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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Parabar 10105A

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act), and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the following hours:

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**Parabar 10105A****1. APPLICANT**

Exxon Chemical Australia Ltd has submitted a standard notification statement in support of their application for an assessment certificate for Parabar 10105A.

2. IDENTITY OF THE CHEMICAL

Parabar 10105A. is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Trade Name: Parapoid 7205 (containing up to 25% of the notified chemical)

Method of Detection and Determination: ultraviolet (UV) and infrared (IR) spectroscopy and gas chromatography

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: pale yellow liquid

Boiling Point: 180°C (initial); 568.6°C (final)

Pour Point: -12.2°C

Density: relative density, 1.0143 kg/m³ at 15.5°C

Vapour Pressure: 0.00295 kPa at 25°C

Water Solubility: 70.097 mg/L at 25°C

**Partition Co-efficient
(n-octanol/water):**

the notified chemical consists of a majority of components with $\log P_{ow} > 6$ and minor components with $\log P_{ow}$ values of 3.04, 4.21 and 4.31

**Hydrolysis as a Function
of pH:**

not determined

Adsorption/Desorption:

the notified chemical was evaluated in three different soils with the water soluble component at a loading of 10 g/L; results were as follows:

| | % <i>adsorbed</i> | % <i>desorbed</i> | <i>K'</i> | <i>K'_{oc}</i> |
|----------------------|----------------------|----------------------|-----------|----------------|
| <i>colorado soil</i> | 53.4 | 29.8 | 4.643 | 190 |
| <i>freehold soil</i> | 32.4 | 61.4 | 1.922 | 229 |
| <i>snyder soil</i> | 27.7 | 64.5 | 1.557 | 77.5 |

Dissociation Constant:

$pK_a = 7.37$

Flash Point:

135°C

Flammability Limits:

not determined

Autoignition Temperature:

340°C

Explosive Properties:

not determined

Reactivity/Stability:

does not degrade, decompose or polymerise
hazardously at room temperature

Comments on Physico-Chemical Properties

Tests were performed at facilities complying with OECD Principles of Good Laboratory Practice.

The initial and final boiling points represent the boiling range temperature estimates for the notified substance.

Concentrations of the notified substance in water were determined by the total organic carbon (TOC) analysis of the equilibrated solutions. Per cent carbon information and results of the TOC analysis were used to calculate the test substance's concentration in water. The results show that the aqueous concentrations had reached equilibrium by day three.

Hydrolysis was not determined. The notifier claims that the notified substance appears not to contain any hydrolysable functional groups. However, some

hydrolysis may be expected in the environment by analogy with organophosphorus insecticides {International Programme on Chemical Safety, 1986 #67}.

A partition coefficient test reported that the notified substance eluted as several discrete chromatographic components when analysed by reverse phase high performance liquid chromatography (HPLC). The majority of these components of the UV detectable test substance were estimated to have log K_{OW} values greater than 6. There were minor components with log K_{OW} values of 3.04, 4.21 and 4.31.

The water soluble fraction of the notified substance showed moderate adsorption to each of the three soils tested, with the highest adsorption and retention obtained on the Colorado soil (highest organic carbon content, OCC). The resultant K_{OCs} indicate that this fraction of the notified substance would exhibit medium to high mobility within soils {McCall, 1981 #68}, with increasing mobility expected in soils with less OCC. The remainder of the substance is expected to be far less mobile.

4. PURITY OF THE CHEMICAL

Degree of Purity: 96%

Toxic or Hazardous Impurities: none

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical is to be used as a component of a lubricant additive package at a concentration of 10 to 25%. It will be imported at a rate of 50 to 150 tonnes per year for the first 5 years.

6. OCCUPATIONAL EXPOSURE

The lubricant additive package containing the notified chemical is to be imported in 200 L drums so that exposure to transport and warehouse workers is expected to be minimal except in the event of an accident.

Following transport to the major formulators of gear oil, the lubricant additive package is pumped from the drum to the blending vessel. It is estimated that 10 to 15 mL maximum is spilt during each transfer. Blending of the notified chemical into batches of 400 to 400 000 litres is estimated to occur a maximum of once per month and workers are potentially exposed for 1 hour at this time. Once added to the blending vessel, losses of the notified chemical are expected to be minimal and packaging into containers of 2 to 200 litres in size is automatic. The final concentration of the notified chemical in the blend is approximately 1.5%.

