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14 February 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Z-51

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

Applicant(s)
Holder of the original assessment certificate (No. 1854, STD/1103):
Lubrizol International, Inc. (ARBN 002 747 944) of 28 River Street Silverwater NSW 2128

Applicant for an extension of the original assessment certificate:
Conoco Phillips Lubricants Australia Pty Ltd (ABN 62 072 486 198) of Level 2, Suite 10 "Ocean Central", 2 Ocean St Maroochydore Qld 4558

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:
Identity of chemical;
Composition; and
Exact manufacture/Import Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting point/Boiling point;
Water solubility;
Hydrolysis as a Function of pH;
Partition Co-efficient;
Absorption/Desorption;
Particle size;
Flammability limits;
Explosive properties; and
Ecotoxicity data

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2004)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
OS180946

MARKETING NAME(S)
Z-51

3. COMPOSITION

DEGREE OF PURITY
>95%

4. INTRODUCTION AND USE INFORMATION

Mode of Introduction of Notified Chemical (100%) Over Next 5 Years
The notified chemical will be imported as a component of concentrate or additive package containing 1 to 10% w/w notified chemical. The imported product will then be distributed to customers who will formulate the final lubricant. Alternatively, lubricant containing the notified chemical will be imported. The final lubricant will contain 0.1 to 1.0% w/w notified chemical.

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

Year	*1*	*2*	*3*	*4*	*5*
	Tonnes	*Tonnes*	*Tonnes*	*Tonnes*	*Tonnes*
Lubrizol	1 - <10	10 - <30	10 - <30	10 - <30	10 - <30
Conoco Phillips	< 1	< 1	< 1	< 1	< 1

USE
The notified chemical will be used as a component of automotive lubricants.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Not stated

IDENTITY OF MANUFACTURER/RECIPIENTS
Lubrizol International, Inc. (ABN 002 747 944)
28 River Street
Silverwater NSW 2128

TRANSPORTATION AND PACKAGING
The imported concentrate containing the notified chemical will be transported by road or rail in isotainer or 330 gallon IBC containers. Smaller quantities will be transported in 55 gallon drums. The formulated lubricant will be transported by road or rail in 1 L plastic containers or 205 L steel drums.

5.2. Operation description
Following importation, the imported concentrate containing the notified chemical will be transported in original packaging to manufacturers of lubricants Australia wide. At the customer's blending facility, the concentrate will be decanted from the containers to a tank where it will be mixed with oil and other additives to give the finished lubricant containing 0.1 to 1% w/w notified chemical. The blending facility is described as being fully automated. Finished lubricant will be packed into containers of various sizes (1 to 250 L containers) using enclosed and fully automated packaging equipment.

Washing of equipment after each batch of lubricant is not required as similar products are blended using the same equipment. If washing is necessary, residual material left in the blend tank or transfer lines are flushed with mineral oil and the washing is used for subsequent blend.

Finished lubricant will be distributed to automobile manufacturers for "factory fill" applications, service garages for lubricant replenishment, and automobile stores for do-it yourself applications. When changing lubricant oil, garage workers will drain the used lubricant in an appropriate container and replace the lubricant by opening the lubricant container and manually decanting the contents of the container.

5.3. Occupational exposure
Transport and Storage
Transport and storage workers will handle sealed drums and containers of concentrate and products containing the notified chemical. Therefore, occupational exposure of these workers to the notified chemical is not expected except in the event of an accident.

Lubricant manufacture
Blending operators may have dermal and limited ocular exposure to the notified chemical as a component of the additive package while transferring the contents of the isotainer into the blending tank and when cleaning blending vessels. Packaging operators may also be exposed dermally to the finished lubricant when containers are overfilled and when the automated packaging machine malfunctions.

Workers involved in the above activities wear personal protective equipment including nitrile or neoprene gloves, chemical goggles or face shield, and protective clothing.

End Use – Service garages
Exposure to garage workers is expected to be confined to dermal contamination with drips and spills when replacing used lubricant. There is also potential for exposure while handling automotive components that have been in contact with the lubricant. Workers will wear protective clothing and gloves when carrying out the above activities.

Retail workers may also be exposed to the lubricant product when the containers are damaged.

5.4. Release

RELEASE OF CHEMICAL AT SITE
Environmental release of the notified chemical is unlikely during importation, storage and transportation, and accidental spills, leaks and catastrophic mechanical failure during a transport accident is the most likely reason for environmental release. Engineering controls (eg. IBC, isotainer and drum specifications) and emergency clean-up procedures (ie. spill response instructions on Safety Data Sheet and label) will limit the impact on the environment of such incidents. Containers holding the notified chemical will be transported directly from the Port facility to various lubricant manufacturing facilities in Australia for storage prior to blending into lubricants. Blending is undertaken using automated procedures and spillage is not expected as blending and packaging will be undertaken in an enclosed system. No aqueous wastes are generated during the blending process. Any spilled material that is not re-used for blending will be cleaned up, containerised and sent for disposal by incineration. The notifier estimates residues in emptied imported containers may comprise <1% of the import volume of the notified chemical. Emptied containers will be rinsed with mineral oil and the rinsate will be re-used in the blending process. Rinsed containers will be sent to a reconditioning facility for disposal. The formulated product (0.1-1% notified chemical) will be contained in 1-205 L containers. These containers will be transported to customer retail outlets throughout Australia (eg. automobile manufacturers, service stations) where the lubricant will be used in motor vehicle engines.

RELEASE OF CHEMICAL FROM USE
The finished lubricants will be sold in various size containers. No information was available on whether the notified chemical is altered during use as a crankcase lubricant in internal combustion engines and therefore it is assumed to be unaffected. There may be some accidental losses when lubricant is added to new vehicles, or changed. These are expected to be minor spills, which would be mostly left on the ground or cleaned up and sent to landfill. These are expected to amount to <1% of the product. In the closed system in which it is used, there is no expected release of the chemical to the environment under normal conditions of use, except for unintended oil leaks, which would mostly drip to road and pavement surfaces. Since the use of the lubricating oils will occur throughout Australia, any releases from use of oils containing the notified chemical would be diffuse.

5.5. Disposal

Imported isotainers and drums
The isotainers and drums are generally cleaned with oil and rinsate is reused in subsequent blending operations. The containers are typically reconditioned and reused. At drum reconditioner facilities, drums are typically steam cleaned with wastewater sent to wastewater treatment. Assuming 0.1% remains in emptied containers after mineral oil rinsing, ≤30 kg/year will be disposed of in wastewater based on a total import volume of <30 tonnes/year of the notified chemical. With a hydrolytic half life in water of <10 minutes (SafePharm Laboratories, 2003), degradation of the notified chemical to simpler compounds is likely in wastewater treatment plants.

Small containers
A proportion of the finished lubricant products are sold to consumers (eg. garages and DIY consumers) in small containers that are likely to be sent to landfill for disposal. Assuming 0.1% remains in the containers after use, a worst case of ~30 kg/year would be sent to landfill.

Used oils
The greatest potential for environmental exposure is through disposal of oil product wastes containing the notified chemical. 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 is 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% of oil (up to 4200 kg of the estimated maximum <30 tonnes of notified chemical imported per year) 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 DIY 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/year), buried or disposed of in landfill (≤1050 kg/year), disposed of in stormwater drains (≤210 kg/year) and used in treating fence posts, to kill weeds or disposed of in other ways (≤2100 kg/year). A proportion of the latter may be disposed of to sewer.

Therefore, about 0.7% (up to 210 kg/year) of the total import volume of the notified substance could potentially enter the aquatic environment via disposal into the stormwater system. Considering the unknown fate of some of the oil used by DIY operator, up to 7% (<2100 kg/year) may also potentially be sent to sewer for disposal. In wastewater, hydrolysis to simpler compounds is likely to occur, and wastewater treatment plant efficiency is expected to be high. 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.

5.6. 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. Public exposure to the notified chemical may occur during do-it-yourself replenishment of lubricant and 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.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Clear, colourless liquid

Freezing Point Less than -20ºC

METHOD OECD TG 102 Melting Point/Melting Range – Determination of Crystallizing Point.
TEST FACILITY Safepharm Laboratories Limited (2003a)

Boiling Point 290.9ºC at 101.3 kPa

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks The notified chemical decomposes at approximately 200ºC at 100.81 kPa (by

Differential Scanning Calorimetry). The boiling point was estimated from vapour pressure data.

