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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Synacto 976

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Infineum Australia Pty Ltd (ABN 24 084 881 863) of Level 2, 6 Riverside Quay, Southbank VIC 3006.

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Spectral Data, Purity, Hazardous and Non-hazardous Impurities, Additives/Adjuvants, and Import Volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Use of analogue data throughout Physicochemical Properties, Toxicological Investigations and Environment sections.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (May 2002), US TSCA (June 2003), Korea (under assessment).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Synacto 976

3. COMPOSITION

DEGREE OF PURITY
High

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported as concentrate (<30% in mineral oil)

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	100-300	100-300	100-300	100-300	100-300

USE
As an antioxidant/anticorrosion additive component in the formulation of emulsifiable cutting oil concentrates for use in mines and other metalworking industries.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Castrol Australia Pty Ltd, Brooklyn VIC.

TRANSPORTATION AND PACKAGING
Synacto 976 will be shipped and road transported in 205 L steel drums directly from dockside to a customer blending facility. The finished lubricant concentrate (containing <30% notified chemical) will be filled in consumer size containers of 2-200 L, usually sealed with screwcaps, and then road transported to end users such as mines and other metalworking industries.

5.2. Operation Description

The notified chemical will be brought into Australia as a mineral oil-based product with approximately 10-15 shipments per year. At a customer blending plant, Synacto 976 will be blended with mineral oil and other ingredients to form a concentrated cutting oil emulsion, typically in batches of 250-5,000 L. The blending and delivery of the lubricant components into a blending tank will occur in a fully enclosed, automated and controlled environment. Workers will only be involved in connecting and disconnecting pipelines and transfer hoses, and operation of valves and pumps via the automated equipment. Packaging of the finished lubricant into end use containers will also be automated using filling lines. On completion of the blending process, it is indicated that residues of the chemical will be flushed through containers, pipelines and transfer hoses with mineral oil, which will then be collected for appropriate disposal.

The concentrated lubricant will be sold and transported to a number of the metalworking industries where they may be diluted with water for use in various metalworking tasks at concentrations of ≤2% notified chemical. It is expected that the lubricant will be contained in the sumps of machines such as lathes until it is worn and needs to be replaced and disposed of, either by recycling, burning, refining or incineration.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and warehouse workers	3-4	--	--
Lubricant processors	1-4	10 min	10-15days/year
Quality assurance workers	1-2	10 min	10-15 days/year
Workers of the metalworking industry (end users)	large	short	

Exposure Details

During transport and storage, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached. Should a spill occur, it is expected to be contained and soaked up with earth or sand before disposal in accord with the MSDS and government regulations.

Inhalation, dermal and ocular exposure due to aerosols, drips and spillages can occur during blending and packaging processes, equipment cleaning and maintenance. For example, lubricant processors when pumping and metering the imported oil into mixing tanks or when connecting/disconnecting transfer lines may be potentially exposed to the notified chemical at concentrations of >50%. While exposure of workers during operating valves and pumps for packaging via automated filling lines could be up 30% notified chemical, those of cleaning, sampling and testing workers are anticipated to be less frequent and in smaller quantities.

The notifier indicates that adequate ventilation will be in place to prevent workers from breathing mist and volatiles during mixing. Operators of the blending plants will wear splash proof goggles, chemically resistant gloves, rubber overshoes, aprons, or other protective clothing, and appropriate

respirators when required. In addition, the entire formulation and packaging process for lubricants containing Synacto 976 is generally automated, enclosed, and expected to be performed by well-trained staff. Copies of the MSDS will be readily accessible in all work areas.

A large number of workers in the mines and metalworking industries will be end users of the cutting oil product. During its end use, the notified chemical will be diluted with water to a required concentration of ≤2%, exposure of these workers therefore is expected to be confined to dermal contamination with drips and spills when replacing the used lubricant. There is also potential for exposure while handling equipment components that have been in contact with the lubricant. Exposure would be minimised by personal protective equipment, industrial hygiene, and good work practices.

5.4. Release

RELEASE OF CHEMICAL AT SITE

At the reformulation site from the transfer of the notified chemical to blending and packaging operations will occur in closed pipes and vessels. The notifier indicates that accidental spillage of the notified chemical occurs during these processes will be contained and soaked up with earth or sand before being transported off-site to an approved industrial facility for appropriate disposal. It is estimated that 1% (3 tonnes based on the maximum import volume of 300 tonnes) of the notified chemical will be left in the import drum and will be disposed by incineration, including drum washings from reconditioning of the containers.

RELEASE OF CHEMICAL FROM USE

The notified chemical is an anticorrosion component of metalworking fluids which will be diluted with water during its end use at the metalworking industries. The notifier indicates that the notified chemical will be contained in the sumps of machines such as lathes until the lubricant needs to be removed and disposed of. It is indicated by the notifier that virtually all of the used lubricant containing the notified chemical will be disposed of either by recycling, burning or refining.

