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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

C I DIRECT VIOLET 107

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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For Enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA

Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA

Telephone: (61) (02) 577-9466 **FAX (61) (02) 577-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**C I DIRECT VIOLET 107****1. APPLICANT**

Epson Australia Pty Ltd of 70 Gibbes Street CHATSWOOD NSW 2067 has submitted a standard notification statement in support of their application for an assessment certificate for C I Direct Violet 107.

2. IDENTITY OF THE CHEMICAL

C I Direct Violet 107 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 have been exempted from publication in the Full Public Report and the Summary Report.

The notified chemical contains no hazardous impurities at levels necessary to classify it as a hazardous substance (11). Therefore, information on the purity of the chemical has been exempted from publication in the Full Public Report and the Summary Report.

Other names:	Substance S161629 C I Direct Violet 107
Trade name:	Pro-jet Fast Magenta 2 Pro-jet Fast Magenta 2 Liquid (formulation)
Molecular weight:	1455 (approximately)
Method of detection and determination:	HPLC separation using a gradient solvent system (methanol containing 1% tetrabutylammonium phosphate, pH 7) with detection at 520 nm

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	dark brown powder
Melting point:	>300 °C
Density:	1480 kg/m ³
Vapour pressure:	< 1.0 x 10 ⁻⁶ kPa (20-50°C) (based on comparative estimates)
Surface Tension (of aqueous solution):	72.5 mN/m at 23°C

Partition co-efficient (n-octanol/water):	$\log P_{ow} < -3.3$ at 25°C
Hydrolysis as a function of pH:	< 10% hydrolysis at pH 7 and 9 (50°C, 8 days); test could not be carried out at pH 4 due to gel formation.
Adsorption/Desorption:	not determined; the notifier states due to insolubility at low pH (not specified) that the notified chemical is likely to exhibit low mobility in soils
Dissociation constant:	not determined; the notified chemical is expected to have dissociation constants typical for the various functionalities
Flash point:	not applicable
Flammability limits:	does not propagate combustion
Autoignition temperature:	381°C
Explosive properties:	not explosive
Reactivity/Stability:	non-oxidising

Comments on Physico-Chemical Properties

Tests were performed according to EEC test guidelines and at facilities complying with OECD principles of Good Laboratory Practice.

By EEC definition, a chemical has surface activity when the surface tension is less than 60 mN.m⁻¹, thus the substance is not considered surface active (EEC Directive 92/69, A5 "Surface Tension" (1992)).

The notifier's comments regarding adsorption/desorption indicate strong adsorption of the notified chemical may occur. However, the relatively high solubility, low partition coefficient, and low fat solubility of the notified chemical would tend to indicate low adsorption. Furthermore, during normal use a proportion of the notified chemical will encounter sewage and recycling effluents, the alkaline nature of these systems is likely to result in low sorption of the notified chemical to solids.

4. PURITY OF THE CHEMICAL

Degree of purity:	74.9% (range 70-80%)
Toxic or hazardous impurities:	none
Additives/Adjuvants:	none

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as a component (typically 4%) in aqueous coloured (magenta) ink formulations for colour ink-jet cartridges, used in ink-jet reprographic processes. It will be imported as a 3-4% aqueous solution in a sealed

cartridge at a rate of 0.5-1 tonne for the first year and 0.5-1.5 tonnes per year for the next 4 years. The notified chemical will be used Australia wide, predominantly in the home and small office markets.

6. OCCUPATIONAL EXPOSURE

The volume of ink in a cartridge will not exceed 50 mL. The volume of any single coloured (non-black) is expected to be < 15 mL. The rate of usage of coloured ink is not uniform. It is stated that normal handling, involving replacement of the spent ink cartridge by service technicians or office workers will not result in exposure to the ink and such exposure should only result if the cartridge is faulty and ruptures. Up to 1000 printer service technicians and several thousand office workers may be potentially exposed to the notified chemical.

7. PUBLIC EXPOSURE

Normal handling involving replacement of spent ink cartridge by consumers is not expected to result in significant exposure to the notified chemical. However, exposure may occur through accidental rupture of a cartridge.

The public may come in contact with paper printed with the formulated ink, but the potential for public exposure is expected to be minimal. This is because the printed paper will contain only milligram quantities of the notified chemical per sheet and the notified chemical being insoluble on contact with the surface of paper.

Negligible public exposure is expected as a result of disposal of empty cartridges or printed paper or recycling of printed paper.

