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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Component B of MC 309

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Infineum Australia Pty Ltd (ABN: 24 084 881 863)
2/6 Riverside Quay
Southbank VIC 3006

BP Australia Ltd. (ABN: 53 004 085 616)
132 McCredie Rd
Guildford NSW 2161

The Shell Company of Australia Ltd. (ABN: 46 004 610 459)
Burleigh St
Newport VIC 3015

Caltex Australia Petroleum Pty. Ltd. (ABN: 17 000 032 128)
MLC Centre
19-29 Martin Pl
Sydney NSW 2000

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 identity
Spectral data
Purity
Identity/% weight of impurities
% weight of adjuvants
Use
Introduction/manufacture volume
Identity/number of recipients

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

Toxicological data were provided for an analogous chemical.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
None.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
MC 309 (the imported formulation containing <60% (w/w) notified chemical in mineral oil)

METHODS OF DETECTION AND DETERMINATION

METHODS	Infrared Spectroscopy Ultraviolet/visible light Spectroscopy
REMARKS	Reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
>90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

4. INTRODUCTION AND USE INFORMATION

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

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<500	<500	<500	<500	<500

USE
The notified chemical is a detergent additive that will be imported as a <60% component of a lubricant additive. After blending with mineral oil, the finished lubricating oil will contain <10% of the notified chemical.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Unknown.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported into Australia in 205 L drums or bulk vessels such as isotainers. Bulk vessels are discharged into shore tanks that are unloaded by pipeline into road tankers, which then transport the product to the blending sites. After blending, the finished lubricant will be transported in bulk liquid trucks.

5.2. Operation description

At the blending site, the concentrate product containing the notified chemical is decanted into a storage tank from which it is pumped into a blend tank. Small samples are typically taken for QC testing prior to a shipment being accepted from the notifier. The additive package is formulated into lubricant products by mixing with mineral oil. Blending of the additive package with mineral oil typically involves the following steps:

1. The additive container is connected by the operator to a transfer system via a flexible transfer hose;
2. The additive is then pumped out of its container through a transfer/stainless steel pipeline into the blend tank typically in batches of 5000-60 000 L.
3. On completion, container/transfer hose/pipeline and pump are cleaned by flushing through with mineral baseoil.

4. The operator disconnects the transfer hose.
5. Blending is fully automated and enclosed.
6. Drumming and/or repacking of the finished lubricant is carried out via an automated filling line.

Mineral oil used for cleaning the equipment is used by incorporation into subsequent batches.

Following reformulation, the oil is transported to the site of use, where it is burnt in the engine with the fuel.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Dock workers	2	5hrs/day	60 days/year
Transport workers (additive)	2	1hr/day	60 days/year
Blending/drumming workers	4	2 hrs/week	52 weeks/year
Blending facility cleaning	4	8hrs/day	1 day/yr
Laboratory workers	2	0.5 hrs/day	6 days/year
Transport workers (finished lubricant)	2	3 hrs/day	30 days/year
End users	~100	8 hrs/day	240 days/year

Exposure Details

Transport and dock workers may come into contact with the additive (containing <60% notified chemical) or the finished lubricant (containing <10% notified chemical) when connecting or disconnecting pipes that transfer the products. Product residue is air blown up discharge lines, which will minimise exposure to drips and spills.

The blending process is, in general, automated and enclosed. Workers will wear industrial clothing and footwear, gloves and safety goggles. Local exhaust ventilation is present. Following the automated filling process, workers will manually package containers for further handling and distribution. Exposure to workers involved in reformulation will be low.

Cleaning of the blending tanks occurs only when there is a change in product formulation. Personal protective equipment will minimise exposure.

End users are unlikely to be exposed to the lubricant except in cases of drips and spills, or during maintenance, when gloves and overalls will minimise exposure.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Losses during transport and transfer are likely to be minimal. Any spills will be contained and collected, placed in labelled containers and either recycled, if possible, or disposed of. Fugitive emissions during transport and blending are considered to be negligible due to the very low vapour pressure of the notified chemical.

