial sites or consumer markets across Australia for use in automobile servicing tasks. It is expected that the lubricant will be filled in the sumps of machines until it is worn and needs to be replaced.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and warehouse workers	small	--	--
Blending workers	1-2	1-3 h	2-4 days/year
Packaging workers	2-3	2-5 h	--
Equipment cleaning worker	2-3	2-4 h	--

Exposure Details
During transport and storage, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached. Should a spill occur, it is expected to be contained and collected using inert absorbent materials, and placed into suitable containers for recovery or disposal in accord with the MSDS and official regulations.

Dermal and ocular exposure due to splashes and spillages can occur during certain blending and packaging processes, equipment cleaning and maintenance. For example, blending workers when pumping and metering the imported lubricant into mixing tanks and packaging workers when connecting/disconnecting transfer lines may be potentially exposed to the notified chemical at a concentration up to 30% and 3% respectively. Exposure of cleaning, sampling and testing workers are anticipated to be less frequent and in smaller quantities.

The notifier indicates that adequate ventilation will be in place to prevent workers from breathing mist and volatiles. Operators of the reformulation plants will wear splash proof goggles, chemically

resistant gloves, rubber overshoes, aprons, or other protective clothing, and appropriate respirators when required. In addition, the entire reformulation and packaging process for the product containing Z-55 within the Lubrizol or its customer blending facilities is generally automated, enclosed, and expected to be performed by well-trained staff. Copies of the MSDS will be readily accessible in all work areas.

Exposure during end use automobile services is expected to be confined to dermal contamination with drips and spills when replacing used lubricant. There is also potential for exposure while handling automobile components that have been in contact with the lubricant. Workers will wear protective clothing and gloves when carrying out these activities.

5.4. Release

RELEASE OF CHEMICAL AT SITE

There will be no environmental exposure associated with the manufacture of the notified chemical in Australia as this does not take place here.

During the reformulating and packaging there is the potential for release due to spills, equipment cleaning and import container residues. However, the empty container and processing equipment will be cleaned with mineral oil, which will then be used in the formulation of the next batch. If the washing oil cannot be used in the next batch it may be disposed of to a recycler or incinerated. The containers will be sent to licensed drum recyclers, and this will also include any drums that cannot be cleaned on site. Spills are expected to be minor and to be contained and adsorbed with earth or sand, drummed and disposed of to a licensed site. It is expected that less than 1% of the annual import volume will be released during reformulation.

RELEASE OF CHEMICAL FROM USE

Since the additive package containing the notified chemical will be used in automotive lubricants, there may be some accidental losses when the oil is added during automobile manufacture, oil changes or "top up". As the notified chemical will thermally decompose during use with a concurrent decline in its concentration in the lubricant, there is no expected release of the chemical to the environment under normal conditions of use, except for oil leaks. However, the major release will be from used oil disposal which will include recycling, reuse, inappropriate disposal, landfill and incineration. Inappropriate disposal examples include burial, release to stormwater, wood treatment and dust suppression.

There will be residual amounts of oil left in emptied containers, which will be disposed of to landfill in the container.

5.5. Disposal

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 used oil could be expected to be disposed of responsibly either to oil recycling or incineration. Assuming this is the case, negligible release of the notified chemical should result from these professional activities. 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. Meinhardt (2002) estimated that DIY activities account for 7-10% of the unaccounted used oil.

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. In a worst case scenario of 14% of the used oil removed by DIY enthusiasts, the notified chemical could be collected for recycling (840 kg), buried or disposed of in landfill (1050 kg), disposed of in stormwater drains (210 kg) and used in treating fence posts, to kill weeds or disposed of in other ways (2100 kg).

Therefore, an amount less than 1% of the total import volume of the notified chemical could be expected to enter the aquatic environment via disposal into the storm water system. Since the use of the

oil products will occur throughout Australia, release from use or disposal will be very diffuse. Release of the notified material in high concentrations is very unlikely except as a result of transport accidents.

Residues in empty containers from garages and DIY consumers would be disposed of in municipal landfills.

Material spilled during repackaging and use will be collected for incineration or disposal to landfill.

5.6. Public exposure

There is potential for dermal exposure with the possibility of ocular and inadvertent oral exposure by the public purchasing the formulated lubricants for do-it-yourself maintenance tasks, or handling components which have been in contact with the oil. However, exposure will be low because the formulated products contain <3% notified chemical and are presented in small size containers.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Light amber viscous liquid

Pour Point -11ºC

METHOD OECD TG 102 Melting Point/Melting Range.
Remarks The pour point was determined using BS2000: Part 15 (equivalent to ISO 3016).
TEST FACILITY SafePharm Laboratories (2003a)

Boiling Point 692ºC at 102.13 kPa (calculated)

METHOD OECD TG 103 Boiling Point - ASTM E537-86.
Remarks Using differential scanning calorimetry, the notified chemical was determined to gradually decompose from 192ºC with no boiling value obtained. The boiling temperature of the main component of the notified chemical was calculated to be 692ºC using an adaptation of the Stain and Brown method (Syracuse Research Corporation Inc 1999).
TEST FACILITY SafePharm Laboratories (2003a)

