File No: NA/548

November 1997

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Parabar 9463

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Parabar 9463

1. APPLICANT

Exxon Chemical Australia Ltd of 12 Riverside Quay SOUTHBANK 3006 has submitted a standard notification statement in support of their application for an assessment certificate for Parabar 9463.

2. IDENTITY OF THE CHEMICAL

Parabar 9463 would be classified as corrosive in accordance with the National Commission's *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (1) and the chemical identity should, therefore, be disclosed in public reports and on the Material Safety Data Sheet (MSDS). However, Parabar 9463 will be imported in a formulation at a concentration that would not require it to be classified as hazardous. In addition, a secondary notification will be required should the concentration of the notified chemical in an imported formulation rise above 5% by weight (see section 15). Therefore, the chemical name, molecular and structural formulae, molecular weight, spectral data and details of exact import volume have been exempted from publication in the Full Public Report and the Summary Report.

Method of Detection and Determination:	gas chromatography; ^{13}C and ^{31}P nuclear magnetic resonance spectroscopy; infrared spectroscopy
Spectral Data:	gas chromatography, ^{13}C and ^{31}P nuclear magnetic resonance spectroscopy and infrared spectroscopy were performed for structural analysis

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	pale yellow liquid
Boiling Point:	100.7°C (initial boiling point); 520.5°C (final boiling point); pour point: - 9°C

Specific Gravity:	0.9768 at 15.5°C
Vapour Pressure:	5.11 X 10^{-4} kPa at 25°C
Water Solubility:	0.71 $mg.L^{-1}$ at 25°C
Partition Co-efficient (n-octanol/water):	log P_{ow} was calculated as 0.28 to 8.10 for the components of the notified chemical
Fat Solubility:	937 $g.kg^{-1}$ standard fat at 37°C
Hydrolysis as a Function of pH:	hydrolysis likely - see notes below
Adsorption/Desorption:	$logK_{oc}$ > 4.64 - see notes below
Dissociation Constant:	pK_a = 4.72
Flash Point:	109°C (closed cup); 151°C (open cup)
Flammability Limits:	not determined
Autoignition Temperature:	234°C
Explosive Properties:	no evidence of thermal or mechanical explosive properties
Reactivity/Stability:	expected to be stable but should be kept separate from strong oxidising agents and water

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines (2, 3) at facilities complying with OECD Principles of Good Laboratory Practice.

Since the notified material is a complex mixture of three chemical types, the physico-chemical properties will reflect those of the components, but it is unlikely that quantitative data on a given physical property will be dominated by any particular component. In the notes below continued reference will be made to components “A”....”F”.

The water solubility was determined as 0.71 $mg.L^{-1}$ using a turbidity method. The rationale behind this methodology was that when dispersed in water at concentrations > 0.71 $mg.L^{-1}$ a turbid dispersion was produced due to dispersion of colloidal sized particles. A plot of measured turbidity against various loadings of the material produced a bilinear graph, and the intersection of the two linear

methodology would not measure the contribution of component E (present as 3% of the substance) since this will be extracted and be truly soluble in water and would not contribute to the turbidity. Further, the true overall solubility will be very dependent on the pH, and component A for example, which is an acidic acid ester will be significantly more soluble at higher pH values. The pH at which the turbidity measurements were performed was not reported with the information in the notification dossier, but it is likely that dissolution and subsequent dissociation of the acid (pK_{a1} = 1.6) would have produced a low ambient pH (this is in fact alluded to in the report on determination of octanol/water partition coefficient). Low pH would have depressed the solubility of component A, and under usual environmental conditions where the ambient pH lies between 4 and 9 it is possible that the solubility of Parabar 9463 would be several orders of magnitude greater than the 0.71 $mg.L^{-1}$ stated by the notifier.

No test reports specifically directed at the pH dependence of hydrolytic degradation accompanied the submission, but the notifier indicates that significant hydrolysis is likely. In the report submitted on determination of dissociation constant, the titration curve exhibited unexpected behaviour above pH 8.5 together with an unexpected inflection around pH 10, and this was attributed to the production of acidic species resulting from hydrolysis of the organic components. Component species A and F were considered the most likely candidates, although hydrolysis of component B was also considered possible. The occurrence of hydrolysis was also encountered in preliminary work aimed at determination of the octanol/water partition coefficient.

