File No: NA/399

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Mexoryl SX Active Ingredient

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

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Mexoryl SX Active Ingredient

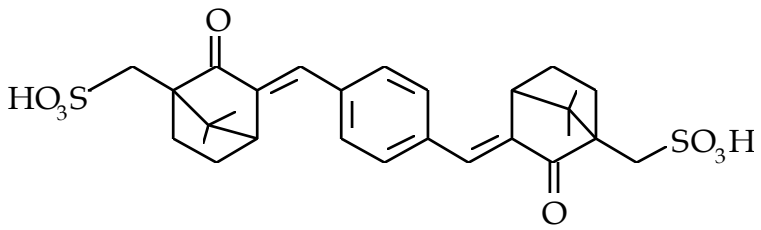
1. APPLICANT

L'Oreal Paris of 256 Bay Road SANDRINGHAM VICTORIA 3191 has submitted a limited notification for assessment of **Mexoryl SX Active Ingredient**.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	bicyclo[2.2.1]heptane-1-methane sulfonic acid,3,3'-(1,4-phenylenedimethylidyne)bis[7.7]-dimethyl-2-oxo
Chemical Abstracts Service (CAS) Registry No.:	92761-26-7 (replaces 90457-82-2)
Other Names:	terephthalylidene dicamphor sulfonic acid 3,3'-terephthalydene 10,10'-dicamphorsulfonic acid (aqueous solution at 33%) 3,3'-(1,4-phenylenedimethylidyne)bis[7.7]-dimethyl-2-oxo-bicyclo[2.2.1]heptane-1-methanesulfonic acid
Trade Name:	Mexoryl SX, Ecamsule
Molecular Formula:	$C_{28}H_{34}O_8S_2$

Structural Formula:



Molecular Weight:	562.3

Method of Detection and Determination:	infrared (IR) and ultraviolet (UV) spectroscopy
Spectral Data:	IR, major characteristic peaks were observed at 1 040, 1 140, 1 635, 1 720, 2 920, 2 950, 3 400 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	brownish liquid (as 33±1% aqueous solution)
Odour:	practically odourless
Boiling Point:	100°C (as 33±1% aqueous solution)
Density:	1 120 kg/m^3
Vapour Pressure:	2.99 kPa at 25°C
Water Solubility:	totally soluble
Partition Co-efficient (n-octanol/water):	log P = -1.08 at 22°C log P = -1.84 at 22°C (concentrated product)
Hydrolysis as a Function of pH:	not supplied
Adsorption/Desorption:	not supplied
Dissociation Constant:	not supplied
Fat Solubility	3.71 mg/100g at 37°±0.5°C
Flash Point:	> 102°C
Flammability Limits:	not supplied
Autoignition Temperature:	> 300°C
Explosive Properties:	not explosive
Reactivity/Stability:	reacts with strong bases and strong oxidants

Comments on Physico-Chemical Properties

The hydrolysis as a function of pH was not provided. The notified chemical contains no groups that would be expected to hydrolyse under environmental conditions. No information was provided on the adsorption/desorption properties of the chemical. Given the chemical's high water solubility and low partition coefficient it is anticipated that it will not strongly adsorb.

The notified chemical contains sulphonic acid groups that would be totally dissociated in water.

On combustion the notified chemical may release carbon and sulphur oxides.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 98%

Toxic or Hazardous Impurities:

Chemical name:	cis-trans isomer of notified chemical
CAS No.:	not supplied
Weight percentage:	<1%
Toxic properties:	*
Chemical name:	4'-carboxy benxylidene-10-camphorsulfonic diacid
CAS No.:	not supplied
Weight percentage:	<0.4%
Toxic properties:	*
Chemical name:	4'-hydroxymethyl benxylidene-10-camphorsulfonic acid
CAS No.:	not supplied
Weight percentage:	<0.5%
Toxic properties:	*
Chemical name:	camphorsulfonic acid
CAS No.:	3144-16-9
Weight percentage:	<0.6%
Toxic properties:	*none listed on Toxline (1), Sax and Lewis (2) or List of Designated Hazardous Substances (3)

*All the toxic/hazardous impurities are at concentrations of no more than 1%, there is no available information on their toxic properties in any of three databases searched (1,2,3). The toxic properties of the isomer may be similar to the notified chemical (refer to section 9).

Non-hazardous Impurities (> 1% by weight):	none
Additives/Adjuvants:	water, notified chemical is imported as a 33±1% aqueous solution; used in formulations (moisturisers and suncreams).

