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### NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

### **FULL PUBLIC REPORT**

### *Callitris intratropica* Oil

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Director Chemicals Notification and Assessment

## FULL PUBLIC REPORT

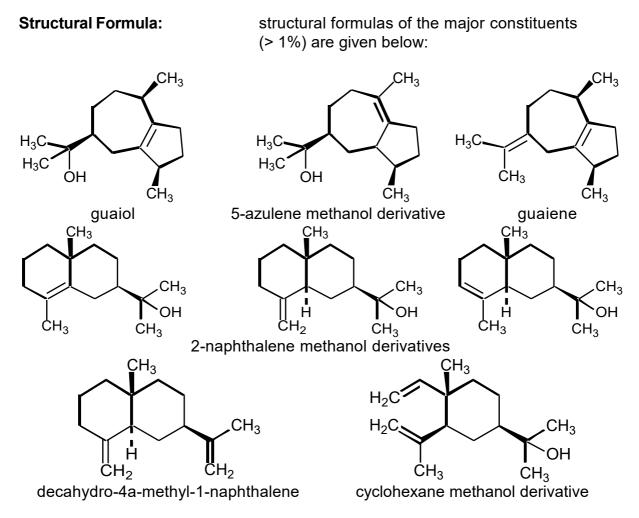
## Callitris intratropica Oil

### 1. APPLICANT

Blue Cypress Holdings of Suite 1/21 Cavenagh Street DARWIN NT 0801 has submitted a standard notification statement in support of their application for an assessment certificate for *Callitris intratropica* Oil. The notifier has not applied for any information to be exempted from publication, hence the data is presented here in its entirety

### 2. IDENTITY OF THE CHEMICAL

Chemical Name:	Oils, Callitris intratropica
Chemical Abstracts Service (CAS) Registry No.:	187348-13-6
Other Names:	Northern Cypress Pine Oil
Trade Name:	Blue Cypress Essential Oil, <i>Callitris intratropica</i> Essential Oil
Molecular Formula:	UVCB, not possible to provide
Molecular Weight:	the chemical is an oil, consisting of a number of major or minor constituents; thus, a specific molecular weight cannot be determined
Method of Detection and Determination:	gas chromatography-mass spectroscopy (GC- MS) semiquantitative analysis, gas chromatography-infrared spectroscopy (GC-IR)
Spectral Data:	GC-MS identifies constituent components of oil; GC-IR, a number of peaks identified between 1 113 and 2 352 cm <sup>-1</sup>



## Weight Percentage of ingredients:

Chemical Name	CAS No.	Weight %
5-azulene methanol derivative	22451-73-6	8.0
cyclohexane methanol derivative	639-99-6	1.5
decahydro-4a-methyl-1-naphthalene	17066-67-0	5.0
elemene	11029-06-4	1.0
guaiene	88-84-6	4.0
guaiol	489-86-1	30.0
2-naphthalene methanol derivatives	1209-71-8	17.0
	473-15-4	
	473-16-5	

### Minor constituents identified by GC-MS at < 1%:

Chemical name	CAS No.
menthol	1490-04-6
terpinol	98-55-5
linalyl ester	7149-26-0
azulene	275-51-4

### 3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	blue-green viscous oil with an aromatic, woody odour
Boiling Point:	122-288°C (boiling point range of constituents)
Specific Gravity:	0.890 - 0.9228 (specific gravity range of constituents)
Vapour Pressure:	not determined; however many of the constituents have a high vapour pressure
Water Solubility:	not determined; the notifier claims that the oil is practically insoluble
Partition Co-efficient (n-octanol/water):	not determined
Hydrolysis as a Function of pH:	not determined
Adsorption/Desorption:	not determined
Dissociation Constant:	not determined
Flash Point:	74°C
Flammability Limits:	see below
Autoignition Temperature:	not determined
Explosive Properties:	combustable but not known to be explosive
Reactivity/Stability:	no oxidising properties or incompatabilities known

## **Comments on Physico-Chemical Properties**

The notified oil is extracted from *Callitris intratropica* pine. It consists of a mixture of around 190 constituents. The oil contains 8 major constituents (>1%, see above) which are closely related in structure. These can be further divided into two subgroups; the alcohols (56.5% of the oil) and the alkenes (10% of the oil). In the following discussion the properties of these classes will be considered based on the properties of guaiol and guaiene, respectively.

