File No: NA/704

8 September 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Hydroxystearyl cetyl ether

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Director
Chemicals Notification and Assessment

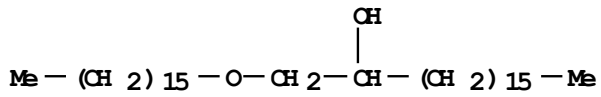
FULL PUBLIC REPORT

Hydroxystearyl cetyl ether

1. APPLICANT

Marigny Australasia Pty Ltd. of 266 Bay Road, Sandringham VICTORIA 3191 has submitted a limited notification statement in support of their application for an assessment certificate for hydroxystearyl cetyl ether. The applicant made no request for exempt information.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	Hydroxystearyl cetyl ether
Chemical Abstracts Service (CAS) Registry No.:	78509-74-7
Other Names:	1-(Hexadecyloxy)-2-octadecanol
Marketing Name:	Chemical in "Mexanyl GY"
Molecular Formula:	$C_{34}H_{70}O_2$
Structural Formula:	
Molecular Weight:	510
Method of Detection and Determination:	Infra red spectroscopy
Spectral Data:	IR peaks approximately at 2925, 2850, 1460, 1125, 1050 & 750 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

The notification statement only included summary information on physicochemical properties. Full study reports were not provided. All physical and chemical properties were determined for the notified chemical (47%) in hexdecanol (53%) (Mexanyl GY).

Appearance at 20°C & 101.3 kPa:	The chemical consists of white flakes with a fatty odour.
Melting Point:	41-66°C
Specific Gravity:	0.3g/cm^3 at 20°C
Vapour Pressure:	3.05 x 10^{-7} kPa at 25°C
Water Solubility:	0.428 mg/L at 25°C ± 5°C
Partition Co-efficient (n-octanol/water):	Log P_{ow} =4.4 at 21°C
Hydrolysis as a Function of pH:	Not Known.
Adsorption/Desorption:	Not Known.
Dissociation Constant:	Not Known.
Flash Point:	Not applicable, as chemical is a solid.
Flammability Limits:	The chemical is non-flammable.
Autoignition Temperature:	Non-autoigniting.
Explosive Properties:	Non-explosive.
Reactivity/Stability:	The product is stable under normal storage, handling and usage conditions.
Surface Activity:	36.5mN/m at 20°C.

3.1 Comments on Physico-Chemical Properties

The notifier has indicated that tests were performed according to European Economic Community (EEC) test guidelines. However, only brief summaries of test reports have been provided.

Water solubility was determined for the commercial product using the shake flask method.

Hydrolysis of the notified chemical is not expected to occur in the environmental pH range due to the lack of functionality considered to be susceptible to hydrolysis.

The notified chemical is unlikely to dissociate due to the expected low water solubility and lack of acid and basic groups.

The notified chemical is expected to sorb moderately to soil, sediments or organic material due to the moderate to low water solubility and high Log Pow.

The notified chemical is expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 mN/m (EEC, 1992).

A search of the ASTER database has provided little information pertaining to physico chemical data.

4. PURITY OF THE CHEMICAL

Degree of Purity: 47% of the notified chemical, with 51-53% 1-hexadecanol

Hazardous Impurities: None Known.

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

Additives/Adjuvants:

Chemical name:	1-hexadecanol
CAS No.:	36653-82-4
Weight percentage:	53%

5. USE, VOLUME AND FORMULATION

The chemical is intended for use as an opacifying agent in hair care products. It will not be manufactured in Australia but imported in flakes as a 47% concentrate in 1-hexadecanol packaged in 25 kg bags. Import volumes are estimated to be approximately 600 kg per annum.

The notified chemical is reformulated in Australia to produce the finished product, a shampoo containing 2.5% Mexanyl GY equivalent to approximately 1.2% of the notified chemical.