However, limited information is available on Australian metal working industry practices, particularly those for small and medium enterprises, relating to disposal of waste fluids (NICNAS 2004). The problem for environmental exposure identified in this report is the potential for inappropriate disposal of the notified chemical by small metal working companies. According to the EU Technical Guidance Document (European Commission 2003) a worst case release to water could amount to 31.6% of the chemical used as water based fluids in the industries. As there would be no significant differences in industry practices between Europe and Australia, this will be used in a worst case PEC calculation for a risk assessment for Australia.

5.5. Disposal

The notified chemical will be disposed of as a component of the used lubricant by recycling, burning or refining. The notified chemical will also be disposed of by incineration as drum washings during the reconditioning of the containers. However, as noted above a portion of metal working fluids is likely to be disposed of to water.

5.6. Public exposure

The notified chemical is intended for use in industry only. While the metal working fluid will be a commercial product, it is expected that use outside industry will be rare or under conditions similar to those for industrial users. Public exposure to the notified chemical therefore will normally only occur in the event of a transport accident or spillage. Such accidents are unlikely.

6. PHYSICAL AND CHEMICAL PROPERTIES

No physicochemical data for the notified chemical were submitted. The following information presented was in relation to the physicochemical properties of an analogue differing in counter ion (analogue A – details are claimed exempt from publication) unless otherwise specified. The information refers to the technical grade including mineral oil. Test results reflect the properties of the mineral oil.

Appearance at 20ºC and 101.3 kPa	Dark brown viscous liquid with a faint petroleum odour

Pour Point -12.7°C

METHOD ASTM D97-93.
Remarks For flow characteristics determination, a test sample was cooled at a specified rate after preliminary heating, and examined at intervals of 3°C. Only the results and a summary of the method were included in the report. This determination may not be conducted in accord with the OECD Good Laboratory Practices.
TEST FACILITY Exxon (1995a)

Boiling Range 114-522°C

METHOD ASTM D2887-93.
Remarks The boiling range was determined by gas chromatographic analysis using a known boiling range distribution of petroleum fractions over the boiling range expected for the test sample. Only the results and a summary of the method were included in the report. This determination may not be conducted in accord with the OECD Good Laboratory Practices.
TEST FACILITY Exxon (1995a)

Density 904.5 kg/m^3 at 15.56°C

METHOD ASTM D4052-91.
Remarks The density was determined by comparing the change in oscillating frequency caused by the change in the mass of the sample tube with calibration data. Only the results and a summary of the method were included in the report. This determination may not be conducted in accord with the OECD Good Laboratory Practices.
TEST FACILITY Exxon (1995a)

Vapour Pressures 1.61×10^{-5} kPa at 24°C
4.48×10^{-5} kPa at 35°C
7.94×10^{-5} kPa at 50°C

METHOD OECD TG 104 Vapour Pressure.
Remarks Vapour pressure was evaluated for approx. 24 h, during which three different flow rates of N_2 (carrier gas) were passed through the glass columns containing the test sample at 24, 35, and 50°C respectively, with one sample for each flow rate. Since the test substance was not a pure compound, the vapour pressure value can only be considered as an estimated value.

The analogue chemical is considered moderately volatile (Mensink *et al* 1995). This appears to be a surprising result, being higher than hexachlorobenzene, which is well known to be relatively volatile. Consideration of the structure suggests it would have very low volatility, and it is likely that the observed volatility is due to residual mineral oil.
TEST FACILITY Exxon (1995a)

Water Solubility 0.006 g/L at 20°C

METHOD OECD TG 105 Water Solubility.
Remarks Water solubility was determined by the shake flask method and TOC analysis. The average of the carbon percent and TOC analysis values of two different flasks (agitated for 1 and 7 days at 30°C respectively, then equilibrated for 24 h at 20°C), which were within 15%, were used to calculate the final water solubility for the test substance.

The analogue chemical is considered to be slightly soluble (Mensink *et al* 1995). However, the notified salt is likely to be more soluble than analogue salts made of other counter ions, though this may be offset by its larger alkyl chain.
TEST FACILITY Exxon (1995a)

Hydrolysis as a Function of pH Not determined

Remarks Test was not conducted as the notified chemical does not contain any hydrolysable functional groups and is poorly soluble in water.

Fat Solubility >1000 g/L in standard fat at 37°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks Fat solubility was determined in duplicate by the shake flask method, gas and normal phase HPLC analysis, using a 105% w/w mixture of the test substance and standard fat. The test compared eight samples treated between 3 and 24 hours over a temperature range of 30-50°C. The notified chemical may be less fat soluble due to its expected greater water solubility than this analogue.
TEST FACILITY Exxon (1995b)

Partition Coefficient (n-octanol/water) log Pow >6 at 22ºC

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks By reverse phase HPLC method, the test substance was shown to consist of several discrete chromatographic components with the majority conferring log Pow values of >6. One component had an estimated Log Pow of 1.7. Reference substances covered log Pow range 1.7-6.2. The test substance has surfactant properties and therefore a true partition coefficient is not defined. However, the apparent coefficient is consistent with the observed water and fat solubilities.
TEST FACILITY Exxon (1995c)

Adsorption/Desorption log K_{oc} = 1.4-1.6
– screening test

METHOD OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.