The range presented for the boiling point of the oil represents the maximum and minimum boiling points of the pure major constituents. This simplified approach

ignores the intermolecular forces within the oil which would be expected to give rise to boiling point elevations. The boiling points of guaiol and guaiene are 288°C {Merck, 1996 #89} and 271°C {US EPA, 1997 #100}, respectively.

The range given for the specific gravity also represents the maximum and minimum specific gravities of the pure major constituents. The true value of the specific gravity of the oil will most likely lie within this range.

The vapour pressure of the oil has not been determined. The notifier has claimed that many of the constituents have a high vapour pressure. However, they did not provide data in support of this claim. Estimation of the vapour pressure for guaiol and guaiene using QSAR calculations gave values of  $1.33 \times 10^{-4}$  {US EPA, 1997 #101} and  $1.21 \times 10^{-3}$  mm Hg {US EPA, 1997 #100}, respectively.

The water solubility of the oil has not been determined. The oil is extracted using steam distillation and separates from the aqueous phase. The predicted partition coefficients of the major constituents are consistent with them having low solubility in water. Estimation of the water for guaiol and guaiene using QSAR calculations gave values of 1.71 {US EPA, 1997 #101} and 1.33 x  $10^{-2}$  mg/L {US EPA, 1997 #100}, respectively.

The hydrolytic decomposition of the oil has not been investigated. The major constituents of the oil do not contain functional groups that will be susceptible to hydrolysis.

The partition coefficient of the oil has not been determined. Calculated partition coefficients (log P) of the major constituents range between 4.8 and 7.0 using the atom/fragment contribution method developed by Syracuse Research Corporation {Syracuse Research Corporation, 1997 #102}. Calculation of Log P using ASTER gave values of 4.52 {US EPA, 1997 #101} and 6.18 {US EPA, 1997 #100} for guaiol and guaiene, respectively.

No data has been provided on the adsorption/desorption behaviour of the notified oil. Calculation of Log  $K_{OC}$  using ASTER gave values of 3.80 {US EPA, 1997 #101} and 4.70 {US EPA, 1997 #100} for guaiol and guaiene, respectively. Hence, the major constituents of the oil are likely to strongly adsorb to soils and sediments.

None of the major constituents contain acidic or basic functional groups which could gain or lose a proton in the pH range 5-9.

Flammability limits are not required for dangerous goods classification if the flash point is above 61°C {Federal Office of Road Safety, 1992 #5}.

## 4. PURITY OF THE CHEMICAL

**Degree of Purity:** 

notifier states that the notified substance is 100% essential oil after separation from water

### Toxic or Hazardous Impurities:

Chemical name: CAS No.: Weight percentage: Toxic properties:	α-pinene 7785-26-4 < 0.05% skin and mucus membrane irritant {Merck, 1996 #89}
Chemical name: Synonyms: CAS No.: Weight percentage:	limonene cinene 138-86-3 < 0.05%
Toxic properties: Non-hazardous Impurities	skin irritant {Merck, 1996 #89; National Occupational Health and Safety Commission, 1994 #10}
(> 1% by weight):	none

Additives/Adjuvants: none

## 5. USE, VOLUME AND FORMULATION

The notified oil is steam distilled from the wood of the *Callitris intratropica* pine and is stated by the notifier to be 100% pure after removal of water. Distillation will occur at one site in the Northern Territory. The oil will be packaged in 20 L polycube plastic containers. The oil will be used in perfumery either by direct addition to cosmetics or by further extraction of constituents for addition. The oil will be produced at the rate exceeding one tonne per annum of which approximately 250 kg will be sold in Australia, the remaining oil will be exported.