On completion of packaging, the transfer hose, pipeline and pump are cleaned of

the notified chemical by flushing with mineral baseoil and the washings are stored in drums and added to the next batch. Clingage to the inside of drums is estimated at 1% and is washed out with water by a drum reconditioner.

The notifier has estimated inhalational exposure to workers in the blending plant as 0.3 mg/kg/month on the basis of a 70 kg man who is estimated to breathe 1 m³ of air per hour. A dilution factor of 25% for the notified chemical in the formulation to be imported is assumed as is a dilution of vapours to 10% during blending as a result of ventilation in an unconfined space.

End users of the final gear oil formulation pump the oil into the gearboxes of industrial equipment in a factory setting by means of a tube. Exposure to the notified chemical in the gear oil is possible in the absence of gloves.

7. PUBLIC EXPOSURE

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

The reformulated products are available to the public for di-it-yourself car services, and thus dermal or ocular exposure may occur when changing gear oils or transmission fluids. Since gear oils and transmission fluids 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.

Minimal amounts will be disposed of during reformulation, as the blending processes are automated with minimal leakage. Accidental spillages during reformulation or transport will be collected and disposed of to approved industrial facilities. The majority (greater than 95%) of the used gear oils or transmission fluids is expected to be disposed of according to government regulations, public exposure from disposal is expected to be minimal.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier expects negligible environmental release of the notified substance during product manufacturing. Fugitive emissions during transport and blending are considered by the notifier to be negligible due to the very low vapour pressure of the substance. If a spillage occurs during the blending processes, it will be contained on-site and soaked up with absorbent material, e.g. sand or soil, before being transported off-site to an approved industrial facility for disposal by incineration. The drumming/ re-packing of the finished lubricant product into consumer sized containers are essentially carried out in an automated filling line. Leakage from product transfer lines is expected to be minimal, with it being collected then recycled or disposed of. On completion of the blending process, containers, transfer hoses, pipelines and pumps are cleaned by flushing through with mineral baseoil.

Release of the lubricants containing the notified substance to the environment during use is expected to be minimal as the notifier claims that the majority of finished lubricant oils (estimated at greater than 95% or approximately 143 t) are destined for use in industrial equipment in factories. They anticipate that consumer sales will only account for a small proportion of total sales. During use, the products are generally considered to be contained in essentially closed systems. Possible environmental release is from leaks or accidents. Leaks of transmission fluids and gear oils are most often minor in nature, and will be diffuse. Release in accidents will be random events and uncommon, as accidents that crack the transmission housing are rare.

The notifier claims that these types of lubricants are not frequently changed, and in many cases, are effective for the life of the machine. It is further claimed that the majority of used oil from industrial sources will be collected and either recycled, re-refined or burnt (for fuel value). Used lubricant will not be released to the environment. The estimated less than 5% (approximately 7 t) of the notified substance that is used in the consumer market could be released to the environment after use. However, the notifier envisages that such lubricant changes would generally be undertaken at a garage with used oil being correctly disposed of.

The notifier estimates that an “empty” container has approximately 1.1% unused residues left inside. Therefore, up to 1.65 tonnes of the notified substance (at a maximum import volume of 150 t) may be present either for incineration as drum washings during reconditioning of the containers or for disposal as consumer container residues. Consumer containers may be recycled. However it is likely that many of these containers will likely be disposed of to landfill.

Fate

The notified substance will be used in industrial and automotive gear oils and transmission fluids, and will share their fate. Therefore, most spent oil will be recycled, re-refined or combusted (if used for fuel value). Incineration products are expected to include oxides of carbon, nitrogen, sulfur and phosphorous. A minor component may be released to the environment from spills and leaks, but this would be widely dispersed. If the notified substance was washed from road surfaces, it would be expected to adsorb to soils or sediments adjacent the road. The substance would be expected to break down in the environment.

Collection of waste lubricants is more easily accomplished from industrial and commercial users than from the section of the community that changes its own {Australian and New Zealand Environment and Conservation Council, 1991 #77}. The notifier has indicated that the vast majority of lubricants containing the notified substance will be used in industrial applications. Gear oil and transmission fluids in the consumer market would generally be replaced by professional mechanics at garages, and not be replaced by the ‘do-it-yourself’ (D-I-Y) public. Therefore, the majority of used lubricant should be properly collected and disposed of.

The notifier has not determined whether the notified substance would be biodegradable. However, they suggest that the notified substance would be

readily biodegradable as the substance is an “amine dithiophosphate” (which they claim are known to easily biodegrade). No references or data were supplied in support of this claim.