8. ENVIRONMENTAL EXPOSURE

• Release

During normal use the notified substance will become bound to cellulosic substrates and in this state is not expected to adversely impact on the environment. Although the notified chemical is soluble at the pH of the ink solution (pH 9), it becomes insoluble on contact with paper, a result of the lower pH of the paper.

Environmental exposure will result from the disposal of printed paper and discarded cartridges. In addition to landfill, printed paper may also be recycled after first being subjected to a de-inking process. De-inking wastes are expected to go to trade waste sewers. On combustion oxides of carbon, nitrogen and sulphur will be released.

Ink residues contained in the emptied cartridges are expected to remain within the cartridge housing.

• Fate

The relatively high water solubility of the notified chemical indicates that unbound residues released directly to the aquatic compartment are likely to remain in solution (particularly in alkaline sewers) where they will be rapidly diluted.

The biodegradation potential of the notified substance was assessed using a manometric respirometer (OECD TG 301F). Results for the biological and chemical

oxygen demand ($BOD_5 < 0.01 \text{ g O}_2/\text{g}$, $COD 0.72 \text{ g O}_2/\text{g}$) indicate that the rapid biodegradation is considered unlikely under aerobic conditions.

The bioaccumulation potential of the notified chemical was not investigated. The low partition coefficient ($\log P_{ow} = -3.3$) and high water solubility ($> 34 \text{ g/L}$) of the notified chemical indicate that significant bioaccumulation is not likely.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of C I Direct Violet 107

Test	Species	Outcome	Reference
acute oral toxicity	rat	$LD_{50} > 2000 \text{ mg/kg}$	1
acute dermal toxicity	rat	$LD_{50} > 2000 \text{ mg/kg}$	2
skin irritation	rabbit	slight irritant	3
eye irritation	rabbit	slight irritant	4
skin sensitisation	guinea pig	sensitiser	5

9.1.1 Oral Toxicity (1)

<i>Species/strain:</i>	Wistar-derived albino rats (Alp K:APF SD)
<i>Number/sex of animals:</i>	5/5
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	gavage (de-ionised water)
<i>Clinical observations:</i>	no significant signs of toxicity
<i>Mortality:</i>	no deaths
<i>Morphological findings:</i>	no macroscopic abnormalities detected at necroscopy
<i>Test method:</i>	directive 84/449/EEC (6) Test B1
<i>LD_{50}:</i>	$> 2000 \text{ mg/kg}$
<i>Result:</i>	low acute oral toxicity in rats

9.1.2 Dermal Toxicity (2)

<i>Species/strain:</i>	Wistar-derived albino (Alp K:APF SD)
<i>Number/sex of animals:</i>	5/5
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	as a paste with de-ionised water

<i>Clinical observations:</i>	no significant signs of toxicity; slight skin irritation overall
<i>Mortality:</i>	no deaths
<i>Morphological findings:</i>	no macroscopic abnormalities detected at necroscopy
<i>Test method</i>	directive 84/449/EEC (6) Test B3
<i>Result</i>	low acute dermal toxicity in rats

9.1.4 Skin Irritation (3)

<i>Species/strain:</i>	New Zealand White rabbit
<i>Number/sex of animals:</i>	3 females
<i>Observation period:</i>	7 days
<i>Method of administration:</i>	sample moistened with de-ionised water applied under occlusive gauze dressing for four hours

Draize scores (7):

<i>Animal #</i>	<i>Time after treatment (days)</i> <i>30-60 min</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>7</i>
<i>Erythema</i>					
1	ⁱ	*	0	0	0
2	*	*	0	0	0
3	*	*	*	*	0
<i>Oedema</i>					
1	0	0	0	0	0
2	0	0	0	0	0
3	1	0	0	0	0

ⁱ See Attachment 1 for Draize scales

* unable to assess due to staining

<i>Test method:</i>	directive 84/449/EEC (6) Test B4
<i>Result:</i>	slight irritant to rabbit skin

9.1.5 Eye Irritation (4)

<i>Species/strain:</i>	New Zealand White rabbit
<i>Number/sex of animals:</i>	3 females
<i>Observation period:</i>	22 days
<i>Method of administration:</i>	test substance (100 mg) instilled in

conjunctival sac of one eye

Draize scores (7):