## 6. OCCUPATIONAL EXPOSURE

Workers exposed to the concentrated oil include those involved in manufacture (1 worker), packing and handling (1-2 workers), storage (1-2 workers), transport (10-20 workers) and cosmetic formulation (10-20 workers). The notifier states that the greatest chance of worker exposure occurs in the manufacturing stage, as the still and/or condenser or associated pipework may yield fumes of the notified oil. The isolation procedures and engineering controls are such that distillation occurs in an open outdoor location, with the still (on concrete mounting) being surrounded by concrete bunding. All joints and connectors in pipework are well sealed ensuring minimal leakage of steam/oil fumes. Inhalation, dermal and ocular exposure are most likely during this stage of operations. Still operators and

packers will be responsible for with clean-up of leakages/overflows, however the notifier states that a regular maintainence program should should ensure that the equipment operates efficiently, without significant loss or leakage of the oil product. The notifier states coveralls for skin protection will be worn at all times, and that safety glasses and neoprene gloves will be worn during handling of containers containing the notified oil.

Transport and storage workers will only be exposed to the notified oil in the event of accidental spillage.

## 7. PUBLIC EXPOSURE

The manufacturing plant will be located at Howard Springs Pine Plantation, Darwin, Northern Territory. Minimal exposure of the public to the oil is expected as a result of the extraction process. Release of significant quantities of the oil will be readily identifiable due to its fragrance, and commercial considerations will promote minimilisation of loss.

Exposure via the dermal route will be potentially widespread and frequent due to use of the oil in cosmetic products. The extent of public exposure will depend primarily on the commercial success of products containing the notified oil, and the nature of those products.

## 8. ENVIRONMENTAL EXPOSURE

## Release

The oil will be extracted from wood chips by steam at one site in the Northern Territory. The notifier has estimated that up to 1% of the oil could be lost during the steam distillation process. This would correspond to a total of 10 kg per annum (at a production rate of 1 tonne per annum) which will be lost to the atmosphere at a rate of approximately 45 g per day (over 225 days of production). The notifier has also estimated that leakages and spills may account for 0.2% of the oil produced (or 2 kg per annum). This will be recovered by treatment with adsorbent material and fed back into the steam distillation process.

The formulation and packaging of the cosmetics (e.g. after-shave) will take place in a closed system. This will reduce the likelihood of the chemical being released into the environment during routine mixing of formulations and packing of final products. For aftershave, packaging is expected to be in 100-150 mL bottles. Spillages are to be contained and not released to sewer. Spilled material will be collected using approved absorbents and disposed of in approved landfills. Should a spillage of the notified oil occur, a maximum of 20 L of the chemical would be released into the environment. This will be collected by treatment with adsorbent material, which will either be incinerated or to be disposed of to landfill.

The use of cosmetic products containing the chemical would be widespread but

diffuse as they would be applied in small quantities to the skin. Release to the environment may occur to the sewer (removal of the cosmetic product from the skin by washing), to the atmosphere (evaporation) or to landfill (disposal of residual quantities of the cosmetics within used containers).

## Fate

*Callitris intratropica* oil is initially intended for use in cosmetics (e.g. after shave) and, as such, would be expected to be released to the environment via consumer use through evaporation or washing the residual chemical off the skin and into the sewerage system.

No data for the biodegradation or bioaccumulation of *Callitris intratropica* oil was provided by the notifier. The notifier has presented arguments based on the structures of the identified constituents to suggest that *Callitris intratropica* oil would be targets for xenobiotic metabolism. The identified constituents of the oil are mainly of sesquiterpenes and aryl alcohols, which posses at least one hydroxy group. Hence, *Callitris intratropica* oil would be readily biodegradable. It is agreed that these types of compounds may be biodegradable. This is confirmed using the predictive model for biodegradation developed by Howard *et al.* {Howard, 1992 #103}, which indicates that the major constituents of the oil would readily biodegrade. This model estimates the biodegradability of chemicals using a chemical substructure based approach. The biodegradability of the major constituents is also supported by QSAR calculations using ASTER, which estimates biological oxygen demand (BOD) half-lives of less than 15 days for both guaiol and guaiene.

Level 1 Mackay calculations for guaiol performed using ASTER {US EPA, 1997 #101} indicate that at equilibrium approximately 38%, 36%, 15% and 11% will be partitioned to soil, sediment, water and air, respectively. Similar calculations for guaiene {US EPA, 1997 #100} show approximately 11%, 10%, 0.1% and 79% will be partitioned to soil, sediment, water and air, respectively.