6. OCCUPATIONAL EXPOSURE

Transport & Storage

The material is transported in hermetically sealed 25kg bags. No exposure is anticipated during transport except in the event of an accident. One storeman is responsible for delivery receipt and transfer of the bags to the storage area by forklift. The delivery and transfer process is estimated to occupy ½ hour/day over 12 days/year. The storeman is issued with safety glasses, protective clothing, dust masks and gloves, which must be worn.

Sampling & Testing

Sampling of the flakes is undertaken by two laboratory technicians in a segregated quarantine area of the store. Quality control testing of samples is undertaken in the chemical laboratory. The technicians are issued with safety glasses, protective clothing, dust masks, and gloves, which must be worn. The chemical laboratory is equipped with fume hoods to be used if necessary.

Exposure is estimated at ½ hour/day over 12 days/year, and may occur by direct contact or inhalation of, and ocular exposure to dust (if flakes are friable).

Formulation

During formulation of the product up to two compounders handle the chemical. The 25kg bags are emptied into an enclosed steam-jacketed mixing vessel (3000kg) and mechanically mixed with other ingredients at 1.2% to form the finished shampoo. The empty bags are disposed of as hazardous waste. The compounder is supplied with a dust mask, safety goggles, full protective clothing and gloves. The formulating area is well ventilated with dust extractors operating in the dispensary area. The Notifier has not estimated duration of exposure for the formulating process, however exposure would be likely during emptying of the bags and disposal of the empty bags. Exposure may occur by direct contact or inhalation of, and ocular exposure to dust (if flakes are friable).

Packaging of finished product

At the end of formulation the mixing vessel is sealed to prevent contamination. The finished product is transferred to the packaging line where one line setter feeds the product into a filler, which transfers the shampoo to the 250 mL consumer packaging. Safety glasses, protective clothing and gloves are supplied and must be worn. The packaging area is well ventilated.

Duration of exposure during filling is estimated at ½ hour/day over 12 days/year. Dermal and ocular exposure may occur.

Cleaning of vessels

After filling, the empty vessel is returned to the formulating area via the wash bay. A third compounder steam cleans the vessel and stores it for future use. Safety glasses, protective clothing and gloves are supplied and must be worn.

Duration of exposure during washing is estimated at 2 hours/day over 12 days/year. Dermal and ocular exposure to the diluted product may occur.

7. PUBLIC EXPOSURE

Shampoos containing the notified chemical are likely to be applied directly to the hair. Repeated public exposure is expected, in the home and in hairdressing salons. The most likely route of exposure will be dermal, as the notified chemical will be applied to the hair and scalp. Typical daily use of shampoo, 0.5 g of notified chemical to a 60kg person, would result in systemic exposure of 0.83 mg/kg/day, assuming 10% absorption. Ocular exposure will also be possible.

Public exposure to the notified chemical during transport, packaging, industrial use and disposal/recycling is expected to be low.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

It is expected that up to 1% (6 kg/yr) of the notified chemical may be released as spills during storage and transport. Release may also occur during reformulation (spills during transfer and dispensing, quality testing, equipment cleaning). Estimated release during formulation may be up to 5% (30 kg) of the annual import volume. The notifier has indicated that all spills released on site will be diverted to the in-house effluent plant. The effluent treatment process is a batch process involving 10,000 litres per treatment cycle. During this process the alkaline effluent is adjusted to a pH range of 6-10 using 32% (v/v) HCL. Ammonia stripping via aeration/evaporation is another feature of this process. The treated water is then released to the Melbourne South-West Waste Water Treatment Plant.

The notified chemical may also be released as residues in import and end-use containers. The notifier has indicated that approximately 2% (12 kg/annum) of the notified chemical will be released as residues in import containers. These containers will be collected and disposed of by a licensed waste disposal contractor either by incineration or discarded to landfill. The notifier estimates that approximately 1% (6 kg/annum) of the notified chemical will be released as residues in empty end use bottles. These bottles will be disposed of to land fill through domestic garbage services.