The drumming/re-packing of the finished lubricant product into consumer sized containers is an automated process. Leakage from product transfer lines is expected to be minimal, and any drips/splashes will be collected for recycling. Containers, transfer hoses, pipelines and pumps are cleaned by flushing through with mineral baseoil, which is then used in subsequent batches.

Approximately 1% of the container volume would remain as residue in an empty container. This equates to up to 5 tonnes per year of waste notified chemical.

RELEASE OF CHEMICAL FROM USE
During use, the finished lubricant oils containing the notified chemical will be injected directly into the combustion chambers, where they will be combusted along with the fuel. Hence, no waste oil will be generated and release of the oil during use will be minimal.

Used containers will contain approximately 1% residue ie up to 5 tonnes of notified chemical per annum.

5.5. Disposal

Spilt material that cannot be recycled will be disposed of to approved landfill or may be incinerated.

Containers/drums will be recycled by licensed contractors who will probably incinerate any residues present, thus up to 10 tonnes of the notified chemical will be incinerated during this process.

5.6. Public exposure

Exposure to the public is expected to be low. The notified chemical is imported, transported to blending sites, and after blending is transported directly to commercial customers. Exposure to the public would only occur in the event of spills or industrial accidents.

6. PHYSICAL AND CHEMICAL PROPERTIES

Tests were performed on the notified chemical in 30% mineral oil.

Appearance at 20ºC and 101.3 kPa Brown viscous liquid.

Pour Point -12ºC

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Pour point was determined using a cloud and pour point apparatus.
TEST FACILITY	HLS (2003)

Boiling Point Not determined (decomposition at 250°C)

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Decomposition was confirmed using differential scanning calorimetry.
TEST FACILITY	HLS (2003)

Density 1130 kg/m^3 at 22ºC

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Determined using a pyknometer.
TEST FACILITY	HLS (2003)

Vapour Pressure <$6.6x10^{-7}$ kPa at 25ºC

METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Determined using a vapour pressure balance.
TEST FACILITY	HLS (2003)

Water Solubility <5 x 10^{-4} g/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks A preliminary test indicated that the definitive test should utilise a modified flask method using slow stirring over an extended period. The TOC was measured on days 2, 3 and 4. A mean TOC of 0.2 mg C/L was determined, which gave a test substance water solubility of less than 0.5 mg/L.
TEST FACILITY HLS (2003)

Fat Solubility > 500g/kg

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks Analytical Method: Ultraviolet spectrophotometry.
HB 307 standard fat simulant was used.
The organic portion of the test substance is highly soluble in fat. Inorganic salts are present and are likely to make up the insoluble portion.
TEST FACILITY HLS (2003)

Hydrolysis as a Function of pH Not determined.
Remarks The notified chemical does not contain any hydrolysable groups.

Partition Coefficient (n-octanol/water) log P_{ow} > 6.3 (estimate)

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks When shaken in a flask it was found that the test substance formed an emulsion between the n-octanol and water due to its surface activity. Therefore, the partition coefficient was estimated by ratio of the substance's solubility in n-octanol and in water. Its n-octanol solubility was >1000 g/L and its solubility in water was <5x10^{-4} g/L, thus log P_{ow} >6.3.
TEST FACILITY HLS (2003)

Adsorption/Desorption log K_{oc} > 4 (estimate)

METHOD QSAR Estimation of the Adsorption Coefficient (Koc)
Remarks The following equations from Lyman et al (1982) were used:
$Log_{10}K_{oc} = 0.544\ log_{10}P_{ow}+1.377$,
$Log_{10}K_{oc} = -0.55\ log_{10}S+3.64$
TEST FACILITY HLS (2003)

Dissociation Constant Not determined due to the low water solubility and complexity of the notified chemical.

Particle Size Not applicable as notified chemical is a liquid.

Flash Point Not determined.

