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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Component A of MC 309

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

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 <80% (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 that will be imported as a <80% component of a lubricant additive. After blending with mineral oil, the finished lubricating oil will contain <20% 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	5 hrs/day	60 days/year
Transport workers (additive)	2	1 hr/day	60 days/year
Blending/drumming workers	4	2 hrs/day	52 days/year
Blending facility cleaning	4	8 hrs/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 <80% notified chemical) or the finished lubricant (containing <20% finished lubricant) 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 -6ºC

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 220°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 1170 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 <1.2 x 10^{-6} 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 Pow > 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 <5 x 10^{-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 >160°C, 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
Human, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation –non-adjuvant test.	evidence of sensitisation
Human, skin sensitisation	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOEL 100 mg/kg bw/day NOAEL >1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome abberation 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	None.

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	Two females were observed to have anogenital staining 6 hours after dosing.
Effects in Organs	One female was observed with a dilated renal pelvis, considered to be incidental.
Remarks - Results	None.

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

TEST FACILITY EBS (1996a)

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	Moderate/severe erythema and very slight/slight oedema were observed following the 24-hour exposure period in all animals on day 1. All animals were free of both erythema and oedema by day 7. Subsequently, desquamation was observed in all animals at day 7, nine animals at day 10 and four animals at day 14. Atonia was observed in three animals on day 3.
Signs of Toxicity - Systemic	One male exhibited transient nasal discharge, unthrifty coat and mouth sores on days 13 and 14, while one other male exhibited nasal discharge on day 14. There was a slight body weight decrease in two males during week 2, and one female during week 1. It cannot be ruled out that these signs were caused by the notified chemical.
Effects in Organs	None.
Remarks - Results	The notified chemical was severely irritating to skin.

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

TEST FACILITY EBS (1996b)

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	Erythema was observed in 3 animals at the 1-hour observation. Desquamation was observed in one animal at the 72-hour observation, but this isolated observation is unlikely to be related to the application of the analogous chemical.

CONCLUSION The analogous chemical was found to be slightly irritating to the skin in this study.

TEST FACILITY EBS(1996c)

7.5. Skin irritation – human volunteers

TEST SUBSTANCE	Analogous chemical.
METHOD	
Test Articles	Article A: 50% analogue chemical in mineral oil Article B: 25% analogue chemical in mineral oil Article C: 10% analogue chemical in mineral oil Article D: mineral oil Article E: 5% sodium lauryl sulfate
Study Design	Test articles were applied simultaneously to a series of skin sites on the upper arms. The amount applied was 0.2 mL, and the substance was covered with a semi-occlusive pad for 24 hours.
Study Group	14 females and 1 male 20-55 years of age.
Vehicle	Mineral oil.
Remarks - Method	Five subjects lost at least one test article before the 24-hour period. These deviations are not thought to have affected the results.
RESULTS	
Remarks - Results	Application of the test substance at a concentration of 50% in mineral oil caused no irritation. Both the test substance (10% and 25% in mineral oil) and the vehicle control (mineral oil) caused mild transient erythema in 2/15 subjects. The irritation responses to the test substance were no higher than the responses to the control. The positive control substance elicited strong skin irritation.
CONCLUSION	The analogous chemical is non-irritating to the skin.
TEST FACILITY	HTR (1996)

7.6. 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	Conjunctival redness, chemosis and discharge were observed after 1 hour

in all animals. Redness persisted in all animals for 24 hours and in two animals at 48 hours.

CONCLUSION The analogous chemical is slightly irritating to the eye.

TEST FACILITY EBS (1997)

7.7. Skin sensitisation – Guinea pig

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 5% (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: 5% (day 28)

2nd challenge topical: 1% (day 35)

Remarks - Method Only female guinea pigs were used, and a bandage was used as a means of restraint and occlusion in this study.

Positive control substance was accidentally used at 35% rather than the 50% stated in the protocol. The positive control still yielded definite evidence of sensitisation.

