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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

IRGACOR® DC11

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NICNAS

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IRGACOR® DC11

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals Pty Ltd (ABN 97 005 061 469)
235 Settlement Road
Thomastown VIC 3074

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 are:

- Chemical name
- Other names
- CAS. Number
- Molecular Formula
- Structural Formula
- Molecular weight
- Spectral Data
- Purity
- Non-hazardous impurities
- Use details
- Manufacture/Import volumes
- Identity of sites/Customers

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

- Vapour pressure
- Water solubility
- Hydrolysis as a function of pH
- Partition Co-efficient
- Absorption/Desorption
- Dissociation constant
- Flash point
- Flammability limits
- Autoignition temperature
- Explosive properties
- Reactivity

Acute toxicity

- Acute oral toxicity
- Acute dermal toxicity
- Acute inhalation toxicity
- Skin irritation
- Eye irritation
- Skin sensitisation

Repeat Dose Toxicity
Genetic Toxicity

- Induction of point mutations
- Induction of germ cell damage
- Chromosome damage

Ecotoxicity

- Fish, Acute Toxicity

Daphnia sp. Acute Immobilisation/Reproduction
Alga, Growth Inhibition Test
Biodegradation
Ready biodegradation
Bioaccumulation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
None.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
IRGACOR® DC 11

SPECTRAL DATA

METHOD	Infrared (IR) spectroscopy
Remarks	A reference spectrum was provided.
TEST FACILITY	Ciba Specialty Chemicals Inc.

METHODS OF DETECTION AND DETERMINATION

METHOD	IR spectroscopy.

3. COMPOSITION

DEGREE OF PURITY
> 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)
Unknown impurities related to the notified chemical.

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. The notified chemical will be imported in 20 kg lined paper bags in cardboard boxes at a neat concentration.

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

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

USE
Used as a corrosion inhibitor for metal working fluids (aqueous) and lubricants (non-aqueous systems).

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS
Lubricant blenders.

TRANSPORTATION AND PACKAGING
The notified chemical, IRGACOR® DC 11 at 100% neat concentration will be imported in 20 kg lined paper bags in cardboard boxes. It will be transported by road from wharf to the notifier's site (Ciba Specialty Chemicals Pty Limited) and stored. No repackaging operations will be carried out at the notifier's site. IRGACOR ® DC 11 will then be transported by road unopened to the blending sites as required.

After formulation of aqueous metal working fluid formulations and oil lubricants the final product containing the notified chemical at a low concentration <10% will be transported by road to metal working shops and automotive factories (both large and small) respectively. Aqueous metal concentrates will be transported in 10L metallised bags, 205 L steel drums, 20 L plastic drums and 500 L plastic IBC's. Oil based lubricants will be transported in 205 L steel drums, 20 L plastic drums and 500 L plastic IBC's.

5.2. Operation description

The notified chemical is not manufactured in Australia. The notified chemical will be formulated into aqueous metal working concentrates and oil based lubricants for use by metal workers and motor mechanics respectively.

Reformulation
The bags (20 kg) of powdered product containing the notified chemical (100%) will be transported by forklift, as required, from the blending plant's warehouse to the production area. At the formulation site the 20 kg bags containing IRGACOR® DC 11 are removed from boxes and bags containing the powder are manually transferred to weighing station where it is weighed before it is manually poured into tanks where it will be mixed with base oil and other additives to produce the metal working concentrates and engine oils. Laboratory technicians at the site will be involved in quality control checks on the metalworking concentrates. The samples are taken via a sampling port into sampling jars. After quality control tests the finished products will then be pumped into:

1. For metal working concentrates: 10L metallised bags, 205 L steel drums, 20 L plastic drums and 500 L plastic IBC's for sale to metalworking customers;
2. For oil lubricants: into 205 L steel drums, 20 L plastic drums and 500 L plastic IBC's for sale to auto-mechanics.

The finished products (both metal-working and oil lubricants) contain < 10% of the notified chemical.

End-use - Metal working operators
At the customer site, the reformulated metal-working concentrate containing less than 10% of the notified chemical will be diluted manually in metalworking baths of volume 200 L and 100000 L to a concentration of <1%. The baths will be topped as required. The contents of the baths will be changed every 12 months and the used fluids will be disposed of by waste disposal contractors. The initial dosing will be bulk from drums and maintenance of the concentrate level will be by automatic dosing pump from the drums.

End-users - motor mechanics
The customer will manually pour the product containing less than 10% of the notified chemical as needed. No dilution of the oil lubricants takes place.

5.3. Occupational Exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and storage	12	1 hour/day	10 days/year
Reformulation:			
Plant operators	20	8 hours/day	50 days/year
Laboratory staff	2-3	6-8 hours/day	20 days/year
Maintenance staff	5	8 hours/day	2 days/year
End-users			
Metal Working operators and motor mechanics	> 1000	2 hours/day	100 days/year

Exposure Details

Transport and storage

Transport and warehouse workers will be exposed to the notified chemical only in the event of a spill or if packaging is accidentally breached.

Reformulation

Dermal, ocular and inhalation exposure to the notified chemical is possible when manually loading the powder into the mixing vessel. The loading operation is carried out under a dust extractor and blending occurs in a closed mixing tank under local exhaust ventilation. Personal protective equipment includes coveralls, dust mask, gloves and eye protection when carrying out the above activities.

Intermittent dermal exposure to the preparations is possible when collecting samples for quality testing. Laboratory workers will wear laboratory coats, gloves and eye protection.

Workers may also be exposed to drips and spills when drumming off finished product and while connecting and disconnecting filling pipes and during cleaning. Workers will wear coveralls, gloves and eye protection when carrying out these activities.

Cleaning and maintenance of formulation equipment

Maintenance of formulation equipment will occur after the equipment has been flushed. Exposure to maintenance workers will be low, as the equipment will have previously been flushed. Maintenance personnel will wear coveralls.