It has been stated by the notifier that the end use product (shampoo) containing the notified chemical is likely to be used by an individual every 1-2 days. The majority of release of the notified chemical is expected to occur at this time. Released product is expected to enter the sewers to be treated with the sewage before being released to the environment. The percentage of notified chemical which will be washed off the hair into the sewer is not known. Consequently, a Predicted Environmental Concentration (PEC) estimate has been calculated assuming all of the notified chemical applied to the hair will be washed off.

8.2 Fate

All spills occurring as a result of formulation are collected and treated in the in-house water treatment plant prior to release to the Melbourne South-Eastern Waste Water Treatment Plant.

Biodegradability of the notified chemical was determined using the Closed Bottle Test (301 D, Directive 84/449/EEC). However, test reports were not provided. After 28 days of incubation, the test substance was biodegraded by 31% at a concentration of 2 mg/L. The level of 60% biodegradation was not reached, so the notified chemical cannot be considered to be readily biodegradable. These results must be viewed with caution, as viability of the test organisms was not reported.

The notified chemical in a liquid hair shampoo would be expected to be released to the environment via consumer use through rinsing the chemical off the hair and into the sewerage system. In the sewer, chemical is anticipated to adsorb to sewage sludge due to the low water solubility, high Log P_{ow} and surface-active nature of the chemical. The sludge will either be landfilled or incinerated. Incineration products will include water and oxides of carbon. The remainder will stay in solution, where it is expected to be further diluted and degraded.

The low molecular weight, Log P_{ow} and the low water solubility indicate that the notified chemical has the potential to bioaccumulate (Connell 1990). However, bioaccumulation would be moderated by the inherent biodegradability of the notified chemical.

9. EVALUATION OF TOXICOLOGICAL DATA

Tests were performed according to corresponding EEC and OECD test guidelines at Safepharm Laboratories Ltd, UK. Only summaries of toxicological tests were provided. Full study reports were not provided. The notifier confirmed that toxicological testing was conducted on the product, Mexanyl GY (containing 47% notified chemical and 53% hexadecanol).

9.1 Acute Toxicity

Summary of the acute toxicity of Mexanyl GY

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	>5000 mg/kg	Not provided
acute dermal toxicity	rat	>2000 mg/kg	Not provided
skin irritation	rabbit	Slightly irritating	Not provided
eye irritation	rabbit	Non irritant	Not provided
skin sensitisation	Unknown	Not sensitising	Not provided

9.1.1 Oral Toxicity

Species/strain: Rat/Sprague Dawley (SD)

Number/sex of animals:	5 males & 5 females
Observation period:	No data provided
Method of administration:	Gavage, single dose of 5000 mg/kg ; vehicle, peanut oil.
Test method:	OECD TG 401
Mortality:	Nil
Clinical observations:	Slight decrease in growth during the first week in males, no effect observed on organs.
Morphological findings:	No data provided
Comment:	Limit test only, one dose used.
LD_{50}*:*	>5000 mg/kg
Result:	The test substance was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity

Species/strain:	Rat, strain unspecified
Number/sex of animals:	5 males & 5 females
Observation period:	No data provided
Method of administration:	Direct application of pure product, at 2000 mg/kg.
Test method:	OECD TG 402
Mortality:	Nil
Clinical observations:	None observed, no effects on organs observed
Morphological findings:	No data provided
LD_{50}*:*	>2000 mg/kg
Result:	The test substance was of low dermal toxicity in rats.

9.1.3 Inhalation Toxicity

No studies performed.

9.1.4 Skin Irritation

Species/strain: Rabbit/New Zealand White (NZW)

Number/sex of animals: 3, sex unspecified

Observation period: 72 hours

Method of administration: Direct application of pure product; 4 hour exposure period.

Test method: OECD TG 404

Draize scores:

Time after treatment (hours)	***Animal #***		
	24	***48***	***72***
Erythema			
1	0	0	0
2	0	0	0
3	1	(1)	1
Oedema			
1	0	0	0
2	0	0	0
3	1	(1)	0

[a] see Attachment 1 for Draize scales

Comment: No 60 min observations as required by the Testing Guidelines was recorded

Result: The test substance was slightly irritating to the skin of rabbits.