RESULTS

Animal	*Challenge Concentration*	*Incidence of dermal scores as a percentage**				
		0	±	*1*	*2*	*3*
Test Group	5%	0	10	53	30	8
	1%	10	35	35	20	0
Control Group	5%	5	70	25	0	0
	1%	5	65	20	10	0

* Sum of scores at 24 and 48 hours.

Remarks - Results The scores for the 5% challenge are indicative of skin sensitisation. The scores for the 1% challenge are somewhat equivocal, due to the high level of skin irritation seen.

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

CONCLUSION There was evidence of reactions indicative of skin sensitisation to the analogous chemical under the conditions of the test.

TEST FACILITY EBS (1996d)

7.8. Skin sensitisation – human volunteers

TEST SUBSTANCE	Analogous chemical.
METHOD	
Test Articles	Article A: 50% analogue chemical in mineral oil Article B: mineral oil Article C: 50% analogue chemical in petrolatum Article D: 50% analogue chemical in petrolatum Article E: petrolatum (Vaseline)
Study Design	Modified Draize procedure (Draize et. Al., 1944). Induction Procedure: Three 24-hour exposures per week for 3 weeks. Semi-occlusive patches were applied to the upper arm for Articles A and B, and occlusive patches for Articles C, D and E. Rest Period: 10-17 days. Challenge Procedure: 24-hour exposure to a naïve site, again with application to the upper arm, using semi-occlusive patches for Articles A and B and occlusive patches for Articles C, D and E.
Study Group	Males or females 20-55 years of age. Pilot phase: 15 females and 8 males completed the study. Main phase: 64 females and 18 males completed the study.
Vehicle	Mineral oil/petrolatum
Remarks - Method	In the pilot study, four subjects had lower than expected exposure duration. Also, the scorer participated in patch application during the sixth induction and thus may have not been blinded to the treatment assignments for all subjects. In the main study, three subjects had lower than expected exposure duration. The scores for one application each for two subjects were not recorded. During the challenge phase, one subject was scored 48 rather than 72 hours post patch removal. No other significant protocol deviations.
RESULTS	
Remarks - Results	Pilot study: Articles A and B were non-irritating during the induction phase, and non-irritating and non-sensitising when challenged. Main study: Articles A, B, C, D and E were all non-sensitising and non-irritating when used for challenge and essentially non-irritating during the induction phase: (scores refer to erythema seen during the induction period) Article A: 4 scores of slight, confluent or moderate patchy erythema. Article B (Article A control): 8 scores of slight, confluent or moderate patchy erythema. Overall, Article A did not show any signs of irritation when compared to the control (Article B). Article C: 17 scores of slight, confluent or moderate patchy erythema. One subject showed papules for two successive applications, followed by scabbing at the next application; the alternate application site for this subject showed no signs of irritation. Article D: 8 scores of slight, confluent or moderate patchy erythema. One

incidence of papules with scabbing that persisted until the end of the application period (6 applications); the alternate application site on this subject showed no signs of irritation.

Article E (Articles C and D control): 11 scores of slight, confluent or moderate patchy erythema.

Overall, the presence of papules and scabbing upon treatment in two test subjects (Articles C and D) but no control subjects (Article E) indicates that the analogue chemical may be a slight skin irritant.

No positive controls were included in this study.

CONCLUSION

A repeated insult patch test was conducted using the analogous chemical diluted with mineral oil or petrolatum to 50% under semi-occlusive or occlusive dressing. The analogue chemical was non-sensitising and slightly irritating under the conditions of the test.

TEST FACILITY

HTR (1997)

7.9. Repeat dose toxicity

TEST SUBSTANCE

Analogous chemical.

METHOD

OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

Species/Strain	Rat/Cr1: CD BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	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	None.
II (low dose)	5/sex	100	None.
III (mid dose)	5/sex	300	None.
IV (high dose)	5/sex	1000	None.
V (control recovery)	5/sex	0	None.
VI (high dose recovery)	5/sex	1000	None.

Mortality and Time to Death

None.