The potential for bioaccumulation was not determined. However, bioaccumulation of the notified substance is not expected due to the chemical’s high partition coefficient ($\log K_{OW} > 6$) and molecular weight of 727 g/mol {Connell, 1989 #3}.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Parabar 10105A

| Test | Species | Outcome | Reference |
|----------------------------|----------------|--------------------------------|---------------------|
| acute oral toxicity | rat | LD ₅₀ > 2 000 mg/kg | {, 1990 #69} |
| acute dermal toxicity | rabbit | LD ₅₀ > 2 000 mg/kg | {Freeman, 1995 #70} |
| skin irritation | rabbit | slight irritant | {, 1990 #72} |
| eye irritation* | rabbit | moderate irritant | {Freeman, 1995 #75} |
| repeat insult patch test** | human | negative | {Plaza, 1995 #74} |

* using an additive package containing 16% of the notified chemical

** using a gear oil containing the notified chemical

9.1.1 Oral Toxicity and Cholinesterase Determination {, 1990 #69}

9.1.1.1 Oral Toxicity

| | |
|----------------------------------|---|
| <i>Species/strain:</i> | rat/Crl:CDBR |
| <i>Number/sex of animals:</i> | 5/sex |
| <i>Observation period:</i> | 14 days |
| <i>Method of administration:</i> | gavage |
| <i>Clinical observations:</i> | four animals exhibited oral or nasal discharge and/or anogenital or abdominal staining; one female exhibited decreased food consumption, slight emaciation, and/or stool abnormalities from days 3 to 8 |
| <i>Mortality:</i> | none |

| | |
|--------------------------------|---|
| <i>Morphological findings:</i> | none |
| <i>Test method:</i> | OECD Guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15} |
| <i>LD₅₀:</i> | > 2 000 mg/kg |
| <i>Result:</i> | the notified chemical was of low oral toxicity in rats |

9.1.1.2 Cholinesterase Determination

This study was conducted because the notified chemical falls into the broad category of organophosphates. A 500 mg/kg oral dose produced decreases in plasma cholinesterase of approximately 38% and 49% for males and females, respectively, 24 hours after dosing. A decrease (12%) in erythrocyte cholinesterase in male animals was observed but no statistically significant decrease occurred in females. At intervals of 1 and 4 hours after dosing, no effects were seen and there was no effect on brain cholinesterase at the 24 hour interval.

The positive control was Parathion at 6.5 mg/kg which resulted in the death of all female animals. In males plasma and brain cholinesterase levels were decreased at all intervals and erythrocyte cholinesterase levels at 1 and 24 hours post-intubation.

9.1.2 Dermal Toxicity {Freeman, 1995 #70}

| | |
|----------------------------------|---|
| <i>Species/strain:</i> | rabbit/New Zealand White |
| <i>Number/sex of animals:</i> | 5/sex |
| <i>Observation period:</i> | 14 days |
| <i>Method of administration:</i> | under occlusive gauze dressing for 24 hours |
| <i>Clinical observations:</i> | one female had ocular discharge at day 7 |
| <i>Mortality:</i> | none |
| <i>Morphological findings:</i> | four animals had desquamation at the site of administration |

Draize scores {Draize, 1959 #4}:

| <i>Time after treatment (days)</i> | <i>Animal #</i> | | | | | | | | | |
|------------------------------------|-----------------|---|---|---|---|---|---|---|---|----|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| <i>Erythemaⁱ</i> | | | | | | | | | | |
| 1 | 2 | 2 | 2 | 3 | 3 | 2 | 2 | 3 | 2 | 3 |
| 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 7 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 2 | 0 |
| 10 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 0 |
| 14 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 |
| <i>Oedemaⁱ</i> | | | | | | | | | | |
| 1 | 2 | 2 | 1 | 2 | 1 | 1 | 2 | 2 | 1 | 2 |
| 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 7 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 |
| 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

ⁱ see Attachment 1 for Draize scales

Test method: OECD Guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}

LD₅₀: > 2 000 mg/kg

Result: the notified chemical was of low dermal toxicity in rabbits and was a moderate to severe skin irritant

9.1.3 Inhalation Toxicity

No data submitted.

