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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

CIN-10097929

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

CIN 10097929

1. APPLICANT

Kodak Australasia Pty Ltd of 173 Elizabeth Street COBURG VIC 3058 has submitted a standard notification statement in support of their application for an assessment certificate for CIN 10097929.

2. IDENTITY OF THE CHEMICAL

CIN 10097929 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, spectral data, details of formulation concentrations for each use have been exempted from publication in the Full Public Report and the Summary Report.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white solid
Melting Point	59.5 - 64.3^{o}C
Boiling Point:	decomposes at 333°C
Specific Density:	1 142.5 kg.m^{-3}
Vapour Pressure:	< 2.1 x 10^{-4} Pa at 25°C
Water Solubility:	0.6 mg.L^{-1} at 25°C
Partition Co-efficient (n-octanol/water):	log P_{ow} = 5.24
Hydrolysis as a Function of pH:	hydrolytically stable at pH 4.0 - 9.0
Adsorption/Desorption:	not determined
Dissociation Constant:	not determined

Particle size	1254.9 µm (50% median)
Flash Point:	not determined
Flammability Limits:	not determined
Autoignition Temperature:	460°C
Explosive Properties:	non-explosive
Reactivity/Stability:	non-oxidising

Comments on Physico-Chemical Properties

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

An attempt to determine the adsorption/desorption characteristics of the notified chemical, according to OECD Guideline 106 {Organisation for Economic Co-operation and Development, 1995-1996 #15}, was unsuccessful due to the low water solubility of the test substance. Based on the high value of the partition coefficient the notified chemical is expected to adsorb strongly to soil/sediments.

Determination of a dissociation constant was attempted, using OECD Guideline 112, but not determined due the low solubility of the notified chemical in water (acidified, neutral and basic), organic solvents (methanol, tetrahydrofuran, 2-propanol, acetonitrile or acetone). The notified chemical contains a tertiary aromatic amine functionality which is expected to have typical basicity.

4. PURITY OF THE CHEMICAL

Degree of Purity:	99.8 %
Toxic or Hazardous Impurities:	none
Non-hazardous Impurities (> 1% by weight):	none
Additives/Adjuvants:	none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It will be imported into Australia in plastic bags containing 10.725 kg of the pure notified chemical. The bags will be contained in cardboard boxes. Import volumes for the notified

chemical are expected to be 35 tonnes per annum over the first five years.

CIN 10097929 will be imported into Australia and used on the Kodak site, Coburg, Victoria, in the formulation of photographic film and paper.

6. OCCUPATIONAL EXPOSURE

It is estimated that 745 batches will be made per year, requiring a total of approximately 11 tonnes of CIN 10097929 per year. The notified chemical will be added to the mix tank along with other substances. The mixture formed will be cooled and stored for up to several weeks. It will then be added to a melt tank where other addenda are added to form a melt. The melt will then be pumped to closely-controlled automated processing equipment used to produce photographic film and paper.

Exposure to the notified chemical during transport and storage is only likely to occur in the event of an accidental spill.

The notifier states that the notified chemical will be re-weighed and added to mixing tanks approximately 745 times per annum, with a total of 24 workers being involved in this process over the given period. Addition of other addenda results in a mixture which will eventually be incorporated into articles. Workers exposed to the notified chemical include 24 flow operators, 5 laboratory technicians, and 29 melt operators. The main routes of exposure for these workers are likely to be oral and ocular.

Inhalational exposure to the powdered form of the notified chemical may occur during re-weighing. To reduce airborne concentrations of the notified chemical, the addition to the mix tank will be conducted using air extractors fitted with fiberglass air filters and mechanical ventilation.

7. PUBLIC EXPOSURE

Following import, the notified chemical will be only available to industrial processors at one site in Australia, and not to the general public.

Once the notified chemical is incorporated into finished products, it will be trapped under overcoat layers. Hence no significant exposure to the general public is expected.

8. ENVIRONMENTAL EXPOSURE

Release

Release of the chemical during the film/paper manufacturing process described above is limited to the one site in Coburg Victoria where that process occurs.