In the sewer, the major alcoholic constituents (structures isomeric with guaiol; ~56%) of *Callitris intratropica* oil are expected to adsorb to sewerage sludge (based on their high predicted partition coefficients, the estimated Log K<sub>OC</sub> and Level 1 Mackay calculations for guaiol {US EPA, 1997 #101}) which will be landfilled or incinerated. In landfill, these alcoholic constituents are not expected to be mobile due to their anticipated low water solubility. Some volatilisation of these constituents would also be expected and it is anticipated that the constituents would be susceptible to biodegradation. Similar behaviour is expected for the major alkene constituents (structures isomeric with guaiene; ~10%), except that volatilisation is expected to be more significant (~80% equilibrates to atmosphere according to level 1 Mackay calculations {US EPA, 1997 #100}).

Incineration would destroy the oil, and create typical decomposition products of water and oxides of carbon.

## 9. EVALUATION OF TOXICOLOGICAL DATA

## 9.1 Acute Toxicity

# Summary of the acute toxicity of Callitris intratropica Oil

Test	Species	Outcome	Reference	
acute oral toxicity	rat	LD <sub>50</sub> > 2 000 mg/kg	{Brook, 1996 #90}	
acute dermal toxicity	rat	LD <sub>50</sub> > 2 000 mg/kg	{Brook, 1996 #91}	
skin irritation	rabbit	moderate irritant	{Brook, 1996 #92}	
*eye irritation	EYTEX	mild irritant	{Pharmatox, 1996 #93}	
skin sensitisation	guinea pig	sensitiser	{Brook, 1996 #94}	

*\*in vitro* predictive method (see text)

# 9.1.1 Oral Toxicity {Brook, 1996 #90}

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5 /sex
Observation period:	14 days
Method of administration:	gavage; 2 000 mg/kg of the test substance was administered in 50% v/v solution in peanut oil
Clinical observations:	Signs of toxicity appeared 1 hour after sample administration; These included piloerection, and slight motodepression; signs disappeared 10 hours after treatment
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD Guidelines for the Testing of Chemicals {Organisation for Economic Co- operation and Development, 1995-1996 #15}
LD <sub>50</sub> :	> 2 000 mg/kg
Result:	the notified oil was of low toxicity to rats when administered orally in a limit test.

# 9.1.2 Dermal Toxicity {Brook, 1996 #91}

Species/strain:	rat/Sprague Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	2 000 mg/kg of notified oil was applied as a 50% v/v peanut oil solution to the shaved dorsal area of each rat; test substance was covered with a gauze patch for 24 hrs; site cleansed with moist gauze and dried
Clinical observations:	no abnormal clinical signs were observed
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines for the Testing of Chemicals {Organisation for Economic Co- operation and Development, 1995-1996 #15}
LD <sub>50</sub> :	> 2 000 mg/kg
Result:	the notified oil was of low toxicity to rats when administered dermally in a limit test

# 9.1.3 Skin Irritation (Brook, 1996 #92)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/female
Observation period:	14 days
Method of administration:	0.5 mL of the test sample was applied to a gauze patch and adhered to the dorsal area of the trunk of the animal as a semi-occlusive dressing; observations were made at 1 hour, 24, 48 and 72 hours 7 and 14 days after the removal of the patch and scored according to the method of Draize {Draize, 1959 #4}

### Draize scores

Time after		Animal #				
treatment	1 hr	24hr	48 hr	72 hr	7 days	14 days
Erythema						
1	2	3	3	3	2	0
2	2	2	2	2	0	0
3	2	3	3	2	0	0
Oedema						
1	0	4	4	2	0	0
2	0	0	0	0	0	0
3	0	2	3	2	0	0
<sup>a</sup> see Attachment 1 for Draize scales						

Test method:similar to OECD guidelines {Organisation for<br/>Economic Co-operation and Development,<br/>1995-1996 #15}Result:Blue Cypress oil is a skin irritant; effects<br/>diminish after 7 days, with no irritancy after 14<br/>days

## 9.1.4 Eye Irritation {Pharmatox, 1996 #93}

The notifier has submitted results of an EYTEX bioassay {Gordon, 1989a #98} which was used to assess the potential irritancy of the test material. The bioassay consists of a highly organised protein matrix that undergoes conformation and hydration changes when tested with a test material which is an eye irritant. These changes are considered relevant to *in vivo* irritation, as the disturbance of protein conformation and hydration have been identified as components of corneal injury and ocular irritation. Changes in turbidity of the EYTEX reagent have limited correlation with expected Draize scores.