Density 932 kg/m^3 at 20ºC

METHOD OECD TG 109 Density of Liquids and Solids.
Remarks Pycnometer method.
TEST FACILITY SafePharm Laboratories (2003a)

Vapour Pressure 6.2 x 10^{-9} kPa at 25ºC

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks The vapour pressure was determined using a vapour pressure balance with measurements over a range of 170-185ºC and linear regression analysis to enable extrapolation to 25ºC.
TEST FACILITY SafePharm Laboratories (2003b)

Water Solubility <1.43 x 10^{-4} g/L at 20ºC

METHOD OECD TG 105 Water Solubility.
Remarks Due to the physical nature of the notified chemical (viscous liquid), the shake flask method was used instead of the column elution method as recommended by the TG 105 for solubilities <10^{-2} g/L. Analytical method: gas chromatography.
TEST FACILITY SafePharm Laboratories (2003a)

Hydrolysis as a Function of pH Not determined

Remarks Test was not conducted due to the complex nature and low water solubility of the notified chemical. The notified chemical does contain functional groups that may hydrolyse. However, this is not likely to occur in the environmental pH 4-9 due to the low water solubility.
TEST FACILITY SafePharm Laboratories (2003a)

Fat (or n-octanol) Solubility Miscible with fat in all proportions

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks Standard fat was used and miscibility assessed visually.
TEST FACILITY SafePharm Laboratories (2003a)

Partition Coefficient (n-octanol/water) log Pow >9.4 at 20ºC

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks HPLC Method. Preliminary estimation, based on the visual assessment of the solubilities in water and octanol, indicated that the log Pow of the notified chemical was greater than 4.92. In the definitive test, four reference substances with log P_{ow}=7.1 (1-phenylnonane), log P_{ow}=8.1 (1-phenylundecane), log P_{ow}=8.7 (1-phenyldodecane) and log P_{ow}=9.4 (1-phenyltridecane) were used. The notified chemical was eluted beyond the reference material with the highest retention time (1-phenyltridecane), thus indicating its log P_{ow} is greater than 9.4.
No pH adjustment was undertaken since the notified chemical would not be ionised in the pH range of 3-14.
TEST FACILITY SafePharm Laboratories (2003a)

Adsorption/Desorption log K_{oc} >5.63

METHOD OECD TG 121 Estimation of the Adsorption Coefficient (K_{oc}) on soil and on sewage sludge using High Performance Liquid Chromatography (HPLC).
Remarks The notified chemical, formamide and 11 reference standards (with log K_{oc} ranging from 1.25 for acetanilide to 5.63 for DDT) were injected in duplicate. The notified chemical was eluted beyond the reference material with the highest retention time (DDT), thus indicating its log K_{oc} is greater than 5.63.
The study was done only on the non ionised form of the notified chemical at pH 7.
TEST FACILITY SafePharm Laboratories (2003a)

Dissociation Constant Not determined

Remarks Due to the complex nature of the notified chemical and its low water solubility, testing was not feasible.

Particle Size Not applicable

Remarks The notified chemical is a liquid.

Flash Point 210±2ºC at 101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point - ASTM D3278-89 (ISO 3679-1983).
Remarks A closed cup equilibrium method was used.
TEST FACILITY SafePharm Laboratories (2003b)

Flammability Limits Not determined

Remarks The notified chemical is not expected to be a flammable, but may be a combustible liquid.

Autoignition Temperature 396±5ºC

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).

Remarks A blue flame and grey fumes were observed when ignition occurred.
TEST FACILITY SafePharm Laboratories (2003b)

Explosive Properties Not expected to be explosive

Remarks Test was not conducted.

Reactivity Stable under normal environmental conditions

Remarks The notified chemical is not an oxidiser. However, it may be incompatible with reactive chemicals and extremes of temperature. Thermal decomposition or burning may release noxious fumes such as oxides of carbon and nitrogen.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity
Rat, acute inhalation	no data available
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation (10% notified chemical)
Rat, repeated dose oral toxicity – 28 days.	NOEL = 15 mg/kg/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration test	non genotoxic
Genotoxicity – in vivo erythrocyte micronucleus test	non genotoxic
Pharmacokinetic/Toxicokinetic studies	no data available
Developmental and reproductive effects	no data available
Carcinogenicity	no data available

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat/Sprague-Dawley (Crl:CD BR)
Vehicle Dried corn oil
Remarks - Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 females	2000	0/3
II	3 males	2000	0/3

LD50 >2000 mg/kg bw
Signs of Toxicity Piloerection was observed in all females on Day 1, and resolved by Day 2, as judged by external appearance and behaviour. No clinical signs of reaction to treatment were observed in any males throughout the 15-day study. Bodyweight gain was considered satisfactory in all animals.
Effects in Organs Abnormalities comprising enlarged, swollen or thickened caecum were revealed at the macroscopic examination at study termination on Day 15 in one female.
Remarks - Results None.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Huntingdon Life Sciences (2003a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified 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 (Crl:CD BR)
Vehicle	None – applied undiluted as supplied
Type of dressing	Occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	0/10

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	No dermal irritation was observed in any animal during the study.
Signs of Toxicity - Systemic	No death or systemic response to treatment was noted during the study.
Effects in Organs	No abnormalities were noted at the macroscopic examination at study termination on Day 15.
Remarks - Results	None.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Huntingdon Life Sciences (2003b)

7.3. Acute toxicity – inhalation

Remarks	Test was not conducted. Inhalation exposure would be unlikely due to the low vapour pressure of the notified chemical.