Soil Type	*Organic Carbon Content (%)*	*PH*	*Koc (mL/g)*
Colorado Soil	2.44	7.05	25
Freehold Soil	0.84	5.05	Not calculated
Snyder Research Farm Soil	2.01	5.53	37

Remarks Sorption was determined in duplicate at a test concentration of ~2 mg/L based on HPLC analysis of water saturated fractions (WSF), which were prepared in three different soils equilibrated 0.01M $CaCl_2$. After 16 h of equilibration no sorption occurred in Freehold soil, approx. 11% sorbed in Colorado soil, and 24% in Snyder Research Farm soil. Since the amount of adsorbed material was <25% stipulated by the guideline for desorption determination, no further desorption testing was conducted. It was concluded that sorption of the water soluble components of the test substance did not occur to any appreciable extent in these soils.

However, noting that with the majority of components having high log Pow values of >6, the analogue chemical (the whole salt) should have a greater sorption to soil.
TEST FACILITY Exxon (1995d)

Dissociation Constant pKa = 6.70 ± 0.10

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks Dissociation constant was determined by the titration method (using a standard base solution) and TOC analysis. The notified chemical is a salt of a strong acid and thus expected to remain dissociated throughout the environmental pH range of 4-9.
TEST FACILITY Exxon (1995e)

Particle Size Not applicable

Remarks The notified chemical is presented as a mineral oil-based product.

Flash Point >130ºC

METHOD ASTM D92.
Remarks Test report not provided.

Flammability Limits Upper: 5.0%
Lower: 1.0%

Remarks Test report not provided.

Autoignition Temperature 340ºC (mineral oil)

Remarks Test report not provided.

Explosive Properties Not considered explosive

Remarks The notified chemical is not expected to be explosive based on its molecular structure.

Reactivity Stable under normal environmental conditions

Remarks The notified chemical is not expected to degrade, decompose or undergo hazardous polymerisation. However, it may not be compatible with strong oxidising agents.

7. TOXICOLOGICAL INVESTIGATIONS

No toxicity data for the notified chemical were submitted. The following toxicological information presented was in relation to an analogue differing in counter ion (analogues A or B) unless otherwise specified. Details of the analogues are claimed exempt from publication.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity (analogue A)
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity (analogue A)
Rat, acute inhalation	no data available
Rabbit, skin irritation	slightly irritating (analogue B)
Rabbit, eye irritation	slightly irritating (analogue B)
Guinea pig, skin sensitisation – non-adjuvant test	evidence of sensitisation (analogue A)
Human, skin sensitisation – repeat insult patch test	no evidence of sensitisation (analogue A)
Rat, repeat dose dermal toxicity – 28 days	NOEAL = 1000 mg/kg bw/day (analogue A)
Genotoxicity – bacterial reverse mutation	non mutagenic (analogue A)
Genotoxicity – in vitro chromosomal aberration test	non geno toxic (analogue A)
Genotoxicity – in vivo micronucleus test	non geno toxic (analogue A)
Pharmacokinetic/Toxicokinetic studies	no data available
Developmental and reproductive effects	no data available
Carcinogenicity	no data available

7.1. Acute toxicity – oral

TEST SUBSTANCE Analogue A

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

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity	No clinical signs of toxicity. All animals gained weight over the 14 days test period.
Effects in Organs	No gross postmortem findings were considered relating to the test material.
Remarks – Results	None.

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

TEST FACILITY Exxon (1995f)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Analogue A

METHOD OECD TG 402 Acute Dermal Toxicity – 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*
I	5 per sex	2000	0/10

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Erythema (well-defined to moderate/severe) was observed in all animals on day 1, and remained well defined in one animal on day 3. Six animals still showed slight erythema on day 3, four on day 7 and one on day 10. Oedema (very slight to slight) was observed in 8/10 animals on day 1. All animals were free of oedema and erythema from the day 3 and day 14 observation, respectively. Other dermal observations in all animals include atonia, cracking and/or desquamation.
Signs of Toxicity - Systemic	All animals gained weight over the 14 days test period. One female was observed with stool abnormalities on days 0-4. No other evidence of systemic toxicity was observed.
Effects in Organs	At the postmortem examination, all animals were noted with desquamation on the dose site which were consistent with the inlife observations.
Remarks – Results	Dermal irritation was the most significant finding and was observed in all animals throughout the study.