Assay	EYTEX Upright Membrane Assay (UMA)
Doses:	30 μL, 50 μL, 100 μL
Test Method:	SOP No. CB 199 (EYTEX <sup>TM</sup> Test Procedure)

30 μL 8.55	
50 μL 11.65	
100 μL 11.99	

Result:

Blue Cypress oil was found to be a minimal to mild eye irritant in this assay

# 9.1.6 Skin Sensitisation {Brook, 1996 #94}

Species/strain:	guinea pig/Dunkin Hartley
Number of animals:	10/sex
Induction procedure:	Day 1: 0.5 ml of neat test sample was applied on a patch to the abraded skin of the animal's right flank and occluded for 6 hours; a total of six induction applications were made, 2/week for three consecutive weeks
Challenge procedure:	12 days after the last induction procedure, 0.5 ml of the test sample was applied as a patch to the animal's left flank, and occluded for 6 hours; skin reactions were recorded 24 and 48 hours after patch removal

Challenge outcome:

o	Test a	Test animals		animals
Challenge concentratio n	24 hours*	48 hours*	24 hours	48 hours
100%	15**/20	6/20	1/10	0/10
<ul> <li>time after patch</li> <li>number of anim</li> </ul>	removal als exhibiting pos	sitive response		
Test method:		Buehler Test, si testing of chem Economic Co-o 1995-1996 #15	icals {Organisat peration and De	ion for
Result:		Blue Cypress o to the skin of 40		

guinea pigs

## 9.2 Repeated Dose Toxicity

not determined

### 9.3 Genotoxicity

# 9.3.1 Salmonella typhimurium Reverse Mutation Assay {Bonin, 1996 #106}

Strains:	TA100, TA98, TA1535 and TA1537
Concentration range:	$1\mu$ g/plate - 316 $\mu$ g/plate (low solubility)
Test method:	similar to OECD guidelines for testing animals {Organisation for Economic Co- operation and Development, 1995-1996 #15}
Comments:	Blue Cyprus oil was toxic towards the tester strain TA 100 at 316 $\mu$ g/plate with evidence of precipitation occurring; no revertant colonies were observed for the tester strains examined over the given concentration range.
Results	the substance can be considered non- mutagenic to bacteria at the dose levels tested

## 9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse {Bonin, 1997 #104}

Species/strain:	mouse/B6C3F1
Number and sex of animals:	35/sex
Doses:	1 000 mg/kg
Method of administration:	intraperitoneal injection
Test method:	similar to OECD Guidelines for Testing of Chemicals {Organisation for Economic Co- operation and Development, 1995-1996 #15}
Result:	at the established maximum tolerable dose of 1 000 mg/kg, Blue Cypress oil was non- clastogenic in the assay

### 9.4 Overall Assessment of Toxicological Data

The notified oil has a low acute oral and dermal toxicity in rats with respective  $LD_{50}$  values exceeding 2 000 mg/kg.

A skin irritation study using rabbits showed that the notified oil is a moderate irritant to the skin. Erythema and oedema were observed during the initial 72 hour period. By day 7, there was no evidence of oedema in any of the animals. Erythema disappeared in 2 of the 3 rabbits by day 7, with the erythema in the third animal non-existent at day 14. In an alternative *in vitro* EYTEX test the notified oil was considered to have the potential to be a mild eye irritant. As the exact correlation between EYTEX and the rabbit Draize test has not been recognised, a cautionary approach would be to consider the chemical likely to be at least a mild eye irritant.

In a guinea pig sensitisation study (Beuhler method), the notified oil was shown to be a skin sensitiser.

The notified oil did not induce the appropriate-fold increases in revertants per plate, and hence is considered to be non-mutagenic under the conditions of the assay. The notified oil was considered non-clastogenic in the mouse micronucleus assay.

On the basis of submitted data the notified oil would be classified as hazardous in relation to skin irritation and skin sensitisation effects according to approved criteria.

### 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Data on the ecotoxicity of *Callitris intratropica* oil have not been provided by the notifier, although they are required by the Act.