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation). US EPA OPPTS 870.2500 Acute Dermal Irritation
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Vehicle	None – applied undiluted as supplied
Observation Period	8 days
Type of Dressing	Semi-occlusive.
Remarks - Method	The humidity of the animal room exceeded the preferred range (40-70%), however it was not considered to have affected the integrity of the study.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			

Erythema/Eschar	0.3	1.3	1.0	2	8 d	0
Oedema	0	0	0	0	0 d	0

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

Remarks - Results: Very slight to well-defined erythema was evident from 1 h after bandage removal in all animals, resolving in one case 48 h later, and in the remaining animals by 8 days after treatment. Primary irritation index = 0.9.

CONCLUSION: The notified chemical is slightly irritating to the skin.

TEST FACILITY: Huntingdon Life Sciences (2003c)

7.5. Irritation – eye

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
US EPA OPPTS 870.2400 Acute Eye Irritation.

Species/Strain: Rabbit/New Zealand White
Number of Animals: 3 males
Observation Period: 4 days
Remarks - Method: No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	0	0.7	1	48 h	0
Conjunctiva: chemosis	0	0	0	0	0 h	0
Conjunctiva: discharge	0	0	0	1	1 h	0
Corneal opacity	0	0	0	0	0 h	0
Iridial inflammation	0	0	0	0	0 h	0

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

Remarks - Results: Injection of the conjunctival blood vessels with or without slight discharge was observed in all animals 1 h after instillation. In one animal, the conjunctival injection persisted for 48 h. The treated eye of two animals was overtly normal by 24 h and the remaining treated eye by 72 h after instillation.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: Huntingdon Life Sciences (2003d)

7.6. Skin sensitisation

TEST SUBSTANCE: Notified chemical

METHOD: US EPA OPPTS 870.2600 Skin Sensitisation - Maximization Test.

Species/Strain: Guinea pig/Hartley-derived Albino

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: 5% w/w in mineral oil, USP
topical: 100% w/w in mineral oil, USP

MAIN STUDY

Number of Animals: Test Group: 10 per sex Control Group: 5 per sex

INDUCTION PHASE	Induction Concentration: intradermal (Day 0): 5% w/w in mineral oil or FCA emulsion topical (Day 7): 100% w/w in mineral oil (FCA emulsion = 1:1 Freund's Complete Adjuvant and water)
Signs of Irritation	Not reported.
CHALLENGE PHASE	
1st challenge	topical (Day 21): 10% w/w in mineral oil
2nd challenge	topical (Day 29): 1% and 2% w/w in mineral oil
Remarks - Method	Due to the observation of excessive irritation in the control group at challenge using 10% notified chemical, a rechallenge was conducted using 1% and 2% notified chemical, 8 days after the 1st challenge.

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	10%	11/20	8/20		
	2%			0/20	0/20
	1%			0/20	0/20
Control Group	10%	5/10	3/10		
	2%			0/10	0/10
	1%			0/10	0/10

Remarks - Results	At the 24 h observation, dermal scores of 1 were noted in 11/20 test animals and 5/10 control animals with 10% challenge; dermal scores graded as ± were noted in 7/20 and 8/20 test animals and 2/10 and 2/10 control animals with 1% and 2% rechallenge, respectively. Overall, following the challenge and rechallenge, group mean dermal scores were considered to be similar in the test and control animals. A historical positive control study with alpha-hexylcinnamaldehyde confirmed the sensitivity of the test system.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test (10% notified chemical).
TEST FACILITY	Charles River Laboratories (2003)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified 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). JMHW Repeated Dose (28 Days) Toxicity in Mammalian Species. US EPA OPPTS 870.3050 Repeated Dose 28-Day Oral Toxicity Study in Rodents.
Species/Strain	Rat/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	Dried corn oil
Remarks - Method	Four treatment concentrations rather than three were used.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*

I (control)	5 per sex	0	0/10
II	5 per sex	15	0/10
III	5 per sex	50	0/10
IV	5 per sex	250	0/10
V (high dose)	5 per sex	1000	0/10
VI (control recovery)	5 per sex	0	0/10
VII (high dose recovery)	5 per sex	1000	0/10

Mortality and Time to Death

There were no unscheduled deaths during the study.

Clinical Observations

Ungroomed coat was seen among rats at 1000 mg/kg/day from Day 12 to Day 28 (termination) or till Day 33 (recovery animals). Salivation (pre and/or post dose) was seen among rats at 50, 250, 1000 mg/kg/day. No changes in behaviour were considered indicative of neurotoxicity. No body weight or food effects were considered to be of toxicological importance.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

At the end of the treatment period, males at 1000, 250 or 50 mg/kg/day showed lower mean haematocrit, haemoglobin concentration and red blood cell values; and females at 1000 mg/kg/day showed higher mean lymphocytes compared with controls. They were all statistically significant except the red blood cell values for males at 250 or 50 mg/kg/day. At the end of the recovery period, no differences from control in haematology were noted.