TEST FACILITY Safepharm Laboratories Limited (2003a)

Density 859 kg/m^3 at 20^{o}C

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Pycnometer Method
TEST FACILITY Safepharm Laboratories Limited (2003a)

Vapour Pressure 5.2×10^{-7} kPa at 25^{o}C

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Vapour Pressure balance measurements in the range 56-80^{o}C.
TEST FACILITY Safepharm Laboratories Limited (draft a)

Water Solubility $<3.15 \times 10^{-5}$ g/L (Estimated)

Remarks The water solubility of the notified chemical was not determined due to its hydrolytic instability. Water solubility was estimated using WSKOW software.
TEST FACILITY Safepharm Laboratories Limited (2003a)

Fat Solubility Miscible in all proportions with standard fat at 37°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks Flask Method
TEST FACILITY Safepharm Laboratories Limited (2003a)

Hydrolysis as a Function of pH Not determined

METHOD OECD TG 111 Hydrolysis as a Function of pH.

PH (buffer)	*T (°C)*	*t½ (minutes)*
1.2	37	<10
4	25	<10
7	25	<10
9	24	<10

Remarks Hydrolysis of all samples was complete within 10 minutes as measured by ^{1}H NMR spectroscopy. No testing was possible by OECD TG 111 due to the absence of a suitable substance-specific method of analysis.
TEST FACILITY Safepharm Laboratories Limited (2003a)

Partition Coefficient (n-octanol/water) Not determined

METHOD Estimated by a fragment constant methodology using KOWWIN software (V 1.66 Syracuse Research Corporation).
Remarks No testing with OECD TG 107 or TG 117 was possible due to the hydrolytic instability of the notified chemical. The notified chemical is much more likely to seek the octanol phase that its hydrolysis products.
TEST FACILITY SafePharm Laboratories Limited (2003a)

Adsorption/Desorption $\log K_{oc} = 5.28$

METHOD OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.
Remarks Due to the hydrolytic instability of the notified chemical, the Koc values for the notified chemical was estimated using Quantitative Structure Activity Relationships (QSAR).
TEST FACILITY Safepharm Laboratories Limited (2003a)

Dissociation Constant Not determined

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks Not determined due to hydrolytic instability.

Particle Size Not determined

Remarks The notified chemical is liquid.

Flash Point 119°C

METHOD EC Directive 92/69/EEC A.9 Flash Point.
TEST FACILITY Safepharm Laboratories Limited (2004a)

Flammability Limits Not determined

Remarks The notified chemical is not expected to be flammable based on its vapour pressure.

Autoignition Temperature 286°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
TEST FACILITY Safepharm Laboratories Limited (2004a)

Explosive Properties Not determined

Remarks The notified chemical is not expected to have explosive properties based on structure..

Reactivity

Remarks The notified chemical is unstable in water.

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	Test not conducted.
Rabbit, skin irritation	moderately irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation – non-adjuvant test.	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOEL 15 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosomal aberration test	non genotoxic
Genotoxicity – in vivo mammalian erythrocyte micronucleus test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat/Sprague-Dawley CD
Vehicle None
Remarks - Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 females	2000	1
2	3 females	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	Hunched posture, ataxia, lethargy, pilo-erection, diuresis, decreased respiratory rate and laboured respiration. At least some clinical signs were seen in all treated animals.
Effects in Organs	Red lungs, dark liver and dark kidneys were observed at necropsy of the animal that died during the study. No abnormalities were noted in surviving animals at necropsy.
Remarks - Results	One animal was found dead 1 day after treatment. Surviving animals appeared normal 2 or 3 days after treatment. Surviving animals showed body weight gain over the study period.

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

TEST FACILITY Safepharm Laboratories Limited (2003b)

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 CD
Vehicle	None
Type of dressing	Semi-occlusive.
Remarks - Method	Initially, 1 animal/sex was treated with 2000 mg/kg. As no abnormalities were observed after 24 hours of treatment, a further group of animals (4 animals/sex) was treated with the test material at the same dose level of 2000 mg/kg.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	No signs of irritation were observed.
Signs of Toxicity - Systemic	No signs of systemic toxicity were observed.
Effects in Organs	No macroscopic abnormalities were seen at necropsy.
Remarks - Results	All animals showed body weight gain over the study period.

CONCLUSION The notified chemical is of low toxicity via the dermal route.

TEST FACILITY Safepharm Laboratories Limited (2003c)

7.3. Acute toxicity - inhalation

The acute inhalation toxicity test was not conducted.

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).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Vehicle	None
Observation Period	14 days
Type of Dressing	Semi-occlusive.
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			
Erythema/Eschar	2	2	2	2	72 hours	0
Oedema	1.67	1.67	1	2	72 hours	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 and very slight to slight oedema were observed in all animals Light brown discolouration of the epidermis was noted in all animals at 24, 48 and 72 hour observations. Loss of skin elasticity was seen in all animals at 72 hour observation. Crust formation, which prevented evaluation of erythema and oedema was noted in all animals at 7 day observation. All treated skin appeared normal at the 14-day observation.
CONCLUSION	The notified chemical is moderately irritating to skin.
TEST FACILITY	Safepharm Laboratories Limited (2003d)

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).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Observation Period	14 days
Remarks - Method	Initially, 1 animal was treated with the right eye treated with the test material and the left eye untreated for control purposes. After consideration of the ocular responses observed from the treated animal, two additional animals were treated. To minimise pain on application of the test material, local anaesthetic (0.5% amethocaine hydrochloride) was instilled to both eyes of all animals before treatment.

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	1	2	2	2	7 days	0
Conjunctiva: chemosis	1	2	2	2	7 days	0
Conjunctiva: discharge	1	1.33	2	3	7 days	0
Corneal opacity	0	0.67	1.67	2	72 hours	0
Iridial inflammation	0.3	0.0.67	1	1	72 hours	0

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

Remarks - Results: All animals had scattered or diffuse to translucent corneal opacity, iridial inflammation and moderate conjunctival irritation. Pale appearance of the nictating membrane was seen in 1 animal. One animal appeared normal at the 72 hour observation and the remaining animals appeared normal at the 14 day observation.

CONCLUSION: The notified chemical is irritating to the eye.

TEST FACILITY: Safepharm Laboratories Limited (2003e)

7.6. Skin sensitisation

TEST SUBSTANCE: Notified chemical

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

Species/Strain: Guinea pig/Hartley-derived albino

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
topical: 50%

MAIN STUDY

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

INDUCTION PHASE: Induction Concentration:
topical: 100%

Signs of Irritation: All animals showed slight to moderate irritation response after occluded topical exposure for 48 hours.

CHALLENGE PHASE

1st challenge: topical: 50% in mineral oil

2nd challenge: topical: 50 and 75% in mineral oil

Remarks - Method: No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group					
	50	1/20	0/20	0/20	0/20
	75	-	-	0/20	0/20
Control Group					
	50	0/10	0/10	0/10	0/10
	75	-	-	0/10	0/10

Remarks - Results: Dermal reactions in the test and control animals were limited to patchy erythema, except for one animal, which had a moderate patchy erythema after exposure for 24 hours at the 1st challenge.

CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test. All animals gained weight during the study.
TEST FACILITY	Charles River Laboratories, Inc. (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).
Species/Strain	Rat/Spague-Dawley Crl:CD IGS BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: none.
Vehicle	Arachis oil BP
Remarks - Method	A range finding oral repeat dose study was conducted to establish the maximum tolerated dose level of the test material. Six male and six female rats were treated for 14 days. Animals treated at 1000 mg/kg/day showed increased salivation from Day 2. No other clinical signs of toxicity were observed. No adverse effects on body weight development and no macroscopic abnormalities were detected for test or control animals. Based on the above observations, 5 dose levels were chosen and the highest dose of 1000 mg/kg/day was determined.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0/10
II (low dose)	5/sex	15	0/10
III (intermediate dose)	5/sex	150	0/10
IV (intermediate II dose)	5/sex	450	0/10
V (high dose)	5/sex	1000	0/10

Mortality and Time to Death

There were no unscheduled deaths during the study.