End-use - Metal working operators

The main route of exposure to the notified chemical by metal working operators will be via dermal or ocular exposure. This can occur while connecting the dosing line pump to the drum or whilst handling objects in the metal working bath however this is expected to be negligible as the metal workers will wear coveralls and PVC or rubber gloves and eye protection.

End-users - motor mechanics

The main route of exposure to the notified chemical by motor mechanics will be via dermal or ocular exposure that may occur during the transfer the lubricant products from the storage containers into the vehicle being serviced and during cleaning of equipment. There is potential for exposure, primarily dermal when lubricants are added to and drained from systems.

A large number of motor mechanics (>1000) may be exposed to the products under a wide range of conditions. However, as these workers are professionals and have been trained in the proper handling of lubricants and oil products, the risk to worker health is minimal. Personal protective equipment such as overalls and safety boots when using products containing the notified chemical will further minimise exposure.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured or repackaged in Australia. Local operation will include transport and storage, formulation of metalworking fluids and engine oils for end use in metalworking industry and by motor mechanics.

IRGACOR® DC 11 will be transported to Australia by ship in 20 Kg lined paper bags in cardboard boxes and will be transported directly to the notifier's warehouse for housing before being distributed to metalworking and automotive industries.

Release to the environment may occur at the notifier's site in the unlikely event of an accident during transport or if the packaging is damaged.

RELEASE OF CHEMICAL FROM USE

Formulation

The notified chemical will be sold and transported in the original 20 Kg lined paper bags in cardboard boxes to the customer sites for reformulation into the finished metalworking fluids and engine oil products. The typical reformulation process involves adding the notified chemical, base oil and other additives into a blending tank, mixing before drumming off the finished product into 10L metallised bags, 205 L steel drums, 20 L plastic drums and 500 L plastic IBC's.

During formulation activities approximately 1% of the material is expected to be left as residue in the 20 kg lined paper bags. A further 1% may be lost as result of spills and equipment leaks. Drum residue would most likely be removed by flushing with suitable solvent and re-used in the formulation process. The drums will be disposed of to landfill. Material lost due to spills and leaks will be placed in labeled containers and collected by waste disposal contractors for incineration. Line flushing at various stages during the formulation of end-use-products is estimated to be <10%, which will be collected and reused or discarded as waste and sent to waste disposal contractors for incineration. Total losses during formulation are estimated as <1000 kg based on import volumes of <10 tonne per year.

The finished lubricants will be sold in 10 L metallised bags, 205 L steel drums, 20 L plastic drums and 500 L plastic IBC's to industrial and commercial customers.

End-use

The residues in the containers that are disposed of and not reused are expected to account to < 1000 kg based on annual import volumes of the notified chemical. The table below provides an estimate of the residue of the notified substance in the empty containers and the disposal method in place.

Finished Product Containers

Type and size of container	Residue in empty container %	Percentage chemical %	Residue of notified chemical in container (kg)	Residue of notified chemical per year (kg)	Disposal method
10 L metallised bags	3	<10	< 0.03	< 150	Landfill
20 L plastic drums	1	<10	< 0.02	< 100	Landfill
205 L steel drums	0.5	<10	< 0.1025	< 500	Landfill
500 L plastic IBC's	0.5	<10	< 0.25	<1000	Reused

Metal working fluids

During use, some metalworking fluids will be lost through splashes and spills, 'dragout' of the cutting fluid on the work piece, on waste metal cuttings and by misting and evaporation (fluid could evaporate, not the notified chemical). These are likely to be contained within bunds at large establishments and either collected by licensed disposal contractors for disposal or disposed to landfill. At smaller work places the lost material would likely be disposed of to landfill with everyday waste. Total losses are expected to be <7% per annum.

Old working fluids are totally removed on a periodic basis and sent to licensed disposal contractor for

disposal.

It is not agreed that there will be limited release during use. 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 is the potential for inappropriate disposal of the notified chemical by small metal working companies. According to the EU Technical Guidance Document (EC, 2003) a worst case release to water could amount to 31.6% of the chemical used as water based fluids in the industries and 18% from oil-based fluids. As there are believed to be no significant differences in industry practices between Europe and Australia, the former is used in this assessment report since the fluids are water based.

Engine oils
The finished lubricants for use in engine oils will be sold in various sized containers for industrial use only. Where motor mechanics perform oil changes or repairs, the used oil generated will be incinerated or sent for recycling.

No information was available on whether the notified chemical is altered during use in internal combustion engines and therefore it is assumed to be unaffected.

There may be some accidental losses when lubricant is added to new, or it is changed in, vehicle engines, which may be about every 5,000-10,000 kilometres for passenger car petrol engines. These are expected to be minor spills, which would be mostly left on the ground or cleaned up and landfilled, and amount to 1% of the product. In the closed system of an engine, there is no expected release of the chemical to the environment under normal conditions of use, except for unintended oil leaks, which would mostly drip to road and pavement surfaces.

Since the use of the lubricating oils will occur throughout Australia, any releases resulting from use or disposal of old oil will be very diffuse.

5.5. Disposal

The material and wastes sent to licensed disposal contractors for disposal will be incinerated, treated (biological treatment) prior to discharge of the treated effluent to sewer or disposed to landfill. There should be minimal amounts of the notified chemical entering the environment from these disposal methods.

Used oils
The greatest potential for environmental exposure is through disposal of oil product wastes containing the notified chemical. A survey by the Australian Institute of Petroleum (AIP, 1995) indicates that of the annual sales of automotive engine oils in Australia, some 60% are potentially recoverable (ie. not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases is disposed of responsibly either to oil recycling or incineration. Assuming this is the case, as the end use oil products containing the notified chemical will only be used in industrial settings, negligible release to the aquatic environment of the notified chemical should result from these professional activities.