In blood chemistry, at the end of the treatment period, both sexes receiving 1000 mg/kg/day showed higher mean creatinine and phosphorus levels compared with controls. Also at this dose, females showed higher mean alkaline phosphatase, alanine and aspartate amino-transferase values; and males showed higher mean glucose, albumin and albumin/globulin ratio, and lower mean cholesterol and triglyceride levels compared with controls. Lower mean cholesterol was also seen in males at 250 mg/kg/day. These differences from control were no longer evident at the end of the recovery period, although both sexes previously treated at 1000 mg/kg/day showed higher mean cholesterol values and previously treated females showed lower albumin and albumin/globulin ratio compared with controls.

In urinalysis, both sexes treated at 1000 mg/kg/day and males treated at 250 mg/kg/day had a higher incidence and severity of ketones. Also at the high dose treatment, both sexes showed higher urinary protein levels than controls with females showing in addition higher specific gravity. No differences from controls were noted after two weeks of recovery.

Effects in Organs

Both sexes treated at 1000 mg/kg/day had statistically significant higher mean body weight adjusted liver weight compared with controls after four weeks of treatment. No such difference for body weight adjusted liver weight was observed after two weeks of recovery.

The macroscopic examination performed at termination revealed enlargement of the liver in all rats treated with 1000 mg/kg/day; forestomach oedema in 2/5 male rats (per group) treated with 250 or 1000 mg/kg/day; forestomach roughening in 1/5 male rats (per group) treated with 250 or 1000 mg/kg/day and 1/5 female rats treated with 1000 mg/kg/day; forestomach thickening in 1/5 female rats treated with 1000 mg/kg/day; and forestomach depression in 1/5 male rats treated with 250 mg/kg/day, compared with none in the respective control groups. Watery contents of the stomach were seen in 5/5 male rats treated with 1000 mg/kg/day compared with none in the male control group.

In the liver, generalised hepatocyte hypertrophy was found at a minimal level in 1/5 male and 1/5 female rat at 250 mg/kg/day, and at a minimal to moderate level in all animals of both sexes at 1000 mg/kg/day, with a dose related increase in incidence and severity in both sexes. At the end of the recovery period, considerable regression in this hepatocyte hypertrophic change was observed. Minimal centrilobular hepatocyte hypertrophy was observed in one recovery female previously receiving 1000 mg/kg/day, but no effects were seen in males.

Evidence of a localised irritant effect was observed in the stomach of 4/5 male rats and 2/5 female rats at 1000 mg/kg/day, and in a single male at 250 mg/kg/day. The changes were generally low grade and included

epithelial erosion/ulceration and inflammation in the non-glandular region, epithelial hyperplasia of the limiting ridge and inflammation in the glandular region. In the recovery animals, there was considerable regression of lesions, with only minimal changes remaining in the non-glandular of a single male previously receiving 1000 mg/kg/day. During the main study, a treatment-related increase in the incidence of minimal myocardial degeneration and inflammatory cell infiltrate was noted in 3/5 and 4/5 male rats at 250 and 1000 mg/kg/day, respectively, compared with 2/5 control males. This finding was also seen in 1/5 female at 50 mg/kg/day and 2/5 females at 1000 mg/kg/day, and a single control female. Recovery animals of both sexes exhibited a return to the incidence level of the respective main study control group, with this finding observed in a single recovery female previously treated with 1000 mg/kg/day, and two control recovery males.

Remarks – Results

Statistically significant differences from control seen at the end of recovery such as lower mean eosinophil values in males; and higher basophil, monocyte and large unstained cell values in females were not considered to be attributable to treatment as the individual values recorded at the end of the recovery period for previously treated animals were generally similar to those recorded for controls and treated animals at the end of the treatment period, ie two weeks earlier. Lower mean activated partial thromboplastin time values compared with controls seen in females at 1000 mg/kg/day were also not considered to be attributable to treatment due to lack of statistical significance, no effect on other clotting parameters in either sex, and no difference noted after two weeks of recovery.

In blood chemistry, lower mean aspartate amino-transferase values seen in all treated male groups compared with controls were not considered to be attributable to treatment as there were no dosage relationships and no other corroborative findings from any of the other investigations performed on this study.

In urinalysis, statistically significant lower urinary protein levels and lower volumes seen at the end of recovery in males and females of the high dose respectively were not considered to be due to treatment as the individual values were within the control range and they would not be expected to change notably over the two week recovery period.

Organ effects in the liver and stomach seen at the high doses were reversible after the recovery period.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 15 mg/kg bw/day in this study, based on clinical observation and haematology.