Residues in various wastes from that site could end up in sewage effluent, in secured landfill sites, or in material subsequently processed for silver recovery. Once the chemical becomes part of the article, the layers containing the notified chemical in low concentrations are securely bound to the film or paper base and overcoated by protective layers. These surface layers will prevent direct exposure to the environment of the notified chemical. Additionally, the chemical is expected to remain immobile during the processing of the film or paper.

The notifier estimates that approximately 3.5% of the mixture from the mix tank could be released to the municipal sewer. This would result in a maximum of 6.3 kg per day release of the chemical. The notified chemical released as an aqueous mixture to the municipal sewer.

Any of the chemical released from the automated processing equipment (up to 5% from the melt tank and processing equipment) is trapped as "filter cake" for later silver recovery. Any chemical trapped in the filter cake would be expected to be destroyed when the filter cake is smelted to regenerate silver, which is performed in the USA.

Additionally, the notifier estimates that up to 1% of the notified chemical generated as waste in the manufacture of film and paper may be sent to a secured landfill.

Fate

Waste from the production of a batch of the aqueous solution is expected to be released to the sewer, with secondary to tertiary sewage treatment by the Werribee treatment works. Level 1 Mackay calculations for CIN 10097929 indicate that at equilibrium approximately 50%, 46%, 4% and 0.2% will be partitioned to soil, sediment, water and air, respectively. Hence, CIN-10097929 should strongly partition to the soils and sediment of Werribee treatment works.

Waste trapped in filter cake is processed in the USA. Empty plastic bags used to ship the chemical, contain traces of the chemical and will be confined to secure landfill. The cardboard boxes will be recycled. Used or waste photographic film and paper would be incinerated, or buried in landfill.

The substance was examined for biodegradation potential using EEC Directive 92/69, Part C.4-C (Modified Sturm Test), and OECD Test Guideline 301B (substance added directly to test carboys due to sparing solubility). No biodegradation was observed during the 28 day test, indicating that the notified chemical is not readily biodegradable under the conditions of the test.

The high partition coefficient and very low water solubility of the notified chemical would indicate a potential for bioaccumulation {Connell, 1989 #3}. However, any potential for bioaccumulation would be moderated by limited exposure to natural waters.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of CIN 10097929

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	> 2 000 $mg.kg^{-1}$	{Shepard, 1994 #87}
acute dermal toxicity	rat	> 2 000 $mg.kg^{-1}$	{Shepard, 1994 #88}
skin irritation	rabbit	not irritating	{Shepard, 1994 #89}
eye irritation	rabbit	slightly irritating	{Shepard, 1994 #90}
skin sensitisation	guinea pig	non-sensitising	{Shepard, 1994 #91}

9.1.1 Oral Toxicity {Shepard, 1994 #87}

Species/strain:	rat/CD®(SD)BR VAF/Plus
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage; 20% suspension in guar gum(0.5 % aqueous suspension)
Clinical observations:	nil
Mortality:	nil
Morphological findings:	no treatment-related changes observed; all animals gained weight
Test method:	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
LD_{50}*:*	> 2 000 $mg.kg^{-1}$
Result:	the notified chemical was of low oral toxicity to rats

9.1.2 Dermal Toxicity {Shepard, 1994 #88}

Species/strain:	rat/CD®(SD)BR VAF/Plus®
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	administered as a solid moistened with water to shaved area; occlusive wrap applied for 24 hours
Clinical observations:	no abnormal signs
Mortality:	nil
Morphological findings:	no treatment-related changes
Test method:	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
LD_{50}*:*	> 2 000 $mg.kg^{-1}$
Result:	the notified chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

not determined

9.1.4 Skin Irritation {Shepard, 1994 #89}

Species/strain:	rabbit/Hra:(NZW)SPF
Number/sex of animals:	3; sex not determined
Observation period:	72 hours
Method of administration:	moistened solid applied under occlusive wrap for four hours to an area of exposed dorsal skin

Draize scores {Draize, 1959 #4} all Draize scores were zero

Test method: similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}

Result: the notified chemical was not a dermal irritant in rabbits

9.1.5 Eye Irritation {Shepard, 1994 #90}

Species/strain: rabbit/Hra:(NZW)SPF

Number/sex of animals: 6; sex not determined

Observation period: 72 hours

Method of administration: single dose of the notified chemical placed into the conjunctival sac of one eye; untreated eye served as a control

Draize scores {Draize, 1959 #4} of unirrigated eyes: no corneal or iridial effects noted.