Clinical Observations

Sores and/or scabs were observed in three 300 mg/kg bw/day group animals and dried red ocular discharge was observed in one 1000 mg/kg bw/day female.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

There was a statistically significant increase in mean activated partial thromboplastin time (25%) in the 1000 mg/kg bw/day males when compared to controls.

During the recovery period, there was a significant decrease in mean prothrombin time (11%) in males, and an increase in mean prothrombin time (14%) in females.

In the absence of a consistent dose response these changes are not considered clinically significant. There were also increases in large unclassified cells in both sexes of the recovery group. In the absence of other meaningful hematology changes, this change is not considered to be clinically significant.

Following the recovery period, there were a number of differences observed in serum chemistry parameters of the treated animals. There were significant increases in mean blood urea nitrogen (38%) and phosphorous (8%) in males, and significant increases in both males and females for total bilirubin (300% and 230%) and a decrease in chloride (both 3%). These differences were not thought to be toxicologically significant, as they were limited to the recovery phase, and there were no corresponding findings in organs during autopsy.

Effects in Organs

One control male had an unidentified tan object in its stomach. There were no other observable anomalies at the postmortem examination.

There were a number of significant changes in mean liver-to-body weight ratios of the animals receiving 300 mg/kg bw/day and 1000 mg/kg bw/day, most likely related to adaptive liver weight increases during dosing:

1000 mg/kg bw/day males showed increased liver-to-body weight (14%) compared with controls.
Recovery group females showed decreased liver-to-body weight (10%) compared with controls.
300 mg/kg bw/day males showed increased liver-to-body weight (14%) compared with controls.

There were no significant histopathological changes that differed between the dose groups and the controls.

Remarks – Results

None.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 100 mg/kg bw/day analogous chemical, based on the changes in liver-to-body weight ratio in males receiving 300 mg/kg bw/day. The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day, based on the lack of other corroborative findings for the liver weight changes.

TEST FACILITY EBS (1996h)

7.10. 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	Rat S9
Concentration Range in Main Test	a) With metabolic activation: 12.5-5000 µg/plate b) Without metabolic activation: 12.5-5000 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.	None.	>100 µg/plate	None.
Test 2	None.	None.	>100 µg/plate	None.
Present				
Test 1	None.	None.	>100 µg/plate	None.
Test 2	None.	None.	>100 µg/plate	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.
CONCLUSION	The analogous chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	EBS (1996e)

7.11. 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 rat liver induced S9 fraction.
Vehicle	tetrahydrofuran
Remarks - Method	Maximum concentrations were determined based on solubility.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	2, 4, 8, 16*, 32* ,64* µg/mL	16 hours	36 hours
Test 2	2, 4, 8, 16*, 32*, 64* µg/mL	16 hours	40 hours
Present			
Test 1	2, 4, 8, 16*, 32*, 64* µg/mL	16 hours	36 hours
Test 2	2, 4, 8, 16*, 32*, 64* µg/mL	16 hours	40 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.	>32 µg/mL	None.
Test 2	None.	None.	>16 µg/mL	None.
Present				
Test 1	None.	None.	>32 µg/mL	None.
Test 2	None.	None.	64 µg/mL	None.

Remarks - Results	DMBA and MNNG were used as positive controls and induced distinct increases in the proportion of cells with structural chromosomal aberrations.
CONCLUSION	The analogous chemical was not clastogenic to CHO cells treated in vitro under the conditions of the test.
TEST FACILITY	EBS (1996f)

7.12. Genotoxicity – in vivo

TEST SUBSTANCE	Analogous chemical.
METHOD	OECD TG 475 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 A statistically significant decrease in the mean percentage of polychromatic erythrocytes was seen in the low dose group compared to the control group. This was not considered to be biologically significant.

Remarks - Results Cyclophosphamide was used as the positive control and showed distinct increases in cells with micronuclei.

CONCLUSION The analogous chemical was not clastogenic under the conditions of this in vivo mammalian bone marrow chromosome aberration test.