Remarks Flash point was estimated as >160ºC, based on similar materials.

Flammability Limits Not determined.

Remarks The flammability limits for the product is as for the diluent oil:
LEL: 1%
UEL: 5%

Autoignition Temperature Not determined.

Remarks The autoignition temperature for the product is as for the diluent oil: 340°C

Explosive Properties	A negative result is predicted on structural grounds.
Reactivity	Expected to be stable under normal environmental conditions. May react with strong oxidising agents.

7. TOXICOLOGICAL INVESTIGATIONS

Toxicological tests were performed on products containing analogous chemicals

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	not performed
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation –non-adjuvant test.	limited evidence of sensitisation
Rat, repeat dose dermal toxicity – 28 days.	NOAEL > 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test	non genotoxic
Genotoxicity – in vivo mammalian bone marrow chromosome aberration test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Analogous chemical.

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.
- Species/Strain: Rat/Crl:CD BR
- Vehicle: None.
- Remarks - Method: No significant protocol deviations.

RESULTS

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

- LD50: >2000 mg/kg bw
- Signs of Toxicity: No signs of toxicity observed.
- Effects in Organs: No abnormalities observed.
- Remarks - Results: No significant protocol deviations.

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

TEST FACILITY EBS (1997a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Analogous chemical.
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rabbit/New Zealand White
Vehicle	None.
Type of dressing	Occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Desquamation was observed in one animal on day 3.
Signs of Toxicity - Systemic	There were no signs of systemic toxicity.
Effects in Organs	None.
Remarks - Results	None.

CONCLUSION	The analogue chemical is of low toxicity via the dermal route.
TEST FACILITY	EBS (1997b)

7.3. Acute toxicity – inhalation

Not performed as the substance is a liquid with a low vapour pressure.

7.4. Irritation – skin

TEST SUBSTANCE	Analogous 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	6
Vehicle	None.
Observation Period	72 hours.
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0	1	1 hour	0
Oedema	0	0	-	0

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

Remarks - Results	Mild erythema was seen in one animal only at the 1-hour observation.
CONCLUSION	The analogue chemical is slightly irritating to the skin.
TEST FACILITY	EBS (1997c)

7.5. Irritation – eye

TEST SUBSTANCE: Analogous chemical.

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3 males.
- Observation Period: 72 hours.
- Remarks - Method: No significant protocol deviations.

RESULTS: None.

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.33	1	1	2	48 hours	0
Conjunctiva: chemosis	0	0	0	0	-	0
Conjunctiva: discharge	0	0	0	0	-	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

- Remarks - Results: At the 1-hour observation, conjunctival redness, chemosis and discharge were seen in all three animals. Redness persisted in all animals for 24 hours and in two animals at 48 hours.

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

TEST FACILITY: EBS (1997i)

7.6. Skin sensitisation

TEST SUBSTANCE: Analogous chemical.

METHOD: OECD TG 406 Skin Sensitisation - Buehler test.
EC Directive 96/54/EC B.6 Skin Sensitisation - Buehler test.
- Species/Strain: Guinea pig/Dunkin Hartley

PRELIMINARY STUDY
- Signs of irritation: A maximum non-irritating concentration could not be determined. At 10% (the lowest concentration tested), the maximum irritation seen was slight patchy erythema.

MAIN STUDY
- Number of Animals: Test Group: 20/female Control Group: 20/female

INDUCTION PHASE: Induction Concentration: 100% topical.
- Signs of Irritation: Slight erythema was seen at 24 and/or 48 hours in all animals.

CHALLENGE PHASE
- 1st challenge: topical: 100%
- 2nd challenge: topical: 100%
- 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	100%	20%	5%	0	0

Control Group	100%	10%	0	0	0

*Only slight, confluent or moderate erythema scores are shown.