Clinical Observations

Increased salivation was observed in all animals in the high or intermediate II dose groups from Days 2 and 3, respectively. Hunched posture and tiptoe gait were observed in one high dose female on Day 27. Red/brown staining around the eye on Day 4 was observed in one intermediate II dose male.

There were no treatment related changes in the functional performance parameters measured, changes in sensory reactivity or significant toxicological changes in the parameters measured for behavioural assessment.

A statistically significant reduction in body weight gain and reduced food was seen in high dose females during Week 3, but all recovered thereafter, except for the female showing clinical signs. Reduced dietary intake throughout the study was also observed in high dose females.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry

A statistically significant reduction in total protein, reduction in cholesterol and increase in albumin/globulin ratio was detected in high dose groups. Reductions in inorganic phosphorus and urea were confined to high dose males, and reduction in creatinine was confined to high dose females.

A statistically significant reduction in cholesterol was extended to the intermediate II dose groups, while a statistically significant reduction in total protein, urea, inorganic phosphorus were confined to male intermediate II dose group.

A statistically significant reduction in urea and cholesterol was observed in intermediate male and female dose group, respectively.

A dose response relationship with treatment was apparent in treated males when measuring plasma levels for urea, total protein, albumin/globulin ratio and cholesterol.

Haematology
High dose animals showed evidence of microcytic hypochromic anaemia with statistically significant reduction in haemoglobin and haematocrit. A lymphocytopenia was also observed in high dose animals as evidence by statistically reduced total leucocyte and lymphocyte count. A statistically significant reduction in platelet count was also observed at this dose level.

Statistically significant reductions in erythrocyte count, mean corpuscular volume (MCV) and mean corpuscular haemoglobin (MCH) was detected in female high dose group. Statistically increased in clotting time was also observed in high dosed females.

Effects in Organs
Pathology
Liver weights were elevated in high dose groups and in female intermediate dose group. Statistically significant reduction in relative thymus weight and an increase in relative kidney weight (statistically significant only in males) were observed in high dose group.

There we no treatment related macroscopic abnormalities detected at terminal kill, except for dark foci on the caudal lobe of the lung of a male in the intermediate dose group.

Histopathology
Centrilobular hepatocyte enlargement was observed in the liver of high dose and intermediate II dose groups, with isolated instances found in the intermediate and low dose groups. Follicular cell hypertrophy in the thyroids was seen in the high dose group and lymphoid atrophy in the thymus was observed in female high dose only.

All other microscopic changes were scattered or of types commonly observed in the strain of animals used in the study, and there were no differences in incidence or severity between control and treated groups.

Remarks – Results
The clinical observations present during the study are a common occurrence when the test material in unpalatable or slightly irritant, and do not normally represent systemic toxicity. Dietary intake and body weight development was adversely affected in female high dose group but these recovered thereafter.

Haematological investigations revealed a microcytic hypochromic anaemia and lymphocytopenia in high dose groups. A reduction in plasma phosphorus in males at the high and intermediate II dose groups may be associated with anaemia since high concentration of phosphorus is normally present in erythrocyte. Similarly, a reduction in cholesterol in high dose and female intermediate II dose groups may have been associated with anaemia. The reduction of platelet count and increase in clotting time seen in high doses females may be related to a general haematopoietic effect or an adverse effect on the liver. Liver weights were increased in high dose group and in female intermediate II group. Histopathological liver changes were also identified in high and intermediate II dose groups at a higher incidence compared with spontaneous occurrences in intermediate and low dose groups. However, centrilobular hepatocyte enlargement is a common observation following administration of xenobiotics and in the absence of associated inflammatory or degenerative changes, the effects seen are considered to be adaptive in nature.

Thyroid follicular cell hypertrophy was observed in high dose group, which may be associated with the changes seen in the liver. Following enzymatic conjugation in the liver, thyroxine is ultimately excreted via the bile. It is possible that hepatic enzymes are induced therefore increasing thyroxine excretion and stimulating compensatory thyroid stimulating hormone (TSH) and thyroxine production resulting in the

microscopic changes identified. Although liver changes may be adaptive, blood chemistry changes as evidence by reduction in plasma protein and increase in albumin/globulin ratio in high dose group, which extended to males in intermediate II dose group, suggest some level of hepatic impairment.

Treatment-related effect on the immune system in the high dose group was observed as indicated by lymphoid atrophy of the thymus in high dose females and reduced thymus weight in all high dosed animals.

Kidney weight was elevated in high dose group while plasma urea and creatine were reduced in male and female high dose group, respectively. In contrast, these parameters are expected to be elevated in the presence of adverse effects on renal function; therefore, the cause of kidney weight increase is not clear.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 15 mg/kg bw/day in this study, based on minor biochemical and adaptive liver changes.

TEST FACILITY	Safepharm Laboratories Limited (2004b)

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. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2uvrA.
Metabolic Activation System	Rat liver S9 fraction from animals pretreated with phenobarbitone/β-naphthoflavone
Concentration Range in Main Test	*Experiment 1* a) With metabolic activation: 50-5000 µg/plate. b) Without metabolic activation: 50-5000 µg/plate. *Experiment 2* a) With metabolic activation: 15-5000 µg/plate. b) Without metabolic activation: 15-5000 µg/plate. *Experiment 3* a) With metabolic activation: 300-1500 µg/plate. b) Without metabolic activation: 300-1500 µg/plate.
Vehicle	Acetone
Remarks - Method	A preliminary test was conducted on TA100 or WP2uvrA to select the appropriate dose and to determine the toxicity of the test material. A third confirmatory experiment was conducted to enhance the weak dose-response relationship observed in the previous experiments.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	5000	5000	none	Positive (TA1535)
Test 2		5000 (TA1535 only)	none	Positive (TA1535)
Test 3		None	none	Negative
Present				
Test 1	5000	5000	none	Negative
Test 2		5000 (TA1535 and TA1537)	none	Negative
Test 3		None	none	Negative

Remarks - Results

A reduction in the growth of bacterial background lawn of all tester strains was observed at 5000 µg/plate in Test 1 and 2 with or without S9. No precipitate was observed at any doses tested either with or without S9.

Statistically significant reproducible increases in revertant colony frequency were observed in TA1535 without S9 at concentrations 500 and 1500 µg/plate in Test 1, and at 1500 µg/plate in Test 2. The third experiment was conducted to confirm the weak dose-response relationship observed in Test 1 and Test 2. In Test 3, a statistically significant increase in revertant colony was observed only at 1500 µg/plate. In all three experiments, the increases never exceeded 1.75 times of the concurrent solvent control and the statistically significant responses in Test 1 and Test 2 were accompanied by a decrease in bacterial background lawns. In addition, a clear dose-response relationship was not evident after inclusion of a tightened dose range in Test 3.

A non-reproducible but statistically significant increase in the revertant colony frequency was observed in TA98 with S9 at 5000 µg/plate in Test 2.

CONCLUSION

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

TEST FACILITY

Safepharm Laboratories Limited (2003f)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
EC Directive 88/302/EEC B.10 – Mutagenicity (*in vitro* mammalian cytogenetic test)

Cell Type/Cell Line: Human lymphocyte

Metabolic Activation System: Rat liver S9 fraction from animals pretreated with phenobarbitone and β-naphthoflavone

Vehicle: None

Remarks - Method

A preliminary test was performed on cell cultures using a 4-hour exposure time with and without metabolic activation (S9) followed by a 20-hour recovery period, and a continuous exposure of 24 hours without S9. The dose range used was 14.22 to 3640 µg/mL. The test material induced clear evidence of toxicity in all the exposure groups. A cloudy or greasy/oil precipitate was observed at and above 910 µg/mL, in the 3

exposure groups. Metaphase cells were present at up to 227.5 μg/mL in the two 4 (20) hour exposure groups. The maximum dose level with metaphases present in the 24-hour continuous exposure group was 113.75 μg/mL. Therefore, the maximum dose selected for metaphase analysis for Test 1 was 455 μg/mL for 4 (20) hour exposure with or without S9, and for Test 2, 341 μg/mL for 4 (20) hour exposure with S9 and 170.63 μg/mL for the 24-hour continuous exposure without S9.