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

TEST FACILITY Exxon (1995g)

7.3. Acute toxicity – inhalation

Remarks	Test was not performed. Inhalation exposure would be unlikely due to the

expected low vapour pressure of the notified chemical.

7.4. Irritation – skin

TEST SUBSTANCE: Analogue B

METHOD: Primary Dermal Irritation Study, equivalent to OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	4 males, 2 females
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks – Method	Number of males/females and age of the male animals were incorrectly selected, however these were considered unlikely to affect the study results or integrity.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.33	1	48 h	0
Oedema	0.00	0	0	0

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

Remarks – Results: Slight erythema was noted in all six animals at 45 min, in four at 24 hours and two at 48 hours interval. Oedema was not noted at any observation intervals throughout the study. Primary irritation index = 0.5. Yellow staining of the dose site was noted in all animals at 45 min and two animals at 24 hours. The test material produced a primary irritation index of 3.2.

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

TEST FACILITY: Exxon (1992a)

7.5. Irritation – eye

TEST SUBSTANCE: Analogue B

METHOD: Ocular Irritation Study, equivalent to OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	5 males, 1 females
Observation Period	72 hours
Remarks – Method	Number of males/females were incorrectly selected, however these were considered unlikely to affect the study results or integrity.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0	2	1 h	0
Conjunctiva: chemosis	0	1	1 h	0
Conjunctiva: discharge	0	1	1 h	0

Corneal opacity	0	0	0 h	0
Iridial inflammation	0	0	0 h	0

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

Remarks - Results: Redness was noted in all six animals, chemosis in one animal, and discharge in two animals at the 1 h observation. No iridial and corneal responses were noted in any animals during the study.

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

TEST FACILITY: Exxon (1992b)

7.6. Skin sensitisation

TEST SUBSTANCE: Analogue A

METHOD: OECD TG 406 Skin Sensitisation – Buehler test.
Species/Strain: Guinea pig/Hartley Albino
PRELIMINARY STUDY: Maximum Non-irritating Concentration:
topical: 100% test material
MAIN STUDY
Number of Animals: Test Group: 20 Control Group: 20
INDUCTION PHASE: Induction Concentration:
topical: 100% test material
Signs of Irritation: No dermal irritation was noted.
CHALLENGE PHASE
1st challenge: topical: 100% test material
2nd challenge: topical: 100% test material
Remarks – Method: Test modifications include: only females used, bandaging as a means of restraint, three induction applications, Draize scale for evaluating dermal reactions, and use of additional 10 animals for the control group.

RESULTS

Animal	*Challenge Concentration*	*Skin Reactions*	*Number of Animals Showing Skin Reactions after:*			
			1st challenge		*2nd challenge*	
			24 h	*48 h*	*24 h*	*48 h*
Test Group	100%	*Erythema*	19/20	15/20	20/20	15/20
		Oedema	2/20	0/20	0/20	0/20
Control Group	100%	*Erythema*	0/10	0/10		
		Oedema	0/10	0/10		
	100%	*Erythema*			1/10	0/10
		Oedema			0/10	0/10

Remarks - Results: At the 24 h post-challenge, 19/20 (95%) treated group animals were observed with erythema: 2 moderate/severe, 11 well-defined, and 6 slight. Two treated animals also had slight oedema. At the 48 h post-challenge, 15/20 (75%) treated group animals were observed with erythema: 5 well-defined and 10 slight, but no oedema. Dermal irritation was not noted in the control group at both 24 and 48 h observations of this challenge.

At the 24 h post-rechallenge, all of the treated animals and one control animal had erythema. The severity of the responses in the treated animals (4 moderate/severe, 11 well-defined, and 5 slight) was greater that the control group (1 slight). Oedema was not noted in any groups. At the 48 h post rechallenge, 15/20 treated animals were observed with erythema: 1 well-defined and 14 slight, and no oedema. No control animals showed dermal irritation at 48 h observations.

	A separate positive control study with 2-mercaptobenzothiazole confirmed the sensitivity of the test system.
CONCLUSION	There was evidence of reactions indicative of skin sensitisation to the analogue chemical under the conditions of the test.
TEST FACILITY	Exxon (1995h)

