

File No: NA/593

November 1998

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION  
AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**Parabar 9443**

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Director  
Chemicals Notification and Assessment

**FULL PUBLIC REPORT****Parabar 9443****1. APPLICANT**

Exxon Chemical Australia Ltd of 12 Riverside Quay SOUTHBANK VIC 3006 has submitted a standard notification statement in support of their application for an assessment certificate for Parabar 9443.

**2. IDENTITY OF THE CHEMICAL**

**Trade Name:** Parabar 9443

**Molecular Weight:** the average molecular weight of the new chemical is greater than 500

**Spectral Data:** ultraviolet-visible (UV/Vis) and Nuclear Magnetic Resonance (NMR) absorption spectra and infrared (IR) spectra were provided for Parabar 9443

**3. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance at 20°C and 101.3 kPa:** amber coloured liquid at 20°C

**Boiling Point:** initial 311.9°C; final 778.7°C.

**Density:** 969.3 kg/m<sup>3</sup>

**Vapour Pressure:** 3.6 x10<sup>-5</sup> kPa at 20°C

**Water Solubility:** 0.61 mg/L at 20°C

**Partition Co-efficient (n-octanol/water):** log P<sub>ow</sub> > 6

**Hydrolysis as a Function of pH:**

hydrolysis of Parabar 9443 has not been determined as it does not contain hydrolysable functional groups and is poorly soluble in water

**Adsorption/Desorption:**

no quantitative determination of adsorption of the notified chemical could be made as the screening tests were inconclusive due to interference with the analytical method used

**Dissociation Constant:**

the notified chemical was determined not to have an observable dissociation

**Flash Point:**

220°C

**Flammability Limits:**

not determined; Upper Limit = 5.0% and Lower Limit = 1.0% (both values as for the diluent oil)

**Autoignition Temperature:**

340°C (as for the diluent oil)

**Explosive Properties:**

none indicated by the molecular structure

**Reactivity/Stability:**

Parabar 9443 is a stable viscous liquid at room temperature; does not degrade or decompose; hazardous polymerisation will not occur; should be stored away from strong oxidising agents

**Comments on Physico-Chemical Properties**

Tests were performed according to EEC/OECD test guidelines 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 concentration in water. The results show that the aqueous concentrations had reached equilibrium by day five. Additionally, *Environment Australia* noted during the test that the pH of the solution decreased by 2.36 pH units. The notifier attributed this pH change to the presence of the C18 succinic acid impurity, which is a byproduct of the chemical reaction used to manufacture the notified chemical.

Hydrolysis was not determined. The notifier claims that the notified substance appears not to contain any hydrolysable functional groups and is poorly soluble in water. *Environment Australia* agrees that the notified chemical is not likely to undergo hydrolysis in the environmental pH range (4-9).

The partition coefficient was investigated using HPLC. Under conditions where reference samples with  $K_{OW}$  ranging from 0.3 to 6.2 were eluted, the test material was not. The experimental conditions were changed and the test material eluted as three discrete components after the reference standard with a log  $K_{OW}$  of 6.2. The notifier identified the minor components as isomerised olefins and C18 succinic acid (noted above). Hence, the log  $K_{OW}$  of the notified chemical and the impurities are greater than 6.

An attempt to characterise the adsorption/desorption properties of the chemical was made, according to OECD TG 106. This was unsuccessful as the low water solubility of the chemical prevented quantification of the results. The low water solubility and high partition coefficient indicate that the chemical would be expected to bind strongly to soils and sediments.

The notified chemical contains a secondary amine which would be expected to display typical basicity. However this is not observed due to the low water solubility of the chemical.

#### **4. PURITY OF THE CHEMICAL**

**Degree of Purity:** > 90%

#### **Toxic or Hazardous**

**Impurities:** none

**Non Hazardous Impurities:** < 10%

#### **5. USE, VOLUME AND FORMULATION**

Parabar 9443 will not be manufactured in Australia. The notified chemical will be imported as a component of a lubricant additive package to impart improved antiwear properties to automatic transmission fluids. The notified chemical will be present at a concentration of 2 to 5% in the finished lubricant. Over the next five years the annual import volume is estimated to be 25 to 125 tonnes Parabar 9443. If sales exceed predicted volumes, imports may rise to 50 to 250 tonnes per annum.