The octanol/water partition coefficients of the individual components were determined by a calculation method since the instability (hydrolysis) of the material in an aqueous environment prevented the acquisition of meaningful analytical data. The results are as tabulated below.

Component	A	B	C	D	E	F
Composition (%)	7	14	28	15	3	33
log K_{ow}	0.28	1.81	5.56	8.10	-1.24	2.83

Notes: The report indicates that the log K_{ow} for component D may be unrealistically large, since the computer program used in the calculations does not account for the folding of long alkyl chains induced through hydrophobic interactions, which decrease the effective partition coefficient.

Most of the material has a high octanol/water partition coefficient indicating affinity for the organic phase. The high solubility in fat (see data above) reflects this property.

The value of K_{oc} which is a measure of the affinity of the material to adsorb onto organic matter was also determined by calculation for some of the individual chemical species. However, the data presented in the report provided appears to be for a material of different composition to that of the presently notified material.

Nevertheless, the calculated values for species A, C, D and F were provided, and are as tabulated below.

Component	A	B	C	D	E	F
Composition (%)	7	14	28	15	3	33
log K_{oc}	0.93	ND	3.69	5.43	ND	3.87

Notes: Data for species B and E were not provided. However, B could be expected to have a significantly larger log K_{oc} than A due to the second n-butyl group, while E is water soluble and will have a very low K_{oc}.

The neat Parabar 9463 contains 3% of an acid (component E) whose pK_{a1} is 1.6, so the material would be expected to exhibit strong acidity. Other apparent dissociation constants for the material were determined using a titration method, and the resultant titration curve exhibited two well defined inflection points corresponding to pK_a values of approximately 5 and 8 respectively. These are presumably correspond to the second dissociation constant of component E and to dissociation of component A. The titration curve exhibited peculiar behaviour for pH> 8.5, and this was attributed to hydrolytic decomposition as discussed above.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 99%

Toxic or Hazardous Impurities: none

Non-hazardous Impurities (> 1% by weight): none

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will be imported as a component (less than 5 wt%) of a lubricant additive package. The chemical can be used in lubricants in which it will be present at a concentration of less than 1 wt%. The estimated import volume over the first five years is expected to be less than 20 tonnes per year.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported into Australia in 200 L drums. The additive package is transported to a customer facility for blending into a finished lubricant in

batches of 10 - 50 kL. Exposure of transport or storage workers is not expected to occur.
The blending procedure is as follows:

- 200 L drums are connected to a transfer system by a flexible hose;
- the additive package is pumped out of containers through the transfer/stainless steel pipeline into the blend tank;
- on completion, the container/transfer hose/pipeline and pump are cleaned by flushing with mineral baseoil.

Following blending, the finished lubricant will be automatically packaged into 1 to 200 L containers for sale to the public or industrial users. It is estimated that less than 50 mL would be spilt during transfer processes at which time dermal exposure is possible.

Exposure of maintenance workers is expected to be low as the systems are flushed following transfer from drums.

Dermal and ocular exposure to end users of the finished lubricant is possible. However, the notified chemical is at a level of less than 1% so that exposure is minimal.

7. PUBLIC EXPOSURE

Public exposure to the notified chemical from transport, reformulation or industrial use is expected to be negligible except in the event of an accident.

Lubricants are available to the public for do-it-yourself car services, and thus dermal exposure may occur when changing them. Since the lubricants are not frequently changed and only up to 5% of the end use products will be sold to the public, public exposure is anticipated to be low.

As the blending processes are automated with minimal leakage, minimal amounts will be disposed of during reformulation. Accidental spillages during reformulation or transport will be collected and disposed of to approved industrial facilities. Public exposure from disposal is expected to be negligible.

8. ENVIRONMENTAL EXPOSURE

Release

During the activities associated with lubricant production there is little likelihood of release since these processes are conducted in purpose constructed facilities where any spills would be contained and soaked up in earth or sand and then sent to an approved industrial facility for appropriate disposal. This is expected to be

either incineration or placement into landfill. Residuals left in drums are anticipated to be 1.1% of imports (less than 220 kg per year) and these would be removed during drum reconditioning and incinerated.