5. USE, VOLUME AND FORMULATION

An import volume of 1 000 kg/annum of Mexoryl SX has been stated by the notifier. The chemical is to be reformulated into sunscreens and moisturisers to be marketed Australia wide.

The imported formulation, Mexoryl SX, will be contained within 30 kg rigid plastic containers for storage and transport, with a maximum of eight containers being transported at one time. The emulsion will not be repackaged before delivery. The solution will be reformulated exclusively at the notifier's factory in Sandringham Victoria, into sunscreens and moisturisers as a 3.96% and 0.6 % component respectively. The end products are to be marketed Australia wide. Similar products containing the notified chemical have been available on the European market for a number of years.

6. OCCUPATIONAL EXPOSURE

The notified chemical will not be manufactured in Australia. It will be imported as Mexoryl SX, an aqueous solution containing 33±1% of the notified chemical. The chemical is highly acidic (pH of 1) and is classified as Class 8 dangerous goods under the *Australian Code for the Transport of Dangerous Goods* (4). Occupational exposure could occur during transport and warehousing in the event of an accident. The aqueous solution will be packaged in 30kg plastic containers and will be transported in loads of no more than eight containers of Mexoryl SX (240kg or 80 kg of the notified chemical). The limited loads and the size of individual containers will limit spills in the event of an accident.

Occupational exposure will be greatest during reformulation. The Mexoryl SX is used to formulate sunscreens and moisturisers. The process involves sampling by the storeman, analysis by the laboratory technician, weighing, blending and cleanup by the compounder and, preparation and maintenance of the automatic filling line by the linefiller. A total of five staff will therefore be exposed to the notified chemical during reformulation at the notifier’s facility.

The main pathways for occupational exposure will be via the eyes and skin. As the notified chemical has a low vapour pressure, inhalational exposure is unlikely.

Inhalational exposure may occur if mists or sprays are generated during the formulation of suncreams and moisturisers, for instance, if mixing systems are pressurised. The final products, suncream and moisturiser, will contain a maximum of 3.96% and 0.6% of the notified chemical respectively. As the formulation containing the notified chemical is corrosive (pH 1), risks through exposure will be greatest prior to reformulation. When reformulated into suncreams and moisturisers the corrosivity is neutralised by the other ingredients

7. PUBLIC EXPOSURE

There is little potential for public exposure to the notified chemical during storage, transport and formulation into products. The chemical is to be packaged in 30 kg rigid plastic containers and a maximum of eight containers will be transported at any one time. Storage for the chemical is in a dedicated Class 8 raw material store. Minor public exposure to the undiluted form of the notified chemical may result from accidental spillage during transport. Such spills are to be contained with inert materials, neutralised with sodium bicarbonate, and disposed of to incineration. Small spills may be diluted with large quantities of water. Losses during storage and formulation will generally be washed into the onsite effluent storage tank for disposal via sewers.

The notified chemical will be transferred to one formulation facility where it will be blended with other compounds into sunscreens and moisturisers as a 3.96% and 0.6% component respectively. The notifier states that products of this type using the notified chemical have been marketed in Europe and USA for two years, and have obtained a “certificate of listing” from the Therapeutic Goods Administration (TGA) in Australia. Production losses of the notified chemical during a typical production run are not expected to exceed 400 g, and this will be washed into the effluent storage tank. There will be some loss from washings after skin application and some of these washings will enter the sewers and drains in a highly diluted form.

There will be extensive public exposure, particularly dermal exposure arising from the use of the sunscreen and moisturiser products.

8. ENVIRONMENTAL EXPOSURE

Release

Washings from in-process cleaning of the manufacturing tank and pipe work will be washed into a 10 000 L effluent treatment tank that will be discharged into the sewer. The notifier estimates that a maximum 396 g of the notified chemical will be lost during this process. This will give a concentration of 40 ppm in the discharge from the effluent tank, and will be further diluted in the sewer to approximately 1 ppb.

The use of products containing the chemical would be widespread, but only in very small volumes when applied to the skin. Release to the environment may occur to the sewer through the removal of the sunscreens or moisturisers from the skin by

washing, or to landfill with the disposal of residual quantities of the cosmetics within used containers.

Taking the worst case assumption that all the chemical to be imported remains suspended and thus is discharged to receiving waters, a predicted environmental concentration (PEC) for the substance in sewage water across Australia can be estimated from the following assumptions: 1 tonne maximum annual use, an Australian population of 17 million and a daily per capita waste water discharge (a conservative estimate) of 150 L. This provides a (PEC) of approximately 1 ppb in sewage water.

Fate

Mexoryl SX is intended for use in sunscreens and moisturisers and, as such, would be expected to be released to the environment via consumer use through washing the residual chemical (assumed to be 100% of that applied) off the skin and into the sewerage system.

The ready biodegradability of the notified chemical was assessed by the 'Closed Bottle' method (OECD TG 301D). Sealed bottles containing the test substance (2.2 mg/L) and inorganic medium were inoculated with activated sewage sludge bacteria and incubated for 28 days. The notified chemical attained 41% biodegradation after 28 days. Therefore, it may not strictly be termed as readily biodegradable, although its inherent biodegradability is uncertain.

No bioaccumulation of the chemical is expected because its very high water solubility and low octanol/water partition coefficient.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

The submission for Mexoryl SX Active Ingredient is a limited submission as no more than 1 000kg of the notified chemical will be imported annually, as such, there is no requirement to submit toxicological data. However, the notifier has submitted an extensive range of toxicological information which is discussed below.

Summary of the acute toxicity of Mexoryl SX Active Ingredient

Test	*Species*	*Outcome*	*Reference*
*acute oral toxicity	rat	LD_{50} > 1 835 mg/kg	#5
*acute dermal toxicity	rat	LD_{50} > 1 637 mg/kg	#7
*skin irritation	rabbit	non-irritant	#8
**eye irritation	rabbit	corrosive/slight irritant (see text)	#10
skin sensitisation	guinea pig	nonsensitising	#13

*acid (36.7% aqueous solution) ** triethanolamine salt
only summaries sighted

9.1.1 Oral Toxicity (#5)

Species/strain:	Sprague-Dawley rats
Number/sex of animals, M/F:	5/5
Observation period:	not stated
Method of administration:	aqueous solution (acid, 36.7% active material), single oral dose
Clinical observations:	none
Mortality:	none
Morphological findings:	none, bodyweight gains normal
Test method:	based on OECD Guidelines for Testing Chemicals (6)
LD_{50}:	> 5 000 mg/kg (> 1 835 mg/kg active material)
Result:	not acutely toxic at a dose of 1835 mg/kg

9.1.2 Dermal Toxicity (#7)

Species/strain:	Sprague-Dawley rat
Number/sex of animals:	10 (sex not stated)
Observation period:	not stated
Method of administration:	to clipped skin; 24 hour exposure to 1 637 mg/kg, aqueous solution (acid, 36.7% active material), under occluded dressing, then

	rinsed
Clinical observations:	no evidence of systemic toxicity
Mortality:	none
Morphological findings:	expected weight gain, no signs of dermal irritation
Test method:	based on OECD Guidelines for Testing Chemicals (6)
Result:	not acutely toxic at a dose of 1 637 mg/kg

9.1.4 Skin Irritation (#8)

Species/strain:	New Zealand rabbit
Number/sex of animals:	3, sex not stated
Observation period:	72 hours after removal of test article
Method of administration:	0.5 ml of aqueous solution (36.7% active material) under an occlusive patch for 4 hours
Draize scores (8):	0
Test method:	based on OECD Guidelines for Testing Chemicals (6)
Result:	aqueous solution not a skin irritant in rabbits

9.1.5.1 Eye Irritation (#10)

Species/strain:	New Zealand rabbit
Number/sex of animals:	6 male
Observation period:	7 days
Method of administration:	neutralised by triethanolamine (aqueous solution too corrosive), containing 10.5% active material, 0.1 ml in one eye of each rabbit
	Draize scores (8): 4.67 (maximum, out of possible 110)
Test method:	conforms to Journal Officiel de la République Française 24/10/1984

Result: triethanolamine salt irritant

9.1.5.2 Eye Irritation (#11)

Species/strain: New Zealand rabbit

Number/sex of animals: 6 male

Observation period: 7 days

Method of administration: neutralised by potassium hydroxide (aqueous solution too corrosive), containing 10.5% active material, 0.1 ml in one eye of each rabbit

Draize scores (8): 8
(maximum, out of possible 110)