The notifier is unable to locate any data on individual constituents and has provided arguments based on the complex makeup of the oil (~190 constituents) its high volatility and low water solubility. It is acknowledged that testing volatile insoluble mixtures presents difficulties {ECETOC, 1996 #105}. However, such tests are routinely carried out, and ecotoxicity results for fish, daphnia and algae would be required should significant exposure of the aquatic compartment be expected, as may be anticipated for consumer products such as detergents or disinfectants.

Acute toxicity data for guaiol calculated using QSAR calculations by {US EPA, 1997 #101} are given in the table:

Species	LC₅₀ mg/L
bluegill sunfish	1.8
(Lepomis macrochirus)	
fathead minnow	2.1
(Pimephales	
promelas)	
channel catfish	0.9
(Ictalurus punctatus)	
rainbow trout	0.8
(Oncorhynchus	
mykiss)	
Daphnia magna	1.3

The above data indicates that guaiol has moderate to high toxicity to fish and *Daphnia magna*.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard posed by the end use of the oil in cosmetic products appears to be small. It will be incorporated at a small percentage in a range of cosmetic products the use of which is expected to be widespread across Australia. Release of the notified oil to the environment may occur as a result of formulation and use of the cosmetic products in which it is used.

As a worst case, an environmental concentration of 0.25 ppb is predicted if all of the imported chemical remains suspended in sewage waters (assuming: 250 kg maximum annual use in Australia, an Australian population of 18 million and a daily per capita waste water discharge of 150 L). However, most is expected to adsorb to sewerage sludge which will be landfilled or incinerated. In landfill the substance is not expected to be mobile due to its low water solubility. Some volatilisation of the constituents would also be expected (particularly for the major alkene constituents) and it is anticipated that the constituents would be susceptible to biodegradation. Hence, little exposure to natural waterways is expected.

Hence, the overall environmental hazard of the chemical can be rated as negligible when used in cosmetics. However, this would need to be reassessed if proposed for use in "down-the-drain" products (e.g. detergents or disinfectants) at a later date.

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

Potential for worker exposure to the notified oil is expected to be greatest during distillation of the oil and subsequent transferral to 20 L drums. Considering the aromatic nature of the oil, inhalation exposure is likely, however this will be minimised by the outdoor location of the still. Depending on the maintainence levels on the still, it is possible that fumes of the oil may cause eye irritation in workers. Contact with the skin through exposure to mists or spills may lead to irritation or sensitisation. The notifier states that coveralls and neoprene gloves will restrict exposure, however given the tropical climate of the Darwin area, workers may not always adhere to personal protective equipment recommendations. If this was to occur, the occupational risk posed to still workers is likely to be moderate.

Exposure of the public to the notified oil is likely to be widespread and repeated, under which circumstances the primary hazards are the skin sensitisation and skin and eye irritancy potential of the oil. The notifier has indicated that the anticipated concentration of the oil in cosmetics is generally less than 1%. At this concentration, skin and eye irritation are unlikely, however skin sensitisation is possible is some persons. This is particulary the case with persons previously sensitised to related perfume constituents. As the oil is a complex UVCB mixture, the potential for cross sensitivity is significant. Cosmetics containing greater than 1% of the oil should cary appropriate warnings regarding its skin sensitisation and eye irritancy potential.

## 13. RECOMMENDATIONS

To minimise occupational exposure to *Callitris intratropica* Oil 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 oil 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 MSDS should be easily accessible to employees.

The Department of Health and Family Services recommend that products containing greater than 1% of the oil should carry the following warnings:

Sensitive persons may experience allergic reactions. Avoid eye and skin contact.

## 14. MATERIAL SAFETY DATA SHEET

The material safety data sheets (MSDS) for the notified oil 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 oil shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. Ecotoxicity results for fish, daphnia and algae would be required should more significant exposure of the aquatic compartment be expected (e.g. from the use of the oil in consumer products such as disinfectants and detergents which will be released directly into the sewer).

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### Attachment 1

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

Erythema Formation	Rating	<b>Oedema Formation</b>	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	3 severe
	367616	Swelling with lids half-closed to completely closed	4 severe	considerable area around eye	

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