	Time after instillation							
Animal	***1 hour***		***1 day***		***2 days***		***3days***	
Conjunctiva	***r[c]***	***c[d]***	***r[c]***	***c[d]***	***r[c]***	***c[d]***	***r[c]***	***c[d]***
1	1	0	0	0	0	0	0	0
2	2	0	1	0	0	0	0	0
3	1	0	0	0	0	0	0	0
4	1	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0
6	1	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
[a] opacity [c] redness [d] chemosis

Irrigated eyes: normal

Test method: similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}

Result: the notified chemical was a slight eye irritant in rabbits

9.1.6 Skin Sensitisation {Shepard, 1994 #91}

Species/strain: guinea pig/Crl:(HA)BR VAF/Plus®

Number of animals: 20 test; 10 control

Induction procedure: day 0 - three pairs of intradermal injections
0.1 mL of notified chemical (5%) in corn oil
0.1 mL of 5% FCA emulsion (equal parts
0.1 mL of notified chemical (5%) in FCA emulsion

day 6 - the application site of all animals painted with approximately 0.5 mL of 10% sodium lauryl sulfate

day 7 - approximately 2 g (25%) of the notified chemical was dermally applied to each animal (control and test) under occlusive dressing. The patches of both groups were left in place for 48 hours

Challenge procedure: day 21 - a 25% concentration of the notified chemical in petrolatum was applied to the left flank of each animal; a second patch with 100% petrolatum was applied to right flank; patches were removed after 24 hours.

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
25%	0/20**	0/20	0/20	0/20

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

Test method: similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}

Result: the notified chemical was not a dermal sensitiser in guinea pigs

9.2 Repeated Dose Toxicity

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex for each test group
Method of administration:	oral/gavage
Dose/Study duration::	0 (control), 100 (low), 300 (mid) and 1 000 (high) $mg.kg^{-1}.day^{-1}$ for a period of 28 days
Clinical observations:	the high dose group showed treatment-related signs of toxicity including hypothermia, depression of general activity, gait disturbances, abnormal respiratory rate, sialorrhea, dehydration, porphyrin tears, nasal discharges, piloerection, hair wet by urine, diarrhoea, and decreases in body weight and feed consumption. animals were euthanatised after 2 days treatment-related signs of toxicity for the mid and low dose groups included sialorrhea; no other effects were noted; all animals survived the study
Clinical chemistry/Haematology	high dose females showed elevated levels of sorbitol dehydrogenase, total bilirubin, serum urea nitrogen and decreased mean serum glucose; effects secondary to dehydration included changes in red blood cell parameters no treatment-related changes were noted in the low and mid dose groups
Histopathology:	effects noted in the high dose group include acute inflammation of the mucosa and submucosa of the forestomach and erosion of the forestomach epithelium, elevated number of mitotic figures in hepatocytes and hepatocyte necrosis were also noted low and mid dose groups showed no abnormal histopathology

Test method:	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
Result:	effects were only observed at high doses; target organs were the stomach and the liver

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assays

Strains:	TA98, TA100, TA1535, TA1537, WP2(pKM101) and WP2*urv*A(pKM101)
Concentration range:	100 - 5 000 µg per plate
Test method:	similar to OECD guidelines
Result:	the notified chemical is not mutagenic in these assays

9.3.2 Chromosomal Aberration Assay in Chinese Hamster Ovary (CHO) Cells

Doses:	0.785 - 25.0 $\mu g.mL^{-1}$
Incubation period:	20 and 44 hours
Test method:	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
Result:	the notified chemical did not induce chromosomal aberrations or polyploidy in CHO cells

9.4 Overall Assessment of Toxicological Data

From the data provided, the notified chemical has low oral (LD_{50} greater than 2 000 $mg.kg^{-1}$) and dermal toxicity (LD_{50} greater than 2 000 $mg.kg^{-1}$). It is not an irritant to the skin, nor a skin sensitiser at a challenge concentration of 25%. Eye irritation studies in rabbits show that the notified chemical is a slight eye irritant. 28-day repeat dose oral toxicity studies show that the notified chemical causes toxic effects at 1 000 $mg.kg^{-1}.day^{-1}$ with effects being observed in the stomach and liver. At doses of 100 and 300 $mg.kg^{-1}.day^{-1}$ all animals survived the 28 day test and no significant signs of toxicity were noted. Increased liver weights noted for animals in these groups were considered to be adaptive responses. No inhalation

toxicity studies were provided by the notifier.

