

File No: NA/619

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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION  
AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**Manadaril**

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Director  
Chemicals Notification and Assessment

**FULL PUBLIC REPORT****Manadaril****1. APPLICANT**

Haarman & Reimer (Australia) Pty Ltd of 9 Garling Road KINGS PARK NSW 2148 has submitted a limited notification statement in support of their application for an assessment certificate for Mandaril.

**2. IDENTITY OF THE CHEMICAL**

The following requests for exempt information were accepted: chemical name, CAS No., molecular and structural formulae, constituents, exact molecular weight, spectral data and exact import volume.

**Marketing Name:** Mandaril

**3. PHYSICO-CHEMICAL PROPERTIES**

**Appearance at 20°C  
and 101.3 kPa:** clear colourless viscous liquid with a fruity odour

**Boiling Point:** 292°C (estimated)

**Density:** 852 kg/m<sup>3</sup>

**Vapour Pressure:** 1.27 x 10<sup>-4</sup> kPa at 20°C  
2.46 x 10<sup>-4</sup> kPa at 25°C

**Water Solubility:** 0.75 mg/L

**Partition Co-efficient**

<b>(n-octanol/water):</b>	$\log P_{ow} > 4.3$ at $22.1 \pm 1^\circ\text{C}$		
<b>Hydrolysis as a Function of pH:</b>	<i>pH</i>	<i>T/°C</i>	<i>Result</i>
	4	50	hydrolysis not observed over 13 d
	7	50	hydrolysis not observed over 13 d
	9	50	hydrolysis not observed over 13 d
<b>Adsorption/Desorption:</b>	not determined (see comments below)		
<b>Surface Tension</b>	not determined		
<b>Dissociation Constant:</b>	not determined (see comments below)		
<b>Flash Point:</b>	147°C		
<b>Flammability Limits:</b>	not flammable		
<b>Autoignition Temperature:</b>	275°C		
<b>Explosive Properties:</b>	not explosive		
<b>Reactivity/Stability:</b>	stable at room temperature and does not evolve any flammable gases in contact with water or humid air		

### 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 water solubility for the notified chemical was determined during the ecotoxicity studies.

The partition coefficient was estimated by determining the ratio of the concentrations of the chemical in the octanol and water phases. The equilibration time and the method of determining the chemical concentrations were unspecified in the provided report.

Given the low solubility of the chemical it is expected to have a high partition coefficient.

Based on the low water solubility of the notified chemical and the high partition coefficient the chemical is expected to strongly adsorb to soils and sediments.

The notified chemical contains no dissociable hydrogens or basic functionalities.

## 4. PURITY OF THE CHEMICAL

**Degree of Purity:** nearly 100%

**Toxic or Hazardous**

**Impurities:** none

**Additives/Adjuvants:** none

**5. USE, VOLUME AND FORMULATION**

The notified chemical will not be manufactured in Australia. It will be imported and used as a component in fragrance/perfume oils as a distinct odourant. The fragrant oils containing the notified chemical (0.1% to 10%) are normally used in scented consumer products such as detergents, cleaners, soaps, technical products (lubricants) and household products (furniture polish). The current application of Mandril-containing fragrance oils will be in shampoos and fabric care goods such as fabric conditioners and prewash sprays. The concentration of Mandril in fragrance oil is 0.1% to 10%, with the average typically being 2%. The resulting concentration of mandril in manufactured end-user consumer products is 0.0002% to 2% with the average being typically 0.04%.

It is estimated that less than 1 000 kg per annum of the notified chemical will be imported in the first five years.

**6. OCCUPATIONAL EXPOSURE**

The notified chemical will be imported in 30 L lacquered aluminium containers and transported from the docks by road to the notifiers warehouse. The chemical is normally stored in its original packaging in a cool location. Under these storage conditions, the chemical remains stable for at least one year.

*Transport and Storage*

Exposure of workers to the notified chemical during transport and storage is not expected except in the event of a spill.