Remarks - Results

The results after the first challenge were equivocal, with slightly higher reactions seen in exposed animals as compared with naïve animals. After 24 hours, 3/20 treated animals exhibited slight erythema, while only 1/10 control animal was scored at this level. One treated animal exhibited moderate erythema, which was higher than any control animal. After 48 hours, 1/20 test animals still showed some erythema, while none of the control animals showed erythema.

The second challenge did not provide evidence of sensitisation. After 24 hours 10% of treated animals developed slight erythema, while 30% of control animals developed slight erythema. By 48 hours no erythema was present in any animal.

20mercaptobenzothiazole was used as the positive control and produced distinct evidence of sensitisation.

CONCLUSION

There was limited evidence of reactions indicative of skin sensitisation to the analogue chemical under the conditions of the test.

TEST FACILITY

EBS (1997d)

7.7. Repeat dose toxicity

TEST SUBSTANCE

Analogous chemical.

METHOD

OECD TG 410 Repeated Dose Dermal Toxicity: 21/28-day Study.

Species/Strain: Rat/Crl:CD BR

Route of Administration: Dermal – occluded

Exposure Information: Total exposure days: 28 days
Dose regimen: 7 days per week
Duration of exposure (inhalation/dermal): 6 hours/day
Post-exposure observation period: 14 days

Vehicle: None.

Remarks - Method: No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	100	0
III (mid dose)	5/sex	300	0
IV (high dose)	5/sex	1000	0
V (control recovery)	5/sex	0	0
VI (high dose recovery)	5/sex	1000	0

Mortality and Time to Death

All animals survived.

Clinical Observations

Very slight erythema was observed in two 300 mg/kg bw/day females one on day 7 and one on day 14; and in four 1000 mg/kg bw/day females on day 3. Well-defined erythema was seen in one 1000 mg/kg bw/day female at day 7. Desquamation was observed in one control male on day 14 and one 1000 mg/kg bw/day male on days 3 and 7, and in several females in all groups (including control) up until day 14.

There were no other relevant clinical observations.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No differences were seen in haematological parameters during the main study. A number of parameters showed significant differences during the recovery period, between day 28 and day 42. These were: decreases in mean corpuscular volume and mean absolute neutrophils (males) and mean percentage of monocytes (females); increases in mean percentage lymphocytes (males and females), mean absolute lymphocytes (females) and mean corpuscular hemoglobin concentration (males). These changes are unlikely to be due to exposure to the notified chemical, as there were no related clinical or histopathological findings, and the changes were limited to the recovery period.

At main study termination, there was an increase in mean triglycerides in the 1000 mg/kg bw/day control group compared with controls. This single difference was considered spurious and not toxicologically significant. There were a number of differences in other serum chemistry parameters in the 1000 mg/kg bw/day recovery group, between day 28 and 42. These findings were not related to clinical or histopathological findings, and were limited to the recovery period, and thus are not thought to be of toxicological significance. These included increases in mean sodium, potassium, glucose and total protein (males) and decreases in phosphorous (males).

Effects in Organs

There were so significant gross post-mortem observations.

There were increases in mean absolute and mean relative kidney-to-body weights for 100 mg/kg bw/day females and a decrease in mean live-to-brain weight of 300 mg/kg bw/day males. In the absence of a clear dose response, these differences are not considered to be significant.

During the recovery period, a number of changes to relative organ weights were seen. These included a decrease in relative brain-to-body weight and testes-to-body weight (males) and liver-to-body weight in females, and an increase in mean relative kidney-to-brain weight (males). These differences were small (<12%), and were not corroborated by other findings, and were thus not considered to be toxicologically relevant.

There were a number of microscopic changes, however these changes occurred in all groups of rats with similar incidence, and thus were not related to the test substance, but likely were related to the shaving and wrapping during the test. Examination of the skin revealed acanthosis and hyperkeratosis of the epidermis, reactive sebaceous gland hyperplasia and occasional multifocal dermal inflammatory cell infiltrations. In the liver, there was a minimal amount of multifocal mononuclear inflammatory cell infiltrations and some cases of focal subcapsular necrosis.