9.1.5 Eye Irritation

Species/strain: Rabbit/NZW

Number/sex of animals: 3, sex unspecified

Observation period: 72 hours

Method of administration: Not specified

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation		
Animal	***1 day***	***2 days***	***3 days***

Cornea	***o***	***a***	***o***	***a***	***o***	***a***
Mean scores of 3 animals	0	*	0	*	0	*
Iris						
Mean scores of 3 animals	0		0		0	

Conjunctiva	***r***	***c***	***d***	***r***	***C***	***d***	***r***	***c***	***d***
Mean scores of 3 animals	0	0	*	0	0	*	0.3	0	*

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge * = information not provided

Comment: No observation recorded at 60 mins post exposure as required by the Testing Guideline. The observed conjunctival erythaema reversed after 24 Hrs.

Result: The test substance was very slightly irritating to the eyes of rabbits.

9.1.6 Skin Sensitisation

Species/strain: Not specified

Number of animals: 20 in the test group plus 10 controls

Induction procedure: Intradermal induction: 0.1 mL 5% w/v in peanut oil.
Topical induction: 0.5 mL 50% w/w in peanut oil.

Challenge procedure: 25% w/v in peanut oil

Test method: Magnusson-Kligman, Directive 84/449/EEC Appendix B6

Comment: No animals displayed signs of irritation or sensitisation

Result: The test substance was not sensitising at a concentration of 25% w/v.

9.2 Repeated Dose Toxicity – Subacute

Species/strain: Rat/SD

Number/sex of animals: 30 males & 30 females (5 per group)

Method of administration: Gavage in peanut oil

Dose/Study duration: 0; 15; 150 & 1000 mg/kg/day for 28 days, 2 recovery groups at 0 & 1000 mg/kg/day.

Test method: Directive 84/449/EEC B7

Clinical observations
In the groups receiving 1000 mg/kg/day, one death occurred in a male at day 32. In all animals in that group there was an increase in salivation from day 10 which ceased upon cessation of treatment. There was weight loss at day 21 & day 28 in some animals on 1000 mg/kg/day. No pathological signs were observed at 15 and 150 mg/kg/day.

Clinical chemistry/Haematology
No data provided

Histopathology
One female at 1000 mg/kg/day displayed pale kidneys. In the male that died at day 32 numerous anomalies of the liver, spleen, kidneys and lungs were observed.

Comment
A complete report of results was not available to make a comprehensive assessment.

Result
The No-Observed-Effect-Level (NOEL) was 150 mg/kg/day based on clinical observations at the next highest dose.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia Coli* Reverse Mutation Assay

Strains:	*Salmonella typhimurium* strains TA 1535, TA 1537, TA 98, TA 100 & *E. Coli* WP2 uvrA-
Metabolic activation:	System not specified
Concentration range:	Five concentrations in the range 8 - 5000µg/box. Actual amounts not specified; precipitation observed at > 1000 µg/box and toxicity at > 5000 µg/kg
Test method:	OECD TG 471
Comment:	No increase in the number of revertants, with or without metabolic activation. The addition of hexadecanol to the positive and negative controls did not affect the numbers of revertant colonies.
Result:	The notified chemical was non mutagenic under the conditions of the test.

9.3.2 Chromosomal Aberration Assay in Human Lymphocytes *in-vitro*

Cells:	Human lymphocytes
Metabolic activation system:	S9 (details not available)

Metabolic Activation	Experiment/ Study Number	Test concentration (μg/mL)	Controls
-S9		7.8; 15.63; 31.25; 62.50 Cells harvested 4h, 20h & 44h after treatment	Positive: not provided Negative: not provided
+S9		125; 250; 500; 1000	Positive: not provided Negative: not provided

All doses selected for metaphase analysis

Test method: OECD TG 473

Comment: No dose related increase in the frequency of chromosomal aberrations was noted.
Total inhibition of mitosis at > 125 μg/mL without S9
Evidence of haemolysis at 1000 μg/mL with S9

Result: The test substance was non-clastogenic under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

The data presented suggests a substance of very low acute oral (LD_{50} > 5000 mg/kg) and acute dermal (LD_{50} > 2000 mg/kg) toxicity.

