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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Emkarate 8500

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

Emkarate 8500

1. APPLICANT

ICI Australia (Operations) Pty Ltd of 1 Nicholson Street, Melbourne 3000 has submitted a standard notification statement in support of their application for an assessment certificate for Emkarate 8500.

2. IDENTITY OF THE CHEMICAL

Emkarate 8500 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Trade Name: Emkarate 8500

Molecular Weight: > 500

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C colourless liquid with a mild odour

and 101.3 kPa:

Boiling Point: > 250°C (at 101.3 kPa)

Density: 0.902 g/cm³ at 20°C

Vapour Pressure: < 0.1kPa at 25°C

Water Solubility: 1.52 mg/L at 20°C

Partition Co-efficient

(n-octanol/water): $\log P_{ow} > 6$

Hydrolysis as a Function

of pH:

not available

Adsorption/Desorption: not available

Dissociation Constant: not available

Flash Point: 225°C (closed cup)

Fire Point: 271°C

Flammability Limits: not flammable

Autoignition Temperature: 390°C

Explosive Properties: unlikely to form explosive vapour cloud

Reactivity/Stability: no oxidising properties

Surface tension: 3.08 mN/m

Comments on Physico-Chemical Properties

At temperatures in excess of 250°C esters of this type tend to decompose. Hydrolysis as a function of pH has not been measured, but it is expected to be high ¹. The notifier claims that the notified chemical readily hydrolyses under physiological and environmental conditions, even though it is relatively insoluble in water. This conclusion is acceptable, however the chemical would be rated as hydrolysable rather than readily hydrolysable.

The notified chemical is likely to display high adsorption to, or association with, sediment/sludge due to the high partition coefficient and low water solubility.

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 (2).

4. PURITY OF THE CHEMICAL

Degree of Purity: > 98%w/w

Toxic or Hazardous none

Impurities:

The notifier expects that the rate of

¹ The notifier expects that the rate of hydrolysis will be similar to that of structurally similar dicarboxylic acid esters. The first order hydrolysis half-life of the alkyl dicarboxylic acid ester, *bis*(2-ethylhexyl) adipate, is 80 days at 25°C and pH 7, while at 25°C and pH 9 the half life is 19.2 hours. [1] *Environment Australia* would not expect the notified chemical to hydrolyse as fast as *bis*(2-ethylhexyl) adipate due to its higher molecular weight and increased lipidophilicity.

Non-hazardous Impurities

other diesters < 1%, these diesters are cross contaminants from other products made on the (> 1% by weight):

same plant

Additives/Adjuvants: none

5. **USE, VOLUME AND FORMULATION**

Used as a lubricant in synthetic engine oils and industrial oils. It is used at approximately 5% of the product formulation.

The notified chemical will only be imported. The estimated usage will be 1-10 tonnes in year 1 and 10-100 tonnes in subsequent years up to year 5.

6. **OCCUPATIONAL EXPOSURE**

The notified chemical is not manufactured in Australia but imported in 205 L steel closed drums. The notified chemical is stored by ICI at their warehouse prior to dispatch to the customer who will use it to blend lubricating oils. Occupational exposure to the notified chemical during transport and warehousing is unlikely and will only occur in event of accidental release.

Occupational exposure to the pure notified chemical is most likely to occur during blending at the facilities of ICI's customers. The notified chemical is first transferred to storage tanks before being pumped to the blending vessel. The blending process takes place at 60-70°C and occurs with gentle stirring to achieve a homogenous blend. The blended lubricant is then transferred to 205, 60 and 20 L closed head drums and 1, 4, 5 and 6 L polyethylene bottles. During blending exhaust ventilation is used to control any vapour hazard.

Three employees will potentially be exposed during the blending operation, two in the blending and filling areas and the third in quality control. Exposure will be for periods of upto 8 hours/day for 12 days/year.

The main route of exposure to the notified chemical will be via dermal contact during blending, packaging or maintenance of the blending equipment. The low vapour pressure of the notified chemical indicates that inhalational exposure is unlikely under normal circumstances.

Occupational exposure to the notified chemical will also occur during use of the lubricant oils containing Emkarate 8500. Exposure to the notified chemical will be limited as the formulations only contain approximately 5% of the notified chemical. Potentially the numbers of mechanics exposed could be in the hundreds, Australia wide.