	Time after instillation														
Animal	1 day			2 days			3 days			4 days			7 days		
Cornea	o ^a	a ^b		o ^a	a ^b		o ^a	a ^b		o ^a	a ^b		o ^a	a ^b	
1	i*	*		*	*		*	*		*	*		*	*	
2		**		*	*		*	*		*	*		*	*	
3		**		*	*		*	*		*	*		0	0	
Iris															
1		*			*			*			*			*	
2		*			*			*			*			*	
3		*			*			*			*			*	
Conjunctiva	r ^c	c ^d	d ^e	r ^c	c ^d	d ^e	r ^c	c ^d	d ^e	r ^c	c ^d	d ^e	r ^c	c ^d	d ^e
1	*	1	0	*	0	0	*	0	0	*	0	0	*	0	0
2	*	1	0	*	0	0	*	0	0	*	0	0	*	0	0
3	*	0	0	*	0	0	*	0	0	*	0	0	0	0	0

ⁱ See Attachment 1 for Draize scales

^a Opacity ^b Area ^c Redness ^d Chemosis ^e Discharge

Test method: directive 84/449/EEC (6) Test B5

Result: slight irritant to rabbit eye

9.1.6 Skin Sensitisation (5)

Species/strain: albino male guinea pig/AlpK: Dunkin Hartley

Number of animals: 20 in test group/10 in control group

Induction procedure: pairs of injections of 50-100 µL: 3% (w/v) test article in corn oil, 3% (w/v) in FCA plus corn oil (1:1) and FCA plus corn oil (1:1); topical induction at day 8 with 2-300 µL of 75% (w/v) in corn oil under occlusive dressing for 48 hours

Challenge procedure: on day 22: 75%, 30%, 10% and 3% (w/v) test article in corn oil under occlusive dressing for 24 hours

Challenge outcome: staining of the challenge sites precluded viewing as a means of determining a positive response; histopathological examination was performed; some reduction in response was observed at the higher concentrations with 10% test article exhibiting the maximum response

Challenge concentration	Induction solvent only		Induction test substance	
	test*	control	test	control
3%	6/10	0/10	13/20	0/20
10%	8/10	0/10	17/20	0/20

* number of animals showing a positive response

Detailed histopathological results:

Challenge concentration		3%		10%	
		Induction solvent	Induction test substance	Induction solvent	Induction test substance
Acanthosis					
focal	-minimal	0.1*	0.05	0.3	0.00
	-slight	0.0	0.00	0.1	0.00
multifocal	-minimal	0.1	0.15	0.1	0.00
	-slight	0.1	0.30	0.1	0.40
diffuse	-slight	0.2	0.15	0.1	0.40
	-moderate	0.0	0.00	0.1	0.05
Inflammatory cell infiltration					
focal	-minimal	0.3	0.05	0.2	0.00
	-slight	0.0	0.05	0.1	0.00
multifocal	-minimal	0.3	0.20	0.2	0.35
	-slight	0.0	0.10	0.3	0.30
	-moderate	0.0	0.00	0.0	0.05

* fraction of animals exhibiting response

Test method: directive 84/449/EEC (6) Test B6

Result: histopathological examination revealed a variable inflammatory reaction with acanthosis and inflammatory cell infiltration in both test and control groups; however, as the reaction was more pronounced in the test group, the substance was judged to be a skin sensitiser

9.2 Repeated Dose Toxicity (8)

Species/strain: Rat/ AlpK: APfSD (Wistar derived)

Number/sex of animals: 6 groups of 5 of each sex (20 of each sex main study group 10 of each sex recovery group)

Method of administration: orally by gavage (de-ionised water)

Dose/Study duration:: 0, 16.4, 164 or 1096 mg/kg/day for 28 days

	plus 14 day recovery
<i>Clinical observations:</i>	no clinical signs of toxicity observed in any of the animals
<i>Clinical chemistry/Haematology</i>	there were no significant observations
<i>Histopathology:</i>	there were no significant changes
<i>Test method:</i>	directive 84/449/EEC (6) Test B7
<i>Result:</i>	no adverse effects attributable to dose substance upto 1096 mg/kg/day

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (9)

<i>Strains:</i>	<i>Salmonella typhimurium</i> TA 1537, TA 1538, TA 98, TA 100 and <i>Escherichia coli</i> WP2P and WP2PuvrA (pKM101)
<i>Concentration range:</i>	200 to 7580 µg/ plate
<i>Test method:</i>	directive 84/449/EEC (6) Test B10
<i>Result:</i>	No significant dose-related induction of mutations above background in the presence or absence of metabolic activation provided by rat liver S9