The notified chemical was slightly irritating to the skin of rabbits and produced slight signs of conjunctival redness in one animal. This had disappeared by 24 hours; therefore the test substance is determined to be slightly irritating to the rabbit eye.

Skin sensitisation was not demonstrated at a challenge concentration of 25% w/v.

The 28 day repeat dose toxicity test examined four doses between 0 and 1000mg/kg/day given by gavage on a daily basis. A reversibility study at the lowest and highest doses was undertaken at the same time. The study reports one death at day 32 in the male reversibility group administered 1000mg/kg/day. The animal exhibited anomalies of the liver, spleen, kidneys and lungs; it was unclear whether these abnormalities were substance related. One female (group not specified), receiving 1000mg/kg/day exhibited “pale kidneys”. Minor changes, including salivation and weight loss were noted in some animals receiving 1000mg/kg/day. The highest dose used did not result in significant toxic effects. Based on clinical observations at the next highest dose, the No-Observed-Effect-Level was 150 mg/kg/day.

Mutagenic testing was undertaken in bacteria (*Salmonella typhimurium* & *E. Coli*) over 5 doses in the range 8 - 5000μg/plate. The test substance was not mutagenic, nor did it induce

chromosomal aberrations in human lymphocytes at doses in the range 7.8 - 1000µg/mL.

The notifier confirmed that the test substance used for toxicological testing was Mexanyl GY (containing 47% notified chemical). In the absence of data to the contrary the notified chemical is determined to have a toxicological profile similar to the test substance.

The notified chemical is not determined to be a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Species	Test	Concentrations (mg/L)	Result (mg/L)
Trout *(Orcorhyncus mykiss)*	96 hr semi-static	unknown	LC0 > 10
Water Flea (*Daphnia sp.*)	48 h Acute Immobilisation		LC0 > 10

The test for acute toxicity on fish was undertaken according to OECD Guideline 203. However, no test report was provided therefore no comments can be made regarding test conditions or sub lethal effects. The concentration of 10 mg/L was the highest concentration that could be prepared.

The test for immobilisation of daphnia was undertaken according to OECD Guideline 202. However, as with the fish toxicity tests, no test report was provided therefore no comments can be made regarding test conditions or sub lethal effects. The concentration of 10 mg/L was the highest concentration that could be prepared in water and auxiliary solvent (Tetrahydrofuran and Tween).

A search of the ASTER database has provided little information pertaining to ecotoxicity. Based on the results above, the notified chemical is considered to be at worst slightly toxic to fish and daphnia.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The vast majority of notified chemical will be discharged to sewer through product use. The notifier has provided a PEC based on likely levels of use.

As the product will be used throughout the country, and sent to sewage treatment plants in both city and country locations, a PEC based on continental use and maximum projected level of use has been calculated:

Maximum Import Volume per annum	600 kg
Amount discharged to sewer	100%
Volume discharged per day	1.64 kg
Sewer output per day*	2 700 mL
Concentration in Sewage Treatment Plant	0.6 μg/L
Concentration in sewage after 20 % (estimated) adsorption to sewage sludge	0.48 μg/L
Further diluted (1:10) in receiving waters	0.05 μg/L
Safety Factor (Daphnia EC_{50}(48 h) ≥ 10 mg/L)	5.0 x 10^{-6}

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

The Safety Factor for this chemical, based on toxicity to *Daphnia magna* and the PEC is wide and suggests the notified chemical will not pose a potential environmental hazard. However, the percentage of the notified chemical adsorbing to sewage sludge may differ from the 20% estimated in the PEC.