Remarks – Results

None.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on no clear treatment-related adverse effects at this level.

TEST FACILITY EBS (1997h)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Analogous chemical.
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction
Concentration Range in Main Test	a) With metabolic activation: 100-5000 µg/plate b) Without metabolic activation: 100-5000 µg/plate
Vehicle	Tetrahydrofuran (THF)

Remarks - Method No significant protocol deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	None.	5000 µg/plate	≥2500 µg/plate	None.
Test 2	None.	≥4000 µg/plate	≥2500 µg/plate	None.
Present				
Test 1	None.	5000 µg/plate	None.	None.
Test 2	None.	None.	None.	None.

Remarks - Results The positive control substances and produced at least a three-fold increase in mean number of revertant colonies when compared with the DMSO control. Negative controls were within historical limits.

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

TEST FACILITY EBS (1997e)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Analogous chemical.

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line CHO cells (WBL)
Metabolic Activation System Aroclor 1254 induced rat liver S9 fraction.
Vehicle tetrahydrofuran
Remarks - Method Concentrations were determined based on cytotoxicity.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	10, 20*, 40*, 80*, 160, 240, 320 µg/mL	16 hours	32 hours
Test 2	10, 20*, 40*, 80*, 160 µg/mL	16 hours	32 hours
Test 3	10, 20*, 40*, 80*, 160 µg/mL	16 hours	56 hours
Present			
Test 1	20, 40, 80*, 160*, 240*, 320, 400 µg/mL	16 hours	32 hours
Test 2	40, 80*, 160*, 240*, 320 µg/mL	16 hours	32 hours
Test 3	40, 80*, 160*, 240*, 320 µg/mL	16 hours	56 hours

*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	-	None.	None.	None.
Test 2	-	None.	None.	None.
Test 3	-	None.	None.	None.
Present				
Test 1	-	None.	None.	None.
Test 2	-	None.	None.	None.
Test 3	-	None.	None.	None.

Remarks - Results	DMBA and MNNG were used as positive controls and induced distinct increases in the proportion of cells with structural chromosomal aberrations. Negative controls were within historical limits.
CONCLUSION	The analogue chemical was not clastogenic to CHO cells treated in vitro under the conditions of the test.
TEST FACILITY	EBS (1997f)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE	Analogous chemical.
METHOD	OECD TG 474 Mammalian Bone Marrow Chromosome Aberration Test.
Species/Strain	Mouse/CD-1
Route of Administration	Oral – gavage
Vehicle	Peanut oil
Remarks - Method	No significant protocol deviations.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5/sex	0	72 hours
II (low dose)	5/sex	500/day	72 hours
III (mid dose)	5/sex	1000/day	72 hours
IV (high dose)	5/sex	2000/day	72 hours
V (positive control, CP)	5/sex	20/day	72 hours

CP=cyclophosphamide. M=mitomycin C.

RESULTS	
Doses Producing Toxicity	None.
Genotoxic Effects	None.
Remarks - Results	Cyclophosphamide was used as the positive control and showed distinct increases in cells with micronuclei. Negative control was within historical limits.
CONCLUSION	The analogue chemical was not clastogenic under the conditions of this in vivo mammalian bone marrow chromosome aberration test.
TEST FACILITY	EBS (1997g)

8. ENVIRONMENT

Environmental tests were performed on products containing analogous chemicals.

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Analogous chemical.
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test (modified Sturm Test).
Inoculum	Fresh activated sludge from local domestic wastewater treatment plant.
Exposure Period	29 days
Auxiliary Solvent	None
Analytical Monitoring	Sodium and barium trap solutions titrated with 0.1N HCl
Remarks – Method	Reference substance – sodium benzoate The test substance (at 20 mg C/L) was tested in triplicate while the reference substance and the blank were tested in duplicate. The temperature was maintained at 22±2°C.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	1.67	2	25.12
6	4.99	6	65.27
8	7.66	8	77.79
12	12.41	12	85.63
27	23.27	27	90.80
29	24.33	29	92.62