During recycling of engine oils, the notified chemical is likely to be adsorbed onto ash within the used oil and be removed during filtration and end up in the sludge. The sludge will be incinerated. Thus, the ultimate fate of the notified chemical is destruction during use or incineration during oil recycling.

5.6. Public exposure

It is expected that during transport, storage, blending and industrial use, exposure of the general public to IRGACOR ® DC 11 will be minimal, except in the event of an accidental spill. The products containing the notified chemical will be for industrial use only and consequently no public exposure is anticipated except in the case of an accidental spill during transport.

6. PHYSICAL AND CHEMICAL PROPERTIES

As indicated below, the physicochemical properties are for a close analogue of the notified chemical except as indicated.

Appearance at 20ºC and 101.3 kPa Odourless, white to off-white crystalline powder
Remarks Notified chemical

Melting Point/Freezing Point ~ 128 ºC

METHOD Not reported
Remarks Analogue
Cited in OPPT (2003)

Boiling Point 250ºC

METHOD Not reported
Remarks Analogue
Cited in OPPT (2003)

Density 953 kg/m^3 at 140ºC

METHOD Not reported
Remarks Analogue
Cited in OPPT (2003)

Vapour Pressure 2.80 kPa at 222ºC

METHOD Not reported
Remarks Analogue
Cited in OPPT (2003)

Water Solubility 30 mg/L

METHOD Not reported
Remarks Analogue
Cited in OPPT (2003)

Hydrolysis as a Function of pH Not determined. No hydrolysable groups present.

Partition Coefficient (n-octanol/water) log Pow = 3.18

METHOD Not reported
Remarks Analogue
Cited in OPPT (2003)

Adsorption/Desorption Not determined

Remarks Based on the water solubility, the absorption of the notified chemical to organic matter in soil is expected to be low.

Dissociation Constant pKa = 4.48±0.20

METHOD Modelled – Advanced Chemistry Development (ACD)
Remarks Analogue
Cited in OPPT (2003)

Particle Size Median = 38.1 μm (fraction below 10 μm = 9.13%)

METHOD Not specified.

Range (μm)	*Mass (%)*
<10	9
<15	31
<25	53
<50	86
<100	99
<150	100

Remarks Notified Chemical
<10 μm, 9% inspirable; <100 μm 99% respirable. Mass median aerodynamic diameter: 38.1 μm.
TEST FACILITY Process & Technology PA422/H.Heiniger/15.06.2005)

Flash Point 220ºC

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks Analogue
Cited in OPPT (2003)

Flammability Limits Not expected to be flammable

Autoignition Temperature 390ºC

METHOD DIN 51794
Remarks Analogue
Cited in OPPT (2003)

Explosive Properties Not expected to be explosive.

Reactivity

Remarks Expected to be stable under normal environmental conditions. Keep away from strong acids, bases and oxidising agents.

7. TOXICOLOGICAL INVESTIGATIONS

No toxicological data were supplied for the notified chemical. The toxicological profile was estimated from data supplied on an analogue. The analogue contains a carbon-chain of similar length and identical functional groups as the notified chemical.

Endpoint and Result	*Test Substance*	*Assessment Conclusion*
Rat, acute oral LD50 >3000 mg/kg bw	Analogue	low toxicity
Rat, acute oral LD50 >17,000mg/kg bw	Analogue	low toxicity
Rat, acute dermal LD50 >6000 mg/kg bw	Analogue	low toxicity
Rat, acute inhalation LC50 >4.3 mg/L/4 hour	Analogue	low toxicity
Rabbit, skin irritation	Analogue	non-irritating
Rabbit, skin irritation	Analogue	non-irritating
Rabbit, eye irritation	Analogue	irritating
Rabbit, eye irritation	Analogue	irritating
Guinea pig, skin sensitisation.	Analogue	no evidence of sensitisation
Rat, repeat dose <gavage> toxicity – 10 days.	Analogue	Insufficient data to set a NOAEL
Rat, repeat dose <gavage> toxicity – 14 days combined with Reproductive/Developmental toxicity screening test.	Analogue	The NOAEL is 1000 mg/kg bw/day NOEL is 100 mg/kg/ bw/day for male rats and NOEL is 500 mg/kg bw for female rats.
Genotoxicity – bacterial reverse mutation	Analogue	non mutagenic
Genotoxicity – bacterial reverse mutation	Analogue	non mutagenic
Genotoxicity – in vivo mouse micronucleus assay	Analogue	non genotoxic
Developmental and reproductive effects	Analogue	The NOAEL is 1000 mg/kg bw/day

7.1.a Acute toxicity – oral

TEST SUBSTANCE Analogue

METHOD OECD TG 401 Acute Oral Toxicity.
- Species/Strain: Rat/Strain not specified
- Vehicle: Corn oil
- Remarks - Method: None

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 females	3000	0/5
2	5 males	3000	0/5

- LD50: >3000 mg/kg bw
- Signs of Toxicity: None
- Effects in Organs: None
- Remarks - Results: Observation period not specified in study report.

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

TEST FACILITY Cited in IUCLID (2000) and in OPPT (2003).

7.1.b Acute toxicity – oral

TEST SUBSTANCE	Analogue
METHOD	No specific test guideline was reported
Species/Strain	Rat/ChR-CD
Vehicle	Peanut oil
Remarks - Method	The test material was administered by intragastric intubation in single doses as a suspension in peanut oil.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 males	2250, 5000, 7500, 11000, 17000	0/5

LD50	>17,000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
Remarks - Results	Observation period was 14 days. Weight loss for 1 day after dosing was noted at 5000 mg/kg and above.
CONCLUSION	The analogue is of low toxicity via the oral route.
TEST FACILITY	Cited in IUCLID (2000) and in OPPT (2003).