9.3.2 In Vitro Cytogenetic Assay in Human Lymphocytes(10)

<i>Species/strain:</i>	<i>Homo sapiens</i>
<i>Number and sex of donors:</i>	1 male and 1 female
<i>Doses:</i>	0, 100 and 250 µg/ml at 68 hour sampling time (M and F); 250 µg/ml at 92 hour sampling (F)
<i>Method of administration:</i>	dosing suspension of the test material was prepared in supplemented RPMI-1640 culture medium followed by serial dilutions; the culture medium was used as the medium control
<i>Test method:</i>	directive 84/449/EEC (6) Test B12
<i>Result:</i>	no significant increases in the percentage of aberrant cells over control values at dose levels in treated cultures from either sex in the presence or absence of S9-mix were observed at any of the sampling times

9.4 Overall Assessment of Toxicological Data

C I Direct Violet 107 was of low acute toxicity via the oral and dermal routes in the rat with both LD₅₀s > 2000 mg/kg. It was a slight irritant to the skin and eye of the rabbit. It was a skin sensitiser in guinea pigs. When rats were treated orally with up to 1096 mg/kg/day for 28 days no results of toxicological significance were observed. C I Direct Violet 107 was found to be non-mutagenic *in vitro* to *Salmonella typhimurium* TA 1537, TA 1538, TA 98 and TA 100 and to *Escherichia coli* WP2uvrA (pKM101) and non-clastogenic in an *in vitro* cytogenetic assay using human lymphocytes.

On the basis of submitted data, the notified chemical would not be classified as hazardous in accordance with Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (11) in relation to acute lethal effects (oral, dermal); irritant effects (skin, eye); sensitising effects (skin) and severe effects after repeated or prolonged exposure (oral route).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following table summarises the ecotoxicity tests provided by the notifier for C I Direct Violet 107. These tests were performed in accordance with OECD guidelines and principles of GLP.

Test	Species	Results
acute toxicity	rainbow trout <i>Oncorhynchus mykiss</i>	^a LC ₅₀ = >180 mg/L (12)
acute toxicity	<i>Daphnia magna</i>	^a NOEC > 82 mg/L (13) ^a EC ₅₀ > 82 mg/L
growth inhibition	<i>Selenastrum capricornutum</i>	biomass: ^a E _b C ₅₀ = 31 mg/L (14) growth rate: ^a NOEC = 6 mg/L ^a E _r C ₅₀ > 100 mg/L ^a NOEC = 12 mg/L
5% inhibition of respiration	activated sludge	^b IC ₅₀ > 1000 mg/L (15)

* NOEC - no observable effect concentraion

^a mean measured result

^b nominal concentration

The fish study made no comment for NOEC (12). However, the test solutions were observed to be opaque and dark pink in colour, and presumably this prevented observations of the toxicity symptoms. The mean measured concentrations ranged from 89-100% of the nominal value.

In the *Daphnia magna* study (13) the mean measured concentration ranged from 15-18% of the nominal. Since the test media reacted with the notified chemical to form a gelatinous precipitate at the bottom of the test solution, the supernatant solution was decanted and used as the test solution. Spectral comparisons of the supernatant with a solution of the notified chemical in deionised water showed no significant differences. Therefore, the integrity of the test solution was maintained. No immobilisation of *Daphnia magna* was observed.

No mortalities were reported in either aquatic study. The results show that the notified chemical is practically non-toxic to the fish and daphnia species studied.

Algal growth inhibition testing indicated the active was slightly to practically non-toxic to algae (14). The test solution was observed to be clear, with a pink to red colouration. The mean measured concentration ranged from 98-108% of the nominal values. The slight algicidal activity measured may be attributed to the reduced light transmittance through the test solution and the possible reduction in photosynthetic activity resulting from the colouration of the test solution by the notified chemical.

The potential effects of the active on sewage treatment were investigated under aerobic conditions. 1000 mg/L (nominal) of the notified substance caused < 5% inhibition in the respiration rate of the microorganism in activated sludge (ETAD Method 103) (15). No significant effects on the sewage treatment systems are considered likely.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

C I Direct Violet 107 is not expected to present a hazard to the environment. During normal use the chemical will be bound to the treated substrate.

The residues of uncured inks from discarded colour cartridges are expected to remain in the cartridge housing.