Transfer of the product during the filling of automatic transmissions would be low, and is estimated to be a maximum of 50 mL per transfer operation. If it is assumed that each transfer uses 10 L of lubricant these losses amount to 0.5% of imports, or less than 100 kg of the notified chemical per year. In the majority of cases filling vehicles with the product would take place at sites of vehicle production or motor garages, and these releases could be expected to be contained and disposed of with other lubricant and petroleum product waste. In most cases this would be through incineration or oil recycling. It is anticipated that only 5% (ie a maximum of 1 tonne per year) of the imported material would reach the consumer/retail market for topping up the lubricant reservoirs, and very little would be released except in the case of accidental spills.

In use the material will be contained in an enclosed system, and release is expected to be insignificant. The lubricants are changed infrequently and the fate of the majority would be associated with that of the systems in which they are contained. In most cases the systems would be drained and the recovered oil sent for recycling. Some of this may be disposed of in an inappropriate manner, and in light of the ecotoxicity data (see below), this could be a concern. However, the material has a strong affinity for organic matter and is likely to be immobilised through association with the organic component of soils and sediments. Old gear assemblies would be sent for metal recovery where it is likely that the residual oil would be destroyed as a consequence of smelting operations.

Fate

The notified chemical is not readily biodegradable in aerobic environments, and the modified Sturm test [OECD Method 301B] indicated only 4% degradation after 28 days.

Incineration of the notified chemical would lead to its complete destruction with production of water vapour and oxides of carbon and sulphur. The contained phosphorus is likely to be oxidised to phosphate and to become part of the mineral component of ash.

If placed into landfill it is likely the material would be slowly degraded as a consequence of slow biological and abiotic processes operative within these facilities leading to production of water, methane and carbon dioxide. It is possible that some hydrogen sulphide and phosphine would also be produced, but these could be expected to oxidise to sulphate and phosphate respectively when released to a moist aerobic environment.

Notified chemical contained in oils and lubricants sent for recycling is likely to be destroyed during the re-refining process or become associated with waste sludge from the recycling plant waste treatment facilities. In the latter case the sludge would be either incinerated or sent to landfill where the fate of the material would be as described above.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Parabar 9463

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 $mg.kg^{-1}$	(4)
acute dermal toxicity	rat	LD_{50} > 500 $mg.kg^{-1}$	(5)
skin irritation	rabbit	corrosive*; non-irritant[#]; slight irritant[$]	(6, 7, 8)
eye irritation	rabbit	not tested due to skin corrosivity	
skin sensitisation	guinea pig	non-sensitiser	(9)

* neat Parabar 9463 [#] 2.7% dilution of Parabar 9463 [$] 0.3% dilution of Parabar 9463

9.1.1 Oral Toxicity (4)

Species/strain:	rat/Crl:CD BR
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage
Clinical observations:	decreased qualitative food consumption and/or stool abnormalities (no stool, soft stool or small amount of stool) were observed in all surviving animals primarily during the first week of the study; during this same period, anogenital staining and/or unthrifty coat was observed in 50% of the surviving animals; in addition, there were limited occurrences of hypoactivity (2 males on days 1,2, and/or 3); tales (1 male on days 0 and 1); slight emaciation (1 male on days 4-6); and clear oral discharge (one female on day 0); all signs were reversible by day 10; all animals displayed increases in body weight over their initial values.
Mortality:	one female on day 0
Morphological findings:	at postmortem examination, all animals which survived to study termination had

	findings in the stomach indicative of irritation from the test material; these findings included adhesion to the liver, diaphragm, spleen, kidney, and/or peritoneum; thickening; misshapen cardiac portion; discoloured mucosa; and/or sloughing of the mucosa; four animals also had thickened, enlarged, and/or discoloured spleens; the female found dead also was observed with stomach abnormalities as well as anogenital staining and discoloured lungs.
Test method:	according to OECD guidelines (2)
LD_{50}:	> 2 000 $mg.kg^{-1}$
Result:	the notified chemical was of low acute oral toxicity in rats