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Analogue
METHOD	No specific test guideline was reported.
Species/Strain	Rabbits/albino
Vehicle	Saline
Type of dressing	Semi-occlusive
Remarks - Method	None

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	6 males	6000	0/6

LD50	>6000 mg/kg bw
Signs of Toxicity - Local	None
Signs of Toxicity - Systemic	None
Effects in Organs	None
Remarks - Results	Slight skin irritation, diarrhoea, and nasal discharge were observed. Two rabbits had weight loss on the day after dosing and there was sporadic weight loss 3-13 days after dosing.
CONCLUSION	The analogue is of low toxicity via the dermal route.
TEST FACILITY	Cited in IUCLID (2000) and in OPPT (2003).

7.3. Acute toxicity – inhalation

TEST SUBSTANCE	Analogue
METHOD	No specific test guideline was reported.
Species/Strain	Rats/Strain not specified.
Vehicle	None
Method of Exposure	Oro-nasal exposure.
Exposure Period	4 hours
Physical Form	solid aerosol (particulate).
Particle Size	3.6 μm in the 0.81 mg/L experiment 4.3 μm in the 4.3 mg/L experiment
Remarks - Method	None.

RESULTS

Group	*Number and Sex of Animals*	*Concentration <units>*		*Mortality*
		Nominal	*Actual*	
1	6 (sex not specified)	-	-	0/6

LC50	>4.3 mg/L/4 hours
Signs of Toxicity	Clinical signs observed in rats immediately after exposure were red ocular and nasal discharge, signs frequently seen in animals being restrained.
Effects in Organs	Necropsy examinations were not conducted.
Remarks - Results	Rats showed dose-related transient weight losses for one day after exposure, followed by resumption of a normal weight gain rate.
CONCLUSION	The analogue is of low toxicity via inhalation.
TEST FACILITY	Cited in OPPT (2003).

7.4.a Irritation – skin

TEST SUBSTANCE	Analogue (100% purity)
METHOD	No specific test guideline was reported.
Species/Strain	Rabbit/Albino
Number of Animals	6 males
Vehicle	None.
Observation Period	2 days
Type of Dressing	Not specified.
Remarks - Method	None
RESULTS	
Remarks - Results	No skin irritation was observed at any time during this study. No further details were reported.
CONCLUSION	The analogue is non-irritating to the skin.
TEST FACILITY	Cited in OPPT (2003).

7.4.b Irritation – skin

TEST SUBSTANCE	Analogue (purity unknown)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit
Remarks - Method	None
RESULTS	
Remarks - Results	Irritation index: 0/8 Redness: X=0 Edema: X=0 No skin irritation was observed at any time during this study. It is assumed that X=the mean score although this was not stated in the summary report provided.
CONCLUSION	The analogue is non-irritating to the skin.
TEST FACILITY	Cited in IUCLID (2000).

7.4.c Irritation – skin

TEST SUBSTANCE	Analogue (purity unknown)
METHOD	No specific test guideline was reported..
Species/Strain	Rabbit
Remarks - Method	None
RESULTS	
Remarks - Results	None reported
CONCLUSION	The analogue is non-irritating to the skin.
TEST FACILITY	Cited in IUCLID (2000).

7.5.a Irritation – eye

TEST SUBSTANCE	Analogue (purity unknown)
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/Not specified
Number of Animals	Not specified
Observation Period	Not specified
Remarks - Method	None
RESULTS	
Remarks - Results	Irritation index (according to Draize): 11.96/110 Cornea: X=0 Iris: X=0.44 Conjunctiva Redness: X=2.50 Chemosis X=1.06 It is assumed that X=the mean score although this was not stated in the summary report provided.
CONCLUSION	The analogue is irritating to the eye.
TEST FACILITY	Cited in IUCLID (2000) and OPPT (2003).

7.5.b Irritation – eye

TEST SUBSTANCE	Analogue (purity 100%)
METHOD	No specific test guideline was reported.
Species/Strain	Rabbit/albino
Number of Animals	2
Observation Period	3 days
Remarks - Method	none
RESULTS	
Remarks - Results	The notified chemical produced a small area of slight corneal opacity and mild conjunctival irritation with no significant iritic effect in a rabbit eye that was not washed after dosing. Corneal opacity was reversible and the eye was normal within 7 days.
CONCLUSION	The analogue is slightly irritating to the eye.
TEST FACILITY	Cited in IUCLID (2000) and in OPPT (2003).

7.6. Skin sensitisation

TEST SUBSTANCE	Analogue (purity unknown)
METHOD	OECD TG 406 Skin Sensitisation
Species/Strain	Female guinea pigs/strain not specified
Remarks - Method	Twenty female guinea pigs were administered the analogue intracutaneously at 0.5% or epidermally at 25 and 50%.
RESULTS	
Remarks - Results	0/20 animals showed a sensitisation 24 or 48 hours after the patch test.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the analogue under the conditions of the test.
TEST FACILITY	Cited in IUCLID (2000) and in OPPT (2003).

7.7.a Repeat dose toxicity

TEST SUBSTANCE	Analogue (99+%)
METHOD	No specific guideline was reported.
Species/Strain	Rat/ChR-CD
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 10 days Dose regimen: 5days per week
Vehicle	Peanut oil
Remarks - Method	Rats were administered the test substance (5000 mg/kg bw) by intragastric intubation as a suspension.

RESULTS

Mortality and Time to Death

No mortality occurred during the study.

Clinical Observations

No signs of cumulative toxicity were observed..

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

None reported.

Effects in Organs
No histopathological lesions were observed.

Remarks – Results
Signs of toxicity observed during the first week included weight loss after the first does and inactivity. During the second week, weight loss was recorded after the sixth dose. During the recovery period, weight gain slightly greater than the control was observed.

CONCLUSION
Insufficient data to establish a NOAEL.

TEST FACILITY Cited in IUCLID (2000) and in OPPT (2003).