TEST FACILITY	Huntingdon Life Sciences (2004)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. JMHW Reverse Mutation Test using Bacteria US EPA OPPTS 870.5100 Bacterial Reverse Mutation Test. Plate incorporation procedure/Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2uvrA (pKM101).
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Concentration Range in Main Test	With metabolic activation: 5, 15, 50, 150, 500, 1500, 5000 µg/plate. Without metabolic activation: 5, 15, 50, 150, 500, 1500, 5000 µg/plate.
Vehicle	DMSO
Remarks - Method	Two independent tests (plate incorporate and pre-incubation) were conducted in triplicate, but only five concentrations were used in Test 2.

RESULTS

Remarks - Results	In test 2 in the presence of S9 mix TA1535 treated at ≥500 µg/plate exhibited approximately double revertant colony counts compared to control. No substantial increases in revertant colonies were noted with any other tester strains at any concentrations in either the presence or absence of S9 mix in both tests. Although there were some reductions noted in revertant colony counts at 5000 µg/plate no thinning of the background lawn of non-revertant cells was observed at any concentrations tested up to 5000 µg/plate. The vehicle and positive controls responded appropriately.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Huntingdon Life Sciences (2003e)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test. US EPA OPPTS 870.5375 In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	Human lymphocytes
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Vehicle	Acetone
Remarks - Method	Two independent tests were conducted in duplicate.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	39.06, 78.13*, 156.25, 312.5, 625, 1250*, 2500, 5000*	3 h	20 h
Test 2	9.77, 19.53, 39.06, 78.13, 156.25, 312.5*, 625*, 1250*, 2500, 5000	20 h	20 h
Present			
Test 1	39.06, 78.13*, 156.25, 312.5, 625, 1250*, 2500, 5000*	3 h	20 h
Test 2	9.77, 19.53, 39.06*, 78.13, 156.25, 312.5, 625*, 1250, 2500, 5000*	3 h	20 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation**	*Genotoxic Effect*
Absent				
Test 1	Not performed	≥1250	≥5000	Negative
Test 2	Not performed	≥1250	≥1250	Negative
Present				
Test 1	Not performed	>5000	≥5000	Negative
Test 2	Not performed	>5000	>5000	Negative

*Precipitate noticeable on slides for microscopic examination.

Remarks - Results	No chromosomal aberrations were seen at any dose level in both the absence and presence of S9 mix, when compared with the solvent control. However, in the absence of S9 mix, the notified chemical at 1250 µg/mL caused a reduction in the mitotic index to 81% (Test 1) and 32% (Test 2) compared to the solvent control. A statistically significant increase in the

proportion of polyploid cells was also observed in the absence of S9 mix (but in Test 2 only). At the end of the exposure period in Test 1 both with and without S9 mix, precipitates were observed in cultures treated at 312.5 µg/mL and above, with oily residue seen at 2500 µg/mL and above.
The vehicle and positive controls responded appropriately.

CONCLUSION The notified chemical was not clastogenic to human lymphocyte cells treated in vitro under the conditions of the test.

TEST FACILITY Huntingdon Life Sciences (2003f)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE Notified chemical

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC B.12 Mutagenicity Mammalian Erythrocyte Micronucleus Test.
JMHW Mutagenicity Mammalian Erythrocyte Micronucleus Test.
US EPA OPPTS 870.5395 Mammalian Erythrocyte Micronucleus Test.

Species/Strain	Mouse/CD-1
Route of Administration	Oral – gavage
Vehicle	Corn oil
Remarks - Method	The temperature of the animal room was outside the preferred range (18-25°C), however it was not considered to have affected the integrity of the study.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	14 males	0	24 & 48
II (low dose)	7 males	500	24
III (mid dose)	7 males	1000	24
IV (high dose)	14 males	2000	24 & 48
V (positive control, M)	5 males	12	24

M=mitomycin C

RESULTS

Doses Producing Toxicity	At 1000 mg/kg, two animals showed signs of underactivity, irregular respiration and salivation. At 2000 mg/kg, one animal showed signs of underactivity and salivation. All animals survived to scheduled termination.
Genotoxic Effects	A statistically significant increase in the number of micronucleated immature erythrocytes over control was observed at 1000 mg/kg and at 24 h sampling time. No significant decreases in the proportion of immature erythrocytes or increases in the incidence of micronucleated mature erythrocytes were seen at either sampling time. The vehicle and positive controls responded appropriately.
Remarks - Results	The observed increase in micronucleated erythrocytes at 1000 mg/kg was not considered to be treatment related as the increase was not dose related, individual and group mean values were within the historical control range, and possibly the low vehicle control values increased the statistical sensitivity.

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

TEST FACILITY Huntingdon Life Sciences (2003g)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test (Modified Sturm test).

Inoculum: Mixed population of activated sludge micro-organisms from plant that predominantly treats domestic sewage.

Exposure Period: 28 days

Auxiliary Solvent: None

Analytical Monitoring: CO_2 analysis – Tekmar-Dohrmann Apollo 900 TOC analyser and Ionic 1555B TOC analyser.
DOC – Shimadzu TOC-5050A TOC analyser.

Remarks - Method: Reference material – sodium benzoate.
Toxicity control was conducted with the test material and sodium benzoate.
The test material was adsorbed onto granular silica gel prior to dispersion in the test medium so as to improve its dispersion and increase surface area exposure. The test concentration used was 10 mg C/L. The temperature was maintained at 21°C.