9.1.2 Dermal Toxicity (5)

Species/strain:	rabbit/NZW
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	12.5% concentration of the test material in peanut oil (maximum concentration which did not produce corrosivity) under occlusive dressing for 24 hours
Clinical observations:	none
Mortality:	none
Morphological findings:	none

Draize scores (10):

Time after treatment (days)	***Animal #***									
	1	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***
Erythema										
1	4[i]	3	4	3	4	4	4	4	4	4
3	4	4	4	4	4	4	4	3	3	4
7	3	3	4	4	4	4	2	2	4	4
10	2	2	2	2	4	4	2	2	2	4
14	2	1	3	2	2	1	2	4	1	1
Oedema										
1	2	4	3	3	3	3	2	4	2	3
3	2	2	2	2	2	2	2	2	2	2
7	2	1	1	1	2	2	2	1	1	2
10	1	1	1	1	1	2	1	0	0	1
14	0	1	1	1	1	0	0	0	0	0

[i] see Attachment 1 for Draize scales

Test method: according to OECD guidelines (2)

LD_{50}: > 500 $mg.kg^{-1}$

Result: the notified chemical was not toxic via the dermal route in a limit test in rabbits; it exhibited moderate to severe erythema and slight to severe oedema in all ten animals

9.1.3 Inhalation Toxicity

not conducted

9.1.4 Skin Irritation (6, 7)

9.1.4.1 Parabar 9463 (6)

Species/strain: rabbit/NZW

Number/sex of animals: 1 male

Observation period: 72 hours

Method of administration: 0.5 mL under semi-occlusive dressing for 3 minutes, 1 hour or 4 hours

Draize scores ( ):

Treatment Time (min)	***Time after treatment (days)***					
	1 hour	***1***	***2***	***3***	***7***	***14***
Erythema						
3	1[a]	3	2	2	1[d]	0[d]
60	4[n]	4[n]	4[n]	4[n]	4[e,x]	4[e,d]
240	4[n]	4[n]	4[n]	4[n]	4[x,e]	1[d]
Oedema						
3	0	3	2	2	1	0
60	2	4	3	3	1	1
240	4	4	2	2	1	1

[a] see Attachment 1 for Draize scales [d] desquamation [x] exfoliation [e] eschar [n] necrosis

Test method: according to EC guidelines ()

Result: the notified chemical was corrosive to rabbit skin

9.1.4.2 MRD-96-747 Containing 2.7% Parabar 9463 (7)

Species/strain: rabbit/NZW

Number/sex of animals: 6 males

Observation period: 7 days

Method of administration: under semi-occlusive dressing for 4 hours

Test method: according to USEPA guidelines ()

Result: 5 animals exhibited slight erythema at 1 hour after patch removal; in one of these animals slight erythema continued to day 3 and desquammation was observed on days 3 and 7; this same anima exhibited slight oedema at the 24 hour time point; the formulation was a slight irritant in rabbits

9.1.4.3 MRD-96-748 Containing 0.3% Parabar 9463 (7)

Species/strain: rabbit/NZW

Number/sex of animals: 6 males

Observation period: 72 hours

Method of administration: under semi-occlusive dressing for 4 hours

Test method: according to USEPA guidelines ()

Result: no erythema or oedema was observed in any animal at either 1, 24, 48 or 72 hours after patch removal

9.1.5 Eye Irritation

not tested

9.1.6 Skin Sensitisation (9)

Species/strain: guinea pig/Hartley Albino

Number of animals: 20 females in the treated group; 20 females for the irritation control group

Induction procedure: 3 pairs of injections of 0.1 mL in the mid-dorsal region near the scapula as follows:

- Freund's Complete Adjuvant (FCA) in water;
- 0.1% test material in peanut oil;
- 0.1% test material in FCA/water;

on day 7, topical induction with 0.5 mL of 5% test material in peanut oil under occlusive dressing

Challenge procedure: 0.4 mL of 0.05% test material in peanut oil under occlusive dressing to the left flank for 24 hours

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
0.05%	3/20	0/20	2/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Test method: Magnusson and Kligman (11)