7.7.b Combined Repeat dose toxicity and Reproductive/Development Toxicity Screening Test

TEST SUBSTANCE	Analogue (100%)
METHOD	OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test.
Species/Strain	Rat/Crl:CD®BR Male and female/12 per sex per dose group
Route of Administration	Oral - gavage
Exposure Information	Total exposure days: 14 days premating through 4-day lactation period (approximately 50 days) Dose regimen: 7 days per week Exposure levels: 0, 100, 500, 1000 mg/kg bw/day
Vehicle	Methyl cellulose (0.5%)
Remarks - Method	Statement of GLP included. No full study report provided. Protocol deviations noted from the summary report include: 1. Weekly clinical observations instead of daily clinical observations as per the OECD guidelines. 2. No haematological measurements from female rats at Day 14 only male rats.

RESULTS
Mortality and Time to Death
There were no mortalities during the study.

Clinical Observations
There were no significant differences in incidence of clinical observations during the study; however, some isolated, transient cases of hypoactivity were observed shortly after dosing in the 500 and 1000 mg/kg bw/day male rats and the 1000 mg/kg bw/day female rats.

There were no significant differences between the control and treated rats with respect to the reproductive performance of male or female rats. Additional details for the reproductive toxicity subset can be found in Section 7.12T.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
The mean total leukocyte counts were decreased in male rats treated with 500 and 1000 mg/kg bw/day the analogue; however, the decreases in the 500 mg/kg bw/day group were not significantly different. The decreases in total leukocyte count were attributable to decreases in lymphocyte counts, which were significant in the 500 and 1000 mg/kg bw/day groups. The absence of both morphological alterations in the spleen and decreases in thymus weights, and normal serum globulin concentrations suggest that the immunological impact was minimal.

Effects in Organs

There were no test item related effects on organ weights, nor were there any gross or microscopic changes attributable to the test item.

Remarks – Results
There were no test item related effects on mean final body weights.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day in this study, based on the summarised report available. The dose level at which no effects were produced was 100 mg/kg bw/day for male rats and 500 mg/kg bw/day for female rats.

TEST FACILITY Cited in OPPT (2003).

7.8.a Genotoxicity – bacteria

TEST SUBSTANCE	Analogue (purity 98%)
METHOD	No specific protocol was reported. Test conducted according to Ames et al. Mut. Res. 31, 347-364. Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100
Metabolic Activation System	Luminal induced rat liver S9
Concentration Range in Main Test	a) With metabolic activation: 10-5000 µg/plate b) Without metabolic activation: 10-5000 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	None.
RESULTS	
Remarks - Results	No full study report provided. Cytotoxicity was observed at 500 µg/plate concentration The analogue was non-mutagenic in all five Salmonella tester strains, with and without metabolic activation, even with addition of 5000 µg/plate.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Cited in IUCLID (2000) and in OPPT (2003).

7.8.b Genotoxicity – bacteria

TEST SUBSTANCE	Analogue (purity 98%)
METHOD	No specific protocol was reported. Procedure unknown
Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100
Metabolic Activation System	Unknown
Concentration Range in Main Test	a) With metabolic activation: 1000 µg/plate b) Without metabolic activation: 1000 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	None.
RESULTS	
Remarks - Results	Negative
CONCLUSION	The analogue was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY	Cited in IUCLID (2000).

7.10. Genotoxicity – in vivo

TEST SUBSTANCE	Analogue (purity 100%)
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test-Draft Guideline EPA Guideline published in 40 CFR 798.5395.
Species/Strain	Mouse/Crl:CD®-1(CR)BR Male and female/10 per sex per concentration
Route of Administration	Oral – gavage
Vehicle	Methyl cellulose (0.5%)
Exposure Information	Preliminary study exposure levels: 1250, 2500, 5000, mg/kg bw. No effects at any of any of these concentrations were observed. Main study exposure levels: 0, 1000, 2000, 5000 mg/kg bw Statement of GLP included.
Remarks - Method	No full study report provided. Protocol deviations noted from the summary report include: 1. Lower number (1000) of polychromatic erythrocytes were evaluated for each animal compared to current OECD protocol which requires 2000 per animal. 2. Unclear if the 1000 polychromatic erythrocytes include 200 erythrocytes from the bore marrow.
RESULTS	
Doses Producing Toxicity	None.
Genotoxic Effects	None. No statistically significant increase in the frequency of micronucleated polychromatic erythrocytes were found in test-item treated animals at any sampling time. Also, no significant decrease in the ratio of young polychromatic erythrocytes to mature normochromatic erythrocytes was observed.
Remarks - Results	No significant changes in body weight were observed in an test item treated group at the time of sacrifice. Several animals within the negative control group and each test-item treated group exhibited ruffled fur either immediately prior to dosing, 3-5 hours post dosing, or the day following the last dose.
CONCLUSION	The analogue was not clastogenic under the conditions of this in vivo Micronucleus Assay.
TEST FACILITY	Cited in OPPT (2003).

7.11T. Developmental toxicity

TEST SUBSTANCE	Analogue (purity 100%)
METHOD	OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test.
Species/Strain	Rat/Crl:CD®BR Male and female/12 per sex per dose group
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 14 days premating through 4-day lactation period (approximately 50 days) Dose regimen: 7 days per week Exposure levels: 0, 100, 500, 1000 mg/kg bw/day
Vehicle	Methyl cellulose (0.5%).
Remarks - Method	Statement of GLP included. No full study report provided.

RESULTS

Group	*Number of Animals*	*Dose mg/kg bw/day*	*Mortality*
1	12	0	0/12
2	12	100	0/12
3	11	500	0/11
4	12	1000	0/12

Mortality and Time to Death
None reported.

Effects on Dams
No significant differences between the control and treated rats with respect to.corpora lutea, or number of implantation sites.