*Quality Control*

A routine quality control inspection of the notified chemical (quantity 25g sample) is carried out by one to 2 workers during storage. Details of the procedure were not provided, however the notifier states that there is unlikely to be any significant exposure to the workers'.

*Mixing*

The notifier states there could be dermal exposure to the notified chemical during compounding into fragrance oil. However, there is also the potential for accidental ocular exposure during manual handling of the notified chemical prior to mixing. The pre-mixing process involves manually decanting the notified chemical from drums and weighing. The notified chemical is subsequently transferred automatically to an enclosed mixer together with other ingredients. The mixing site is equipped with local exhaust ventilation to capture aerosols generated during mixing. Five to 6 workers will take up to 2 1/2 hours to complete the process and they will wear chemically resistant (eg PVC) gloves. According to the

notifier the frequency of fragrance oil formulation will depend on customer demand and is estimated to be about 50 times a year. The fragrance oil containing 0.1% to 10% notified chemical is packaged into 60 kg drums for delivery to customers. The notifier has provided no details of the packaging process.

#### *Reformulation*

Very few details are provided on this process. The notifier states that the production of consumer goods with fragrance oil containing the notified chemical is mostly carried out in a fully automated closed systems. However, there could be some exposure pumping the formulation to the mixer and in packaging of the final consumer products (liquid preparations) containing 0.0002% to 2% of the chemical.

## **7. PUBLIC EXPOSURE**

There will be negligible public exposure from transport, storage, reformulation and disposal. Once mixed into the fragrance oil, the notified chemical will be packed into 60 kg drums for dispatch to consumer goods producers for incorporation into 2 sectors of Australian consumer goods namely shampoos and fabric care goods at 0.0002% to 2%. The notifier indicated that the majority (about 98.5%) of the notified chemical will be released through the consumer products to the sewer. A small amount of waste (<1%) from reformulation into fragrance compounds and consumer products is to be disposed of by incineration and the residue in “empty” consumer product containers (0.5% maximum) would probably go to landfill. Accidental spills will be taken up with absorbent materials and then disposed of by incineration if the suggestions in the Material Safety Data Sheet (MSDS) are followed.

The notified chemical, being highly lipophilic and part of an end-user consumer product, is expected to have widespread public exposure through skin absorption. However, inhalation is unlikely to be a major route of exposure due to low vapour pressure (0.00246 hPa) of the notified chemical.

## **8. ENVIRONMENTAL EXPOSURE**

### **Release**

The major release of the chemical to the aquatic environment would be through the end-use products. The notifier estimates 98% of the import volume to be released in this way. Incorporation of the fragrance compounds containing the chemical to consumer goods is done using fully automated closed systems. Therefore, waste from the production processes is not expected to exceed 1% of the import volume (2 kg per annum). This waste is likely to be disposed of largely by incineration.

A further 1% of the import volume (2 kg per annum) is expected to be lost as residues in empty import (0.5%) and consumer product (0.5%) containers that may go mostly to landfill.

## **Fate**

The substance was examined for biodegradation potential using EEC Directive 92/69, Part C.4-D (Manometric Respirometry Test), and OECD Test Guideline 301F. The substance exhibited 79% degradation after 28 days, indicating that it is readily biodegradable under the conditions of the test.

The ready biodegradability suggests the potential for bioaccumulation would be low.

The bulk of the chemical will finally find its way to the sewer. Due to the low water solubility and the high partition coefficient of the chemical, it is expected to adsorb to the sludge. Most will be removed in the sewer, due to the tendency of the chemical to partition to sediment and its ready biodegradability. Small amounts of highly diluted chemical may be carried with the water discharged from the sewer. It will be further diluted after discharge.

In landfill, the chemical will eventually undergo hydrolysis and degradation. Incineration of the chemical will destroy it, yielding water vapour and oxides of carbon and nitrogen.