7. PUBLIC EXPOSURE

Engine oil products containing Emkarate 8500 will be available to the public for engine oil exchanges on private vehicles, and this usage is expected to account for 50% of sales. Members of the public using the product would be expected to come into contact with Emkarate 8500 during engine oil top ups or exchanges, primarily on the hands and forearms but possibly in the eyes from splashes. In most circumstances contact is likely to be intermittent, of short duration and to involve only small areas of skin. In the event of a spill, or when used by a motor vehicle enthusiast, more extensive and/or prolonged exposure is possible.

In the event of a spill dispersion is unlikely given the low vapour pressure and low water solubility of Emkarate 8500. Similarly, release during manufacturing procedures is unlikely to be significant. The majority of waste oil containing Emkarate 8500 collected by licensed waste disposal contractors will be sold as fuel oil. As Emkarate 8500 is a non halogenated, hydrocarbon its combustion products are not expected to be more toxic than those of the oil which constitutes the bulk of the disposed product.

8. ENVIRONMENTAL EXPOSURE

Release

The manufacturing process is waste free as blend tank washes are then used in lower quality products. Accidental spillages during the formulation will be contained by plant bunding. Spilt material from small spills will be mopped up, with larger spills being diverted to a sump that is regularly pumped by a waste-oil disposal contractor. It is estimated that 100 kg per annum of the notified substance may be disposed of in waste oil from this source, which will be incinerated.

The notifier claims that most of the notified chemical will be released as waste oil as the result of engine oil changes performed in automotive/ industrial workshops, and by the "do-it-yourself" (D-I-Y) public. Waste oil is regularly collected from workshops by licensed oil recyclers. The notifier believes that most of the collected waste oil containing the notified chemical will be resold as fuel oil.

The notifier did not provide data on the residues of notified chemical left in the product containers. These residues are likely to be minimal (the chemical is incorporated into the synthetic oils at a maximum of 5%). The containers supplied to the public (of 1 L, 4 L, 5 L and 6 L size) are made of recyclable plastic. However it is likely that many of these containers are likely to be disposed of to landfill. The 205 L, 60 L and 20 L closed head drums are likely to be supplied to automotive/industrial workshops, which will probably be collected for drum recycling.

Fate

The notified chemical will be used in automotive and industrial oils, and will share their fate. Most of the oil will be either combusted during use or recovered and recycled/used for fuel. A minor component will be released to the environment from spills and leaks, but this would be widely dispersed. If the notified chemical was washed off road surfaces it would be expected to sorb to, or be associated with, soils or sediments adjacent the road.

Collection of waste oils is more easily accomplished from industrial and commercial users than from the small but significant D-I-Y market (3). The notifier has indicated that up to 50% of the chemical (up to 50 tonnes/year at maximum import volumes) will be used in the oil products supplied for automotive lubricants. It is estimated from the ANZECC Report (3) that 35% of the oil used for automotive purposes will not be collected and some could be disposed of in an inappropriate manner ².

Biodegradation

Test results show that the notified chemical undergoes 23% degradation after 28 days (OECD TG 301B - Modified Sturm Test). This would generally indicate that the chemical is not readily biodegradable. However, because of the stringency of the test, a result of less than 60% yield of CO₂ (within 28 days) does not necessarily mean that the chemical is not biodegradable under environmental conditions, but indicates that further testing will be necessary to establish biodegradability. The level of biodegradation (23%) indicates some degradation is occurring.

The notifier claims that aliphatic esters such as the notified chemical undergo an appreciable level of biodegradation in both effluent treatment processes and in the environment.

Bioaccumulation

As the notified chemical has a water solubility of 1.52 mg/L, a partition coefficient of greater than 6 and undergoes only limited biodegradation, it could be a potential bioaccumulator. However the proposed use, the large molecular weight (4) and the potential for biodegradation in the environment indicate that significant bioaccumulation is not likely.

² No figures are available for how much automotive oil was collected for re-use, but an estimate of about 35% of all oil sold is not collected and possibly disposed of in an inappropriate manner (3). Therefore, this percentage will be specifically applied to automotive oils.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Emkarate 8500

Test	Species	Outcome	Reference
acute oral toxicity	rat	LD ₅₀ > 2 000 mg/kg	5
skin irritation	rabbit	not classified as an irritant	6

9.1.1 Oral Toxicity (5)

Species/strain: Alderley Park, SPF rats

Number/sex of animals: 2M/2F

Observation period: 8 days

Method of administration: gavage in corn oil

Clinical observations: diarrhoea and urinary incontinence in one

male rat

Mortality: nil

Morphological findings: nil

Test method: similar to OECD Guidelines for Testing

Chemicals (7)