Remarks - Results	Degradation of the reference substance exceeded 60% by day 6, thus validating the test conditions. By the end of the study, degradation of the test substance reached 24%.
CONCLUSION	Since the test substance did not reach 60% degradation it cannot be classified as readily biodegradable.
TEST FACILITY	EBS (1997j)

8.1.2. Bioaccumulation

Not determined. The notified chemical has the potential to bioaccumulate but this is unlikely due to its low environmental exposure.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogous chemical.
METHOD	OECD TG 203 Fish, Acute Toxicity Test – semi-static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - semi-static.
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	244 mg $CaCO_3$/L

Analytical Monitoring	Total Organic Carbon (TOC)
Remarks – Method	The test material was prepared as a Water Accommodated Fraction (WAF) due to its expected low water solubility. The mixtures were stirred at room temperature for 24 h and allowed to settle for 1 h. Following the settling period the water phase containing the WAF was removed from the bottom outlet of the vessel. Each concentration was tested in duplicate, with the media renewed daily, using freshly prepared WAF. The test vessels were exposed to 16 hours of light and 8 hours of dark. The dissolved oxygen, pH and temperature were measured before and after media renewal. These environmental parameters all varied within acceptable limits.

RESULTS

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

LL50	>1000 mg/L (WAF) at 96 hours.
NOEL	1000 mg/L (WAF) at 96 hours.
Remarks – Results	No insoluble test substance was observed in the test solutions throughout the study. The TOC results indicated that less than 1 mg C/L was present in the test solutions.

CONCLUSION Under the study conditions the test substance is not toxic to fish, up to the limit of its water solubility.

TEST FACILITY EBS (1997k)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Analogous chemical.

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test – static test.
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – static test.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	244 mg $CaCO_3$/L
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks - Method	The test material was prepared as a Water Accommodated Fraction (WAF) due to its expected low water solubility. The mixtures were stirred at room temperature for 24 h and allowed to settle for 1 h. Following the settling period the water phase containing the WAF was removed from the bottom outlet of the vessel. Each test was performed in quadruplicate with no daily renewal, and the temperature was maintained at 21.4ºC. The test vessels were exposed to 14 hours of light and 10 hours of dark. The dissolved oxygen and pH were measured at time 0 and on termination. The environmental parameters all varied within acceptable limits.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		20	0	0
62.5		20	0	0
125		20	0	0
250		20	0	0
500		20	0	5
1000		20	0	0

LL50	>1000 mg/L (WAF) at 48 hours
NOEL	1000 mg/L (WAF) at 48 hours
Remarks - Results	No insoluble test substance was observed in the test solutions throughout the study. The TOC results indicated that less than 1 mg C/L was present in the test solutions.

CONCLUSION Under the study conditions the test substance is not toxic to aquatic invertebrates, up to the limit of its water solubility.

TEST FACILITY EBS (1997l)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be used in lubricants and will share their fate. Therefore, most of the notified chemical will be burnt within engines. Incineration products are expected to include oxides of carbon and sulphur, and calcium salts (in the ash).

A small amount is likely to be released to the environment from spills and leaks, however these would be widely dispersed. Losses during transfer would be expected to adsorb to soil.

The notified chemical was found to be not readily biodegradable with 24% degradation after 28 days. The inherent biodegradability was not measured, but based on this result it would not be expected to be persistent.

The potential for bioaccumulation was not determined. Due to the high estimated partition coefficient (log K_{OW} > 5), low water solubility (<$5x10^{-4}$ g/L) and high fat solubility, bioaccumulation of the notified chemical is possible (Connell 1989). However, biological membranes are not permeable to chemicals of large molecular size (Gobas *et al.* 1986; Connell 1989). This combined with the low aquatic exposure would indicate that bioaccumulation of the notified substance is not expected.