TEST FACILITY EBS (1996g)

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 16 mg C/L) was tested in triplicate while the reference substance (at 16 mg C/L) and the blank were tested in duplicate. The temperature was maintained at 22±3°C.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	0.51	2	32.76
6	4.96	6	73.31
9	7.65	9	82.45
12	13.27	12	88.47
15	17.46	15	90.92
29	24.98	29	93.82

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 25%.
CONCLUSION	Since the test substance did not reach 60% degradation it cannot be classified as readily biodegradable.
TEST FACILITY	EBS (1996i)

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	150 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
100		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	The TOC analysis indicated that the total organic carbon content of the WAFs was below the quantification limit of 1 ppm.

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

TEST FACILITY EBS (1996j)

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	200 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. A surface slick was observed in the 400 mg/L (WAF) solution. Each test was performed in quadruplicate with no daily renewal, and the temperature was maintained at 21.4ºC. The test vessels were exposed to 16 hours of light and 8 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
25.6		20	0	0
64		20	0	0
160		20	0	0
400		20	0	0
1000		20	0	0

EL50	>1000 mg/L (WAF) at 48 hours
NOEL	1000 mg/L (WAF) at 48 hours
Remarks - Results	The TOC analysis indicated that the total organic carbon content of the WAFs was below the quantification limit of 1 ppm.

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 (1996k)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Analogous chemical.

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

Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range	Nominal: 62.5, 125, 250, 500 and 1000 mg/L (WAF)
Auxiliary Solvent	None.
Water Hardness	Not stated.
Analytical Monitoring	DOC
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. No insoluble material was observed in the WAF throughout the study. Each test was performed in triplicate with no daily renewal, and the temperature was maintained at 22.6ºC. Cell density was measured using a Turner filter fluorometer. The pH was measured at time 0 and on termination. The environmental parameters all varied within acceptable limits.

RESULTS

Biomass		*Growth*	
E_bL_{50}	*NOEL*	*E_rL_{50}*	*NOEL*
mg/L (WAF) at 72 h	*mg/L (WAF)*	*mg/L (WAF) at 72 h*	*mg/L (WAF)*
>1000	125	>1000	1000

Remarks – Results The DOC analysis indicated that the dissolved organic carbon in the WAFs was below the detection limit of 1 ppm.

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

TEST FACILITY EBS (1996l)

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 25% 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/DOC results indicated that less than 1 ppm of 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 80% 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 (<80% notified chemical) is diluted to <20% 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 < 80% 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 relatively low concentration (<20%) 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

The analogous chemical was of low acute toxicity via the oral or dermal routes. Three independent mutagenicity tests found no evidence of mutagenicity. The eye irritation test was negative.

No dermal irritation persisting for longer than 1 hour was observed in the skin irritation test. However, skin irritation was observed in a number of other tests. In guinea pigs, it was found that a dilute solution of the analogue chemical (5% in peanut oil) produced slight-moderate irritation. In the acute dermal toxicity test on rabbits, large amounts of analogue chemical in contact with the skin under occlusive dressing for 24 hours produced high levels of irritation. In the human sensitisation test, the analogue chemical was found to be slightly irritating. However, in the human irritation test the analogue chemical was found to be non-irritating. These test results indicate that the notified chemical is slightly irritating, however classification of the notified chemical as a hazardous substance is not indicated.

The guinea pig sensitisation study indicated that the analogue chemical is a sensitiser. However, following rechallenge at 1% the results were equivocal. Also a human repeat insult patch test resulted in no signs of sensitisation. Thus, classification is not indicated.

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 based on animal studies using a close analogue. Studies in human volunteers indicated that the notified chemical is unlikely to be a skin irritant or sensitiser. 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 implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during reformulation and end use:
  - Implementation of general health surveillance and monitoring programs as required including any potential for skin sensitisation.

- 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(1) of the Act; if
- Additional skin sensitisation information/studies on and adverse effects of the notified chemical have become available.

or

(2) 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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