#### **6. OCCUPATIONAL EXPOSURE**

Parabar 9443 will be imported in 205 L containers as a component of an oil additive package at a concentration of 10 to 50%. Four workers will be involved in unloading the additive blend at the port for storage and road transport. It is anticipated that there will be

approximately 12 truck deliveries per year of the bulk additive blend to commercial customer blending facilities. Lubricant processors at customer facilities will blend the additive containing the notified chemical with mineral oil and other additives in 250 to 25 000 L batches. During blending, the additive container is connected by an operator to the transfer system via a flexible transfer hose. Additive is then pumped to the blend tank. On completion the hose, pipeline and pump are cleaned of additive by flushing with mineral oil. All transfer and blending operations are automated. Typically 4 workers will be involved in this process. Dermal and ocular exposure could occur during connection of hoses and during maintenance work on containers and pumps. The final concentration of Parabar 9443 is estimated at 2 to 5% weight of the blended lubricant. Mixed lubricant is finally dispensed automatically into consumer sized, screw top sealed containers, ranging from 2 to 200 L. The finished product is sold and transported in these containers to retail outlets, vehicle fleet operators and industrial users throughout Australia.

The notifier states that exposure will be minimal during blending and transport operations due to the use of contained liquid handling systems.

## **7. PUBLIC EXPOSURE**

The blending processes are automated with minimal leakage. Slight losses during the connection/disconnection of transfer hoses would be collected and recycled or disposed of according to government regulations. As the notified chemical is not volatile, air contamination is unlikely. Public exposure from transport or formulation is expected to be negligible.

Transmission fluids are available to the public for do-it-yourself car services, and thus dermal or ocular exposure may occur when changing transmission fluid. However, transmission fluid is not frequently changed and in some vehicles transmission oil is effective for the life of the vehicle, and public exposure from do-it-yourself transmission oil changes is not anticipated to be infrequent. When transmission oil is contained in the enclosed transmission system, there will be little public contact.

Minimal amount will be disposed of during reformulation. The majority of the notified chemical will be disposed of with the used oils. The notifier estimated that over 80% of the used transmission fluid would be disposed of by recycling, burning or refining according to government regulations. Should an accidental spill occur, public exposure would be minimised by the accidental release procedure outlined in the Material Safety Data Sheet (MSDS), ie contained with sand or earth and disposed of according to government disposal regulations.

## **8. ENVIRONMENTAL EXPOSURE**

- **Release**

The notifier expects negligible environmental release of the notified substance during product manufacture. Fugitive emissions during transport and blending are considered negligible by

the notifier due to the very low vapour pressure of the notified substance. If a spillage occurs during blending, 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 carried out in an automated filling line. Leakage from product transfer lines is expected to be minimal, leaks will be 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.

During the activities associated with lubricant production there is little likelihood of release. Processes are conducted in purpose constructed facilities where any spills would be contained, soaked up using earth or sand and sent to an approved industrial facility for appropriate disposal via incineration or landfill. Residuals left in drums are anticipated to be 1.1% of imports (550-2,750 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, losses amount to 0.5% of imports, or between 250 and 1250 kg of the notified chemical per year. In the majority of cases, the filling of transmissions with the product would take place at sites of vehicle production or motor garages. 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.

During end use as a component of automotive transmission oil the material will be contained in an enclosed system, and release is expected to be insignificant. Transmission oils are changed infrequently and the majority of transmission fluid shares the fate of old transmissions and differentials. In most cases, old transmissions would be drained and the recovered oil sent for recycling. The notifier estimates that 80% of cars are serviced at garages and used oil would be either disposed of properly or recycled. The used oil from the remaining 20% of cars not serviced by garages could be disposed of improperly, resulting in the potential release of up to 20% of the notified chemical (50 tonnes per annum at the maximum proposed rate of import) to the environment. The Australian Institute Of Petroleum survey 1995 (1) confirms that 80% of transmission fluids sold are collected. However, any releases would be diffuse and in small quantities (<5% of oil). Additionally, the material is expected to have a strong affinity for organic matter and is likely to be immobilised through association with the organic component of soils and sediments. The 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 TG 301B) indicated only 47% degradation after 29 days.

The notified chemical will be used in automatic 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.

Automatic transmission fluids in the consumer market would generally be replaced by professional mechanics at garages, and not be replaced by the ‘do-it-yourself’ public. Therefore, the majority of used lubricant should be properly collected and disposed of.

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 766 g/mol (2).