9.1.4 Skin Irritation {, 1990 #72}

Species/strain: rabbit/New Zealand White

Number/sex of animals: 6 males

Observation period: 7 days

Method of administration: 0.5 mL of the notified chemical was administered under a semi-occlusive dressing for 4 hours

Draize scores {Draize, 1959 #4}:

| <i>Time after treatment</i> | <i>Animal #</i> | | | | | |
|-----------------------------|-----------------|----------|----------|----------|----------|----------|
| | <i>1</i> | <i>2</i> | <i>3</i> | <i>4</i> | <i>5</i> | <i>6</i> |
| <i>Erythema</i> | | | | | | |
| 0.6 hours | 1 ^a | 0 | 0 | 2 | 1 | 2 |
| 1 day | 2 | 0 | 0 | 1 | 0 | 2 |
| 2 days | 2 | 1 | 1 | 0 | 0 | 1 |
| 3 days | 2 | 1 | 1 | 0 | 1 | 1 |
| 7 days | 0 | 0 | 0 | 0 | 0 | 0 |

^a see Attachment 1 for Draize scales

Test method: not stated

Result: the notified chemical was a slight skin irritant in rabbits

9.1.5 Eye Irritation {Freeman, 1995 #75}

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3/sex

Observation period: 3 days

Method of administration: 0.1 mL into the conjunctival sac of one eye of each animal

Draize scores {Draize, 1959 #4} of unirrigated eyes:

| Animal | Time after instillation | | | | | | | | | | | |
|---------------------|--------------------------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| | 1 hour | | | 1 day | | | 2 days | | | 3 days | | |
| Cornea ^a | | | | | | | | | | | | |
| 1 | 0 | | | 1 | | | 0 | | | 0 | | |
| 2 | 0 | | | 0 | | | 0 | | | 0 | | |
| 3 | 0 | | | 0 | | | 1 | | | 0 | | |
| 4 | 0 | | | 0 | | | 0 | | | 0 | | |
| 5 | 0 | | | 0 | | | 0 | | | 0 | | |
| 6 | 0 | | | 2 | | | 0 | | | 0 | | |
| Iris | no iridal effects seen in any animal | | | | | | | | | | | |
| Conjunctiv | r ^b | c ^c | d ^d | r ^b | c ^c | d ^d | r ^b | c ^c | d ^d | r ^b | c ^c | d ^d |
| a | | | | | | | | | | | | |
| 1 | 3 | 3 | 3 | 2 | 2 | 0 | 1 | 1 | 0 | 0 | 0 | 0 |
| 2 | 3 | 2 | 3 | 2 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3 | 3 | 3 | 3 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 4 | 2 | 2 | 3 | 1 | 2 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| 5 | 2 | 2 | 3 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6 | 3 | 4 | 3 | 2 | 2 | 0 | 1 | 1 | 0 | 0 | 0 | 0 |

¹ see Attachment 1 for Draize scales

^a no opacity seen; scores are given for ulceration, viz, absence of corneal epithelium where a score of 1 represents up to 25% and a score of 2 represents 25% to 50% absence of epithelium

^b redness ^c chemosis ^d discharge

Test method:

OECD Guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}

Result:

the notified chemical was a moderate to severe eye irritant in rabbits at when scored at 1 hour post-instillation and a slight to moderate irritant thereafter

9.1.6 Skin Sensitisation {Plaza, 1995 #74}

A standard skin sensitisation test in guinea pigs was not conducted. However, a repeated insult patch test using human volunteers was submitted on a finished oil containing the notified chemical.

A pilot study with the test article undiluted and diluted 50% in mineral oil was conducted. As a result the undiluted test article was used for the main study.

Ninety-five subjects were treated with the test article under semi-occlusive dressings. Induction was carried out at 24 hour intervals for a total of 9 patches on the same site. Challenge was conducted by the application of patches on the original and adjacent sites and scored at 48 and 96 hours.

No evidence of allergic dermatitis was observed at the challenge sites. Mild erythema was observed in one subject following the third induction but this had cleared by the fourth induction.

9.2 Repeated Dose Toxicity

No data submitted.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay {Freeman, 1996 #73}

| | |
|-----------------------------|---|
| <i>Strains:</i> | TA 98, TA 100, TA 1535, TA 1537, TA 1538 |
| <i>Concentration range:</i> | 50 - 1 000 µg/plate |
| <i>Test method:</i> | according to Maron and Ames {Maron, 1983 #76} |
| <i>Result:</i> | evidence of toxicity was observed at 5 000 µg/plate so that 1 000 µg/plate is the highest dose at which a reliable conclusion can be drawn; no increase in the mutation frequency was observed at any dose in any of the strains tested either in the presence or absence of metabolic activation provided by rat liver S9 fraction |

9.4 Overall Assessment of Toxicological Data

The notified chemical exhibited low acute toxicity in rats (oral LD₅₀ > 2 000 mg/kg) and rabbits (dermal LD₅₀ > 2 000 mg/kg). It was a slight skin irritant in rabbits. An additive package containing the notified chemical at a level of 16% was a moderate eye irritant in rabbits. Assuming the irritation was due to the notified chemical, it should be considered a moderate to severe eye irritant and should be classified as such according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) {National Occupational Health and Safety Commission, 1994 #66}.