Test method: conforms to Journal Officiel de la République Française 24/10/1984

Result: potassium salt irritant

9.1.5.3 Eye Irritation (#12)

Species/strain: New Zealand rabbit

Number/sex of animals: 6 male

Observation period: 7 days

Method of administration: neutralised by sodium hydroxide (aqueous solution too corrosive), containing 10.5% active material, 0.1 ml in one eye of each rabbit

Draize scores (8): 6.33
(maximum, out of possible 110)

Test method: conforms to Journal Officiel de la République Française 24/10/1984

Result: sodium salt irritant

9.1.6 Skin Sensitisation (13)

Species/strain: Hartley-Dunkin guinea pig

Number of animals: 20

Induction procedure: Intradermal injection of Freunds Complete Adjuvant (FCA) and 48-hour dermal applications of 10.4% solution of test chemical (neutralised with triethanolamine under occlusive patches)

Challenge procedure: after a 14 day rest period a challenge application of 10.4% solution of the test chemical was performed

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hrs****	***48 hrs****	***24 hrs***	***48 hrs***
10.4%	**0	0	0	0

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

Test method: corresponds to AFNOR : FD n^0 T 03-300 method

Result: no signs of sensitisation

9.2 Repeated Dose Toxicity (14)

Species/strain: Sprague-Dawley rats

Number/sex of animals, M/F: 10/10 per dose group

Method of administration: as aqueous solution by oral route

Dose/Study duration:: dose groups 0, 100, 300 and 1 000 mg/kg/day, 90 days

Clinical observations: no treatment related clinical signs; there was some evidence of variation in thyroid weight in the male animals fed the test article however there was some doubt as to validity of this observation as the control animals were found to have unusually low thyroid weights

Clinical phosphoremia in high dose males at week 4

chemistry/Haematology	and decreased protein, albumin and globulin levels were seen in high dose females at week 13
Histopathology:	none
Test method:	based on OECD Guidelines for Testing Chemicals (6)
Result:	no dose related effects in 300 mg/kg/day dose group, some dose related clinical chemistry/haematological effects at 1 000 mg/kg/day dose group

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (15)

Strains:	*S. typhimurium* TA 98, TA 100, TA 1535, TA 1537, TA 1538 and *Escherichia coli* WP2*uvrA*
Concentration range:	test article neutralised by triethanolamine at concentrations of 367 - 43 306 μg/ plate with or without rat liver S9
Test method:	based on OECD Guidelines for Testing Chemicals (6)
Result:	non-mutagenic in bacteria, controls gave appropriate response

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (16)

Species/strain:	Swiss OF1 mice
Number and sex of animals, M/F:	two groups of 5/5
Doses:	2 000 mg active ingredient/kg
Method of administration:	single oral dose
Test method:	based on OECD Guidelines for Testing Chemicals (6)
Result:	test article did not induce cytogenetic damage

9.3.3 Other toxicological data

An extensive body of toxicological data was provided in summary form by the notifier. The characteristics of the test chemical as an aqueous solution (highly acidic) required that in a number of tests it be modified due to factors such as ocular tolerance. This is acceptable as in the intended end use as cosmetic preparations it is neutralised by bases such as sodium or potassium hydroxide, by triethanolamine or other amines. Consequently the studies have been performed on a range of salts as well as the acid in most instances. The results are summarised in the following tables, non clinical toxicological studies and dermatological studies:

9.4 Overall Assessment of Toxicological Data

This assessment is based on report summaries only. Full reports have not been sighted. As there is no evidence to suggest excessive concern as to the hazardous nature of the notified chemical and, as this submission is in the limited category, this is acceptable.

In acute oral studies in rats using the acid, triethalanoamine salt, sodium and potassium salt, acute toxicity was found to be low with respective LD_{50} of > 1 835, > 2 092, > 2 092 and > 2 092 mg/kg and there was no evidence of systemic toxicity or abnormalities at necropsy. The acute dermal toxicity of the acid to rats was low with an LD_{50} of > 1 637 mg/kg. In a 90-day oral repeat dose study in rats, no dose related effects were found at 300 mg/kg/day. At 1 000 mg/kg/day there was phosphoremia in males at week 4 and decreased protein, albumin and globulin levels in females at week 13. There was some evidence of variation in thyroid weight in the male animals fed the test article, however, there was some doubt as to validity of this observation as the control animals were found to have unusually low thyroid weights. Follow up 21-day studies using the triethalanoamine and sodium salts (not audited) on thyroid metabolism found no treatment related changes at dose rates of 305 mg/kg and 444mg/kg respectively.