7.7. Skin sensitisation – human volunteers

TEST SUBSTANCE	Analogue A
METHOD	Repeat Insult Patch Test (in-house protocol)
Study Design	Induction Procedure: Nine repeat, 24 h semi-occlusive applications (three per week) of 0.1 mL undiluted (100%) test substance to the intact upper arms. Rest Period: 10-15 days Challenge Procedure: Single 24 h semi-occlusive applications of 10% test substance to the original and alternate naïve sites on the upper arm or paraspinal region of the back. Rechallenge was performed at 5% test substance on a naïve site to confirm reactions indicative of contact sensitisation. Skin reactions were evaluated post application at 48 h and 96 h during induction and challenges.
Study Group	Up to 123 volunteers, aged 21 or older (96 completed cases)
Vehicle	Mineral oil
Remarks - Method	Vehicle control was not conducted.
RESULTS	
Remarks - Results	The test results were not sufficiently documented so that an exact percentage of adverse effect responses could not be obtained for the test substance. However, 37 subjects exhibited mild to moderate erythema accompanied by oedema, vesicles, papules and scabbing, with the reaction spreading beyond the test area in 25 subjects, beginning with the third induction application. One subject exhibited mild erythema and four subjects exhibited mild erythema with papules at the 96 h challenge evaluation. In the confirmatory rechallenge, one subject exhibited mild erythema with a mild papular response at the 48 h post application, and this was resolved by the 96 h evaluation. These responses were considered consistent with clinical irritation.
CONCLUSION	A human repeat insult patch test was conducted using 100% concentration of the analogue A under semi-occlusive dressing. There was no evidence of clinical sensitisation observed in any of the subjects who completed the study under this condition of the test.
TEST FACILITY	Hill Top Research (1993)

7.8. Repeat dose toxicity

TEST SUBSTANCE	Analogue A
METHOD	Repeat Dose Dermal Toxicity Study, equivalent to OECD TG 410 Repeat Dose Dermal Toxicity 21/28-Day Study.
Species/Strain	Rat/Crl:CDBR
Route of Administration	Dermal – occluded
Exposure Information	Total exposure days: 28 days;

	Dose regimen: 7 days per week; Duration of exposure: 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 per sex	0	0/10
II (low dose)	5 per sex	100	0/10
III (mid dose)	5 per sex	300	0/10
IV (high dose)	5 per sex	1000	0/10
V (high dose recovery)	5 per sex	1000	0/10

Remarks – Results

There was a low incidence of slight erythema (but no oedema) observed sporadically in the treated animals. Microscopic examination of the treated skin of most rats revealed variable amounts of thickening of the epidermis due to acanthosis and hyperkeratosis, sebaceous gland hyperplasia, and focal dermal inflammation. These changes occurred in all groups including controls. However, the severity tended to be increased in the male treated group rats and the females of the 300 and 1000 mg/kg groups. The microscopic changes in the skin of the rats necropsied after the 14-day recovery period were decreased over those examined immediately after treatment indicating a mild irritating and reversibility of the effects.

The focal liver necrosis observed in some female animals (0-20% incidence in all groups, including controls) following the main study sacrifice on Day 28 was not dose related and most likely due to compression from the wrapping procedure. Similar findings have also been noted in control animals on previously conducted rat dermal studies in this laboratory. Liver necrosis was not observed in any of the satellite animals following recovery, indicating this change was reversible. Thus, effects in the liver were not considered related to treatment with the test material.

In conclusion, topical application of the test material under the conditions of this study elicited no signs of overt systemic toxicity. There were no adverse clinical signs, postmortem findings, or histopathological findings; significant changes in body weight, food consumption, or absolute/relative organ weights; or clinically significant changes in haematology, clotting potential, or serum chemistry which were judged to be treatment-related.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on systemic effects.

TEST FACILITY Exxon (1995i)

7.9. Genotoxicity – bacteria

TEST SUBSTANCE Analogue A

METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure.
Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100.
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 250-5000 µg/plate. b) Without metabolic activation: 250-5000 µg/plate.
Vehicle	Tetrahydrofuran (THF)
Remarks - Method	No significant protocol deviations

RESULTS

Remarks - Results In either the initial or repeat assays, the test substance did not induce a

significant increase in revertant colonies (≥3 times the THF controls) in any tester strain at any dose levels tested with or without metabolic activation. Toxicity (a notable reduction in the background lawn and/or a greater than 50% reduction in the mean number of revertant colonies when compared to the vehicle control) was not observed at any dose tested with or without metabolic activation. The vehicle and positive controls responded appropriately.

CONCLUSION The analogue chemical was not mutagenic to bacteria under the conditions of the test (5000 µg/plate).

TEST FACILITY Exxon (1995j)

7.10. Genotoxicity – in vitro

TEST SUBSTANCE Analogue A

METHOD In vitro Chromosomal Aberration Test, equivalent to OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.

Cell Type/Cell Line	Chinese Hamster Ovary (CHO-WBL) cells
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Vehicle	Tetrahydrofuran (THF)
Remarks - Method	No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	10*, 20*, 40*, 80, 120, 160	16 h	16 h
Test 2	10*, 20*, 40*, 80, 120, 160	16 h	16 h & 40 h
Present			
Test 1	10*, 20*, 40*, 80, 120, 160	3 h	16 h
Test 2	10*, 20*, 40*, 80, 120, 160	3 h	16 h & 40 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>40	>40	≥40	Negative
Test 2	>40	>40	≥40	Negative
Present				
Test 1	>40	>40	≥40	Negative
Test 2	>40	>40	≥40	Negative

Remarks – Results There were no statistically significant differences between any dose group and vehicle control for either the initial or repeat assay (mean percentage of aberrant cells for all groups was between 0-5%). In the initial 16 h assay, there were statistically significant dose related trends (increasing with dose) in the percentage of aberrant cells for both the activated and non-activated series. However, these trends were not reproducible and therefore not considered to be biologically significant. The vehicle and positive controls responded appropriately.

CONCLUSION The analogue chemical was not clastogenic to CHO cells treated in vitro under the conditions of the test (40 µg/mL).

TEST FACILITY Exxon (1995k)

7.11. Genotoxicity – in vivo

TEST SUBSTANCE	Analogue A
METHOD	In vivo Mammalian Bone Marrow Micronucleus Test, equivalent to OECD TG 474 Mammalian Erythrocyte Micronucleus 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 per sex	0	24
II (low dose)	5 per sex	500	24
III (mid dose)	5 per sex	1000	24
IV (high dose)	5 per sex	2000	24
V (positive control, CP)	5 per sex	20	24

CP=cyclophosphamide.

RESULTS	
Doses Producing Toxicity	The high dose (2000 mg/kg bw) reached the limit dose for a non-toxic test substance. There were no deaths or test substance-related clinical findings during the study.
Genotoxic Effects	No dose-related increases or statistical differences in micronuclei formation were observed at any dose levels tested.
Remarks – Results	There were no statistically significant decreases in the percentage of polychromatic erythrocytes (PCE) compared with the vehicle control, indicating no cytotoxicity. The vehicle and positive controls responded appropriately.
CONCLUSION	The analogue chemical was not clastogenic under the conditions of this in vivo bone marrow micronucleus test.
TEST FACILITY	Exxon (1995l)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data for the notified chemical were submitted. The following biodegradability information presented was in relation to an analogue differing in counter ion (analogue A) unless otherwise specified. Details of this analogue are claimed exempt from publication.

8.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue A
METHOD	OECD TG 301 B Ready Biodegradability: CO2 Evolution (Modified Sturm Test).
Inoculum	Fresh activated sludge from domestic wastewater treatment plant (WTP)
Exposure Period	29 days
Auxiliary Solvent	None
Analytical Monitoring	Back titration of unreacted $Ba(OH)_2$ in CO_2 traps with 0.1 N HCl and TOC analysis (for positive control)
Remarks – Method	Test was conducted (without toxicity control) in triplicate using a concentration of approx. 20 mg carbon/L. % biodegradation =

$CO_2/ThCO_2$, where $ThCO_2$ = theoretical CO_2 evolution calculated from elemental analysis.

RESULTS

Test Substance		*Reference Substance – Sodium Benzoate*	
Day	*Mean % Degradation*	*Day*	*Mean % Degradation*
1	0.1	1	23.2
10	1.2	10	72.0
13	4.5	13	78.6
20	8.4	20	85.0
29	9.1	29	86.1

Remarks – Results: Since the test substance degraded 9.1% after 29 days it is considered not readily biodegradable. The degradation of the positive control sodium benzoate were >60% after 14 days, confirming the validity of the test.

CONCLUSION: The analogue chemical is not readily biodegradable.

TEST FACILITY: Exxon (1995m)

8.1.2. Bioaccumulation

No bioaccumulation study was provided for the notified chemical. However, based on the log Pow of >6 for the analogue A, the notified chemical would have the potential to bioaccumulate.

8.2. Ecotoxicological investigations

No ecotoxicological data for the notified chemical were submitted. The following information presented was in relation to the ecotoxicological data of an analogue differing in counter ion (analogue A) unless otherwise specified. Details of this analogue are claimed exempt from publication.

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Analogue A

METHOD

Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	196 mg $CaCO_3$/L
Analytical Monitoring	TOC (Total Organic Carbon)

Remarks – Method: The test was performed to determine the acute toxicity of the water accommodated fraction (WAF) of the test substance to rainbow trout. The WAF was prepared by adding an appropriate amount of the test substance in a Teflon disk to 11 L of dilution water at a loading rate of 1000, 300, 70, 10 and 1 mg/L and stirred for approximately 72 h (which was considered sufficient to generate the WAF as demonstrated by the TOC results of a pre-test equilibrium study). Test substance was observed stuck to the teflon disks and some brown test substance was observed at the surface of the 1000 mg/L treatment level. After settling for approx 1 h, the WAF was removed through the outlet at the bottom of the stirring vessel. Two replicates (10 fishes per replicate) were used for each treatment and control. Samples were removed on day 0, and on day 2 and 4 (composite of replicates) for TOC analysis.

Observations for mortality, abnormal behaviour and appearance of the fish were performed on all replicate chambers at 21, 48, 72, and 96 h. Water quality measurements (pH, dissolved oxygen and temperature) were within acceptable limits throughout the test. The TOC values for the

control ranged from 0.8-4.0 mg/L, and for the WAFs from 0.8-5.4 mg/L. It is not stated whether solutions were clear or had undissolved material.

RESULTS

LL50 (50% Lethal Loading)	>1000 mg/L (WAF) at 96 h
Remarks – Results	No mortality occurred at any loading rates tested during the 96 h exposure period.

CONCLUSION	The analogue chemical is not toxic to rainbow trout up to the limit of its water solubility.
TEST FACILITY	Exxon (1995n)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Analogue A
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test – Static Test.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	196 mg $CaCO_3$/L
Analytical Monitoring	TOC
Remarks - Method	The test was performed to determine the acute toxicity of the Water Accommodated Fraction (WAF) of the test substance to Daphnia magna. This was prepared as for the fish test above. A pre-test equilibrium study indicated that approximately 72 h was sufficient to generate the WAF. The loading rates for this test were also 1000, 300, 70, 10 and 1 mg/L. Four replicates (5 fish per replicate) were used for each treatment and the control. Samples were removed on day 0 and at termination for TOC analysis. Observations for immobilisation of the daphnids were performed on all replicate chambers at 24 and 48 h. Water quality measurements (pH, dissolved oxygen and temperature) were within acceptable limits throughout the test. The TOC values for the control were 0.95-0.97 mg/L, and for the WAFs ranging from 0.6-3.4 mg/L. It is not stated whether solutions were clear or had undissolved material.

RESULTS

Loading Rates mg/L Nominal	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
Control	20	0	0
1	20	0	0
10	20	0	0
70	20	0	1
300	20	0	1
1000	20	4	5

EL50 (50% Effect Loading)	>1000 mg/L at 48 hours (noting that the TOC was only 2.1-2.3 mg/L at the 1000 mg/L treatment level).
Remarks - Results	The maximum loading of the WAF causing no immobilisation was 10 mg/L.
CONCLUSION	The test substance shows some toxicity to *Daphnia magna* at the concentrations present in the WAFs. However, it is unclear whether this was a physical effect caused by the undissolved material.
TEST FACILITY	Exxon (1995o)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

At the reformulation site if accidental spillage of the notified chemical occurs during the blending process it will be contained and soaked up with earth or sand before being transported off-site to an approved industrial facility for appropriate disposal. Residues in the import drum will be disposed of by incineration together with drum washings from the reconditioning of the containers. Therefore, there is little environmental exposure during the reformulation process.

The reformulated product will be sold to metalworking industries for dilution with water and to be used as metalworking lubricants. The notifier indicates that the notified chemical will be contained in the sumps of machines such as lathes until as the lubricant needs to be removed and disposed of. The notifier indicates that virtually all of the notified chemical in the used lubricant will be disposed of appropriately either by recycling, burning or refining.

However, limited information is available on Australian metal working industry practices relating to disposal of waste fluids. Based on the EU Technical Guidance Document (European Commission 2003) a worst-case release to water could amount to 31.6% of the water-based chemical used in the metal working industries. This value will be used in a worst case PEC calculation for Australia.

In calculating the PEC, the following were assumed: (1) usage of the maximum import volume of 300 tonnes is evenly distributed over a 365 day period; (2) usage is nationwide, with a population of 19.5 million contributing 200 L of water per person per day to the sewer, (3) there is no adsorption or degradation in the sewer prior to release and (4) all will be released from small operators with a worst case release to sewer of 31.6% or 95 tonnes per year. The calculated worst-case scenario daily PEC in the sewer effluent thus is 66.4 µg/L as a continental release in Australia. Based on the respective dilution factors of 1 and 10 for rural areas and coastal discharges of effluents, the PECs of the notified chemical in rural areas and coastal water may approximate 66.4 and 6.64 µg/L, respectively.

9.1.2. Environment – effects assessment

On the basis of the ecotoxicological data provided for the analogue A, it is considered that the notified chemical would have a low impact on aquatic organisms. However, based on the TOC analysis in the ecotoxicity studies for fish and *Daphnia magna*, it is apparent that the toxic effect will be limited by the TOC dissolved at the nominal concentration of 1000 mg/L of the test substance, ie approximately 4 mg/L. While fish were not affected at this lower level, up to 25% daphnia were immobilised, though it is not clear whether this was a physical effect.

Rainbow trout (*Oncorhynchus mykiss*): 96 h LC50 >4 mg/L
Daphnia magna: 48 h EC50 >4 mg/L

A worst case Predicted No Effect Concentration (PNEC) is >4 µg/L, using a safety factor of 1000 as only two trophic levels are available for the analogue A and the lowest acute 48 hour EC50 for *Daphnia magna* of >4 mg/L. This is based on the assumption that the WAF is representative of the whole material and the observed immobilisation is not a physical effect.

9.1.3. Environment – risk characterisation

The worst-case PECs and Risk Quotients for the aquatic environment based on a maximum of 300 tonnes are summarised below:

	PEC	Q
Sewage effluent/coastal city:	6.64 µg/L	6.64/4 = 1.67
Sewage effluent/rural areas:	66.4 µg/L	66.4/4 = 16.7

The worst case risk quotients indicate an unacceptable risk (Q>1) for both fresh water and marine organisms.

On the basis of the structural and physico-chemical data provided, the volatility of the notified chemical is expected to be low and the soil adsorption can be assumed to be 80% based on the hydrophobicity of the long alkyl chain present in the notified chemical. The modified risk assessment is based on a 80% adsorption in sludge. Thus the PECs of the notified chemical in rural areas and coastal water may approximate 13.3 and 1.33 µg/L, respectively. This would correspond to the respective Q values of <3.3 and <0.33 µg/L. The risk quotients indicate an unacceptable risk (Q>1) for fresh water organisms and an acceptable risk (Q<1) for marine organisms.

The risk can be further mitigated for fresh water organisms based on a 300 tonnes maximum proposed usage. Given that only about 25% of effluent is released into fresh water in Australia, the Q is 3.3/4 <0.83, indicating an acceptable risk to the environment, even using the assumptions described in section 9.1.2.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

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

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

End users of the cutting oil lubricant may be exposed to notified chemical during oil replacement or handling equipment components that have come into contact with the oil. They will wear gloves, overalls, safety boots, and observe industrial hygiene and safe work practices.

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

9.2.2. Public health – exposure assessment

The notified chemical is intended only for use in industry and will not be available to the public. Once incorporated into a commercial product, the metalworking fluid containing the notified chemical is not expected to leak during normal use. Indirect exposure via accidental spill or environmental release will be negligible taking into account the physicochemical characteristics of the chemical such as high molecular weight, low vapour pressure and water solubility. The public exposure is therefore determined to be negligible.

9.2.3. Human health - effects assessment

Based on the available toxicity data of its analogues, the notified chemical is expected to have a low acute oral and dermal toxicity (LD50>2000 mg/kg bw). It would not be irritating to the skin and eyes of the rabbit on exposure, but may have sensitising potential considering the test results of a non-adjuvant study in guinea pigs of the analogue A. However in a human repeat dose patch testing with the same chemical in over 100 volunteers, there was no evidence of clinical sensitisation observed in any of the subjects who completed the study. On the basis of this human study which was conducted to a recognised protocol though not well documented, the notified chemical would not be classified as hazardous for skin sensitisation effects. The NOAEL for the analogue A was established as 1000 mg/kg bw/day, based only on the systemic effects observed in a 28-day repeat dose oral study in rats. The notified chemical is expected to

be negative in vitro and in vivo genotoxicity assays.

Based on the available data, the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified chemical is expected to be low, given the low hazard of the chemical, the automated process and engineering controls implemented at blending facilities, the industrial hygiene, good work practices and safety measures including use of appropriate personal protective equipment by workers. Moreover, the notified chemical will be used at formulation sites where operatives are familiar in using such products and good handling procedures and housekeeping are the norm.

Large numbers of workers in the mines and metalworking industries will be potentially exposed to the oil containing the notified chemical. However, they are adequately trained and wear suitable protective clothing and gloves when replacing the used oil. Workers are advised to avoid eye and skin contact with lubricant and oil products and observe general hygiene practices such as washing of hands thoroughly once completing their tasks. In addition, the concentration of the notified chemical in these end use oil products will not exceed 2%.

The notified chemical may be present in formulations containing hazardous ingredients. If these formulations are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

9.2.5. Public health – risk characterisation

Given the notified chemical will only be used in the mining and metalworking industries, the risk to public health is considered negligible.

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

10.1. Hazard classification

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

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

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

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, the chemical is considered to pose an acceptable 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 the proposed manner.

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

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical introduced as a mineral oil-based product:
  - Use of closed systems at the blending and packaging sites, including enclosed and automatic transfer lines/pumps for loading and emptying of transport drums and mixing vessels;
  - Adequate ventilation for the plant operators.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during reformulation and end use:
  - Adequate training for staff in handling lubricant and oil products;
  - 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 during reformulation and end use:
  - Chemical goggles/face shields for plant operators;
  - Industrial standard protective clothing and impermeable gloves for plant operators and metalworking workers;
  - Vapour masks or appropriate respirators if required.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of either by recycling, burning, refining or incineration.

Emergency procedures

- Spills/release of the notified chemical should be handled by containment with suitable

absorbents (eg sand or earth), collection and storage in a sealable and labelled container for recycle or disposal in accord with local 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(1) of the Act; if
- Import volume exceeds 300 tonnes per annum, it is required a better set of physiochemical data for the notified chemical, a better estimate of release to the sewer, particularly in the rural areas, and an acute toxicity test report for algae be submitted for review and assessment.
- 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.

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