In the presence and absence of metabolic activation, the notified chemical was not mutagenic in bacteria, and did not produce chromosomal aberrations in CHO cells. No micronucleus assay data were provided by the notifier. This lack of *in vivo* data is acceptable given the negative results of the *in vitro* tests.

On the basis of the toxicity data submitted by the notifier, the notified chemical would not be classified as hazardous according to the National Occupational Health and Safety Commisssion's *Approved Criteria for Classifying Hazardous Substances*{National Occupational Health and Safety Commission, 1994 #9}.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out to OECD Test Methods.

Test	Species	Results
Acute Toxicity[a] (96 h, static)	Fathead minnow *Brachydanio rerio*	0.50 $mg.L^{-1} \leq EC_{50} \leq$ 0.92 $mg.L^{-1}$ 0.12 $mg.L^{-1}$ < NOEC < 0.16 $mg.L^{-1}$
Acute Toxicity[a] (48 h, static)	*Daphnia magna*	EC_{50} = 0.67 $mg.L^{-1}$ NOEC = 0.50 $mg.L^{-1}$ EC_{50} = 0.85 $mg.L^{-1}$ [c] (0.43, 1.26 $mg.L^{-1}$; 95%)
Chronic Toxicity[b] (21 d, flow-through)	*Daphnia magna*	Reproduction LOEC = 100 $\mu g.L^{-1}$ NOEC = 63 $\mu g.L^{-1}$ Survival LOEC = 460 $\mu g.L^{-1}$ NOEC = 210 $\mu g.L^{-1}$
Growth Inhibition[a] (72 h)	Algae *Scenedesmus capricornutum*	NOEC = 0.270 $mg.L^{-1}$

[a]Test material was added as a stock solution in N,N-dimethylformamide. [b]Test material was added as a stock solution in acetone. [c]Calculated from data provided by the notifier.
NOEC - no observable effect concentration

The effect of the notified chemical in the fish acute toxicity test was examined at six concentrations in replicates (mean measured concentrations of 0.07, 0.08, 0.16, 0.33, 0.70 and 2.20). The NOEC and EC_{50} were determined separately for each set of replicate concentrations. The test report provided by the notifier suggested that the presence of the N,N-dimethylformamide carrier solvent, used to prepare the stock solution of the notified chemical, had an effect on the toxicity of the notified chemical. Mortalities between 0 and 100% were only observed at 0.70 $mg.L^{-1}$ (30 and 90% for each of the replicates), hence, there is insufficient data to calculate an EC_{50} using probit analysis.

The effect of the notified chemical on Daphnia was examined at six concentrations in replicates (mean measured concentrations of 0.23, 0.33, 0.57, 1.06 and 2.26). The test report provided by the notifier suggested that the presence of the N,N-dimethylformamide carrier solvent, used to prepare the stock solution of the notified chemical, had an effect on the toxicity of the notified chemical. An EC_{50} of 0.85 $mg.L^{-1}$ with 95% confidence limits of 0.66 and 0.98 $mg.L^{-1}$ was calculated, using combined replicates and carrier solvent control data as the blank. This would indicate that the effect of the carrier solvent is not likely to be significant.

The chronic effect of the notified chemical to Daphnia was investigated at five concentrations (33, 63, 100, 210 and 460 $\mu g.L^{-1}$). All Daphnia in the highest concentration were dead within 9 days of commencing the test. Survival of ≥93% was observed in all remaining concentrations. Sublethal effects including lethargy, reduced pigmentation and size were observed at the second highest concentration (210 $\mu g.L^{-1}$). Statistically significant reductions in the number of offspring were observed at concentrations above 100 $\mu g.L^{-1}$.