A gear oil containing the notified chemical at 1% was negative in a repeat

insult patch test in humans.

The notified chemical was not mutagenic in *S. typhimurium*.

The notified chemical would not be classified as hazardous according to the Approved Criteria in relation to acute toxic effects or skin irritancy.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicological data were not supplied for the notified substance. The notifier argues that as the notified substance will be a component of gear oils and transmission fluids, the use of which are in essentially enclosed systems, (aquatic) environmental exposure will be very low. Such lubricants are changed very infrequently, often never, and any such changes will generally be done by professional mechanics. The vast majority (>95%) of lubricants containing the notified substance will be used in industrial applications, with consumer sales only accounting for a very minor portion of total sales.

This omission is accepted on the basis of the likely low exposure to the environment, in particular the aquatic compartment. However, the presence of organophosphate and quaternary amine functionalities is noted, both of which may have high toxicity. The notifier claims that the substance was notified in the United States and Canada without ecotoxicity data being submitted. However, ecotoxicity data may be required in the US should very high (unspecified) production targets be met. The substance is already listed on EINECS and used in Europe.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The end use of the notified substance is as a component of gear oils and transmission fluids. The main environmental exposure will be from inappropriate disposal of waste lubricant. An unlikely worst case scenario would be if all the lubricant sold to the consumer market was uncollected and dumped into a sewer in some country centre. This would give a concentration of about 4.1 mg/L per day¹. For a major city, the amount would only be about 41.1 µg/L per day¹, due to the much higher dilution factors expected.

It is expected that the substance will be moderately adsorbed to soil and sediment during the waste water treatment process. Therefore, the actual concentration in the effluent will be significantly less. With its use Australia wide, i.e. not concentrated in one town or city, and with good industrial and public practice, possible concentrations of the notified substance exposed to the environment would be expected to be further reduced. Considering the pattern of use for

¹ Given 5% of the lubricant is sold to the consumer market and not collected, then of the 150 tonnes of the notified substance, 7.5 t would not be collected. This would be 20.5 kg/day (i.e. 7.5 tonnes/365 days). The dilution at a rural town could reasonably be expected to be about 5 ML, while for a major city, say Melbourne, it would be 500 ML. This would give final concentrations of the substance of 4.11 mg/L per day and 0.04 mg/L per day, respectively.

products containing the notified substance, Environment Australia believes that exposure and thus hazard to the environment, and in particular the aquatic compartment, will be very low.

Disposal of containers with waste lubricant (residues of and used lubricant) should not result in any significant environmental exposure. Waste lubricant may be recycled or incinerated. Incineration of the lubricant for fuel value or due to container reconditioning will destroy the substance. Used/waste lubricant collected by industrial and commercial users, that is not re-used, is expected to be disposed of to approved industrial facilities. D-I-Y consumer lubricant, if disposed of to domestic landfills, should remain in the containers. If leaks occur the substance should remain within the landfill, absorbing to soil and sediment. The notified substance should break down over time due to its expected biodegradability.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

From the available toxicological data the notified chemical is unlikely to exhibit acute toxic effects in humans. It may be a slight skin irritant and a moderate eye irritant (when in an additive package) although a rabbit study suggested that eye irritation could be severe for a short period following exposure. A negative mutagenicity test in bacteria suggests that the chemical has limited genotoxic potential.

Exposure to the notified chemical is expected to be low. Firstly, the maximum concentration of the notified chemical in the lubricant additive package to be imported is 25%. Secondly, at each site, blending of the notified chemical into gear oil is estimated to occur once per month for one hour. The likely dose by inhalation has been calculated at 0.3 mg/kg/month. It is stated that the chemical has an offensive odour so that its presence is easily detectable and exposure can be avoided. Dermal exposure is stated to be possible only when disconnecting the coupling from the line used to transfer the lubricant additive package from the drum in which it is imported to the blend tank. In this case, about 10 to 15 mL is estimated to be spilt. At a maximum batch size of 400 000 litres of gear oil, this represents a maximum of 450 mL of the chemical spilt per batch. Thus, repeated or prolonged exposure to the notified chemical is not likely to occur and a sub-chronic study to assess the hazard was judged to be unnecessary. For the same reason a standard guinea pig skin sensitisation assay was also judged to be unnecessary. The risk of adverse health effects to workers involved in blending the lubricant additive package into gear oil is expected to be low. Nevertheless, eye protection as described below should be worn due to the possibility of severe transient eye irritation.