## 9. EVALUATION OF TOXICOLOGICAL DATA

### 9.1 Acute Toxicity

#### Summary of the acute toxicity of Parabar 9443

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	rat	LD <sub>50</sub> > 2 000 mg/kg	(3)
acute dermal toxicity	rabbit	LD <sub>50</sub> > 2 000 mg/kg	(5)
skin irritation	rabbit	non irritant	(6)
eye irritation	rabbit	non irritant	(7)
skin sensitisation	guinea pig	mild sensitiser	(8)

#### 9.1.1 Oral Toxicity (3)

<i>Species/strain:</i>	rat/Crl:CD·BR
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	oral intubation
<i>Clinical observations:</i>	none
<i>Mortality:</i>	none
<i>Morphological findings:</i>	one female exhibited raised white areas on the glandular mucosa of the stomach

<i>Test method:</i>	similar to OECD guidelines (4)
<i>LD<sub>50</sub>:</i>	> 2 000 mg/kg
<i>Result:</i>	the notified chemical was of low acute oral toxicity in a limit test in rats

### **9.1.2 Dermal Toxicity (5)**

<i>Species/strain:</i>	rat/Crl:CD <sup>1</sup> BR
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	single dose of 2 000 mg/kg was applied to a clipped area of skin (not less than 10% body surface); covered with gauze patch and secured with plastic sleeve; removed and washed with peanut oil at 24 hours
<i>Clinical observations:</i>	all animals gained weight over the period of the study; no signs of systemic toxicity or skin irritation were seen in any animal
<i>Mortality:</i>	none
<i>Morphological findings:</i>	none
<i>Test method:</i>	similar to OECD guidelines (4)
<i>LD<sub>50</sub>:</i>	> 2 000 mg/kg
<i>Result:</i>	the notified chemical was of low acute dermal toxicity in rats

### **9.1.3 Skin Irritation (6)**

<i>Species/strain:</i>	Rabbits/New Zealand White
<i>Number/sex of animals:</i>	3 females
<i>Observation period:</i>	7 days
<i>Method of administration:</i>	0.5 mL neat dose under gauze patch with semioclusive dressing secured to clipped backs; removed after 4 hours



<i>Test method:</i>	according to OECD guidelines (3)
<i>Observations:</i>	no signs of erythema, edema or any other signs of dermal irritation were noted in any animal at any of the time intervals up to 72 hours
<i>Result:</i>	notified chemical was non-irritant to rabbit skin

#### **9.1.4 Eye Irritation (7)**

<i>Species/strain:</i>	rabbit/New Zealand White
<i>Number/sex of animals:</i>	3 males
<i>Observation period:</i>	72 hours
<i>Method of administration:</i>	0.1 mL of neat dose introduced into lower conjunctival sac of right eye of each animal; left eye served as control.
<i>Test method:</i>	similar to OECD guidelines (3)
<i>Observations (unirrigated eyes):</i>	no signs of erythema, edema or any other signs of ocular irritation were noted at any of the time intervals up to 72 hours
<i>Result:</i>	The notified chemical was non-irritant to rabbit eye

#### **9.1.5 Skin Sensitisation (8)**

<i>Species/strain:</i>	Guinea pig/Hartley albino
<i>Number of animals:</i>	40 females (20 test and 20 controls)
<i>Induction procedure:</i>	<p>Day 1: 3 pairs of intradermal injections:</p> <ul style="list-style-type: none"> <li>0.1 mL Freund's complete adjuvant</li> <li>0.1 mL FCA: water 1:1 (v/v)</li> <li>0.1 mL of 5% concentration of the notified chemical in peanut oil</li> <li>0.1 mL of 5% concentration of the notified chemical in FCA: distilled water (1:1 (v/v))</li> </ul> <p>Day 7: occluded application of the filter paper soaked in 0.4 mL of undiluted test material for 48 hours</p>

*Challenge procedure:* Day 21: 0.4 mL of undiluted test material was applied to previously clipped right flank by Hilltop Chamber secured by Elastoplast; chamber was removed at 6 hours and remnant Parabar 9443 was removed with peanut oil after an additional 21 hours; day 28 rechallenged to left flank as above

*Challenge and Rechallenge outcome:*

<b>Challenge/ Rechallenge Concentration</b>	<b>Test animals</b>		<b>Control animals</b>	
	<b>24 hours*</b>	<b>48 hours*</b>	<b>24 hours</b>	<b>48 hours</b>
23 day 100%	12/20**	3/20	3/20	1/20
30 day 100%	3/20	0/20	2/20	1/20

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

*Test method:* Similar to OECD guidelines (3)

*Result:* The notified chemical was a mild sensitiser to the skin of guinea pigs

## **9.2 Repeated Dose Toxicity**

### **9.2.1 Repeated Dose Oral Toxicity (9)**

*Species/strain:* Rats/Crl:CD.BR

*Number/sex of animals:* 5/sex for 5 groups (1 control, 3 treated groups plus a high dose group with a 14 day recovery period)