Result: the notified chemical was not a skin sensitiser in guinea pigs under the conditions of the study

9.2 Repeated Dose Toxicity (12)

Species/strain:	rat/Crl:CD BR
Number/sex of animals:	5/sex in each group
Method of administration:	gavage in corn oil
Dose/Study duration::	doses of 0, 10, 50 or 150 $mg.kg^{-1}.dy^{-1}$ (control, low, mid or high dose groups respectively) for 28 days with a 14 day recovery group at the high dose
Clinical observations:	no treated-related clinical signs
Clinical Chemistry/ Haematology	clinical chemistry: no correlated dose-related findings; a number of small differences in the recovery group animals unrelated to organ toxicity haematology: no statistically significant differences between control and treated animals; a number of small differences in the recovery group animals unrelated to organ toxicity
Histopathology:	organ weights were unaffected by treatment; minimal to moderate submucosal oedema and/or inflammation in the forestomach of 3 male and 4 female rats of the high dose group; this was not observed in the recovery group; a number of other non-dose-related microscopic changes were judged to be spontaneous in origin
Test method:	according to OECD guidelines (2)
Result:	no signs of systemic toxicity were observed; treatment-related effects were limited to local stomach irritation at the highest dose of 150 $mg.kg^{-1}.dy^{-1}$

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (13)

Strains:	TA 1535, TA 1537, TA 1538, TA 98, TA 100
Concentration range:	20 - 100 μg/plate (without S9); 25 - 400 μg/plate (with S9)
Test method:	according to OECD guidelines (2)
Result:	the chemical was mutagenic in TA 1535 in either the presence or absence of metabolic activation provided by rat liver S9 fraction; maximum mutagenic potency was approximately 2 mutants per microgram; a dose response was observed in TA 100 but mutagenicity was not conclusively demonstrated

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (14)

Species/strain:	mouse/CD-1
Number and sex of animals:	5/sex/dose group (plus an extra 2/sex in the high dose group to ensure sufficient survivors)
Doses:	0, 375, 750 or 1 500 $mg.kg^{-1}$ (control, low, mid and high doses, respectively)
Method of administration:	gavage in corn oil
Test method:	according to OECD guidelines (2)
Result:	no increase was observed in the frequency of micronuclei in polychromatic erythrocytes at any dose level and cytotoxicity in the bone marrow was observed at a dose level of 1 500 $mg.kg^{-1}$

9.3.3 Chromosomal Aberration Assay in Chinese Hamster Ovary (CHO) Cells (15)

Doses/Duration:	8, 16, 24 μg/mL (without S9 fraction) for 16 hours; 40, 80, 100 μg/mL (with S9 fraction) for 16 and 40 hours

Test method:	according to OECD guidelines (2)
Result:	no statistically significant trends or individual results were obtained with the cell cultures containing rat liver S9 fraction; without S9 and at the 16 hour harvest times, statistically significant trends were observed in 2 experiments but only a single individual result (at a dose of 16 μg/mL) was significantly different from the control; the chemical should be considered weakly clastogenic

9.4 Overall Assessment of Toxicological Data

The notified chemical was of low acute oral toxicity in rats (LD_{50} greater than 2 000 $mg.kg^{-1}$) and exhibited an acute dermal LD_{50} greater than 500 $mg.kg^{-1}$ (a higher dose could not be administered due to the corrosive nature of the new chemical). The chemical was corrosive to rabbit skin and was predicted to be a severe eye irritant. A lower concentration - similar to that to be imported - was not a skin irritant in rabbits. A lower concentration - similar to that to be used in the final lubricant - was a slight skin irritant in rabbits. The notified chemical was not a skin sensitiser in guinea pigs when tested at a low concentration (0.1% for intradermal induction and 0.05% for challenge).

The notified chemical exhibited localised stomach irritation when tested in a 28-day oral repeat dose study in rats but no other organ toxicity.

The notified chemical was shown to induce base-pair substitution mutations in bacteria and may be weakly clastogenic.