A third experiment (Test 3) was also conducted using the same exposure conditions as Test 1 without S9.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 28.44, 56.88*, 113.75*, 227.5*, 341, 455	4 hours	20 hours
Test 2	0*, 7.11, 14.22, 28.44*, 56.88*, 113.75*, 170.63*	24 hours	
Test 3	0*, 200, 225*, 250*, 275*, 300, 325	4 hours	20 hours
Present			
Test 1	0*, 28.44, 56.88, 113.75, 227.5*, 341*, 455	4 hours	20 hours
Test 2	0*, 28.44, 56.88*, 113.75*, 227.5*, 284.25, 341*	4 hours	20 hours

*Cultures selected for metaphase analysis.

RESULTS

Remarks - Results

Test 1
Similar toxicity to that seen in the preliminary test was observed. The maximum dose level with scorable metaphases was 227.5 μg/mL without S9 and 341 μg/mL with S9.

A dose-related inhibition of mitotic index was observed and approximately 50% mitotic inhibition was achieved at 341 μg/mL with S9. No clear dose level showing 50% mitotic inhibition was observed in the absence of S9 because the toxicity response curve was extremely steep.

A small but statistically significant increase in the frequency of cells with aberrations at 227.5 μg/mL (maximum dose level for metaphase analysis) the absence of S9 was observed. Since the dose level showing adequate level of toxicity had not been achieved, an additional test (Test 3) without S9 was conducted. There was no statistically significant increase in cells with aberrations in the presence of S9.

No statistically significant increase in the numbers of polyploid cells at any dose level was observed.

Test 2
The maximum dose level with scorable metaphases was 170.63 μg/mL (maximum dose level tested) without S9 and 341 μg/mL with S9. Approximately 50% mitotic inhibition was achieved at 113.75 μg/mL without S9 and 341 μg/mL with S9.

No statistically significant increases in the frequency of cells with chromosome aberrations were observed with or without S9.

No statistically significant increase in the numbers of polyploid cells at any dose level was observed.

Test 3

The maximum dose level with scorable metaphases was 300 μg/mL without S9, and approximately 50% mitotic inhibition was achieved at 275 μg/mL, which was selected as the maximum dose level for evaluation.

No statistically significant increases in the frequency of cells with chromosome aberrations without S9.

No statistically significant increase in the numbers of polyploid cells at any dose level was observed.

The positive and negative control values were within the expected ranges, indicating that the test system responded appropriately.

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

TEST FACILITY Safepharm Laboratories Limited (2004c)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE

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

Species/Strain	Mice/albino Crl:CD-1 (ICR)BR
Route of Administration	Oral – gavage
Vehicle	Dried arachis oil
Remarks - Method	A range finding study was conducted to determine the suitable dose level and route of administration for the micronucleus test. Four animals (2/sex) were treated with dose levels of 2000 or 1500 mg/kg by oral gavage. There were no deaths observed during the study. Clinical signs observed include hunched posture, lethargy, ataxia, decreased respiratory rate, laboured respiration, pilo-erection and ptosis. Since there was no marked difference in the toxicity of the test material between males and females, it was considered acceptable to use male animals in the main study. Based of the result of the study, the maximum tolerated dose (MTD) selected for the main study was 1500 mg/kg.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I	7 males	1500	48
II	7 males	1500	24
III	7 males	750	24
IV	7 males	375	24
V (Vehicle control)	7 males	0	48
VI (Vehicle control)	7 males	0	24
VII (Positive control)*	7 males	50	24

*CP=cyclophosphamide

RESULTS

Doses Producing Toxicity	There was a marked and statistically significant decrease in polychromatic erythrocytes/normochromatic erythrocytes (PCE/NCE) ratio was observed in 1500 mg/kg at 48-hour group compared with the concurrent vehicle control. Hunched posture, lethargy and ataxia were observed in animals dosed with 1500 mg/kg in both the 24 and 48-hour groups. The clinical observation and the decreased in PCE/NCE ratio was taken to confirm that systemic absorption has occurred and exposure to the target tissue was achieved. The mean body weights of all treated groups were comparable with the control groups.
Genotoxic Effects	There were no statistically significant increases in the frequency of micronucleated PCEs at any dose groups at any sampling time compared with the control group.
Remarks - Results	The positive control group induced significant increase in micronuclei indicating that the test system responded appropriately.

CONCLUSION	The notified chemical was not clastogenic in this in vivo mouse micronucleus assay under the conditions of the test.
TEST FACILITY	Safepharm Laboratories Limited (2003g)

8. ENVIRONMENT

8.1. Environmental fate

Due to the hydrolytic instability of the notified chemical, data on environmental fate of the 2 main hydrolysis products identified as Product A and Product B are provided. This is in the form of several laboratory test reports, as well as the IUCLID Datasets for both chemicals.

8.1.1. Ready biodegradability

TEST SUBSTANCE	Product A: Not biodegradable (European Commission, 2000). Product B: Based on BOD5 being in excess of 50% COD using both an industrial and a municipal seed inoculum, this chemical should substantially degrade in a conventional wastewater treatment plant (Dow Chemical, 1980). The IUCLID dataset contains summaries of a number of biodegradation tests from which it is not clear whether Product B is readily biodegradable, though it appears to be inherently biodegradable based on >95% degraded within 5 days when tested by OECD Guideline 302B "Inherent Biodegradability: Modified Zahn-Wellens Test", in what

appears to be at least 3 different tests.

8.1.2. Bioaccumulation

TEST SUBSTANCE	Product A: BCF = *ca* 0 according to the IUCLID dataset when tested at 34 mg/L over 90 days at 25°C on *Oncorhynchus tschawytscha* (no further details). Product B: BCF = 26.7 (estimated based on water solubility determination where log BCF = -0.508 log S + 3.41; where S = solubility in water [μmole/L]; Dow Chemical, 1980). The IUCLID Dataset also includes a result for BCF of *ca* 27, but gives no further details.

8.2. Ecotoxicological investigations

Due to the hydrolytic instability of the notified chemical, data on the ecotoxicity of the 2 main hydrolysis products (Product A and Product B) are provided. Again, this is in the form of several laboratory test reports, as well as the IUCLID Datasets for both chemicals.

8.2.1. Acute toxicity to fish

8.2.1.1. Acute toxicity of Product A to fish

TEST SUBSTANCE	Product A
METHOD	Acute Toxicity for Fish – continuous flow through test
Species	Catfish (*Ictalurus punctatus*), Goldfish (*Carassius auratus*), and Rainbow Trout (*Salmo gairdneri*).
Exposure Period	Embryos exposed from fertilisation through hatching and 4 days post-hatching fry. Trout (28 days), catfish (9 days), goldfish (7 days).
Auxiliary Solvent	None
Water Hardness	50 and 200 mg $CaCO_3$/L
Analytical Monitoring (mean ±SE)	Catfish: Hardness ~50 ppm: Temp. 25±0.4°C; DO 7.3±0.1; pH 7.5±0.1 Hardness ~200 ppm: Temp. 24.7±0.6°C; DO 7.6±0.1; pH 7.6 Goldfish: Hardness ~50 ppm: Temp. 24.8±0.3°C; DO 7.4; pH 7.9±0.1 Hardness ~200 ppm: Temp. 24.8±0.3°C; DO 7.5; pH 7.6±0.1 Rainbow trout: Hardness ~50 ppm: Temp. 13.7±0.1°C; DO 9.2±0.1; pH 7.7±0.1 Hardness ~200 ppm: Temp. 13.3°C; DO 9.6±0.1; pH 7.9±0.1
Remarks – Method	Culture medium was prepared from distilled, double deionised water pre-tested for contamination (acceptable) and tests were performed in Pyrex test containers. Test animals were exposed to between 10-15 test substance concentrations Quantitative determinations of Product A were performed. Probit analyses were performed to determine LC1 and LC50 values.

RESULTS

Remarks – Results

Lethality data are presented below.
Sublethal teratogenic effects included mostly vertebral column abnormalities; however, some fry had dwarf bodies, cranium fin, nervous system, yolk sac and abdomen abnormalities.