 LD_{50} : > 2 000 mg/kg

Result: low acute oral toxicity

9.1.2 Skin Irritation (7)

Species/strain: New Zealand white rabbit

Number/sex of animals: 3F

Observation period: 3 days

Method of administration: 0.5 ml applied to shaved area under a semi-

occlusive dressing for four hours

Draize scores (8):

Time after		Anima	<i>l</i> #
treatment (days)	1	2	3
Erythema			
1	^a 1	2	2
3	0	0	0
Oedema			
1	1	2	2
3	0	0	0

^{*} see Attachment 1 for Draize scales

Test method: similar to OECD Guidelines for Testing

Chemicals (7)

Result: not classified as an irritant according to the

criteria of Worksafe Australia (9), some

evidence of irritant effects

9.2 Genotoxicity

9.2.1 Salmonella typhimurium/Escherichia coli Reverse Mutation Assay (10)

Strains: S. typhimurium TA 98, 100, 1535 and 1537

E. coli WP2, WP2uvrA

Concentration range: 100 - 5 000 µg/plate, all strains with and

without S9 metabolic activation

Test method: similar to OECD Guidelines for Testing

Chemicals (7)

Result: not mutagenic in this system

9.3 Review of Submitted Analogue Data

ICI have justified the omission of a range of scheduled toxicity data on the basis of alternative data for analogues. Di (2-ethylhexyl)sebacate or DEHS and diethyl sebacate are structurally similar carboxylic acid esters, they have molecular weights of 427 and 258 respectively. The molecular weights of these two analogues are less than Emkarate 8500 and perhaps of greater relevance are below the threshold of 500 Daltons. They therefore have the potential to cross biological membranes whereas this is less likely for Emkarate 8500 as its molecular weight is in excess of 500 Daltons.

The following assessment is based on a summary provided by the notifier and a review of the referenced material; the original reports were unsighted but are based on citations in Patty's Industrial Hygiene and Toxicology (11) and BIBRA (12). DEHS has a low oral toxicity in rats of greter than 12 g/kg (13). In an inhalation study rats were exposed to a vapour of 250 mg/m³ DEHS for 4 hours/day, 5 days/week for 13 weeks, no adverse systemic or pulmonary effects were found (13). Acute dermal toxicity studies undertaken with diethyl sebacate and DEHS gave LD₅₀ values of 7.32 ml/kg and greater than 10 ml/kg respectively for guinea pigs (12); they thus have a low dermal toxicity to guinea pigs. This suggests that the notified chemical will also have limited dermal toxicity. Another similar chemical dibutyl azelate was a slight dermal irritant in a study using guinea pigs. DEHS gave no indications of skin irritantancy in a guinea pig study. Eye irritation results were only available for dibutyl azelate and these were negative in a guinea pig study.

Skin sensitisation studies have been undertaken with DEHS in volunteers (48 hour challenge patch test) and with rabbits, results were negative in both studies (12).

A 21 day repeat dose study using 2% DEHS in male rats showed a significant increase in liver weight, proliferation of liver peroxisomes and increased levels of peroxisome enzymes (12). A four generation study with rats fed a diet containing 200 ppm (about 10 mg/kg/day) of DEHS gave no reported adverse effects on growth, reproduction or suckling (12). There was no reported evidence of carcinogenicity when fed this diet for up to 19 months. In a repeat dose study (500 mg/kg DEHS three times per week for eleven weeks) following a single dose of a known carcinogen there was no increase in the number of liver foci in rats (12). DEHS was not mutagenic in an Ames test with and without metabolic activation (12).

9.4 Overall Assessment of Toxicological Data

Only limited toxicological information on the notified chemical was provided by ICI. These results indicate that the notified chemical is of only limited toxicological relevance. In an acute rat study it had a low oral toxicity. It was not a skin irritant according to the Worksafe Australia criteria (9) in rabbits, although there was limited oedema and erythema 24 hours after application. In an Ames test with and without metabolic activation it was not a mutagen at doses up to 5 000 μ g/plate.

These results are similar to those obtained for structurally similar carboxylic acid esters such as di(2-ethylhexyl) sebacate (DEHS) and diethyl sebacate.

DEHS had a low oral toxicity in rats with no adverse systemic or pulmonary effects found. Both DEHS and diethyl sebacate have a low dermal toxicity. DEHS was not a skin irritant. Dibutyl azelate was a slight dermal irritant but was not an eye irritant.