Effects on Foetus
No significant differences between the control and treated rats with respect to foetal weight, or sex ratio.

Remarks – Results
There were no test item related effects on clinical observations in pups or pup body weights.

Pregnancy ratios were 11/12, 10/12, 10/11 and 11/12 for the 0, 100, 500, and 1000 mg/kg groups, respectively. A summary of other reproductive outcomes (means/litter) are provided in the table below:

Concentration (mg/kg)	0	100	500	1000
Corpora Lutea:	19.6	18.0	19.6	20.2
Implantations:	17.2	17.5	18.5	16.8
Total No. of Resorptions:	NR	NR	NR	NR
Total No. of Foetuses:	15.2	15.6	16.4	15.5
Total No. of Live Foetuses:	15.2	14.6	16.2	15.5
Mean Foetal Weight (g):	6.7	6.6	6.5	6.5
Sex Ratio (male/female):	0.15	0.15	0.48	0.47
NR = Not Reported				

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day in this study, based on the maternal and developmental toxicity results reported in this study.

TEST FACILITY Cited in OPPT (2003).

7.12T. Toxicity to reproduction – one generation study

TEST SUBSTANCE	Analogue (purity 100%)
METHOD	OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test.
Species/Strain	Rat/Crl:CD®BR Male and female/12 per sex per dose group
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 14 days premating through 4-day lactation period (approximately 50 days). Exposure levels: 0, 100. 500, 1000 mg/kg bw/day
Vehicle	Methyl cellulose (0.5%).
Remarks – Method	Statement of GLP included. No full study report provided.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
1	12 males, 12 females	0	None reported
2	12 males, 12 females	100	None reported
3	12 males, 12 females	500	None reported
4	12 males, 12 females	1000	None reported

Mortality and Time to Death
None reported.

Effects on Parental (P) animals:
There were no significant differences between the control and treated rats with respect to the reproductive performance of male or female rats which included mating index and fertility indices, gestation length, number of implantation sites, sex ratio, gestation ratio, percentage of pups born alive, and number of pups surviving to day 4 of lactation.

Effects on 1st Filial Generation (F1)
There were no test item related effects on clinical observations in pups or pup body weights.

Remarks - Results
A summary of reproductive outcomes are provided in the table below:

Dose (mg/kg)	0	100	500	1000
Mating Index (%):	100.0	100.0	91.7	100.0
Fertility Index (%):	91.7	83.3	90.9	91.7
Gestation Length (days):	22.3	22.2	22.2	22.4
Implantations (mean/litter):	17.2	17.5	18.5	16.8
Implantation efficiency (%):	NR	NR	NR	NR
Gestation Index:	100.0	100.0	100.0	100.0
Mean % Born Alive:	100.0	95.0	98.7	100.0
0-4 Day Viability (%):	99.4	98.2	97.3	98.8
Sex Ratio (male/female):	0.51	0.51	0.48	0.47
NR = Not Reported				

CONCLUSION
The no-observed-adverse-effect level (NOAEL) was 1000 mg/kg bw/day based on the effects observed for reproductive and neonatal toxicity.

TEST FACILITY Cited in OPPT (2003).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Domestic sewage
Exposure Period	28 days
Auxiliary Solvent	Acetone
Analytical Monitoring	No
Remarks - Method	Standard test. Dosed at 2 mg/L dissolved in acetone. Two flasks per sampling time. No additional information.

RESULTS

Test substance		*<Reference Substance>*	
Day	*% Degradation*	*Day*	*% Degradation*
5	45	Not reported	Not reported
15	86	Not reported	Not reported
28	71	Not reported	Not reported

Remarks - Results	Meets the criteria for readily biodegradable
CONCLUSION	The analogue is readily biodegradable and the notified chemical would be expected to be readily biodegradable as well.
TEST FACILITY	Cited in OPPT (2003).

8.1.2 Inherent biodegradability

TEST SUBSTANCE	Analogue
METHOD	OECD Guideline 303 A "Stimulation test – Aerobic Sewage Treatment: Coupled Unit Test"
Inoculum	Activated sludge
Auxiliary Solvent	Nil
Analytical Monitoring	No
Remarks – Method	The concentration used was 10 mg C/L related to DOC
RESULTS	94.4-98.8% degradation. The observed degradation refers to a mean residence time of 3 hours.
Remarks – Results	Very good elimination/degradation of the analogue
CONCLUSION	Analogue is inherently biodegradable and the notified chemical would be expected to be as well.
TEST FACILITY	Cited in OPPT (2003).

8.1.3. Bioaccumulation

The moderate water solubility and ready degradation will limit bioaccumulation to levels below those of environmental concern.

8.2. Ecotoxicological investigations

As indicated previously, all the ecotoxicological data are for a close analogue, of the notified chemical.

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Sodium salt of Analogue
METHOD	DIN 38412 Part 15

Species	Golden orfe
Exposure Period	48 hour
Remarks – Method	The sodium salt increases the solubility of the analogue and will be significantly higher than that of the notified chemical. Concentrations tested were 200, 500 and 1000 mg/L. No other details.

RESULTS

LC50	>1000 mg/L at 48 hours.
NOEC	1000 mg/L at 48 hours.
Remarks – Results	As report not sighted, reliability cannot be determined

CONCLUSION	The sodium salt of the analogue is non-toxic to fish.
TEST FACILITY	Cited in OPPT (2003)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Analogue

METHOD

Species	*Daphnia magna*
Exposure Period	24 hours acute study
Remarks - Method	No details reported

RESULTS

LC50	>27.6 mg/L at 24 hours
NOEC	27.6 mg/L at 24 hours
Remarks - Results	There were no effects up to 27.6 mg/L. No additional data reported.