Factors such as the small import volume, the conservative estimate of the PEC and the inherently biodegradable nature of the notified chemical are likely to diminish the risk associated with use up to the maximum levels proposed.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Considering the limited toxicology information provided, the notified chemical does not meet the criteria for classification as a hazardous substance according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

The acute oral and dermal toxicities are low (LD_{50} > 5000 mg/kg and > 2000 mg/kg respectively). It was slightly irritating to the skin and eyes of rabbits, but was not a skin sensitiser. No evidence of genotoxicity was observed in tests undertaken on bacteria and human lymphocytes.

Systemic effects were noted in a 28 day oral study although the relationship to the test substance was unclear and effects occurred in few animals. Clinical observation found a NOEL of 150 mg/kg/day.

Occupational Health & Safety

Processing of the notified chemical will involve transport workers, storeman, laboratory technicians, three compounders and clean up personnel.

Occupational exposure can arise from the flakes (47% notified chemical), dust (if the flakes are friable), and the liquid form of the formulated product. There is unlikely to be exposure during transport and storage except in the event of an accident. There is a risk of exposure via the lungs, skin and eyes to the flakes (and possibly dust) during sampling and testing, and formulation (1.2% notified chemical). Standard procedure to reduce the risk of adverse

effects requires the use of local ventilation and the wearing of dust masks, safety goggles, full protective clothing and gloves (plastic or impervious gloves) .

Packaging and cleaning of vessels carries a risk of exposure to the liquid product via the skin and eyes. Standard procedure requires the use of local ventilation and the wearing of safety goggles, full protective clothing and gloves.

Personnel involved in clean up of a spill should wear anti-slip footwear.

Exposure is possible over 12 days/year for all categories of workers.

Public Health

The notifier estimates consumers may experience maximum systemic exposure of 0.83 mg/kg/day (assuming a 10% absorption). The low acute toxicological hazard associated with this chemical should lead to a low risk of adverse effects in members of the public using shampoo products containing the notified chemical.

Public exposure from transport, formulation and disposal of the notified chemical is unlikely.

13. RECOMMENDATIONS

To minimise occupational exposure to hydroxystearyl cetyl ether 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) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990); impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);

- Spillage of the notified chemical should be avoided. Spillages should be swept/vacuumed promptly and collected into containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion;

- A copy of the Material Safety Data Sheets (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for Mexanyl GY was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

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 may be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

Secondary notification under Section 64 of the Act will be required if the method of use changes in such a way as to greatly increase the environmental exposure of the notified chemical, particularly to natural waters, or if additional information becomes available on adverse environmental effects of the chemical.

If import volumes increase to over 1 tonne per annum full reports of all physico-chemical, toxicological and ecotoxicological tests (including biodegradation), will be required.

16. REFERENCES

Chimex Material Safety Data Sheet Version 3 (30/01/95).

Connell, D.W. (1990). General Characteristics of Organic Compounds Which Exhibit Bioaccumulation. In: Connell, D.W. ed, Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA.

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International Cosmetic Ingredient Dictionary and Handbook Seventh Edition 1997.

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Standards Australia (1987). Australian Standard 2919-1987, Industrial Clothing. Sydney, Standards Association of Australia.

Standards Australia (1990). Australian Standard 3765.1-1990, Clothing for Protection Against Hazardous Chemicals Part 1 Protection against General or Specific Chemicals. Sydney, Standards Association of Australia.

Standards Australia (1994). Australian Standard 1336-1994, Eye Protection in the Industrial Environment. Sydney, Standards Association of Australia.

Standards Australia/Standards New Zealand (1992). Australian/New Zealand 1337-1992, Eye Protectors for Industrial Applications, Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994). Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Sydney/Wellington, Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1998). Australian/New Zealand Standard 2161.2-1998, Occupational Protective Gloves, Part 2: General requirements. Sydney, Standards Association of Australia.

Attachment 1

The Draize Scale (Draize, 1959) 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 (Draize *et al*., 1944) 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.
		Swelling with lids half-closed	3 mod.		
Diffuse beefy red	3 severe	Swelling with lids half-closed to completely closed	4 severe	Discharge with moistening of lids and hairs and considerable area around eye	3 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

MSDS