*Method of administration:* Gavage daily at a dose volume of 5.0 mL/kg

*Dose/Study duration:* 100, 300, 1 000 mg/kg for a minimum of 6 hours per day for 28 days

*Clinical observations:* no changes in body weight, food consumption or other adverse signs

*Clinical chemistry/Haematology:* no changes in haematology, serum chemistry, or clotting factors

*Histopathology:* nil

*Test method:* similar to OECD guidelines (3)

*Result:* no treatment related organ toxicity following repeat oral dosing for 28 days at dose levels of up to 1 000 mg/kg in the rat

### 9.2.2 Repeated Dose Dermal Toxicity (10)

*Species/strain:* rats/Crl:CD.BR

*Number/sex of animals:* 5/sex for 5 groups (1 control, 3 treated groups, plus a high dose group with a 14 day recovery period)

*Method of administration:* topical on clipped skin applied on gauze and covered with a plastic wrap

*Dose/Study duration:* 100, 300, 1 000 mg/kg for a minimum of 6 hours per day for 28 days

*Clinical observations:* no changes in body weight, food consumption or other adverse signs

*Clinical chemistry/Haematology:* no changes in haematology, serum chemistry, or clotting factors

*Histopathology:* nil

*Test method:* similar to OECD guidelines (3)

*Result:* no treatment related toxicity following repeat dermal dosing for 28 days at dose levels of up to 1 000 mg/kg in the rat

## 9.3 Genotoxicity

### 9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (11)

*Strains:* TA 98, TA 100, TA 1535, TA 1537, TA 1538

*Concentration range:* 50, 100, 500, 1 000 and 5 000 µg.plate<sup>-1</sup>

*Test method:* similar to OECD guidelines (3)

*Result:* the notified chemical was not considered to be mutagenic in the bacterial strains tested in either the presence or absence of metabolic activation provided by rat liver S9 fraction

### 9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (12)

<i>Species/strain:</i>	mice/CD-1
<i>Number and sex of animals:</i>	5/sex
<i>Doses:</i>	500, 1 000, 2 000 mg/kg
<i>Method of administration:</i>	oral gavage; 3 treatments 24 hours apart
<i>Test method:</i>	similar to OECD guidelines (3)
<i>Result:</i>	no increase in micronucleated polychromatic erythrocytes occurred and no cytotoxicity was induced

### 9.4 Chromosomal Aberration Assay in Chinese Hamster Ovary Cells (13)

<i>Clone:</i>	Chinese Hamster Ovary cells
<i>Doses:</i>	10, 20, 39, 78, 156, 313, 625, 1 250 and 2 500 $\mu\text{g}\cdot\text{mL}^{-1}$ final concentration diluted in acetone (up to precipitation limit in media) for 16 hours with or without S9 mix
<i>Test method:</i>	according to OECD guidelines (3)
<i>Result:</i>	Parabar 9443 did not induce structural chromosomal aberrations in Chinese Hamster Ovary Cells, in either the presence or absence of metabolic activation

### 9.5 Overall Assessment of Toxicological Data

Parabar 9443 shows low acute oral and dermal toxicity in rats with the respective LD<sub>50</sub> values of > 2 000 mg/kg for both routes of administration. The notified chemical was not a skin or eye irritant in rabbits.

Parabar 9443 was a mild skin sensitiser in guinea pigs. Parabar 9443 in repeat dose oral and dermal toxicity studies in rats did not induce treatment related toxicity.

No mutagenicity was observed in bacteria and no increase in micronuclei occurred in mouse bone marrow cells. Similarly no clastogenicity was observed in Chinese Hamster Ovary Cells *in vitro*.

Based on the animal studies summarised above, Parabar 9443 would not be classified as hazardous according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (14).

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out according to OECD Test Methods.

<i>Species</i>	<i>Test</i>	<i>Concentrations (mg/L)</i>	<i>Result (mg/L)</i>	<i>Reference</i>
Rainbow trout ( <i>Oncorhynchus mykiss</i> )	96 h semi static acute	0, 1 000 <sup>a</sup>	LL <sub>50</sub> <sup>b</sup> > 1 000	(15)
Water Flea ( <i>Daphnia magna</i> )	48 h static acute	0, 62.5, 125, 250, 500, 1 000 <sup>a</sup>	EL50 <sup>c</sup> > 1 000	(16)
Algae ( <i>Selenastrum capricornutum</i> )	72 h growth	0, 1 000 <sup>a</sup>	EL <sub>50</sub> <sup>c</sup> > 1 000	(17)
Activated sludge	30 min respiration inhibition	0, 1, 5, 10, 25, 50	EC <sub>50</sub> > 50	(18)

<sup>a</sup>Amount of test substance used (or loading level) to prepare the water accommodated fraction (WAF) used in testing. <sup>b</sup>Lethal Loading causing 50% mortality. <sup>c</sup>Loading causing 50% effect in test organism.