The notified chemical would be classified as hazardous according to the Approved Criteria due to its corrosive nature.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier supplied two sets of ecotoxicological data. The first set was performed with neat Parabar 9463, and showed the material to be **moderately to very highly toxic** to the aquatic species tested against. A second set of tests were performed on a test material known as MRD-96-747 which contains 2.7% of the notified substance dissolved in mineral oil. This test substance is of similar composition to the additive formulation that it is intended to import. The results from these tests indicated the material to be far less toxic than the undiluted material. Both sets of ecotoxicology tests were performed using OECD or USEPA approved Test Methods.

The test data generated with the neat Parabar 9463 are as follows -

Test	***Species***	***Results (Nominal)***
Acute Toxicity [OECD 203]	*Oncorhynchus mykiss* (Rainbow trout)	LL_{50}(96 h) = 1.5 $mg.L^{-1}$
Acute Immobilisation [OECD 202]	*Daphnia magna*	EL_{50}(48 h) = 0.09 $mg.L^{-1}$
Growth Inhibition [OECD 201]	Algae *Selenastrum capricornutum*	EL_{50}(72 h) < 0.13 $mg.L^{-1}$
Respiration Inhibition [OECD 209]	Aerobic Waste Water Bacteria	No inhibition

The tests on rainbow trout were performed in duplicate using the water accommodation fraction (WAF) of the test material in a semi-static (renewal) system over a 96 hour period. Around 80% of the water was removed daily and replaced with fresh water containing the respective WAF of the test material. The loading range of WAF's tested was between 0.19 and 3.0 $mg.L^{-1}$. The results indicate the material to be highly toxic to this species.

The acute immobilisation tests on Daphnia were performed in a static test over a 48 hour test period with water accommodated fractions of the notified substance for nominal loadings between 0.001 $mg.L^{-1}$ and 0.1 $mg.L^{-1}$. The tests were replicated four times for each substance loading and the data indicate the test material to be highly toxic to this species, with a 48 hour 50% Effect Loading of 0.09 $mg.L^{-1}$.

Inhibition of increase in algal (*Selenastrum capricornutum*) biomass were also tested in a static test over a 72 hour test period with water accommodated fractions of the notified substance at nominal loadings of 0.13, 0.25, 0.50, 1.0 and 2.0 $mg.L^{-1}$. The tests were performed in triplicate for each substance loading, and the 72 hour EL_{50} based on area under the growth curve was determined as < 0.13 $mg.L^{-1}$, and consequently the test material is highly toxic to this algal species.

Tests on the effect of the new material on the respiration of activated sludge bacteria were also conducted using nominal loadings of 5, 25 and 50 $mg.L^{-1}$. No reduction in the rate of oxygen uptake was observed, and it was concluded that the material does not inhibit bacterial respiration. The control used in this test was 3,5-dichlorophenol, for which an EC_{50} of 20.8 $mg.L^{-1}$ was determined.

These tests performed with neat Parabar 9463 indicate that the material is **moderately to very highly toxic** to several aquatic species.

Since the new chemical will be imported as a 2.7% solution in mineral oil, the notifier provided test data on a diluted formulation known as MRD-96-747, and these are as follows -

Test	*Species*	*Results (Nominal)*
Acute Toxicity [OECD 203]	*Oncorhynchus mykiss* (Rainbow trout)	LL_{50}(96 hour)>1 000 $mg.L^{-1}$
Acute Immobilisation [OECD 202]	*Daphnia magna*	EL_{50}(48 hour)>1 000 $mg.L^{-1}$
Algal Toxicity [OECD 201]	Algae *Selenastrum capricornutum*	EL_{50}(72 h) = 276 $mg.L^{-1}$

The tests on rainbow trout were performed in duplicate using the water accommodation fraction (WAF) of the test material in a semi-static (renewal) system over a 96 hour period. Around 80% of the water was removed daily and replaced with fresh water containing the WAF of the test material produced at a loading equivalent to 1 000 $mg.L^{-1}$. No mortality of the fish occurred over the 96 hour test period, and accordingly the lethal loading (50% mortality) is greater than 1 000 $mg.L^{-1}$. Although these results indicate the notified material to be non-toxic to rainbow trout when exposed to the WAF produced from a 2.7% solution in mineral oil, the toxicity of the undiluted material is **high** - see data above.