Catfish (Test Water Hardness 50 ppm)

Concentration mg/L		*Test Responses at Hatching (H) and 4 Days Post-Hatching (PH)*				
Nominal	*Actual (mean±SE)*	*% Hatchability*	*% Normal Survival*		*% Dead or Teratogenic*	
			H	PH	H	PH
0.01	---	100	100	100	0	0
0.05	---	100	100	100	0	0
0.1	0.11±0.01	100	100	100	0	0
0.5	0.49±0.01	100	99	99	1	1
1	1.01±0.02	99	99	95	1	5
5	5.42±0.29	95	93	85	7	15
7.5	7.43±0.12	95	92	80	8	20
10	10±0.05	93	88	75	12	25
25	24.9±0.19	82	75	61	25	39
50	51.4±0.88	81	77	75	23	25
100	98.3±1.14	81	76	67	24	33
150	151±4.2	73	66	56	34	44
200	177±6.39	72	65	0	35	100
300	306±10.6	0	0	0	100	100

LC50 (Hatching H)	220 mg/L (95% CI 167-290; Litchfield-Wilcoxon graphical method)
LC50 (Post-hatching PH)	155 mg/L (95% CI 111-217; Litchfield-Wilcoxon graphical method)
LC1 (H)	0.1 mg/L
LC1 (PH)	0.5 mg/L

CONCLUSION

Very slightly toxic (LC50 ≥100 mg/L) to catfish embryos and fry following pre- and 4 days post-hatching in test water of hardness 50 ppm as $CaCO_3$ (Mensink *et al*., 1995).

Catfish (Test Water Hardness 200 ppm)

Concentration mg/L		*Test Responses at Hatching (H) and 4 Days Post-Hatching (PH)*				
Nominal	*Actual (mean±SE)*	*% Hatchability*	*% Normal Survival*		*% Dead or Teratogenic*	
			H	PH	H	PH
0.01	---	100	98	98	2	2
0.05	---	100	99	98	1	2
0.5	0.53±0.02	100	98	94	2	6
0.75	0.77±0.01	100	98	98	2	2
1	0.96±0.01	96	93	86	7	14
2.5	2.33±0.12	99	97	87	3	13
5	4.90±0.07	95	91	82	9	18
7.5	7.40±0.10	95	91	75	9	25
10	9.43±0.23	94	87	65	13	35
25	25.1±0.27	90	65	40	35	60
50	48.3±0.84	83	58	28	42	72
75	77.7±0.54	71	40	9	60	91
150	140±5.0	57	44	2	56	98
300	302±29	0	0	0	100	100

LC50 (Hatching H)	102 mg/L (95% CI 23-180; Litchfield-Wilcoxon graphical method)
LC50 (Post-hatching PH)	22 mg/L (95% CI 19-25; Litchfield-Wilcoxon graphical method)

LC1 (H)	0.3 mg/L
LC1 (PH)	0.2 mg/L
CONCLUSION	Harmful (LC50 10-100 mg/L) to catfish embryos and fry following 4 days post-hatching in test water of hardness 200 ppm as $CaCO_3$ (United Nations, 2003).
TEST FACILITY	USEPA (1977)

Goldfish (Test Water Hardness 50 ppm)

Concentration mg/L		*Test Responses at Hatching (H) and 4 Days Post-Hatching (PH)*				
Nominal	*Actual (mean±SE)*	*% Hatchability*	*% Normal Survival*		*% Dead or Teratogenic*	
			H	PH	H	PH
0.05	---	99	99	99	1	1
0.10	0.10±0.01	97	96	96	4	4
0.50	0.49±0.04	98	98	98	2	2
1	0.90±0.04	98	98	98	2	2
5	5.2±0.48	99	98	98	2	2
7.5	7.0±0.1	93	93	93	7	7
10	9.2±0.23	96	94	94	6	6
25	22.5±2.5	86	85	78	15	22
50	48.7±3.7	69	64	52	36	48
100	108±22	66	60	4	40	96
200	188.7±5.8	53	49	0	51	100
300	288±3.46	34	8	0	92	100

LC50 (Hatching H)	178 mg/L (95% CI 131-242; Litchfield-Wilcoxon graphical method)
LC50 (Post-hatching PH)	46 mg/L (95% CI 32-66; Litchfield-Wilcoxon graphical method)
LC1 (H)	0.6 mg/L
LC1 (PH)	0.6 mg/L
CONCLUSION	Harmful (LC50 10-100 mg/L) to goldfish embryos and fry following 4 days post-hatching in test water of hardness 50 ppm as $CaCO_3$ (United Nations, 2003).
TEST FACILITY	USEPA (1977)

Goldfish (Test Water Hardness 200 ppm)

Concentration mg/L		*Test Responses at Hatching (H) and 4 Days Post-Hatching (PH)*				
Nominal	*Actual (mean±SE)*	*% Hatchability*	*% Normal Survival*		*% Dead or Teratogenic*	
			H	PH	H	PH
0.05	---	98	97	97	3	3
0.1	0.12±0.01	98	96	96	4	4
0.5	0.47±0.04	95	95	95	5	5
1	0.90±0.02	98	98	98	2	2
5	4.5±0.26	97	96	96	4	4
7.5	6.8±0.3	94	93	93	7	7
10	8.33±0.48	85	85	85	15	15
25	32±4.0	79	78	76	22	24
50	51.3±4.7	80	80	67	20	33
100	96.7±1.76	61	59	35	41	65
200	191±2.0	56	48	0	52	100
300	290±6.0	35	21	0	79	100

LC50 (Hatching H)	170 mg/L (95% CI 115-251; Litchfield-Wilcoxon graphical method)
LC50 (Post-hatching PH)	75 mg/L (95% CI 50-112; Litchfield-Wilcoxon graphical method)
LC1 (H)	0.2 mg/L
LC1 (PH)	0.2 mg/L

CONCLUSION	Harmful (LC50 10-100 mg/L) to goldfish embryos and fry following 4 days post-hatching in test water of hardness 200 ppm as $CaCO_3$ (United Nations, 2003).
TEST FACILITY	USEPA (1977)

Rainbow Trout (Test Water Hardness 50 ppm)

Concentration mg/L		*Test Responses at Hatching (H) and 4 Days Post-Hatching (PH)*				
Nominal	*Actual (mean±SE)*	*% Hatchability*	*% Normal Survival*		*% Dead or Teratogenic*	
			H	PH	H	PH
0.001	---	100	98	96	2	4
0.01	---	95	90	89	10	11
0.1	0.11±0.01	97	96	96	4	4
1	1.00±0.03	97	77	77	23	23
5	4.74±0.07	94	90	84	10	16
10	9.26±0.17	97	97	97	3	3
25	23.5±0.67	94	93	93	7	7
50	45.5±1.11	77	76	76	24	24
100	94±2.83	64	61	58	39	42
200	190±3.34	55	40	27	60	73

LC50 (Hatching H)	150 mg/L (95% CI 90-249; Litchfield-Wilcoxon graphical method)
LC50 (Post-hatching PH)	100 mg/L (95% CI 70-142; Litchfield-Wilcoxon graphical method)
LC1 (H)	0.1 mg/L
LC1 (PH)	0.1 mg/L

CONCLUSION	Very slightly toxic (LC50 ≥100 mg/L) to rainbow trout embryos and fry following pre- and 4 days post-hatching in test water of hardness 50 ppm as $CaCO_3$ (Mensink *et al*., 1995).
TEST FACILITY	USEPA (1977)

Rainbow trout (Test Water Hardness 200 ppm)

Concentration mg/L		*Test Responses at Hatching (H) and 4 Days Post-Hatching (PH)*				
Nominal	*Actual (mean±SE)*	*% Hatchability*	*% Normal Survival*		*% Dead or Teratogenic*	
			H	PH	H	PH
0.001	---	100	95	93	5	7
0.01	---	92	82	79	18	21
0.1	0.10	100	91	89	9	11
0.5	0.47±0.03	93	83	81	17	19
1	0.98±0.01	94	70	68	30	32
5	4.85±0.07	84	64	63	36	37
10	9.40±0.30	78	67	67	33	33
25	23.8±0.75	69	47	46	53	54
50	48.3±2.72	82	64	63	36	37
100	100.2±2.80	67	33	33	67	67
200	186±3.00	65	51	44	49	56

LC50 (Hatching H)	100 mg/L (95% CI 61-163; Litchfield-Wilcoxon graphical method)
LC50 (Post-hatching PH)	79 mg/L (95% CI 35-165; Litchfield-Wilcoxon graphical method)
LC1 (H)	0.001 mg/L
LC1 (PH)	0.001 mg/L
CONCLUSION	Harmful (LC50 10-100 mg/L) to rainbow trout embryos and fry following 4 days post-hatching in test water of hardness 200 ppm as $CaCO_3$ (United Nations, 2003).
TEST FACILITY	USEPA (1977)

8.2.1.2. Other Fish Data for Product A

:
Lewis and Valentine (1981) contains the following results:
Freshwater species:
96 h LC50 Mosquito fish (*Gambusia affinis*) of 980 mg/L
48 h LC50 Rainbow trout 339 mg/L
283 h LC50 Coho salmon (*Onchorhynchus kisutch*) 113 mg/L

Marine species:
283 h LC50 to yearling Coho salmon 12 mg/L

The original papers have not been examined for these results, which are consistent with those reported in Section 8.2.1.1.

The IUCLID Dataset contains brief details for 3 species of fish and appears to be the same as from USEPA (1977) above though the 3-24 day LC50s range from 260-1260 mg/L (European Commission, 2000).

8.2.1.3. Acute toxicity of Product B to fish

TEST SUBSTANCE	Product B
METHOD	Static Acute Toxicity Test
Species	Fathead minnow (*Pimephales promelas*) Average weight 0.59 g and length 31.5 mm.
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	95-134 mg $CaCO_3$/L
Analytical Monitoring	Test temperature 12°C.
Remarks – Method	Test material was added to the test aquaria volumetrically from a 500 mL stock solution. 10 L of test solution per aquaria. Aquaria were monitored daily for mortality. 16 h light: 8 h dark. Fish were not fed during the test. LC50 value was calculated using Probit analysis.

RESULTS

Concentration mg/L		*Number of Fish*	*Percent Mortality (%)*
Nominal	*Actual*		*96 h*
0	0	10	0
5	Not determined	10	0
10	"	10	0
15	"	10	0
20	"	10	0
25	"	10	10
30	"	10	40
35	"	10	100
40	"	10	100
45	"	10	100
50	"	10	100

LC50	29.7 mg/L at 96 hours (95% CI 27.4-31.9).
NOEC	10 mg/L
CONCLUSION	Harmful (LC50 10-100 mg/L) to fathead minnow (United Nations, 2003).
TEST FACILITY	Dow Chemical (1980)

8.2.1.4. Other fish data for Product B

The IUCLID Dataset for Product B contains a number of results for testing to the fathead minnow, rainbow trout and carp giving 96 h LC50s in the range of 17.1 – 29.5 mg/L (European Commission, 2000). There are few details, but the results are consistent with those reported in Section 8.2.1.2.1.

8.2.2. Acute toxicity to aquatic invertebrates

8.2.2.1. Acute toxicity to aquatic invertebrates of Product A

TEST SUBSTANCE	Product A
METHOD	Acute Toxicity Test with *Daphnia magna* - Static Test (USEPA, 1975)
Species	*Daphnia magna*
Exposure Period	48 h
Auxiliary Solvent	None
Water Hardness	166 (range 135-217) mg $CaCO_3$/L
Analytical Monitoring	Temperature, DO (>9 mg/L) and pH (7.1-8.7) were monitored daily. Test temperature 20±2°C. 16 h light illumination.
Remarks - Method	Stock solution was prepared by adding analytical grade Product A to carbon-filtered groundwater. The test concentrations were made up by appropriated dilution of stock solution made up to 200 mL. Daphnids were not fed during the test. No water renewal or aeration. Mortality was recorded daily.
RESULTS	
LC50	226 mg/L at 48 hours (95% CI 200-246 mg/L)
NOEC	<200 mg/L at 48 hours
Remarks - Results	
CONCLUSION	Very slightly acutely toxic (LC50 ≥100 mg/L) to *Daphnia magna* (Mensink *et al*., 1995).
TEST FACILITY	Lewis and Valentine (1981)

8.2.2.2. Other acute toxicity to aquatic invertebrates data for Product A

The IUCLID Dataset for Product A contains a single result of 48 h EC50 = 658-875 mg/L for *Daphnia magna* (European Commission, 2000), ie less toxic than above.

8.2.2.3. Chronic toxicity to aquatic invertebrates of Product A

TEST SUBSTANCE	Product A
METHOD	Chronic Toxicity/Reproductive Test with *Daphnia magna* – Semi-static Test (USEPA, 1975)
Species	*Daphnia magna*
Exposure Period	21 d
Auxiliary Solvent	None
Water Hardness	166 (range 135-217) mg $CaCO_3$/L
Analytical Monitoring	Temperature, DO and pH were monitored daily. Test temperature 20±2°C, pH 7.1-8.7, DO >9.0 mg/L. 16 h light illumination.
Remarks - Method	Stock solution was prepared by adding analytical grade test substance to carbon-filtered groundwater. The test concentrations were made up by appropriated dilution of stock solution made up to 200 mL. Daphnids were fed during the test. Water renewal 3 times per week. Test chambers were aerated. Daphnids in test chambers were monitored daily for mortality. Measured test substance concentrations were within 5% of

nominal concentrations.

RESULTS

Concentration mg/L Actual	*Number of D. magna*	*% Mortality*	*Mean Brood Size (± SD)*
0	5	9	32 ± 15.7
6	5	Not stated	29 ± 18.9
13	5	Not stated	23 ± 16
27	5	14	22 ± 16.4
53	5	32	16 ± 12.7
106	5	100	0

LC50	53 mg/L at 21 days (95% CI 44.1-64.5 mg/L)
EC50 (reproduction)	53 mg/L at 21 days
LOEC (reproduction)	13 mg/L at 21 days
NOEC (reproduction)	6 mg/L at 21 days
Reemarks- Results	Mean brood size and as a consequence total young produced were the most sensitive reproduction parameters, as time of first reproduction (9-10 days) was not significantly affected.
CONCLUSION	Very slightly chronically toxic (NOEC ≥1 mg/L) to *Daphnia magna* (Mensink *et al*., 1995).
TEST FACILITY	Lewis and Valentine (1981)

8.2.2.4. Other chronic toxicity to aquatic invertebrates data for Product A

Lewis and Valentine (1981) note that the literature indicates Larval mosquitoes (*Anopheles quadrimaculus*) are sensitive to 50 mg/L Product A with only 2% proceeding to the adult stage.

8.2.2.5. Acute toxicity to aquatic invertebrates of Product B

TEST SUBSTANCE	Product B
METHOD	Static Acute Toxicity Test
Species	*Daphnia magna*
Exposure Period	48 h
Auxiliary Solvent	None
Water Hardness	95-134 mg $CaCO_3$/L
Analytical Monitoring	Test temperature 20°C.
Remarks – Method	200 mL test solution per container. LC50 value was calculated using Probit analysis.

RESULTS

Concentration mg/L		*Number of Daphnids*	*Percent Mortality (%)*
Nominal	*Actual*		*48 h*
0	0	30 (3 replicates)	7%
0.01	Not determined	30 (3 replicates)	0
0.05	"	30 (3 replicates)	0
0.10	"	30 (3 replicates)	0
1	"	30 (3 replicates)	0
10	"	30 (3 replicates)	7
25	"	30 (3 replicates)	20
50	"	30 (3 replicates)	67
75	"	30 (3 replicates)	90
100	"	30 (3 replicates)	100

LC50	35.2 mg/L at 48 hours (95% CI 29-41).
NOEC	1 mg/L
CONCLUSION	Harmful (LC50 10-100 mg/L) to *Daphnia* (United Nations, 2003).
TEST FACILITY	Dow Chemical (1980)

8.2.2.6. Other acute toxicity to aquatic invertebrates data for Product B

The IUCLID Dataset for Product B contains a number of results for *Daphnia magna* with a 48 h EC50 of 39 mg/L (European Commission, 2000) as well as 24 h EC50s ranging 19-44 mg/L (European Commission, 2000), as well as a result for *Artemia salina* of 24 h EC50 = 19 mg/L (European Commission, 2000). Again, these values are consistent with the above observations.

8.2.3. Algal growth inhibition test

8.2.3.1. Algal growth inhibition test of Product A

Lewis and Valentine (1981) note that the literature indicates levels of 28-56 mg/L Product A did not affect 19 species of marine algae; however, concentrations of 56-278 mg/L Product A caused shifts in algae population composition. Further, green algae (*Chlorella*) growth was affected at concentrations of 278-556 mg/L. Based on this, Product A is harmful to algae (United Nations, 2003).