Level 1 Mackay calculations for the notified substance indicate that at equilibrium approximately 6.1%, 5.7%, 3.9% and 84.3% will be partitioned to soil, sediment, water and air, respectively. The Mackay model assumes an equilibrium is established between all phases. In the environment an equilibrium state will not be reached, as chemical which reaches the atmosphere will be effectively removed from the system (by diffusion into the atmosphere or blown away by wind). Hence, over time the sediment/water and water/air partitioning will be driven toward the loss of the chemical to the atmosphere. In the atmosphere it is likely that the substance will be degraded through reaction with hydroxyl radicals (1) or ozone (2).

## **9. EVALUATION OF TOXICOLOGICAL DATA**

### **9.1 Acute Toxicity**

No toxicity data are required for chemicals which will be imported at volumes of less than 1 tonne per annum, according to the Act. However, the data summarised below were provided by the notifier.

The following evaluation is derived from summaries of Mandarin data provided by the notifier. Full test reports were not requested

## Summary of the acute toxicity of Mandaril

<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	rat	LD <sub>50</sub> > 2 000 mg/kg	(4)
skin irritation	rabbit	slight to moderate irritant	(5)
eye irritation	rabbit	slight eye irritant	(6)
skin sensitisation	guinea pig	not sensitising	(7)

### 9.1.1 Oral Toxicity (3)

<i>Species/strain:</i>	rat/not provided
<i>Number/sex of animals:</i>	not provided
<i>Doses:</i>	not provided
<i>Observation period:</i>	not provided
<i>Method of administration:</i>	gavage
<i>Clinical observations:</i>	not provided
<i>Mortality:</i>	not provided
<i>Morphological findings:</i>	not provided
<i>Test method:</i>	similar to OECD guidelines (8)
<i>LD<sub>50</sub>:</i>	> 2 000 mg/kg
<i>Result:</i>	the notified chemical was of very low acute oral toxicity in rats

### 9.1.2 Dermal Toxicity (4)

<i>Species/strain:</i>	rat/not provided
<i>Number/sex of animals:</i>	not provided
<i>Observation period:</i>	not provided

<i>Method of administration:</i>	not provided
<i>Clinical observations:</i>	not provided
<i>Mortality:</i>	not provided
<i>Morphological findings:</i>	not provided
<i>Test method:</i>	similar to OECD (8) and EC guidelines (9)
<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 Inhalation Toxicity

No inhalation toxicity data were provided by the notifier.

### 9.1.4 Skin Irritation (5)

<i>Species/strain:</i>	rabbit/not determined
<i>Number/sex of animals:</i>	3/not provided
<i>Observation period:</i>	72 hours
<i>Method of administration:</i>	not provided

*Draize scores (10):*

<i>Test material</i>	<i>Erythema/Eschar</i>			<i>Oedema</i>		
	<i>Animals</i>			<i>Animals</i>		
	<i>1</i>	<i>2</i>	<i>3</i>	<i>1</i>	<i>2</i>	<i>3</i>
Undiluted	0.0*	1.0	1.0	0.0	0.0	0.3
50% (v/v)	0.7	1.7	2.0	0.0	1.3	1.3
10% (v/v)	0.0	0.3	0.7	0.0	0.0	0.0
5% (v/v)	0.0	0.0	0.0	0.0	0.0	0.0

\* = average of 24, 48 and 72 hour readings  
see Attachment 1 for Draize scales

<i>Test method:</i>	similar to OECD guidelines (8)
<i>Result:</i>	the notified chemical is a slight to moderate skin irritant in rabbits



### 9.1.5 Eye Irritation (6)

<i>Species/strain:</i>	rabbit/not provided
<i>Number/sex of animals:</i>	3/not provided
<i>Observation period:</i>	72 days
<i>Method of administration:</i>	undiluted; not provided
<i>Draize scores (9) of unirrigated eyes:</i>	slight conjunctival redness was observed in all 3 animals, reversible within 48 hours
<i>Test method:</i>	according to OECD guidelines (8)
<i>Result:</i>	the notified chemical was a slight eye irritant in rabbits