RESULTS

Test substance		*Sodium Benzoate*		*Test Material And Sodium Benzoate*	
Day	*% degradation*	*Day*	*% degradation*	*Day*	*% degradation*
1	12	1	24	1	18
6	48	6	49	6	46
10	58	10	56	10	62
12	61	12	61	12	61
20	64	20	69	20	66
28	71	28	85	28	70

Remarks - Results: The 10 day window criteria, whereby the test material must reach 60% degradation within 10 days after it has reached 10% degradation, was met.
The sodium benzoate reached 85% degradation in 28 days and satisfied the 10 day window.
The toxicity control reached 70% degradation by day 28 thus indicating that the material was not toxic to sewage micro-organisms.

CONCLUSION: Since the test material reached 71% degradation by day 28 and met the 10-day window criteria, it can be classified as readily biodegradable.

TEST FACILITY: SafePharm Laboratories (2003c)

8.1.2. Bioaccumulation

No bioaccumulation data was submitted. However due to its low water solubility and readily biodegradation, the notified chemical is not likely to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical

METHOD	OECD TG 203 Fish, Acute Toxicity Test – semi-static.
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	None
Remarks – Method	Test material was prepared as the Water Accommodated Fraction (WAF). To ensure thorough mixing the test material was melted in a water bath at 50°C prior to use. A preliminary range finding test indicated that a single concentration of 1000 mg/L WAF was needed. The WAF was prepared by mixing the test material (21 g) with water (21 L) for 23 hours and then left to stand for 1 hour. At this stage there was a brown oily slick observed on the surface of the mixture. The aqueous phase (WAF) was then siphoned off by mid-depth siphoning. The WAF contained dissolved test material and any leachates from the test material. The WAF was observed to be clear and colourless with no micro-dispersions or undissolved test material present. A TOC analysis was performed on the test solution at 0, 24, 72 and 96 hours. Preliminary work indicated that it was not possible to determine the concentration of the test material in the WAF preparation, so actual concentrations were not determined. There were 2 replicates of the test concentration with 10 fish per replicate.

RESULTS

Concentration mg/L (WAF)		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	-	10	0	0	0	0	0
1000	-	20	0	0	0	0	0

LC50	> 1000 mg/L WAF at 96 hours.
NOEC (or LOEC)	1000 mg/L WAF at 96 hours.
Remarks – Results	No sub-lethal effects were observed. Temperature was maintained at 14 ± 0.4°C, pH ranged from 7.5–8.1 and dissolved oxygen ranged from 92 –95 % ASV. The TOC analysis showed no significant differences in the amount of carbon present within the 1000 mg/L loading rate of WAF test samples when compared to the controls, indicating essentially that none of the test material had dissolved.
CONCLUSION	The study shows that the test material is not toxic to fish up to its limit of water solubility.
TEST FACILITY	Safepharm Laboratories (2004a)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	None
Remarks - Method	Test material was prepared as the Water Accommodated Fraction (WAF). To ensure thorough mixing the test material was melted in a water bath at

50ºC prior to use. A preliminary range finding test indicated that a single concentration of 1000 mg/L WAF was needed. The WAF was prepared by mixing the test material (2.5 g) with water (2.5 L) for 23 hours and then left to stand for 1 hour. At this stage there was a brown oily slick observed on the surface of the mixture. The aqueous phase (WAF) was then siphoned off by mid-depth siphoning. The WAF contained dissolved test material and any leachates from the test material. The WAF was observed to be clear and colourless with no micro-dispersions or undissolved test material present.
A TOC analysis was performed on the test solution at 0, 24 and 48 hours.
Preliminary work indicated that it was not possible to determine the concentration of the test material in the WAF preparation, so actual concentrations were not determined.
There were 4 replicates of the test concentration and 2 controls with 10 daphnia per replicate.

RESULTS

Concentration mg/L (WAF)		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	20	0	0
1000	-	40	0	0

LC50	>1000 mg/L WAF at 48 hours
NOEC (or LOEC)	1000 mg/L WAF at 48 hours
Remarks - Results	No sub-lethal effects were observed. Temperature was maintained at 20.8ºC, pH was 8.0 and dissolved oxygen ranged from 91–93 % ASV. The TOC analysis showed no significant differences in the amount of carbon present within the 1000 mg/L loading rate of WAF test samples when compared to the controls, indicating essentially that none of the test material had dissolved.

CONCLUSION The study shows that the test material is not toxic to daphnia up to its limit of water solubility.