The IUCLID Dataset for Product A contains very similar details to the above.

8.2.3.2. Algal growth inhibition test of Product B

The IUCLID Dataset for this chemical contains 48 h EC50 of 10-50 mg/L to *Chlorella emersonii* (European Commission, 2000), and 72 h EC50s of 11.5 and 13.3 mg/L to *Scenedesmus subspicatus* (European Commission, 2000), indicating Product B is harmful to algal species.

8.2.4. Acute toxicity to amphibians

TEST SUBSTANCE	Product A
METHOD	Acute Toxicity for frog – continuous flow through test
Species	Leopard frog (*Rana pipiens*) and Fowler's Toad (*Bufo fowleri*)
Exposure Period	Embryos exposed from fertilisation through hatching and 4 days post-hatching larvae. 7.5 days.
Auxiliary Solvent	None
Water Hardness	50 and 200 mg $CaCO_3$/L
Analytical Monitoring (mean ±SE)	Leopard frog: Hardness ~50 ppm: Temp. 25±0.3°C; DO 7.7±0.2; pH 7.7

Hardness ~200 ppm: Temp. 25.0±0.3°C; DO 7.8±0.2; pH 7.7

Fowler's toad:
Hardness ~50 ppm: Temp. 23.7±0.6°C; DO 6.8±0.1; pH 7.6±0.1
Hardness ~200 ppm: Temp. 23.7±0.6°C; DO 6.8±0.1; pH 7.6±0.1

Remarks – Method Probit analyses were performed to determine LC1 and LC50 values.

RESULTS

Remarks – Results Lethality data are presented below.
Sublethal teratogenic effects included predominantly vertebral column, yolk sac and abdomen abnormalities.

Leopard Frog (Test Water Hardness 50 ppm)

Concentration mg/L		*Test Responses at Hatching (H) and 4 Days Post-Hatching (PH)*				
Nominal	*Actual (mean±SE)*	*% Hatchability*	*% Normal Survival*		*% Dead or Teratogenic*	
			H	PH	H	PH
0.05	---	99	99	96	1	4
0.10	0.09±0.01	100	99	99	1	1
0.50	0.39±0.03	100	100	99	0	1
1.0	0.93±0.01	100	99	99	1	1
5	4.5±0.1	98	97	97	3	3
10	9.15±0.29	99	98	93	2	7
25	32.5±4.5	99	95	91	5	9
50	47.5±2.18	98	96	91	4	9
100	84.5±2.87	96	93	87	7	13
200	188±6.93	90	36	16	64	84
300	298±16.4	77	0	0	100	100

LC50 (Hatching H) 157 mg/L (95% CI 127-194; Litchfield-Wilcoxon graphical method)
LC50 (Post-hatching PH) 130 mg/L (95% CI 99-171; Litchfield-Wilcoxon graphical method)
LC1 (H) 26 mg/L
LC1 (PH) 13 mg/L

CONCLUSION Very slightly toxic (LC50 ≥100 mg/L) to leopard frog embryos and larvae following pre- and 4 days post-hatching in test water of hardness 50 ppm as $CaCO_3$ (Mensink *et al*., 1995).

TEST FACILITY USEPA (1977)

Leopard Frog (Test Water Hardness 200 ppm)

Concentration mg/L		*Test Responses at Hatching (H) and 4 Days Post-Hatching (PH)*				
Nominal	*Actual (mean±SE)*	*% Hatchability*	*% Normal Survival*		*% Dead or Teratogenic*	
			P	PH	P	PH
0.10	0.13±0.01	100	99	99	1	1
0.50	0.53±0.09	100	99	99	1	1
1.0	0.92±0.02	100	100	100	0	0
5	4.6±0.15	97	96	94	4	6
10	8.93±0.27	98	97	97	3	3
25	25.2±0.44	96	96	95	4	5
50	45.7±1.67	96	94	94	6	6
100	86±3.46	94	92	88	8	12
200	193±8.11	87	29	14	71	86
300	288±16	49	0	0	100	100

LC50 (Hatching H) 145 mg/L (95% CI 117-180; Litchfield-Wilcoxon graphical method)
LC50 (Post-hatching PH) 135 mg/L (95% CI 109-168; Litchfield-Wilcoxon graphical method)
LC1 (H) 23 mg/L
LC1 (PH) 22 mg/L

CONCLUSION Very slightly toxic (LC50 ≥100 mg/L) to leopard frog embryos and

larvae following pre- and 4 days post-hatching in test water of hardness 200 ppm as $CaCO_3$ (Mensink *et al*., 1995).

TEST FACILITY USEPA (1977)

Fowler's Toad (Test Water Hardness 50 ppm)

Concentration mg/L		*Test Responses at Hatching (H) and 4 Days Post-Hatching (PH)*				
Nominal	*Actual (mean±SE)*	*% Hatchability*	*% Normal Survival*		*% Dead or Teratogenic*	
			H	PH	H	PH
0.05	---	100	99	99	1	1
0.10	0.1±0.01	100	98	98	2	2
0.50	0.46±0.14	100	99	99	1	1
1.0	0.97±0.12	100	97	97	3	3
5	5.0±0.38	100	98	98	2	2
10	9.4±0.4	100	99	99	1	1
25	24±2.1	100	98	98	2	2
50	48.7±3.7	100	99	98	1	2
100	96±17.5	98	74	73	26	27
200	189±6.9	91	4	0	96	100
300	279±9.0	81	0	0	100	100

LC50 (Hatching H) 148 mg/L (95% CI 120-183; Litchfield-Wilcoxon graphical method)

LC50 (Post-hatching PH) 145 mg/L (95% CI 118-179; Litchfield-Wilcoxon graphical method)

LC1 (H) 25 mg/L

LC1 (PH) 25 mg/L

CONCLUSION Very slightly toxic (LC50 ≥100 mg/L) to Fowler's toad embryos and larvae following pre- and 4 days post-hatching in test water of hardness 50 ppm as $CaCO_3$ (Mensink *et al*., 1995).

TEST FACILITY USEPA (1977)

Fowler's Toad (Test Water Hardness 200 ppm)

Concentration mg/L		*Test Responses at Hatching (H) and 4 Days Post-Hatching (PH)*				
Nominal	*Actual (mean±SE)*	*% Hatchability*	*% Normal Survival*		*% Dead or Teratogenic*	
			H	PH	H	PH
0.05	---	100	98	98	2	2
0.10	---	100	98	98	2	2
0.50	0.45±0.04	100	97	97	3	3
1.0	0.93±0.04	100	98	98	2	2
5	4.5±0.2	95	93	93	7	7
10	8.3±0.3	95	93	93	7	7
25	22.3±3.3	96	94	94	6	6
50	53.5±4.5	96	73	72	27	28
100	93±1.0	94	66	65	34	35
200	204±4.0	91	9	0	91	100
300	308±8.6	31	2	0	98	100

LC50 (Hatching H) 135 mg/L (95% CI 104-175; Litchfield-Wilcoxon graphical method)

LC50 (Post-hatching PH) 123 mg/L (95% CI 94-161; Litchfield-Wilcoxon graphical method)

LC1 (H) 5.0 mg/L

LC1 (PH) 5.0 mg/L

CONCLUSION Very slightly toxic (LC50 ≥100 mg/L) to leopard frog embryos and larvae following pre- and 4 days post-hatching in test water of hardness 200 ppm as $CaCO_3$ (Mensink *et al*., 1995).

TEST FACILITY USEPA (1977)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Possible exposure could result from accidental spillage of bulk containers of the imported additive package containing the notified chemical at <10%. Losses during blending are low and will be contained before disposal at an approved industrial facility. Incineration of the waste oil will generate water vapour and oxides of carbon. As the only end use of the new chemical is expected to be in engine oil in an essentially closed system, release to the environment during use should be low.