The fish study was conducted as a limit test. The total organic carbon (TOC) was measured in the WAF at a loading level of 1 000 mg/L after 24 and 48 h of stirring, in a preliminary study. TOC levels of 0.18 and 0.19 mg/L were found after 24 and 48 h, respectively. Fish were exposed to the WAF at a loading level of 1 000 mg/L. In preparing the WAF, the mixture of chemical and water was stirred for 24 h and left to stand for approximately one hour before separating the WAF. No mortalities or sublethal effects were observed during the test.

The WAFs in the daphnia study were prepared using the same equilibration and settling times as in the fish study. After 48 h, 5% and 15% immobility was observed for loading levels of 500 and 1 000, respectively. No other observations were made.

As with the fish study, the algal study was conducted as a limit test. There were no effects observed at the 1 000 mg/L loading on the growth (area under the growth curve) and average specific growth rate compared to controls.

No appreciable inhibition was observed during the 30 minute activated sludge respiration inhibition test.

The ecotoxicity data for the notified chemical indicate that is not toxic to aquatic organisms up to the limit of its solubility. The notified chemical did not inhibit the respiration of the activated sludge at levels up to 50 mg/L.

## **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 transmission filling are performed under well controlled conditions. 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 the production of non hazardous gases

## **12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS**

Parabar 9443 has low acute oral and dermal toxicity and is not an eye irritant or a skin irritant. There was no systemic toxicity following repeat-dose oral and dermal studies in experimental animals. Parabar 9443 is a mild skin sensitiser. Genotoxicity studies were negative. Parabar 9443 cannot be determined to be hazardous substance according to NOHSC Approved Criteria, on the basis of the toxicity studies provided.

Parabar 9443 will be imported as a component (10% to 50%) of an imported lubricant oil additive. There should be no exposure to the chemical in pure form. In the event of an accident, transport workers would be exposed to Parabar 9443 in the oil additive mixture. The new chemical has a molecular weight in excess of 500 and low volatility, and is therefore unlikely to be absorbed across biological membranes such as the skin or to be inhaled in the event of a spill.

Since the delivery, blending and dispensing processes used in reformulation are automated and enclosed, worker exposure to Parabar 9443 should be low. Exposure could occur during connection of hoses and during maintenance work on containers, pumps and connections. Exposure would be controlled because the connections are flushed with mineral oil on completion of transfers. Data from acute and repeat dose toxicity studies and irritation studies indicate a low risk of systemic or irritant topical effects in workers.

The notified chemical is a skin sensitiser and this is a risk to workers who may become contaminated with the notified chemical. Therefore workers should wear personal protective equipment when handling the chemical.

Employers and workers should be aware that the notified chemical will be blended with mineral oil and other additives that may have adverse health effects, and need to take preventive measures to minimise exposure.

Public exposure may occur through the dermal or ocular route when changing transmission fluids, but the exposure will be infrequent. The notified chemical has low acute and repeat dose toxicity. The undiluted chemical was shown to be a weak skin sensitiser in guinea pigs, but the skin sensitisation potential would be highly reduced at less than or equal to 5% in transmission oils. The proposed use is not expected to present a significant health hazard to the public.

### **13. RECOMMENDATIONS**

To minimise occupational exposure to Parabar 9443 the following guidelines and precautions should be observed:

- Industrial clothing should conform to the specifications detailed in AS 2919 (19) and AS 3765.1 (20);
- Impermeable gloves or mittens should conform to AS 2161 (21);
- All occupational footwear should conform to AS/NZS 2210 (22);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should 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) for the product should be easily accessible to employees.

Worker exposure to mineral oil and other oil additives should be controlled by the wearing of appropriate personal protective equipment as detailed in the MSDS.

### **14. MATERIAL SAFETY DATA SHEET**

The MSDS for the imported product containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (23).

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

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## Attachment 1

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

<b>Erythema Formation</b>	<b>Rating</b>	<b>Oedema Formation</b>	<b>Rating</b>
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**

<b>Opacity</b>	<b>Rating</b>	<b>Area of Cornea involved</b>	<b>Rating</b>
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**

<b>Redness</b>	<b>Rating</b>	<b>Chemosis</b>	<b>Rating</b>	<b>Discharge</b>	<b>Rating</b>
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**

<b>Values</b>	<b>Rating</b>
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