### 9.1.6 Skin Sensitisation (7)

<i>Species/strain:</i>	guinea pig/not provided
<i>Number of animals:</i>	not provided
<i>Induction procedure:</i>	5% (w/v) of notified chemical in arachis oil injected; undiluted chemical for topical application (time not recorded)
<i>Challenge procedure:</i>	occluded application of undiluted notified chemical
<i>Challenge outcome:</i>	no evidence of contact hypersensitivity (details not provided)
<i>Test method:</i>	according to OECD guidelines (8)
<i>Result:</i>	the notified chemical was not a skin sensitiser in albino guinea pigs

### 9.2 Repeated Dose Toxicity (11)

<i>Species/strain:</i>	rat/Wistar
<i>Number/sex of animals:</i>	60/sex (5/sex/dose group and 5/sex/ recovery group )
<i>Method of administration:</i>	gavage; vehicle polyethylene glycol 400

<i>Dose/Study duration::</i>	<p>the test substance was administered daily for a period of 28 days:</p> <p>control: 0 mg/kg/day</p> <p>low dose: 40 mg/kg/day</p> <p>mid dose: 200 mg/kg/day</p> <p>high dose: 1 000 mg/kg/day</p> <p>recovery groups:</p> <p>control: 0 mg/kg/day</p> <p>high dose: 1 000 mg/kg/day</p> <p>all animals were sacrificed at the end of the treatment period</p>
<i>Clinical observations:</i>	not provided
<i>Clinical chemistry/Haematology</i>	not provided
<i>Histopathology:</i>	not provided
<i>Test method:</i>	according to OECD guidelines (4)
<i>Result:</i>	<p>the notifier states clear effects (not described) and mortality were observed at 1 000 mg/kg/day; no treatment-related effects were observed at 200 mg/kg/day; the NOEL is established at 200 mg/kg/day</p>

### 9.3 Genotoxicity

#### 9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (12)

<i>Strains:</i>	<i>Salmonella typhimurium</i> TA 1535, TA 1537 TA 1538, TA 98 and TA 100
<i>Concentration range:</i>	0.0003 – 30 µL/plate (with or without S9 mix)
<i>Test method:</i>	not stated
<i>Result:</i>	the notified chemical was not mutagenic in the bacterial strains tested in the presence or absence of metabolic activation

### 9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (13)

<i>Species/strain:</i>	mouse/NMRI
<i>Number and sex of animals:</i>	not provided
<i>Doses:</i>	24, 48, and 72 hour preparation interval 250, 500 and 1 000 mg/kg
<i>Sacrifice times:</i>	24, 48 and 72 hours
<i>Method of administration:</i>	not provided
<i>Test method:</i>	according to OECD guidelines (4)
<i>Result:</i>	the notified chemical did not induce micronuclei in mouse bone marrow polychromatic erythrocytes

### 9.3.3 Human Repeat Insult Patch Test for Skin Sensitisation (14)

<i>Species:</i>	humans
<i>Number/sex of animals:</i>	81 (sex not specified)
<i>Observation period:</i>	24 hours
<i>Induction procedure:</i>	0.3 mL of a 10% solution of the notified chemical and the vehicle (1:1 ethanol/diethylphthalate) applied on lateral surface of the upper arm three times a week for 24 hours for three weeks
<i>Challenge procedure:</i>	after two weeks occluded application of a 10% solution of the notified chemical on the original and alternate arm for 24 hours
<i>Challenge outcome:</i>	irritant potential of the notified chemical was very low; no reaction to sensitisation seen at challenge
<i>Result:</i>	no evidence for skin sensitisation

## 9.4 Overall Assessment of Toxicological Data

The assessment is based on summaries of toxicity data provided in the submission. The notified chemical was of very low oral toxicity and low dermal toxicity in rats (oral LD<sub>50</sub> > 2 000 mg/kg; dermal LD<sub>50</sub> > 2 000 mg/kg). No inhalation toxicity data were provided by the notifier. The notified chemical was a slight to moderate skin irritant and a slight eye irritant in rabbits. The notified chemical was not a skin sensitiser when tested in guinea pigs. A Human Repeat Insult Patch Test using a 10% solution of the notified chemical showed there was no potential for skin sensitisation and a low potential for irritation in humans.