The finished gear oil has the notified chemical at a maximum concentration of 1.5% so that the risk of adverse health effects to end users is expected to be minimal. This is supported by a negative repeated insult patch test in humans using an oil similar to that into which the notified chemical is to be blended.

13. RECOMMENDATIONS

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

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 {Standards Australia, 1994 #21} to comply with Australian/New Zealand Standard (AS/NZS) 1337 {Standards Australia/Standards New Zealand, 1992 #23};
- Industrial clothing should conform to the specifications detailed in AS 2919 {Standards Australia, 1987 #18};
- Impermeable gloves or mittens should conform to AS 2161 {Standards Australia, 1978 #17};
- All occupational footwear should conform to AS/NZS 2210 {Standards Australia/Standards New Zealand, 1994 #24};
- Spillage of the notified chemical should be avoided, spillages 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 Material Safety Data Sheet (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* {National Occupational Health and Safety Commission, 1994 #13}.

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. No other specific conditions are prescribed.

16. REFERENCES

1. International Programme on Chemical Safety 1986, *Organophosphorus Insecticides: A General Introduction*, Environmental Health Criteria, vol. 63, World Health Organisation, Geneva, Switzerland.
2. McCall, J.P., Laskowski, R.L. & Dishburger, H.J. 1981, *Measurement of Sorption Coefficients of Organic Chemicals and Their Use In Environmental Fate Analysis, Test protocols for environmental fate and movement of toxicants. Proceedings of a symposium*, Association of Official Analytical Chemists. 94th Annual Meeting, Washington DC.
3. Australian and New Zealand Environment and Conservation Council 1991, *Used lubricating oil: Generation, recovery and reuse in Australia Prepared by Technisearch Ltd for the Waste and Resources Committee (WRAC)*.
4. Connell, D.W. 1989, 'General characteristics of organic compounds which exhibit bioaccumulation', in *Bioaccumulation of Xenobiotic Compounds*, CRC Press, Boca Raton.
5. *Acute Oral Toxicity Study in the Rat with Cholinesterase Determination*, Project no., 171177, Exxon Biomedical Sciences Inc, NJ, USA, 1990.
6. Freeman, J.J. 1995, *Acute Dermal Toxicity Study in the Rabbit*, Project no., 114407, Exxon Biomedical Sciences Inc, NJ, USA.
7. *Primary Dermal Irritation Study in the Rabbit*, Project no., 171104, Exxon Biomedical Sciences Inc, NJ, USA, 1990.
8. Freeman, J.J. 1995, *Ocular Irritation Study in the Rabbit without Eyewash with APK 940680*, Project no., 196613, Exxon Biomedical Sciences Inc, NJ, USA.
9. Plaza, M.E. 1995, *Repeated Insult Patch Test (Modified Draize Procedure) for EC 328860A-1*, Project no., 95-1607-70, Hill Top Research Inc, OH, USA.
10. Organisation for Economic Co-operation and Development 1995-1996, *OECD Guidelines for the Testing of Chemicals on CD-Rom*, OECD, Paris.
11. 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.
12. Freeman, J.J. 1996, *Microbial Mutagenesis in Salmonella Microsome Plate Incorporation Assay*, Project no., 114407, Exxon Biomedical Sciences Inc, NJ, USA.
13. Maron, D.M. & Ames, B.N. 1983, 'Revised Methods for *Salmonella* Mutagenicity Test', *Mutation Research*, vol. 113, pp. 173-215.

14. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australian Government Publishing Service, Canberra.
15. Standards Australia 1994, *Australian Standard 1336-1994, Eye protection in the Industrial Environment*, Standards Association of Australia, Sydney.
16. Standards Australia/Standards New Zealand 1992, *Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.
17. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing*, Standards Association of Australia, Sydney.
18. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves)*, Standards Association of Australia, Sydney.
19. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear*, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.
20. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*, Australian Government Publishing Service, Canberra.

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 |