The effect of the notified chemical was only tested at one concentration (0.270 $mg.L^{-1}$) in the algal growth inhibition test. This concentration was achieved by dissolving the chemical in N,N-dimethylformamide. The concentration of the test material decreased from 0.861 $mg.L^{-1}$ to 0.270 $mg.L^{-1}$ during the duration of the test. This decrease in concentration was attributed to precipitation. No adverse effect on either the algal growth rate or biomass was observed during the test.

The ecotoxicity data for the notified chemical indicate that it is highly toxic to fish. The results of the acute toxicity test for Daphnia indicate that the chemical can be considered to be highly toxic. Chronic toxicity studies for Daphnia indicate that the notified chemical is chronically toxic to Daphnia at concentrations above 100 ppb (i.e. also chronically highly toxic). The results of the algal toxicity test indicate that the chemical is not toxic to algae at concentrations up to 270 $\mu g.L^{-1}$.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The maximum expected daily discharge of the chemical to sewer is ~6.3 kg. In the sewer, this quantity will be diluted initially by flow from the Kodak plant (which reaches approximately 400,000 L per day). This flow mixes into the average daily inflow to the Werribee treatment plant of 500 ML, giving a maximum concentration in sewage effluent of 130 ppb.

This PEC value indicates a Q (chronic) value of 1.3 and a Q (acute) value of 0.15, using a LOEC of 100 ppb and an EC50 of 850 ppb, respectively. These hazard quotients indicate a potential aquatic hazard. However, CIN-10097929 will only enter the aquatic environment when the aqueous solution containing the notified substance is discharged to the sewer. Most of the chemical is expected to be removed through the sewerage treatment process by partitioning to sediment (sludge) or soils of Werribee Farm. Based on Level 1 Mackay calculations, the concentration of the notified chemical in receiving waters from Werribee farm

would be reduced to <5 ppb (96% adsorption).

An additional 1% of the notified chemical may be sent to a secured landfill as a result of the manufacture of film and paper. Residues in the mixture going to secured landfill and those in film and paper going to landfill, would presumably degrade at a slow rate, depending on conditions. The chemical is not expected to be mobile in landfill given its low water solubility and high partition coefficient.

Due to the flammability of this substance, residues in filter cake would be destroyed during smelting, as would residues in used containers, paper and film if incinerated.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Occupational exposure to CIN 10097929 will be minimal owing to the automated processing equipment employed by Kodak. Exposure to dusts of the notified chemical during weighing and batch preparation pose the greatest risk to workers. The risk associated with the latter will be minimised by air extractors fitted to the mix tank. The risk of worker exposure during re-weighing of the notified chemical should be minimal, provided the workers use the recommended overalls, safety glasses, gloves and dust mask. Formation of the mixture is likely to minimise worker exposure to the notified chemical during reformulation.

While public exposure to the notified chemical is possible following and accident during transport of CIN 10097929, under normal conditions of transport, handling and industrial use, the likelihood of public exposure to the notified chemical is very low. The cleanup procedures recommended in the Material Safety Data Sheet will assist in minimising public exposure in the event of a spill. There may be widespread public contact with photographic articles containing the notified chemical, however the notified chemical will be trapped under overcoat layers. On this basis, the potential for public exposure to the notified chemical during use of articles incorporating this material is minimal.

13. RECOMMENDATIONS

To minimise occupational exposure to CIN 10097929 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 #21} to comply with Australian/New Zealand Standard (AS/NZS) 1337 {Standards Australia/Standards New Zealand, 1992 #23};

- Industrial clothing should conform to the specifications detailed in AS 2919 {Standards Australia, 1987 #18};

- Impermeable gloves or mittens should conform to AS 2161 {Standards Australia, 1978 #17};
- All occupational footwear should conform to AS/NZS 2210 {Standards Australia/Standards New Zealand, 1994 #24};
- 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 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* {National Occupational Health and Safety Commission, 1994 #13}.

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*, vol. 49, pp. 2-56.

9. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australian Government Publishing Service, Canberra.

10. Standards Australia 1994, *Australian Standard 1336-1994, Eye protection in the Industrial Environment*, Standards Association of Australia, Sydney.

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

12. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing*, Standards Association of Australia, Sydney.

13. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves)*, Standards Association of Australia, Sydney.

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

15. 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 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