DEHS was not a sensitiser in a rabbit study nor in a patch test using human volunteers.

A repeat dose study using 2% DEHS in rats gave an increase in liver weights, proliferation of liver peroxisomes and increased levels of peroxisome enzyme. The notifier argues with some justification that the relevance of this to humans is limited. The predicted metabolic pathway of the notified chemical and DEHS is via hydrolysis to the alcohol and dicarboxylic acid. It is thus readily metabolised. A four generation reproductive study using DEHS gave no evidence of effects on reproduction nor carcinogenicity. In addition DEHS was not a promoter in a study when administered repeatedly after a single dose of a known carcinogen.

On the basis of the submitted data on the notified chemical it would not be classified as hazardous according to the criteria of Worksafe Australia (9). In addition, the analogue data does not indicate any additional deleterious effects that will affect this classification.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier.

Test	Species	Results (Nominal ^a)
Acute Toxicity	Rainbow Trout	96hr LC ₅₀ > 1000 mg/L [°]
- Semi-static ^b	Salmo gairdneri	
Growth Inhibition d	Micro-organisms	6hr EC ₅₀ > 10 mg./L °
	Pseudomonas putida	

a. The test material did not completely dissolve in the test system;
b. Test solutions were changed at 24 hourly intervals during the 96 hour exposure;
c. Maximum nominal concentration tested; and
d. The procedure measures the degree of inhibition of growth of a pure culture of *Pseudomonas putida* during a 6 hour period when the cells are in the logarithmic growth phase.

The ecotoxicity data show that the notified chemical is practically non-toxic to rainbow trout up to the level of its solubility. The bacteria did not show any inhibition of growth at the nominal concentration tested.

No test data were supplied for the acute toxicity to water flea or growth inhibition of algae on the basis of the low toxicity shown in the above fish and bacteria toxicity studies. However, the notifier expects that the notified chemical will be non-hazardous to aquatic organisms because:

1. A structure activity relationship ³ suggests that the notified chemical is non-hazardous to protozoan species;

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³ Quantitative structure activity relationships were developed using regression analysis of the IGC₅₀ in mM as the measurement of relative toxicity (Y) and log K_{OW} as the single molecular descriptor (X) (13). The calculated LC_{50} for fish assuming a log K_{OW} of 6 is 1 395 mg/L, which is consistent with the measured LC_{50} of > 1 000 mg/L.

- 2. The EC₅₀ for water fleas is expected to be within one order of magnitude of the fish species tested ⁴. The mechanism of aquatic toxicity for all diesters has been described as non-polar narcosis for both fish and a ciliate (13). Therefore, the notifier concluded that it is highly unlikely that water fleas would exhibit significantly greater toxicity than fish; and
- 3. Furthermore, the notified chemical has a similar structure to many endogenous fatty esters (waxes). These natural waxes form protective coatings for leaves of many plants. They are formed and used extensively by marine plankton organisms (15). As the substance is similar to chemicals produced endogenously by many plants and has a low acute aquatic toxicity, the notifier expects the notified chemical to have a low order of toxicity to algae.

According to the above information presented by the notifier, it is expected that the notified chemical will be of low toxicity to both water fleas and algae up to the level of its solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical will be used in general purpose lubricants for automotive and industrial oil blends. The main exposure will be from inappropriate disposal of oil. A worst case scenario would be if all the uncollected oil was dumped into a sewer in some country centre. This would give a concentration of about 9.6 mg/L per day 5 . For a major city, the amount would only be about 95.9 μ g/L per day. As these predicted environmental concentrations (PEC) cannot exceed the water solubility and ecotoxicity tests show that the chemical is expected to be non-toxic to rainbow trout up to the limit of its solubility, effects in fish are not expected. From the information presented by the notifier, the PEC values for the notified chemical should also be at least an order of magnitude lower than the EC₅₀ values for both water flea and algae.

The actual concentration of the notified chemical would be limited by its water solubility (1.52 mg/L), and with its high log partition coefficient (> 6) the concentration in water is expected to be significantly below the stated solubility in water. Further, with its use Australia wide (*ie* not concentrated in one town or city), and with good industrial and public practice, aquatic exposure to the chemical is expected to be significantly less, resulting in environmental concentrations well below these levels. Therefore, it is unlikely that this would cause any acute effects.