CONCLUSION	The analogue is, rated as slightly toxic and a similar result could be expected for the notified chemical.
TEST FACILITY	Cited in OPPT (2003)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Analogue

METHOD

Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 5.8 mg/L
Remarks - Method	A saturated solution of the analogue was tested. No other information.

RESULTS

Remarks - Results	No toxic effect on algae growth was observed. The NOEC was 5.8 mg/L and the EC50 is > 5.8 mg/L

CONCLUSION	The analogue is rated as moderately toxic and a similar result could be expected for the notified chemical.
TEST FACILITY	Cited in OPPT (2003)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Analogue

METHOD

Inoculum	*Pseudomonas putida*

Exposure Period	6 hours
Concentration Range	Nominal: 205 mg/L
Remarks – Method	No additional information.

RESULTS

EC10	205 mg/L
Remarks – Results	None

CONCLUSION The analogue did not inhibit the respiration of *P. putida*

TEST FACILITY Cited in IUCLID (2000).

ADDITIONAL TESTS

8.3E. Assimilation test

TEST SUBSTANCE Analogue

METHOD Draft DIN 38412 Part 12

Species	*Scenedesmus subspicatus*
Exposure Period	24 hours
Concentration	Nominal: 15.3 mg/L. Measured by DOC content of saturated solution.
Remarks - Method	Inhibition of oxygen release as a function of substance concentration. No other details.

RESULTS No toxic activity was observed up to 15.3 mg/L.

Remarks - Results	The NOEC was 15.3 mg/L. No other information presented.

CONCLUSION The analogue did not inhibit the respiration of the algae at 15.3 mg/L. Similar results would be expected for the notified chemical.

TEST FACILITY Cited in OPPT (2003).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

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

Losses during formulation are expected to be minimal because the process is automated and when the equipment used is cleaned, the washings will be either used in the formulation of the next batch or sent to a licensed disposal contractor for disposal. In these situations release would only be through accidental spills that would be recycled or collected for incineration.

The material and wastes sent to licensed disposal contractors for disposal will be incinerated, treated (biological treatment) prior to discharge of the treated effluent to sewer or disposed to landfill. There should be minimal amounts of the notified chemical entering the environment from these disposal methods and exposure will be negligible.

Metal working fluids.
Estimates of the predicted environmental concentrations (PECs) resulting from the use of metal working fluids in a worst case scenario, for the 31.6% of the import volume being discharged into the sewer Australia wide, where the receiving waters from the sewage treatment plants (STPs) is either ocean outfall or inland river, are provided in the following table.

Process or Dilution Factor	
Typical product release expected per day	12.6 kg[a]
Australian Population Volume of water used per person	20.1 million 200 L/day
Daily water volume entering sewer	4,020 ML
Concentration in sewage effluent entering STP	3.1 µg/L
Dilution factor in receiving waters	1:10 (Ocean)
Predicted environmental concentration in receiving waters No removal of chemical in sludge:	0.31 µg/L
Dilution factor in receiving waters	1:1 (River)
Predicted environmental concentration in receiving waters No removal of chemical in sludge:	3.1 µg/L

[a]Based on the maximum import volume for the product of 10,000 kg per annum of which 31.6% is released to sewers and an exposure frequency of 250 days/year.

Engine oil
Losses during addition to motors will be low and very diffuse. Environment exposure will be minimal.

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

End use products containing the notified chemical will be used exclusively in industrial settings. Hence, it is anticipated that waste oils containing the notified chemical will be disposed of responsibly and either be recycled or incinerated. This will limit aquatic environmental exposure and the calculation of a meaningful PEC is not possible.

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

The notified chemical is not expected to bioaccumulate due to its water solubility and ready biodegradation.

9.1.2. Environment – effects assessment

Summary of ecotoxicological investigations for the analogue:

Organisms	NOEC
Golden orfe	1000 mg/L (48 h)
Daphnia magna	27.6 mg/L (24 h)
Scenedesmus subspicatus	5.8 mg/L (72 h)
Pseudomonas putida	EC10 = 205 mg/L
Scenedesmus subspicatus	15.3 mg/L (24 h, inhibition of oxygen release)

Summary of modelled data for the notified chemical from US EPA EPIWIN.

Organism	Acute EC50 mg/L
Freshwater fish	368 (96 h)
Daphnid	413 (48 h)
Green algae	269 (96 h)

Normally the EC50 are used to determine the PNEC but as there were no EC50 determined, the NOEC will be used. The lowest NOEC from the analogue laboratory data is the effect on the freshwater green algae (*Scenedesmus subspicatus*, renamed *pseudokirchneriella subcapitata*) at 72 h. Data for three trophic levels are available which would normally indicate a safety factor of 100. However, these data are for an analogue, hence, a safety factor of 1000 will be used. Therefore, the PNEC from analogue data is 5.8/1000 = >5.8 µg/L.

From the modelled data the most sensitive organism is mysid shrimp and with a safety factor of 1000, the PNEC is 269 µg/L. The lowest PNEC from analogue data will be used for risk characterisation.

9.1.3. Environment – risk characterisation

The risk of the release of 31.6% imported notified chemical during use as in water based metal working fluids can be estimated by determining the aquatic risk quotient (RQ = PEC/PNEC).

Removal by STP	PEC	PNEC	Risk Quotient (RQ)
		Ocean	
0%	0.31 µg/L	5.8 µg/L	0.05
		River	
0%	3.1 µg/L	5.8 µg/L	<0.01

The values of the worst case risk quotients for the aquatic environment are significantly less than 1, for both marine and fresh water organisms, indicating no immediate concern to the aquatic compartment. Note that the comparison is with a NOEC. The risk quotients will be further lowered as not all the chemical will be used in metal working fluids and the ready biodegradability of the chemical will mean that it will be degraded during sewage treatment

Overall, the environmental hazard from the proposed formulation and use of the notified chemical is expected to be low.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical is a crystalline powder when imported and will be used in liquid metalworking fluids at a concentration of <1% and oil lubricants at a concentration of <10% of the notified chemical in the respective finished products. Exposure during transport and storage would only occur through accidental breaching of the transport containers containing the notified chemical.