In a 28-day repeat dose oral study in rats, clear effects, including mortality, were observed at 1 000 mg/kg/day, the highest dose tested. The nature of the effects was not described. Based on the absence of findings at the mid dose, the NOEL was established at 200 mg/kg/day.

The notified chemical was not found to be mutagenic in the bacterial Reverse Mutation Assay in bacteria and did not induce micronuclei in the *in vivo* bone marrow mouse micronucleus assay.

On the basis of the toxicity summaries provided, the notified chemical would not be classified as hazardous according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (15).

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

While not required by the Schedule to the Act, 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<sup>a</sup> (mg/L)</i>	<i>Result (mg/L)</i>	<i>Reference</i>
Rainbow trout (Oncorhynchus mykiss)	96 h acute	0, 0.75	LC <sub>50</sub> > 0.75 NOEC = 0.75	(16)
Water Flea (Daphnia magna)	48 h acute	0, 0.75	EC <sub>50</sub> > 0.75 NOEC = 0.75	(17)
Algae (Selenastrum capricornutum)	72 h growth	0, 0.00075, 0.0015, 0.0075, 0.015, 0.075, 0.15, 0.375, 0.75	ERC <sub>50</sub> = 1.00 EBC <sub>50</sub> = 0.26 NOEC = 0.075	(18)
Activated Sludge	respiration inhibition	100, 1,000, 10,000	EC <sub>50</sub> > 10 000	(19)

<sup>a</sup>Nominal concentrations

No mortality or immobilisation was observed during either the fish or daphnia studies, respectively. The studies were performed at the water solubility limit.

Both the growth rate and the biomass production of the algal species tested were significantly inhibited by concentrations of the chemical above the water solubility of 0.75 mg/L.

During the bacterial study, 17.2% inhibition of respiration was observed at all test concentrations, compared with the control.

The ecotoxicity data for the notified chemical indicate that the chemical is not toxic to fish or daphnia up to the limit of its solubility. It is highly toxic to algae and shows slight inhibition of bacterial respiration at concentrations well above the solubility limit.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Since most of the import volume of the chemical expected to reach the sewer, the notifier has predicted the environmental concentration (PEC) of 0.121 ng/L in surface water. This assumes 25% of the imported chemical is used in Sydney with 1 117 ML of sewerage per day. This agrees with the PEC calculated by Environment Australia for nationwide use:

<b>Import Volume</b>	200 kg
<i>Amount discharged to sewer</i>	100%
<i>Sewer output per day*</i>	2 700 ML
<i>Concentration in Sewage Treatment Plant</i>	0.20 µg/L (ppb)

\*Sewer output based on an Australian population of 18 million, each using 150 L water per day.

These PECs are about three orders of magnitude lower than the toxicity limits of sensitive aquatic organisms.

The sludge containing the chemical after removal from the sewerage treatment plant will either be disposed as landfill or incinerated. In landfill the chemical will remain associated with the soil and undergo slow hydrolysis and degradation. Incineration will destroy the chemical. The moderate volatility of the substance will result in its eventual partitioning to the atmosphere. In the atmosphere it is likely that the substance will be degraded through reaction with hydroxyl radicals (1) or ozone (2).

The environmental hazard from the notified chemical is expected to be low.