Lubricant containing the notified chemical:

The main environmental exposure is expected to result from inappropriate disposal of waste lubricant product, assuming a worst case scenario of about 14% of oil changes in Australia are performed by DIY enthusiasts resulting in ~0.7% released to stormwater and 7% released to sewer. This improper disposal is, however, widespread across Australia. A proportion of the waste lubricant is likely to become associated with soils or sediments, as will the chemical released to landfill as container residues. Notified chemical released into the sewer, stormwater and aquatic environment would be expected to rapidly hydrolyse to simpler compounds, Product A and Product B. However, as a worst case, if all of the estimated quantity sent to stormwater (0.7% or <210 kg) was released into the stormwater drains in a single metropolitan area with a geographical footprint of 500 square kilometres, and an average annual rainfall of 500 mm. With a maximum annual release into this localised stormwater system of 210×10^6 mg/y and the annual volume of water drained from this region estimated to be approximately 250×10^9 L, the resultant predicted environmental concentration (PEC) in the receiving environment is <0.00084 mg/L, with dilution and dispersion also likely to occur. In addition, if the estimated worst case quantity sent to sewer were not treated (ie. $\leq 2100 \times 10^6$ mg/year), a national average effluent concentration of ~0.0014 mg/L may be expected based on a national wastewater flow of 1.46×10^{12} L/annum. River and ocean PECs following sewer effluent discharge of 0.0014 and 0.00014 mg/L may be derived using dilution factors of 1 and 0.1, respectively. These are very much worst case scenarios, and in reality releases of the notified chemical are expected to be mostly attenuated, diffuse and probably at lower levels than estimated in these calculations.

9.1.2. Environment – effects assessment

Product A

Product A is acutely harmful to some fish species embryos and fry (LC50 10-100 mg/L) and very slightly toxic to some amphibians LC50 >100 mg/L based on the 2 species tested. It is very slightly chronically toxic (lowest NOEC 6 mg/L) to *Daphnia magna*. A predicted no effect concentration (PNEC) for freshwater organisms of 0.6 mg/L has been derived by dividing the lowest NOEC available by an assessment factor of 10 to account for interspecies sensitivity. This value is within the estimated background concentration range for this chemical in some freshwater systems.

Product B

This hydrolysis product is harmful to fish, daphnia and algae, with the most toxic result being a 72 h EC50 of 11.5 mg/L to green algae (Note: from the IUCLID Dataset and not assessed above). Using this result and an assessment factor of 100, a PNEC of 0.115 mg/L may be derived.

9.1.3. Environment – risk characterisation

As a rough indication of risk, comparison can be made between the PEC and the PNEC of each individual hydrolysis product due to the lack of ecotoxicity data for the notified chemical and due to the ready hydrolysis of the notified chemical. Further it is assumed that each would act independently in a water body. Based on this the RQ for Product A is 0.0014/0.6 = 0.002 and for Product B is 0.0014/0.115 = 0.012. As in both cases the RQ is <<1 , taking into account the very worst case natures of the PEC calculations, the risk from use of the notified chemical in lubricants is expected to be low.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and Storage

Dermal exposure to drips and spills of blended lubricant is possible during the connection and disconnection of transfer hoses during the filling of bulk tankers. Worker exposure will be minimised by the use of overalls, safety boots and gloves.

Reformulation

During the reformulation process, there is expected to be minimal worker exposure. The transfer of the imported lubricant additive package from bulk tankers into storage tanks and charging of blending tanks are highly automated processes. Incidental dermal exposure to splashes, drips and spills may occur during the connection and disconnection of the lines. The blending process is automated and occurs in closed system. The blending is transferred automatically to storage tanks. The notified chemical has skin and eye irritation potential and special precautions should be taken to avoid skin and eye exposure when carrying out the above activities.

Drum filling or packaging is again an automated process and worker intervention is not required unless the filling line operation requires adjustment and the packaging machine malfunctions. Bulk road tanker filling is performed by a transfer hose. Dermal exposure to drips and spills of blended lubricant is possible during the connection and disconnection of transfer hoses.

Maintenance workers involved in cleaning blending and filling equipment may have dermal exposure to residues containing the notified chemical.

Workers involved in the blending activities receive training in the handling of additive packages, and wear personal protective equipment such as nitrile or neoprene gloves, chemical goggles or face shield, and protective clothing.

Laboratory Staff

Laboratory staffs are expected to have minimal exposure due to the brief sampling periods and the small quantities involved.

End Users

End users of the finished product may be exposed to notified chemical when the blended oil products are added and drained from systems, while handling automotive components that have come into contact with the oil and during cleaning of equipment. The notifier recommends that workers will wear similar protective equipment to those recommended during reformulation when using products containing the notified chemical.

Retails workers may be exposed to the lubricant product when the containers are damaged. The use of personal protective equipment is not mandatory. However, PPE will be used and selected commensurate to work responsibilities.

9.2.2. Public health – exposure assessment

The engine oil containing the notified chemical is available for use as DIY lubricant product; therefore, public exposure will be widespread. 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.

However, the public exposure to the notified chemical is low due to the low concentration of the notified chemical in the engine oil, and the low frequency of use.

9.2.3. Human health - effects assessment

The notified chemical has a low acute oral and dermal toxicity. It is moderately irritating to skin as evidenced by reversible skin discolouration, very slight to well defined erythema and very slight to slight oedema. Based on the scores for erythema, it is classified as irritation to skin. The notified chemical is also irritating to eyes as it had reversible effect on the cornea, iris, and conjunctivae. Based on the scores for chemosis, it is classifiable as irritating to eyes. There was no evidence to indicate that the notified chemical is a skin sensitiser. In a 28-day oral repeat dose study, microcytic hypochromic anaemia and lymphocytopenia in high dose groups were observed. Histopathological liver changes, which were considered adaptive changes, were also observed in high and intermediate II dose groups at a higher incidence compared with spontaneous occurrences in intermediate and low dose groups. However, blood chemistry changes observed in high dose and intermediate II dose groups suggest some level of hepatic impairment. The NOEL is set at 15 mg/kg bw/day (the lowest tested dose), based on the minor biochemical changes and adaptive liver changes observed at higher doses.

The notified chemical showed negative results in the in vitro bacterial mutation test, in vitro mammalian cytogenetic test and in vivo mutagenicity test.

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), and warrants the risk phrases: R36/38 – Irritating to eyes and skin.

9.2.4. Occupational health and safety – risk characterisation

Overall, the risk of adverse effects arising from exposure to the notified chemical is low due to largely enclosed and automated operations in the manufacture of lubricants, and the low concentration of the notified chemical in end use lubricants. However, due to the eye and skin irritation potential of the notified chemical, dermal and ocular exposure should be avoided when handling the notified chemical and the products containing it.

The low concentration of the notified chemical in the lubricant products, the limited contact with the notified chemical during manufacture of lubricant products, the engineering controls and the use of recommended PPE would ensure that occupational risk posed by the notified chemical is low when used as specified in the notification.

9.2.5. Public health – risk characterisation

Public exposure to the notified chemical will arise from DIY end use of lubricant products. While there may be occasional exposure to the lubricant product when carrying out oil change at home, the oil residues involved will contain low levels of the notified chemical, which are not expected to give rise to irritant effects.

Based on the expected low exposure during use and the low concentration of the notified chemical in the lubricant products, the risk to public health is considered low.

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:
R36/38 – Irritating to eyes and 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 Irritant Category 3
Symbol: None
Signal word: Warning
Hazard statement: Causes mild skin irritation

Eye Irritant Category 2A
Symbol: Exclamation mark
Signal word: Warning
Hazard Statement: Causes serious eye irritation

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 as a component of lubricant product.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

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

11.2. Label

The label for the notified chemical and products containing the notified chemical provided by the notifier were 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:
  - R36/38 – Irritating to eyes and skin

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥20%: R36/38 - Irritating to eyes and skin

- Products containing more than 5% notified chemical and available to the public must carry the following safety directions on the label:
  - S24/25: Avoid contact with skin and eyes.

- S37/38/39: Wear suitable protective clothing, gloves, and eye/face protection.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Enclosed and automated transfer, mixing and packaging operations
  - Exhaust ventilation during manufacture of engine oil products

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoid splashing during transfer operations and when cleaning equipment

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - 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.

Environment

Disposal

- The notified chemical should be disposed of in a manner consistent with local jurisdiction waste management regulations by incineration or recycling. Emptied containers should be recycled or sent to landfill for disposal.

Emergency procedures

- Spills/release of engine oils containing the notified chemical not be released to waterways or sewer. Spills/leaks should be contained by applying absorbent materials to the spill or pumping to spilled material into labelled containers. Where feasible and appropriate, remove contaminated soil. Place contaminated materials in disposable containers and dispose of in a manner consistent with local jurisdiction waste management regulations.

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.

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