⁴ Klapow and Lewis (14) reviewed the relationship between the kind of test organism and its influence on toxicity data. They reported that well over half of the lethal levels of pollutants tested in different species fell within one order of magnitude.

 $^{^5}$ Given 35% of the oil is not collected, then of the 50 000 kg of the notified chemical in automotive oil for home use, 17500 kg would not be collected (*ie* 35% x 50 000 kg). This would be 47.9 kg/day (*ie* 17 500 kg/365 days). The dilution at a rural town could reasonably be expected to be about 5 ML, while for a major city, say Melbourne, it would be 500 ML. This would give final concentrations of the oil of 9.6 mg/L per day and 95.9 μ g/L per day, respectively.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical, a carboxylic acid ester, will only be imported as concentrate for blending into a range of lubricating oils at a concentration of approximately 5%. Only limited toxicological data were provided for the notified chemical with supporting documentation provided for similar analogues. The notified chemical has a low oral toxicity and is not a classifiable as an irritant although there were clinical indications of irritancy potential in a study using rabbits. The analogue data suggests that chemicals such as Emkarate 8500 are unlikely to cause significant toxicological effects such as toxicity via oral, dermal or inhalational exposure, mutagenesis, teratogenesis or carconogenesis. There is some potential for irritancy in carboxylic esters and in the absence of definitive eye irritation test data for the notified chemical it is advisable that eye exposure to the concentrate be limited by personnel protective equipment. The molecular weight of Emkarate 8500 is in excess of 500 Daltons, this will limit absorption across biological membranes and subsequent systemic effects. The molecular weight is not sufficiently high to completely preclude absorption. Carboxylic acid esters are readily broken down via hydrolysis hence even with chronic exposure significant bioaccumulation is unlikely.

Occupational exposure to the notified chemical will occur at two levels, to the concentrate during blending and to a 5% concentration during use of the resultant formulations. The blending and transfer operations are the most probable areas in which occupational exposure will occur. The potential for both eye and dermal exposure exists especially during transfer of the concentrate and blended formulations. Blending takes place at elevated temperatures however the use of exhaust ventilation during this process will limit exposure to fumes. Exposure to the concentrate will be limited to 12 days per year for those staff associated with the blending process. Occupational exposure to the blended lubricating oils will be much more widespread with the notifier unable to provide a definitive number of potentially exposed employees as this will be dependent on market penetration. However the mechanics using the lubricants will only be exposed to formulations containing approximately 5% of the notified chemical.

From a public health perspective the primary toxicological concerns associated with Emkarate 8500 are skin irritation and the potential for eye irritation. In both instances minor discomfort rather than significant injury would be the expected outcome from significant exposure. As Emkarate 8500 constitutes only 5% of the final product, significant exposure to the notified chemical is unlikely and consequently the risk of significant adverse outcomes is considered likely to be negligible.

The notified chemical on the basis of submitted toxicological data and with reference to the submitted analogue data would not be classified as hazardous according to the criteria of Worksafe Australia (9). The risk through occupational exposure to the notified chemical is considered to be low.

13. RECOMMENDATIONS

To minimise occupational exposure to Emkarate 8500 the following guidelines and precautions should be observed when handling the concentrate:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (16) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (17);
- Industrial clothing should conform to the specifications detailed in AS 2919 (18) and AS 3765.1 (19);
- Impermeable gloves or mittens should conform to AS 2161 (20);
- All occupational footwear should conform to AS/NZS 2210 (21);
- Spillage of the notified chemical 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 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 Material Safety Data Sheets* (22).

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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- 8. 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**.
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- 15. *In* 'Lehninger A.L. 1982, "Principles of Biochemistry", A.L. Lehninger (ed.), Worth, p.309.
- 16. Standards Australia 1994, Australian Standard 1336-1994, Eye protection in the Industrial Environment, Standards Association of Australia Publ., Sydney.
- 17. Standards Australia/Standards New Zealand, 1992. Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.
- 18. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing*, Standards Association of Australian Publ., Sydney.
- 19. Standards Australia 1990, Australian Standard 3765.1-1990, Clothing for Protection against Hazardous Chemicals Part 1 Protection against General or Specific Chemicals, Standards Association of Australia Publ., Sydney.
- 20. Standards Australia 1978, Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves), Standards Association of Australia Publ., Sydney.
- 21. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear,* Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.
- 22. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets* [NOHSC:2011(1994)], Australian Government Publishing Service, 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	3 severe
	36761 6	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