TEST FACILITY Safepharm Laboratories (2004b)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	
Nominal	1000 mg/L
Actual	Not available
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	None
Remarks - Method	Test material was prepared as the Water Accommodated Fraction (WAF). To ensure thorough mixing the test material was melted in a water bath at 60ºC prior to use. A preliminary range finding test indicated that a single concentration of 1000 mg/L WAF was needed. The WAF was prepared by mixing the test material (2 g) with culture medium (2 L) for 23 hours and then left to stand for 1 hour. At this stage there was a brown oily slick observed on the surface of the mixture. The aqueous phase (WAF) was

	then siphoned off by mid-depth siphoning. The WAF contained dissolved test material and any leachates from the test material. The WAF was observed to be clear and colourless with no micro-dispersions or undissolved test material present. One litre of the WAF was inoculated with algal cells. A TOC analysis was performed on the test solution at 0 and 72 hours (no algal cells present). Preliminary work indicated that it was not possible to determine the concentration of the test material in the WAF preparation, so actual concentrations were not determined. There were 6 replicates of the test concentration and 3 controls.
RESULTS	
	E_bL_{50} (72 h) > 1000 mg/L WAF, where EL is effective loading rate. E_rL_{50} (72 h) > 1000 mg/L WAF, where EL is effective loading rate. NOEC = 1000 mg/L.
Remarks - Results	Neither the growth nor the biomass were affected by the test material. The E_bL_{50} and E_rL_{50} were determined by inspection of the area under the growth curve data after 72 hours and inspection of the growth rates for the period 0-72 hours, respectively. The mean cell density in the controls increased by a factor of 66 from $1.13X10^4$ to $7.42X10^5$ cells per mL. The temperature was maintained at 24°C, while the pH at 0 h ranged from 7.2 to 7.3 and then at 72 h ranged from 8.4-8.5. This variation was within acceptable limits.
CONCLUSION	The study shows that the test material is not toxic to algae up to its limit of water solubility.
TEST FACILITY	SafePharm Laboratories (2004c)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Mixed population of activated sewage sludge micro-organisms from plant that predominantly treats domestic sewage.
Exposure Period	3 hours
Concentration Range	
Nominal	1000 mg/L
Remarks – Method	Since the test material was a complex reaction mixture the test was done at a nominal concentration in excess of the water solubility level. Prior to use the test material was melted in a water bath prior to use, then a measured amount was dispersed in water. Reference material: 3,5-dichlorophenol at 3.2 and 32 mg/L. Temperature was maintained at 21°C.
RESULTS	
EC_{50}	>1000 mg/L
NOEC	1000 mg/L
Remarks – Results	The 3 hour EC_{50} of the reference material (3,5-dichlorophenol) was 13 mg/L. The variation in respiration rates between the controls was ± 1%. These two results satisfy the test validity criteria.
CONCLUSION	The test material was not toxic to the sewage sludge microorganisms.

TEST FACILITY SafePharm Laboratories (2003d)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Release of the notified chemical will only occur during blending and use since it will not be manufactured in Australia.

Losses during blending are expected to be minimal because the process is highly automated and the equipment used will be cleaned with oil and these washings will be used in the formulation of the next batch. In these situations release would only be through accidental spills that would be recycled or collected for incineration. Losses during addition to motors will also be low.

As indicated in section 5.5, the fate of used oils in Australia has been the subject of a number of surveys with at least 60% of all used oils being collected for recycling and resold mainly as fuel oil. The fate of the remaining 40% of used oil could include a substantial portion being reused especially in the mining, agricultural and transport sectors. The Australian Institute of Petroleum survey (AIP 1995) indicated no evidence that bulk used oil was being dumped, but admitted there was some uncertainty as to the fate of 40% of used oil generated, but not collected for recycling.

This improper disposal is, however, widespread across Australia. Most disposed of improperly or to landfill is likely to become associated with soils or sediments. The chemical is not expected to be mobile or to leach from landfill sites because of its poor water solubility. The notified chemical is readily biodegradable therefore will breakdown in the environment.

The main environmental exposure is expected to result from inappropriate disposal of waste lubricant product. Assuming a worst case scenario of about 14% of lubricant will be used on the DIY market, only about 20% of this, ie 840 kg of notified chemical, is expected to be collected for recycling, approximately 25% (ie 1050 kg notified chemical) will go to landfill and up to 2100 kg will be disposed of in other inappropriate ways (treat fence posts, kill weeds etc.) and 5% (210 kg) is estimated to be released into the stormwater drains.

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

It is difficult to estimate the Predicted Environmental Concentration (PEC) of the notified chemical released into the stormwater drains, with potential to enter the aquatic environment. However, a worst case estimated PEC might be calculated if it is assumed that all of the 5% of the notified substance (ie 210 kg) expected to be released into the stormwater drains in 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 210 kg and the annual volume of water drained from this region estimated to be approximately 250 X 10^6 m^3, the resultant PEC is approximately 0.84 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.

Any notified chemical burned in the engine, recycled for fuel, or disposed of by incineration would result in the evolution of water vapour and oxides of carbon and nitrogen. Sludges from waste treatment plants or oil recycling facilities may also be incinerated.

The notified chemical is not expected to cross biological membranes due to its high molecular weight and low water solubility and is therefore not expected to bioaccumulate.

9.1.2. Environment – effects assessment

The ecotoxicity data indicate the notified chemical is not toxic to aquatic organisms up to the

limit of its water solubility (all LC_{50} were greater than 1000 mg/L WAF). Since three trophic levels were studied the safety factor used is 100. Therefore the PNEC is 1000/100 = 10 mg/L. Since TOC testing indicated that very little notified chemical was in solution, it is more likely that the test concentration would be closer to 1 mg/L, giving a PNEC of 10 μg/L.