9.1.2. Environment – effects assessment

Based on the analogue ecotoxicity data provided, the notified chemical is not likely to be toxic to aquatic organisms (up to the limit of its water solubility). In the ecotoxicity studies the TOC results indicated that less than 1 mg C/L (<1 ppm organic carbon) was present in the test WAF solutions. A PNEC cannot be determined.

9.1.3. Environment – risk characterisation

A PEC cannot be determined. However due to the expected low exposure to the notified chemical, the risk to the aquatic compartment is low.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport & Storage

Occupational exposure to the notified chemical during transport and storage of imported product containing less than 60% notified chemical is only likely in the event of accidental spills involving breach of import containers. Exposure in these circumstances is expected to be infrequent and acute, and can be limited by use of skin and eye protection, including gloves, goggles and protective clothing, during clean-up operations.

Blending and Re-blending Operations

During blending operations the imported additive product (<60% notified chemical) is diluted to <10% for use in oils. Exposure during the blending process should be minimal as this is conducted in an automated, closed system. Intermittent dermal, eye and inhalation exposure is possible during connection and disconnection of transfer equipment, during sealing and labelling of drums, and during equipment cleaning and maintenance. Dermal and ocular exposure due to spills or splashes can be limited by the use of protective clothing, eyewear and gloves. Inhalation exposure will be minimal as the vapour pressure is low, and formation of aerosols is unlikely.

Dermal exposure during blending operations was estimated using the EASE model (HSE, 1994). Assuming non-dispersive use and intermittent direct handling of the product containing <60% notified chemical, and assuming 10% absorption (MW > 500), 70 kg bodyweight, and 840 cm^2 surface area, the estimated dermal exposure during blending is 0-48 µg/kg bw/day of the notified chemical. This level of exposure would be substantially reduced by the use of protective clothing and gloves.

Exposure to the notified chemical by all routes will also be limited by the frequency of handling,

which is expected to be once per week or less.

End Use
End users of the lubricant are likely to be trained technicians, and will generally not come into contact with the lubricant during regular activities. There may be some exposure due to drips and spills, and during cleaning operations. Overall exposure to the notified chemical will be limited by its low concentration (<10%) in end use products.

9.2.2. Public health – exposure assessment

The notified chemical will not be available to the public. Exposure would only occur in the event of a spill or container rupture.

9.2.3. Human health – effects assessment

In the sensitisation study, there was limited evidence of sensitisation.The Buehler test is considered positive if 15% or more animals are positive. As this is not the case, classification of the notified chemical as a hazardous substance is not indicated.

All other tests (acute and repeat-dose toxicity, irritation and mutagenicity) indicated low hazard.

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 2004).

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is not expected to be harmful to human health, based on the results of toxicological tests on an analogous chemical. In addition to the low hazard presented by the notified chemical, exposure will be controlled through the use of enclosed blending facilities and PPE such as protective clothing, eyewear and gloves. Thus, there is a low OHS risk due to likely low hazard and low exposure.

9.2.5. Public health – risk characterisation

It is not expected that the public will be exposed to the notified chemical. In the unlikely case of a spill, the low hazard presented by the notified chemical translates to low risk to public health.

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 hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

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.

On environmental grounds the notified chemical would be classified as Chronic IV.

10.2. Environmental risk assessment

The notified 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 Negligible Concern to public health when used in lubricant additives that are not available to the public.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

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

11.2. Label

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

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- A copy of the MSDS should be easily accessible to employees.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced or as diluted for use:
  - Avoid contact with eyes and skin
  - Wear chemical resistant apron, jacket and rubber boots.
  - Wear chemical resistant gloves
  - Wear safety goggles
- 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.
  - Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Environment

- The following control measures should be implemented during reformulation in order to minimise environmental exposure:
  - All process areas, including loading and unloading sites are to be bunded with no storm drains present.

Disposal

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

Emergency procedures

- Spills/release of the notified chemical should be handled by containment and recycling if possible or the use of absorbents (eg sand) then collection into a sealable labelled containers and disposal to landfill.

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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