Skin irritation studies in rabbits found that the triethalanoamine, sodium and potassium salts were non irritant when 0.5 ml of a 10.4% aqueous solution was applied to exposed rabbit skin. A similar study using a 36.7% aqueous solution of the test chemical gave similar results. A stronger solution may produce irritant effects due to the strongly acidic nature of the notified chemical. Skin sensitisation tests using guinea pigs gave negative results with both the triethalanoamine salt (10.4% aqueous solution) and the acid (1% solution).

Ocular irritation tests indicated that all three salts were irritants when 0.1 ml of a 10.5% test solution of each salt was applied to the eye of rabbits. The potassium salt had the highest index score of 8 out of a possible 110. Ocular irritation studies using the acid were not performed due to the inevitable results.

In teratogenic studies using the triethalanoamine salt in rats, no effects were found at doses up to 300 mg/kg/day. Genotoxicity studies using the triethalanoamine salt and *S. typhimurium* at doses up to 43 306 μg/plate, with or without rat liver S9, found no mutagenic effects. In additional studies using *E. coli* at doses up to 5 000 μg/ plate, with or without rat liver S9, no mutagenic effects were found. Other genotoxicity tests both *in vivo* (mouse micronucleus using acid) and *in vitro* (mammalian cell mutation using triethalanoamine salt) gave negative results at doses up to 2 000 mg/kg and 3 000 μg/ plate respectively.

On the basis of the strongly acidic nature of the test chemical it is classified as hazardous. The toxicological studies summarised above indicate that the

neutralised acid and potassium salts produce minimal indications of toxicity in a wide range of tests with the exception of rabbit eye irritation studies. It is probable that the neutralised acid, potassium and sodium salts of the notified chemical would be classified as hazardous due to the irritation effects found in the rabbit eye studies. The index scores have not been specified for corneal opacity, iris lesion, conjunctival erythema or oedema. A cautionary irritant classification on the basis of the overall index scores has been assigned, ie hazardous. Eye irritation studies using the acid were not performed due to the corrosive nature of the acid.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Although no ecotoxicological data have to be provided for chemicals imported at rates less than 1 000 tonnes per annum according to the Act, the company did provide data for 48h LC50 fish test and aquatic invertebrates test. The species used were rainbow trout and *Daphnia magna*. These studies were conducted according to international standards (EEC directives and OECD Guidelines). The results are summarised below.

Test	Species	Result	
Acute toxicity	Rainbow Trout	48h EC_{50}	=> 100 mg/L
		48 hr NOEC	=> 100 mg/L
Acute toxicity	*Daphnia magna*	48h EC_{50}	=> 100 mg/L
		48 hr NOEC	=> 100 mg/L

The ecotoxicity studies were conducted using Mexoryl SX dissolved in water. The test reports indicate the chemical is practically non-toxic to fish and *Daphnia*. The toxicity of the chemical to algae was not tested.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Release of the notified chemical to the environment may occur as a result of formulation and use of the cometic products in which it is used (sunscreens and moisturisers). As a worst case, an environmental concentration of 1 ppb is predicted if all the imported chemical remains dissolved in sewage waters (assuming: 1 tonne maximum annual use, an Australian population of 17 million and a daily per capita waste water discharge of 150 L). However, its widespread use, and its expected low toxicity indicate that the overall environmental hazard of the chemical can be rated as negligible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical will be imported as Mexoryl SX, an aqueous solution containing 33±1% of the notified chemical. The chemical is highly acidic (pH of 1) and is classified as Class 8 dangerous goods under the *Australian Code for the Transport of Dangerous Goods* (4). Occupational exposure during transport and warehousing may occur through accidental spillage, however, this will be minimised due to the limited amount transported at any one time (240kg) and the individual container size (30kg).

Occupational exposure will be greatest during reformulation. A total of five staff will be potentially exposed during reformulation. These are a storeman, laboratory technician, compounder and linefiller.

The main pathways for occupational exposure will be via the eyes and skin. As the notified chemical has a low vapour pressure, inhalational exposure is unlikely. Inhalational exposure however may occur if mists or sprays are generated during the formulation of suncreams and moisturisers, for instance if mixing systems are pressurised. The final products, suncream and moisturiser, will contain a maximum of 3.96% and 0.6% of the notified chemical respectively.