Exposure during reformulation

There is potential for dermal, ocular and inhalation exposure during the manual weighing and transfer of the notified chemical into mixing tanks, especially if dust is produced. The median particle size of an acceptable analogue is in the inspirable range and 9% are in the respirable range. Local exhaust ventilation is used for weighing and loading the powder into the mixing vessel and PPE (gloves, coveralls, disposable dust mask and safety eye glasses) would be worn. After addition of the notified chemical to the mixing tank a lid is placed on it and the remaining processes occur within a closed system. The resulting products contain <10% of the notified chemical.

Exposure during end-use
There is potential for dermal and ocular exposure during the process of diluting the concentrated metal working fluid lubricants and oil products. Inhalation exposure would not be a consideration at this stage due to the normal high viscosity and low volatility of lubricants and oil products. The dilution process occurs via automated dosing directly from the drum concentrate to the metalworking baths, thereby minimising dermal and ocular exposure at this stage. The main routes of exposure will be dermal and ocular and will occur during the use of the lubricants and oil products by motor mechanics during the servicing of vehicles and during the cleaning of equipment. Further dermal and ocular exposure may occur when lubricants are added to and drained from systems. Exposure is further minimised by the presence of only a small concentration of notified chemical present <1% during end-use for metal-working and <10% for oil applications. Additionally motor mechanics are trained in the proper handling of lubricants and oil products.

9.2.2. Public health – exposure assessment

The notified chemical is for industrial use only. Public exposure is only anticipated in the event of a spill during transport and storage through accidental breaching of the transport containers containing the notified chemical. Public exposure during normal use patterns will be negligible.

9.2.3. Human health – effects assessment

The notified chemical was not tested however an acceptable analogue had the following toxicological properties and was used for classifying the notified chemical.

The analogue was of low acute oral, dermal and inhalation toxicity in rats. The analogue was not a skin irritant in rabbits and was not a skin sensitiser in guinea pigs. The analogue was an eye irritant in rabbits.

In a 10-day repeat dose toxicity study in rats there was insufficient data to establish a NOEL or NO(A)EL. In a 14-day combined repeat dose and reproductive/developmental toxicity screening test the NOEL for male rats wast established to be 100 mg/kg bw/day and for female rats 500 mg/kg bw/day. No adverse effects were reported up to the highest dose tested, thus the NO(A)EL was established to be 1000 mg/kg bw/day.

The notified chemical was neither mutagenic in bacteria nor clastogenic in the in vivo micronucleus assay.

In a 14-day combined repeat dose and reproductive/developmental toxicity screening test the NOEL for male rats was established to be 100 mg/kg bw/day and for female rats 500 mg/kg bw/day. No adverse effects were reported up to the highest dose tested, thus the NO(A)EL was established to be 1000 mg/kg bw/day.

The notified chemical showed no effect on reproductive organs in the repeated dose exposure study.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004) and assigned the following risk phrase Xi: R36 Irritant: Irritating to eyes.

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is a crystalline powder when imported and will be used in aqueous metalworking fluids <1% of the notified chemical in the finished products and oil lubricants at a

concentration of <10% of the notified chemical in the finished products. In preparation of the concentrated metal working fluids and oil lubricants (<10% of notified chemical) the main routes of exposure are dermal, ocular and inhalation during handling of the powdered form. The notified chemical is classified as hazardous Xi:R36 (Irritating to eyes) and therefore ocular protection is required to minimize the risk. The extent of potential dermal, ocular and inhalation exposure is reduced by the use of engineering controls and PPE, in particular the use of eye protection during reformulation where exposure to 100% of the notified chemical is possible.

In the end-use of the diluted metalworking fluids, the notified chemical will be present at a concentration of <1%, there is potential for dermal and ocular exposure. Due to the very low concentration of notified chemical in the product and the use by trained workers exposure should be minimal.

In the end-use of the oil lubricants, the notified chemical will be present at a concentration of <10%, there is potential for dermal and ocular exposure. Due to the low concentration of notified chemical in the product and the use by trained workers exposure should be minimal.

Although the notified chemical is hazardous worker exposure to the notified chemical will be low. The risk to the workers during reformulation and end-use of the notified chemical will be low due to the use and disposal in the manner described.

9.2.5. Public health – risk characterisation

Although the notified chemical is hazardous, public exposure to the notified chemical will be low. The risk to the public from importation of the notified chemical for use and disposal in the manner described is considered to be 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 classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

Xi: R36 Irritating to eyes

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.

	Hazard category	***Hazard statement***
Irritant	2A*	Causes serious eye irritation

*Note: Insufficient data in the summary report to determine if the effects were irreversible therefore a conservative hazard category of 2A was determined.

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used as a component in metalworking fluids and engine lubricants.

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

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health, hazard classification for the notified chemical:
  - Xi: R36 Irritant: Irritating to eyes

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

- The following safety phrases should appear on the MSDS and label for the notified chemical:
  - S25: Avoid contact with eyes

Exposure Standard

CONTROL MEASURES
Occupational Health and Safety

- The following engineering controls should be implemented to minimise occupational exposure to powder form of the notified chemical:
  - Closed systems for formulation
  - Local exhaust ventilation during weighing and transfer of the notified chemical powder

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Gloves
  - Protective clothing
  - Safety eye protection
  - Dust mask or respirator when sufficient ventilation is not available.

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

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

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

Environment

- Use and storage of the notified chemical in sealed and bunded areas

Disposal

- The notified chemical should be disposed of by incineration.

Emergency procedures

- In case of spill of the notified chemical dampen down powder and avoid dust. Scoop into marked containers for disposal as chemical waste.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:
  – if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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