Recycling of treated paper could result in the release of a proportion of the notified chemical to the aquatic compartment where it will be rapidly diluted to environmentally negligible levels. Where recycling does not occur, the notified chemical will be widely distributed in landfills around Australia where the notified chemical is expected to remain bound to the treated paper. In the event of leaching the environmental effects are expected to be negligible due to the low toxicity and low bioaccumulation potential of the notified chemical. Biodegradability is limited (16).

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The toxicological profile of C I Direct Violet 107 suggests that it is unlikely to be acutely toxic via the oral and dermal routes and is likely to be neither mutagenic nor clastogenic. It is expected to be a slight skin and eye irritant and a weak skin sensitiser. It is unlikely to exhibit toxic effects on repeated or prolonged exposure. C I Direct Violet 107 is not classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (11) in relation to the toxicological data provided.

The notified chemical is to be used in ink-jet reprographic processes and is to be imported in sealed ink-jet cartridges which are inserted directly into ink-jet printers. Therefore, exposure to the notified chemical during normal handling is not expected other than in the unlikely event that the cartridge is faulty and ruptures.

The occupational health risk associated with importation, storage, use or disposal of the notified chemical is expected to be minimal.

The potential for public exposure to the notified chemical by handling the ink cartridges is expected to be negligible. Exposure by contact with the printed paper is also expected to be negligible because of the low level of the notified chemical used in the ink and its insolubility on the surface of paper.

13. RECOMMENDATIONS

To minimise occupational exposure to C I Direct Violet 107 the following guidelines and precautions should be observed:

- in the event of a spill or during routine cleaning or maintenance, if engineering controls or work practices are insufficient to reduce exposure of C I Direct Violet 107 to a safe level, personal protective devices which conform to and are used in accordance with Australian Standards (AS) or Australian/ New Zealand Standards (AS/NZS) for eye protection (AS 1336, AS/NZS 1337) (17,18), impermeable gloves (AS 2161) (19) and overalls (AS 2919) (20) should be worn; and
- a copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the ink containing C I Direct Violet 107 was provided in accordance with the *National Code of Practice for the Preparation of a Material Safety Data Sheets* (21).

This MSDS was provided by Epson Australia Pty Limited 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 Epson Australia Pty Limited.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of C I Direct Violet 107 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

1. Project AR5633, January 1991. *Acute Oral Toxicity Study with S161629 in Rats*. ZENECA Toxicology Laboratory, Cheshire, United Kingdom.
2. Project CR3091, Jan 1994. *Acute Dermal Toxicity Study with S161629 in Rats*. ZENECA Toxicology Laboratory, Cheshire, United Kingdom.
3. Project EB4239, Dec 1993. *Primary Skin Irritation Study with S161629 in Rabbits*. ZENECA Toxicology Laboratory, Cheshire, United Kingdom.
4. Project FB4801, Feb 1994. *Primary Eye Irritation Study with S161629 in Rabbits*. ZENECA Toxicology Laboratory, Cheshire, United Kingdom.
5. Project GG6014, Feb 1994. *Contact Hypersensitivity to S161629 in Albino Guinea Pigs, Maximisation Test*, ZENECA Toxicology Laboratory, Cheshire, United Kingdom.
6. EEC Commission Directive 84/449 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations, *Official Journal of the European Communities* No. L 251 (19 September 1984).
7. 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**.

8. Project KR1196, April 1994. *Subacute 28-Day Oral Toxicity Gavage Study with S161629 in Rats*. ZENECA Toxicology Laboratory, Cheshire, United Kingdom.
9. Project YV3269, Oct 1993. *Salmonella typhimurium and Escherichia coli Reverse Mutation Assay for Azo dyes with S161629*. ZENECA Toxicology Laboratory, Cheshire, United Kingdom.
10. Project SV0701, Feb 1994. *An Evaluation in the in Vitro Cytogenetic Assay in Human Lymphocytes*. ZENECA Toxicology Laboratory, Cheshire, United Kingdom.
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15. Project BL5098/B, Dec 1993. *Effect on the respiration of activated sludge*. ZENECA Environmental Laboratory, Devon, United Kingdom.
16. Project BL5006/B, Dec 1993. *Determination of Biodegradability*. ZENECA Environmental Laboratory, Devon, United Kingdom.
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 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ., Sydney, Australia.
20. Standards Australia, 1987, *Australian Standard 2919 - 1987 Industrial Clothing*, Standards Association of Australia Publ., Sydney, Australia.
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, Australia.

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

<i>Values</i>	<i>Rating</i>
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