The acute immobilisation tests on Daphnia were performed in a static test over a 48 hour test period with water accommodated fractions of the notified substance for nominal loadings of 62.5, 125, 250, 500 and 1 000 $mg.L^{-1}$. The tests were replicated four times for each substance loading and no immobilisation was observed. The 50% Effect Loading was determined at greater than 1 000 $mg.L^{-1}$. Although these results indicate the notified material to be non-toxic to daphnia when exposed to the WAF produced from a 2.7% solution in mineral oil, the toxicity of the undiluted material is **high** - see data above.

Inhibition of increase in algal (*Selenastrum capricornutum*) biomass were also tested in a static test over a 96 hour test period with water accommodated fractions of the notified substance at nominal loadings of 62.5, 125, 250, 500 and 1 000 $mg.L^{-1}$. The tests were performed in triplicate for each substance loading, and the 96 hour EL_{10}, EL_{50} and EL_{90} based on growth inhibition rate were 153, 276 and 460 $mg.L^{-1}$ respectively.

The ecotoxicity data for the notified chemical indicate that it is non-toxic to those aquatic species tested when they were exposed to formulation containing 2.7% of the notified chemical.

It is apparent that the undiluted material is highly toxic to aquatic life. However, when associated with a large excess of hydrocarbon solvent (mineral oil) the toxicity is very appreciably reduced. The reason for this is unclear, and it is difficult to understand how much more of the toxic components are dissolved into water in one case and not the other. However, a possible explanation may be that when the 2.7% formulation is dispersed in water the new material is associated with micelles or other types of colloidal aggregate (for which it would act as an

emulsifier, or stabilising factor), and is not therefore available for direct contact with, or assimilation by aquatic organisms.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical is small provided it is used in the manner indicated.

Releases of the material to the environment are expected to be low as both product formulation and vehicle filling are performed under well controlled conditions and spills and other losses will be minimal. The ultimate fate of the majority of the material is expected to be incineration of waste oil resulting in its destruction with production of non-hazardous gases and phosphate minerals.

However, the material is toxic to aquatic organisms - particularly to Daphnia and algae - and release into the water compartment should be avoided.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is expected to be corrosive and genotoxic in humans but is likely to be of low acute toxicity via the oral route and is not likely to be of high acute toxicity via the dermal route. It is unlikely to cause severe systemic effects on repeated or prolonged exposure other than as a result of its corrosive nature. It is unlikely to be a skin sensitiser at the concentrations used in the final manufactured lubricant but cannot be conclusively ruled out as a sensitiser at the concentration to be imported.

The notified chemical will be imported at a low concentration in steel drums so that exposure of transport and storage workers is unlikely. Formulation into the finished lubricant is conducted in an automated blending system with possible low dermal exposure occurring after disconnecting transfer hoses and from accidental spillage. Following shipping to customers, the notified chemical will be at a low concentration in the lubricant so that exposure levels are likely to be minimal despite the fact that dermal exposure to lubricants can be high depending on work practices used.

Although the notified chemical is corrosive and genotoxic, the health risk to workers involved in transport, storage, use or disposal is expected to be low given the low levels in the formulation to be imported and in the final lubricant.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

- Industrial clothing should conform to the specifications detailed in AS 2919 ( );
- Impermeable gloves or mittens should conform to AS 2161 ( );
- All occupational footwear should conform to AS/NZS 2210 ( );
- Spillage of the notified chemical should be avoided, spillage should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* ( ).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. In addition, secondary notification shall be required if the concentration of the notified chemical in an imported formulation is likely to exceed 5 wt%.

16. REFERENCES

1. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australian Government Publishing Service, Canberra.

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4. Freeman, J.J. & Frank, E.R. 1996, *Acute Oral Toxicity in the Rat*, Project no., 149202, Exxon Chemical Company, NJ, USA.

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10. Draize, J.H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US*, vol. 49, pp. 2-56.

11. Magnusson, B. & Kligman, A.M. 1970, *Allergic Contact Dermatitis in the Guinea-pig: Identification of Contact Allergens*, Thomas C C, Illinois.

Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe