File No: NA/535

September 1997

# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

## **FULL PUBLIC REPORT**

CIN 10078604

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Director Chemicals Notification and Assessment

## **FULL PUBLIC REPORT**

#### CIN 10078604

#### 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 10078604.

#### 2. IDENTITY OF THE CHEMICAL

CIN 10078604 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 and details of exact import volume have been exempted from publication in the Full Public Report and the Summary Report.

**Generic Name:** substituted heterocyclic compound

Trade Name: CIN 10078604

Molecular Weight: < 1 000

Method of Detection infrared, ultraviolet-visible and nuclear magnetic

and Determination: resonance spectroscopy

#### 3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C

and 101.3 kPa: white solid

**Melting Point:** 55.5 - 65.5°C

Specific Gravity: 1.2073

**Vapour Pressure:** < 2.32 x 10<sup>-6</sup> kPa at 25°C

**Water Solubility:** < 0.1 mg.L<sup>-1</sup> at 25°C (column elution method)

890 µg.L<sup>-1</sup> (high performance liquid

chromatography (HPLC) method)

**Partition Co-efficient**  $log K_{ow} > 4.5$  (flask shaking method)

(n-octanol/water):  $log K_{ow} = 6.5 (HPLC method)$ 

**Hydrolysis as a Function**  $T_{1/2}$  at pH 4.0 = 191 hours at 25°C (estimated)

 $T_{1/2}$  at pH 7.0 = 2 262 hours at 25°C (estimated)  $T_{1/2}$  at pH 9.0 = 372 hours at 25°C (estimated)

Adsorption/Desorption: not determined (see comments below)

**Dissociation Constant:** not determined (see comments below)

Particle Size: range: 38 to greater than 2 360 μm

median size:  $2 320 \mu m$ 

Flash Point: not determined

Flammability Limits: not highly flammable

**Autoignition Temperature:** 393°C

of pH:

**Explosive Properties:** non-explosive

Reactivity/Stability: not oxidising

# **Comments on Physico-Chemical Properties**

Tests were performed according to EEC/OECD test guidelines (1, 2) at facilities complying with OECD Principles of Good Laboratory Practice.

The hydrolysis studies on the notified chemical were undertaken in 5% N,N-dimethylformamide solutions at elevated temperatures. The estimated half-lives at 25°C indicate that the chemical is relatively resistant to hydrolytic decomposition, particularly at near neutral pH.

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 but not completed due the visually observed insolubility of the notified chemical in water (acidified, neutral and basic), aqueous 5% organic (5% N,N-dimethylformamide, 5% acetone or 5% methanol) mixtures and acidified and basic aqueous organic (5% N,N-dimethylformamide or 5% acetone) mixtures. The notified chemical contains nitrogen atoms that appear from the above would only be protonated at low pH.

#### 4. PURITY OF THE CHEMICAL

**Degree of Purity:** 99.9% (range: 98 - 100%)

**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 in pure form, for use as a film and photographic paper manufacturing chemical.

Greater than one tonne of the notified chemical will be imported annually for each of the first 5 years.

#### 6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported in pure form, in plastic bags contained within a fibre drum. Each bag will contain 11 kg of CIN 10078604.

Waterside, warehouse and transport workers will be handling unopened drums containing the notified chemical. These workers are only expected to come into contact with CIN 10078604 in the event of an accident or leaking packaging.

Reweighing of the notified chemical is not expected to be needed in Australia. Inhalation, dermal and ocular exposure to the notified chemical may occur when workers add the notified chemical to a mix tank. Inhalation exposure is expected to be minimised by the large particle size of the notified chemical, which falls outside the range considered respirable (cited in (3)). The notifier states that exposure to CIN 10078604 will be minimised by carrying out the addition of the notified chemical to the mix tank under air extractors fitted with fibreglass filters and mechanical ventilation.

A number of other components are added to the mix tank to form a dispersion. Dermal exposure to the notified chemical in solution may occur at this stage. Eye contact is expected to be limited to splashes. The notifier states that each batch preparation will take approximately 15 minutes and that a number of batches may be made each day.

This dispersion may be chilled and stored for up to several weeks. Worker exposure is expected to be minimal during the pumping of the dispersion, (containing the notified chemical at a concentration of < 10%), into melt tanks. Other components are added and the dispersion is then pumped to closely controlled automated

equipment, where it will be incorporated into photographic film and paper. The final concentration of the notified chemical is less than 5%. Once the notified chemical is incorporated into these articles, no additional worker exposure is anticipated, as the chemical will then be covered by overcoat layers.

#### 7. PUBLIC EXPOSURE

The notified chemical, which will be incorporated into a dispersion at a concentration of less than 5%, will be applied to the surfaces of photographic film and paper. The coating will be overlayed by protective layers. In addition, the notified chemical is firmly bound in the matrix of the coating. CIN 10078604 will not be available to the general public, and will be used by industrial trade customers only. Accordingly, it is anticipated that the public will not be exposed to the notified chemical.

There is potential for minor public exposure during formulation, transport and disposal of the chemical if accidentally spilt. This is minimised by the recommended practices during formulation, storage and transportation.

#### 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 (< 5%) 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 aqueous dispersion (< 10% CIN 10078604) from the mix tank could be released to the municipal sewer. This would result in a maximum of 9.25 kg per day release of the chemical.

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% waste may be generated in the manufacture of film and paper (containing the notified chemical at < 5%), which 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 sewer, with secondary to tertiary sewage treatment by the Werribee treatment works. Waste trapped in filter cake is processed in the USA. Empty plastic bags used to ship the chemical, containing a traces of it, 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) (1, 2). Over the 28 day test, biodegradation reached 8% and 6% in the two replicates, indicating the chemical was not readily biodegradable under the conditions of the test. It was also found that the substance was not inhibitory to microorganisms under these conditions.

The extremely high partition coefficient and very low water solubility of the notified chemical would indicate little potential for bioaccumulation (4). 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 10078604

Test	Species	Outcome	Reference
acute oral toxicity	rat	> 2 000 mg.kg <sup>-1</sup>	(5)
acute dermal toxicity	rat	> 2 000 mg.kg <sup>-1</sup>	(6)
skin irritation	rabbit	non-irritating	(7)
eye irritation	rabbit	slight irritant	(8)
skin sensitisation	guinea pig	non-sensitiser	(9)

## **9.1.1 Oral Toxicity (5)**

Species/strain: Rat/CD®(SD)BR VAF/Plus®

Number/sex of animals: 5/sex

Observation period: 14 days

*Method of administration:* single limit dose of 2 000 mg.kg<sup>-1</sup> of the test

material by gavage; vehicle was guar gum

Clinical observations: diarrhoea was observed in 2 rats on the day of

dosing; no other abnormal clinical signs were

noted

Mortality: none

Morphological findings: none

Test method: similar to OECD guidelines (1)

 $LD_{50}$ : > 2 000 mg.kg<sup>-1</sup>

Result: the notified chemical was of low acute toxicity

when orally administered to rats in a limit test

9.1.2 Dermal Toxicity (6)

Species/strain: rat/CD®(SD)BR VAF/Plus®

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: single topical application of 2 000 mg.kg<sup>-1</sup> of

solid test material moistened with water; site occluded for 24 hours; at the end of exposure, residual test material was washed off with

running water

Clinical observations: none

Mortality: none

Morphological findings: none

Test method: similar to OECD guidelines (1)

 $LD_{50}$ : > 2 000 mg.kg<sup>-1</sup>

Result: the notified chemical was of low acute toxicity

when administered dermally to rats

9.1.4 Skin Irritation (7)

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

Number/sex of animals: 3/sex not determined

Observation period: 72 hours

Method of administration: single topical doses of 0.5 g of solid test

material moistened thoroughly with water; site was covered by occlusive wrap for 4 hours; application site was rinsed with running water

7

at the end of exposure

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Draize scores (10): all Draize scores at all time points were zero

Test method: similar to OECD guidelines (1)

Result: the notified chemical was not a skin irritant

when tested in rabbits

9.1.5 Eye Irritation (8)

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

Number/sex of animals: 6/sex not determined

Observation period: 7 days

Method of administration: 0.1 g of the test substance was placed into the

conjunctival sac of the right eye; the treated eye of three of the animals was immediately washed with running distilled water; the eye of the other three animals remained unwashed;

the untreated eyes served as control

Draize scores (10) of unirrigated eyes:

#### Time after instillation

Animal	1 h	our	1 0	day	2 d	ays	3 da	ays	7 da	ays
Cornea		there were no corneal effects noted in any animals								
Iris		the	ere wer	e no irio	dial effe	ects not	ed in a	ny anim	nals	
Conjunctiva	<b>r</b> a	<b>C</b> <sup>b</sup>	rª	<b>C</b> <sup>b</sup>	rª	<b>C</b> <sup>b</sup>	rª	<b>C</b> <sup>b</sup>	rª	<b>C</b> <sup>b</sup>
1	1	1	2	2	2	1	1	0	0	0
2	2	3	3	3	2	0	1	0	0	0
3	2	2	1	0	0	0	0	0	0	0
4*	1	0	0	0	0	0	0	0	0	0
5*	1	1	1	0	0	0	0	0	0	0
6*	1	0	0	0	0	0	0	0	0	0

<sup>&</sup>lt;sup>1</sup> see Attachment 1 for Draize scales

<sup>&</sup>lt;sup>a</sup>redness <sup>b</sup>chemosis \*the treated eye of these rabbits was washed with distilled water immediately following instillation of the test substance

Irrigated eyes: irrigation had a palliative effect (see above

table)

Test method: similar to OECD guidelines (1)

Result: the notified chemical was a slight eye irritant in

rabbits

## 9.1.6 Skin Sensitisation (9)

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

Number of animals: 30/male (20 test; 10 control)

Induction procedure: Day 1: 3 pairs of intradermal injections:

0.1 mL Freund's complete adjuvant

(FCA):water (1:1(v/v))

- 0.1 mL of 5% concentration of test

material in corn oil

- 0.1 mL of 5% concentration of test

material in FCA:water (1:1 (v/v))

Day 7: test area treated with 0.5 mL per

injection site of 10% (w/w) sodium

lauryl sulfate in petrolatum

Day 8: occluded application of 25%

concentration of test material in

petrolatum for 48 hours

Challenge procedure: Day 21: occluded application of 25%

concentration of test material for

24 hours

#### Challenge outcome:

	Test a	nimals	Control animals		
Challenge concentration	24 hours*	48 hours*	24 hours	48 hours	
25%	0/20**	0/20	0/10	0/10	
50%	0/20	0/20	0/10	0/10	

<sup>\*</sup> time after patch removal

Test method: similar to OECD guidelines (1)

Result: the notified chemical is not a skin sensitiser in

<sup>\*\*</sup> number of animals exhibiting positive response

#### guinea pigs

# 9.2 Repeated Dose Toxicity (11)

Species/strain: rat/CD®(SD)BR VAF/Plus®

Number/sex of animals: 20/sex

Method of administration: gavage; vehicle was corn oil

Dose/Study duration: the test substance was administered daily for

a period of 29 days:

control: 0 mg.kg<sup>-1</sup>.day<sup>-1</sup> low dose: 100 mg.kg<sup>-1</sup>.day<sup>-1</sup> mid dose: 300 mg.kg<sup>-1</sup>.day<sup>-1</sup> high dose: 1 000 mg.kg<sup>-1</sup>.day<sup>-1</sup>

all animals were sacrificed at the end of the

treatment period

Mortality: one animal died during the study as a result of

gavage error

Clinical observations: the mean terminal body weight for males in

the high dose group was significantly lower than controls; this result was not statistically significant when compared with control values; mean body weights for female groups were

comparable throughout the study

Clinical animals in the high dose group exhibited

chemistry/Haematology: increases in mean prothrombin time (males)

and increased mean platelet count (females); these changes were not considered to be of

toxicological importance

mean alanine aminotransferase and aspartate

aminotransferase were also increased in animals from the high dose group; there were

no corresponding changes in liver

histopathology; these changes were not thought to be of toxicological significance

Histopathology: the mean absolute thymus weight for males in

the high dose group was significantly lower

than the control group

Test method: similar to OECD guidelines (1)

Result: administration of doses of up to

1 000 mg.kg<sup>-1</sup>.day<sup>-1</sup> of the notified chemical did not induce changes of toxicological

significance in rats

# 9.3 Genotoxicity

# 9.3.1 Salmonella typhimurium Reverse Mutation Assay (12)

Strains: TA98, TA100, TA1535, TA1537 and

Escherichia coli WP2uvrA

Concentration range: 50 - 5 000 μg per plate; assays were carried

out in the presence or absence of S9 mix

Test method: similar to OECD guidelines (1)

Result: the notified chemical was found not to be

mutagenic in the bacterial strains tested under

the conditions of this assay

## 9.3.2 Chromosomal Aberration Assay in Chinese Hamster ovary cells (13)

Concentration range: 0.625 - 9.96 μg.mL<sup>-1</sup> (without S9 mix)

cells were incubated with the test article for 17.8 hours (for 20.0 hour assays) or 42.1

hours (for 44.3 hour assay) 1.57 - 49.8 μg.mL<sup>-1</sup> (with S9 mix)

cells were incubated with the test article for 3 hours, washed, and harvested 20 or 44.3 hours after the start of treatment

Test method: similar to OECD guidelines (1)

Result: a weakly positive response was noted at a

single dose level with metabolic activation that did not persist in the extended assay; the relevance of this result is questionable

the notified chemical was not considered to be clastogenic when tested in Chinese Hamster ovary cells under the conditions of this assay

# 9.4 Overall Assessment of Toxicological Data

The notified chemical was found to be of low acute toxicity in rats when administered by the oral and dermal routes ( $LD_{50} > 2\,000\,\text{mg.kg}^{-1}$  in both studies). The notified chemical was not a skin irritant when tested in rabbits, but caused slight eye irritation in the same species. The results of a guinea pig maximisation test indicate that the chemical is not a skin sensitiser.

There were no adverse findings of toxicological significance at doses of up to 1 000 mg.kg<sup>-1</sup>.day<sup>-1</sup> when rats were treated with the test material in a 28-day repeat-dose oral toxicity study.

The notified chemical was not mutagenic in bacteria in the presence or absence of metabolic activation, and was not clastogenic when tested *in vitro* in Chinese Hamster ovary cells.

Based on the results of the toxicity studies summarised above, the notified chemical would not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (14).

#### 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out to OECD Test Methods (1).

Test	Species	Results
Acute Toxicity <sup>a</sup> (96 h, static)	Fathead minnow Pimephales promelas	NOEC > 2.0 mg.L <sup>-1</sup>
Acute Toxicity <sup>a</sup>	Daphnia magna	$0.54 \text{ mg.L}^{-1} \le EC_{50} \le 0.75 \text{ mg.L}^{-1}$
(48 h, static)		$0.32 \text{ mg.L}^{-1} < \text{NOEC} < 0.58 \text{ mg.L}^{-1}$ EC <sub>50</sub> = 0.77 mg.L <sup>-1c</sup>
Chronic Toxicity <sup>b</sup> (21 d, flow-through)	Daphnia magna	NOEC ≥ 42 µg.L <sup>-1</sup>
Growth Inhibition <sup>a</sup> (72 h)	Algae Selenastrum	NOEC = 1.745 mg.L <sup>-1</sup>
,	capricornutum	
Respiration	Micro-organisms in	NOEC = 1 000 mg.L <sup>-1</sup>
Inhibition	aerobic activated sludge	

<sup>&</sup>lt;sup>a</sup>Test material was added as a stock solution in N,N-dimethylformamide.

The effect of the notified chemical was only tested at one concentration (2.0 mg.L<sup>-1</sup>) in the fish acute toxicity test. The concentration was well above the solubility limit of the chemical in pure water and was achieved by dissolving the chemical in N,N-dimethylformamide. Some cloudiness in the test media was observed. At this concentration no effect on the fish was observed.

The effect of the notified chemical on *Daphnia* was examined at five concentrations in replicates (mean measured concentrations of 0.23, 0.33, 0.57, 1.06 and 2.26 mg.L<sup>-1</sup>). The NOEC and EC<sub>50</sub> 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. As noted from the table the notifier was unable to accurately estimate an EC<sub>50</sub> but an EC<sub>50</sub> of 0.77 mg.L<sup>-1</sup> with 95% confidence limits of 0.43 and 1.26 mg.L<sup>-1</sup> was

<sup>&</sup>lt;sup>b</sup>Test material was added as a stock solution in acetone.

<sup>&</sup>lt;sup>c</sup>Calculated from data provided by the notifier.

calculated, using combined replicates and carrier solvent control data as the bank. 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 (2.0, 3.8, 11, 20 and 42  $\mu$ g.L<sup>-1</sup>). No adverse effects on the survival or reproduction of *Daphnia* were observed throughout the 21-day duration of the test. The chronic NOEC and EC<sub>50</sub> values for the notified chemical are therefore assumed to be greater than or equal to 42  $\mu$ g.L<sup>-1</sup>. From this the chemical appears to have a low acute/chronic ratio (< 10).

The effect of the notified chemical was also only tested at one concentration (1.745 mg.L<sup>-1</sup>) in the algal growth inhibition test. This concentration was also well above the solubility limit of the chemical in pure water and was achieved by dissolving the chemical in N,N-dimethylformamide. The concentration of the test material decreased from 2.145 mg.L<sup>-1</sup> to 1.745 mg.L<sup>-1</sup> 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 the notified chemical is not toxic to fish, algae or microorganisms at concentrations well above its solubility. 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 not chronically toxic to *Daphnia* at concentrations up to 42 ppb.

#### 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The maximum expected daily discharge of the chemical to sewer is approximately 9.25 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 190 ppb.

This predicted environmental concentration (PEC) value indicates a Q (chronic) value of 4.5 and a Q (acute) value of 0.25, using a NOEC of 42 ppb and an EC $_{50}$  of 770 ppb, respectively. These hazard quotients indicate a potential aquatic hazard. However, the value (NOEC > 42 ppb) used to calculate the chronic hazard quotient is a lower limit for the NOEC and the EC $_{50}$  is expected to be higher, reducing the Q (chronic) value. Additionally, CIN 10078604 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 Weribee Farm. Thus, the concentration of the notified chemical in receiving waters from Weribee farm is expected to be significantly lower than the PEC of 190 ppb.

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 waste dispersion 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

There is negligible occupational health risk posed to waterside, warehouse and transport workers, who will be handling fibre board cartons containing the notified chemical in pure form. These workers will only be exposed to the notified chemical in the event of accident or leaking packaging.

There is a low health risk posed to workers in the Kodak plant who will be handling the pure chemical in powdered form. Inhalation, dermal and ocular exposure may occur while workers are handling the chemical in powdered form. Inhalation exposure is expected to be minimal, due to the large particle size of the notified chemical. Based on results from animal studies, slight eye irritation may result if exposure occurs via this route. Skin irritation or sensitisation is not expected to occur in workers, based on animal studies.

The risk of adverse health effects resulting from exposure to the notified chemical is reduced once the chemical is in dispersion form. The concentration of the notified chemical is less than 10% following the initial mixing process, and less than 5% in the final dispersion form.

Once incorporated into photographic film and paper, the health risk posed to workers and the public by the notified chemical is negligible.

Minor public exposure may result from disposal of unused chemical, or accidental spillage of the notified chemical during transport and storage and during formulation. However, adequate measures are described by the notifier to minimise the risk of public exposure during formulation, disposal or in the event of accidental spillage.

#### 13. RECOMMENDATIONS

To minimise occupational exposure to CIN 10078604 the following guidelines and precautions should be observed:

- It is good work practice to wear industrial clothing which conforms to the specifications detailed in Australian Standard (AS) 2919 (15) and occupational footwear which conforms to Australian and New Zealand Standard (AS/NZS) 2210 (16) to minimise exposure when handling any industrial chemical;
- Spillage of products containing the notified chemical should be avoided, spillages should be cleaned up promptly and put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;

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

#### 14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (17).

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.

Secondary notification under Section 64 of the Act will be required if the method of use changes in such a way to greatly increase the environmental exposure to the notified chemical, particularly exposure of natural waters.

#### 16. REFERENCES

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- 16. 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.
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# **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	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
easily discernible  Diffuse beefy red	3	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and	3 severe
	severe	Swelling with lids half-closed to completely closed	4 severe	hairs and 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