9.1.3. Environment – risk characterisation

The worst-case PEC calculated above is significantly below studied toxic levels and the resulting risk quotient (Q = PEC/PNEC=0.84/10) is significantly below 1. Further, the low water solubility of the notified chemical and its limited release to the aquatic environment (mainly via stormwater drainage in a dispersed fashion) can be expected to reduce the possibility of sufficient amounts to remain in solution to cause acute toxicity. The notified chemical's ability to become associated with the sediments and biodegradation will further reduce the risk to the aquatic life.

Overall, the environmental risk from the proposed reformulation 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 and the potential toxic effects to fish and other aquatic organisms the notified chemical should be prevented from entering waterways.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

During transport and storage, workers are unlikely to be exposed to the notified chemical. In the event of an accident, spills will be removed in accord with the MSDS and government regulations.

During reformulation, packaging and cleaning procedures, dermal and ocular exposure will potentially occur due to splashes, drips and spills of the notified chemical. In particular, when workers connect or disconnect transfer hoses, decant or pump the lubricant additive package from bulk containers into a blend tank, or pack the finished lubricant into consumer drums. Workers may also make dermal contact with contaminated drum surfaces when inserting bungs and labelling the drums and residues of the notified chemical when flushing mineral oil through blend tanks and transfer lines. However, the blending and packaging processes are mainly automated and will occur in an enclosed system, worker intervention is not required unless the machine malfunctions or needs adjustment. The plant operators generally receive adequate training in handling additive packages, observe safe work practices and wear personal protective equipment such as gloves, chemical goggles, protective clothing, and respirators when required.

Quality control personnel may be potentially exposed to the notified chemical when sampling and testing formulations containing it. However, they will handle only small quantities and will wear appropriate personal protective equipment. The testing of lubricant formulations will be carried out in a well-ventilated booth.

End users of the finished lubricant may be exposed to notified chemical during oil replacement or handling automotive components that have come into contact with the oil. They will wear gloves, overalls, and safety boots.

Overall, on the basis of the engineering controls, safe work practices and personal protective equipment, worker exposure to the notified chemical would be limited.

9.2.2. Public health – exposure assessment

Exposure of the general public to the notified chemical as a result of accidental spill or dermal contact with the formulated lubricant during DIY automotive servicing tasks is assessed as being low because of the low concentration of the notified chemical in the oil product and the low frequency of use.

9.2.3. Human health – effects assessment

The notified chemical has a low acute oral and dermal toxicity in rats (LD50>2000 mg/kg/bw). It is slightly irritating to the skin and eyes of the rabbit. It shows no sensitising activity at 1% and

2% solution in an adjuvant study in guinea pigs. The NOEL was established to be 15 mg/kg bw, based on clinical observations and haematology, in a 28-day repeat dose oral study in rats. The notified chemical was not mutagenic in a bacterial reverse mutation assay, and did not reveal any genotoxic potential in vitro and vivo tests.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002). However, the MSDS indicates that dust and/or mist generated from processing of the notified chemical may cause mechanical irritation to the eyes and respiratory tract if inhaled. Repeated or prolonged skin contact with excessive lubricants and greases may result in skin irritation and/or dermatitis (oil acne or folliculitis) (NZDermNet, 2004).

9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified chemical is expected to be low, given the low hazard of the chemical, the automated process and engineering controls, the good work practices and safety measures including use of appropriate personal protective equipment by workers.

The notified chemical may be present in formulations containing hazardous ingredients. If these formulations 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.

9.2.5. Public health – risk characterisation

Members of the public may make dermal contact with the lubricant containing the notified chemical. However, the risk to public health will be negligible because the notified chemical is present at low concentrations and has low acute oral and dermal toxicity.

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

10.1. Hazard classification

Based on the available data the notified chemical is not classified as a hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

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.

The notified chemical is not classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) for both health and environmental hazards.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, 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.

10.3.2. Public health

There is No Significant Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product 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 product 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

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in the lubricant additive package:
  - Enclosed and automated processes at the blending and packaging sites, including enclosed and automatic transfer lines/pumps for loading and emptying of the mixing and transport vessels;
  - Adequate ventilation for the plant operators and local exhaust ventilation for quality control personnel.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in the lubricant additive package:
  - Adequate training for staff in handling oils and lubricants;
  - Implementation of general health surveillance and monitoring programs as required.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in the lubricant additive package:
  - Industrial standard protective clothing and gloves;
  - Safety glasses with side-shields/chemical goggles;
  - Vapour respirators if required.

  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.

Environment

- The following control measures should be implemented by formulators to minimise environmental exposure during blending of the notified chemical:
  - Blending should be carried out in bunded areas with no access to stormwater drains.

- The following control measures should be implemented by end users to minimise

environmental exposure during use of the lubricant containing the notified chemical:
- Topping up should be done in a suitable area so that spills or used lubricant can be collected and stored in a sealable container for disposal.

Disposal

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

Emergency procedures

- Spills/release of the notified chemical should be handled by containment, absorption with soil, sand or similar material. Spilt material and all absorbent should be collected and placed in a labelled sealable container for disposal to landfill or incineration.

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

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