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

Based on the toxicological data provided the notified chemical is not expected to exhibit acute or sub chronic toxicity and is not likely to be a skin sensitiser or genotoxic. However, it is likely to be a skin and eye irritant. The Human Repeat Insult Patch Test for skin sensitisation showed no evidence of skin sensitisation potential in humans but a 10% solution of the notified chemical showed a very low irritancy potential. The notified chemical cannot be determined to be a hazardous substance, according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (15).

Exposure of transport and storehouse workers to the notified chemical is likely to occur only in the event of an accident, where the packaging is breached

Exposure of workers involved in the mixing of fragrance oils containing the notified chemical may occur, but is likely to be restricted to the stage of normally pouring and weighing the required amounts of the notified chemical for the mixing batch. Skin exposure and potentially eye contact via splashing, may occur at this point. Workers are to carry out this work on a regular basis (about 50 times per year) however the duration of handling, up to 2.5 hours, is short. Fragrance oil mixing process will involve mainly automated equipment. The main occupational health risk to workers involved in fragrance manufacture during transfer of the pure notified chemical is likely to be skin irritation. This can be minimised by the use of protective gloves and clothing as outlined below. Eye irritation is a potential health risk but ocular exposure is likely to be rare. Inhalation exposure is considered to be negligible because of the very low vapour pressure of the notified chemical and the fact that local exhaust ventilation is in place. Some dermal and (accidental) eye exposure may occur during the packaging of the fragrance oil mixture into 60 kg drums. The highest concentration of the notified chemical present in this mixture is given as 10%. Details on worker controls operating during this stage were not provided, however, according to the information submitted, workers would be wearing at least protective gloves.

The production of consumer goods with fragrance compounds containing the notified chemical is carried out in fully automated closed systems. However, no details with regard to transfer of the fragrance oil mixture or the packaging of the end-consumer products has been provided by the notifier. Fragrance mixtures and consumer products containing the notified chemical is likely to be minimal, since, the approximate concentration of the notified chemical in these products are in the range of 0.0002% to 2% with an average concentration of 0.04%. It would be preferable for workers involved in the formulation of end use products wear at least protective gloves, to protect against the components in the fragrance mixture

The notified chemical will be used in scented consumer products such as shampoos and fabric care goods. Therefore widespread public exposure could occur via the dermal route.

There is no data on dermal absorption, so the worst case of 100% dermal absorption is used in the following estimates of internal dose. Other reference values such as application rates, quantity of products remaining on the skin after use and body weight were adopted from the

*Risk Assessment of Existing Substance: Technical Guidance Document* (Health & Safety Executive, 1994) with slight modification for some parameters.

Shampoo with an average concentration of the notified chemical (0.04%) would result in a systemic exposure of 0.0068 mg/kg/day, based on the following assumptions.

volume used per application = 12 cm<sup>3</sup>  
density of the product = 0.852 g/cm<sup>3</sup> at 25°C  
fraction remaining on the skin after rinsing = 10%  
weight fraction of notified chemical = 0.04% (average)  
dermal absorption = 100%  
frequency of use = once/day, every day  
body weight = 60 kg

Assuming a person cleans his/her own clothes and uses 2 rinse-off products (shampoo and conditioner), the total daily exposure for products containing an average amount of notified chemical would be 0.02 mg/kg/day (ie 3 times 0.0068 mg/kg/day). In a worst case scenario, whereby products contained the maximum amount of notified chemical (2%), the total daily exposure would be 1.02 mg/kg/day, (3 times 0.34 mg/kg/day). In comparison with the NOEL of 200 mg/kg/day established in a 28-day oral gavage study in rats, the above estimated internal doses would represent safety margins of about 9 800 for average content products and 195 for maximal content products.

### 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 (20) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (21);
- Industrial clothing should conform to the specifications detailed in AS 2919 (22);
- Impermeable gloves or mittens should conform to AS 2161 (23);
- All occupational footwear should conform to AS/NZS 2210 (24);
- 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 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* (25).

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