There is negligible potential for public exposure to the notified substance arising from importation, storage, transportation and formulation into sunscreen and moisturiser products. There will be extensive public exposure from the end-use application of the chemical as a sunscreen agent and skin moisturiser component, but the notified substance is at a low concentration (3.96% and 0.6% respectively) in these products. There appears to be little dermal absorption following contact; however there is a risk of eye irritation as the agent is a severe irritant in the undiluted form due to its low pH. This hazard is mitigated by the formulation of pH neutral end products.

The notified chemical is classified as hazardous as it is strongly acidic and therefore corrosive.

13. RECOMMENDATIONS

To minimise occupational exposure to Mexoryl SX Active Ingredient the following guidelines and precautions should be observed.

. When using the notified chemical (in the imported formulation) the following protective equipment should be worn:

- impervious gloves conforming to Australian Standards (AS) AS 2161 (17),

- protective eye goggles conforming to AS 1336 (18),and Australian and New Zealand Standards AS/NZS 1337 (19)

- protective clothing conforming to AS 3765.2 (20), and

- protective footwear conforming to AS/NZS 2210 (21).

. Good personal hygiene practices should be observed.

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

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of a Material Safety Data Sheets* (22).

This MSDS was provided by the applicant as part of their 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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2. Sax and Lewis 1989, *Dangerous properties of hazardous materials*, Van Nostrand Reinhold, New York

3. National Occupational Health and Safety Commission, 1994*, List of designated hazardous substances* [NOHSC:10005(1994)], AGPS, Canberra, 1994

4. Federal Office for Road Safety 1992, *Australian Code for the Transport of Dangerous Goods by Road and Rail,* 5th Edition, Australian Government Publishing Service Publ., Canberra.

5. Anonymous 1989, Report No. 1016-109/150 - Mexoryl SX (Acid) Acute Oral Toxicity on the Rat, Safepharm Laboratories, Derby, U.K.

6. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris, France.

7. Anonymous 1990, Report No. 4222-109/310 - Mexoryl SX (Acid) Acute Dermal Toxicity on the Rat, Safepharm Laboratories, Derby, U.K.

8. Anonymous 1990, Report No. 109/311 - Mexoryl SX (Acid) Acute Dermal Irritation in the Rabbit, Safepharm Laboratories, Derby, U.K.

9. Draize, J. H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US,* **49**.

10. Anonymous 1987, Report No. 712332 - Mexoryl SX (Triethanolamine salt) Acute Ocular Irritation in the Rabbit, Hazleton-IFT, St Germain-sur-l'Arbresle, France

11. Anonymous 1987, Report No. 712331 - Mexoryl SX (Potassium salt) Acute Ocular Irritation in the Rabbit, Hazleton-IFT, St Germain-sur-l'Arbresle, France

12. Anonymous 1987, Report No. 712330 - Mexoryl SX (Sodium salt) Acute Ocular Irritation in the Rabbit, Hazleton-IFT, St Germain-sur-l'Arbresle, France

13. Anonymous 1988, Report No. 80-24410 - Mexoryl SX (Triethanolamine salt) Delayed Cutaneous Sensitisation in the Guinea pig, Hazleton-IFT, St Germain-sur-l'Arbresle, France

14. Anonymous 1988, Report No. 801205 - Mexoryl SX (Triethanolamine salt*) In vitro* genotoxicity in *S. typhimurium*, Hazleton-IFT, St Germain-sur-l'Arbresle, France

15. Anonymous 1992, Report No. 8809 - Mexoryl SX (Acid) Micronucleus test by Oral Route in Mice, Hazleton-IFT, St Germain-sur-l'Arbresle, France

16. Standards Australia, 1978. *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves*), Standards Association of Australia Publ., Sydney, Australia.

17. Standards Australia, 1994. *Australian Standard 1336-1994, Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, Australia

18. Standards Australia, Standards New Zealand 1992. *Australian/ New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

19. Standards Australia, 1990 Australian Standard 3765 - 1990. *Clothing for Protection Against Chemical Hazards*, Part 1, *Protection against General or Specific Chemicals*; Part 2, *Limited Protection Against Specific Chemicals*, Standards Australia Publ., Sydney, Australia.

20. Standards Australia, Standards New Zealand 1994. *Australian/ New Zealand Standard 2210 - 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications,* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

21. National Occupational Health and Safety Commission, 1994. *National Code of Practice for the Preparation of Material Safety Data Sheets*, [NOHSC:2011(1994)], AGPS, Canberra.

Attachment 1

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

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe