

File No: EX/28(NA/717)

**June 2001**

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION  
AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**NT-13**

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 the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

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Director

## Chemicals Notification and Assessment

**FULL PUBLIC REPORT**

**NT-13**

**1. APPLICANTS**

**Original Holder of Assessment Certificate (First Applicant)**

An Assessment Certificate for the notified chemical known by the name NT-13 was granted to Canon Australia Pty Ltd of 1 Thomas Holt Drive NORTH RYDE NSW 2113

The Assessment Report for NT-13 is identified by the sequence number NA/717.

**Second Applicant**

Since granting of the abovementioned Assessment Certificate, Hewlett-Packard Australia Limited of 31-41 Joseph Street BLACBURN VIC 3130 has submitted a notification statement in support of their application for an extension of the original Assessment Certificate for NT-13. Canon Australia Pty Ltd has agreed to this extension.

Hewlett-Packard Australia Limited intends to import less than one tonne per annum over the next five years as a toner ingredient. No new information on the new chemical has been submitted by Hewlett-Packard Australia Limited since the original notification statement submitted by Canon Australia Pty Ltd in matters affecting occupational, environmental or public exposure. The original assessment report (NA/717) is reproduced here in full and without amendment, for the record as EX/28 (NA/717).

## 2. IDENTITY OF THE CHEMICAL

The following requests for exempt information were accepted: chemical name, other names, CAS No., molecular and structural formulae, exact molecular weight and spectral data.

<b>Marketing Name:</b>	NT-13
<b>Other Name:</b>	TT 035
<b>Method of Detection and Determination:</b>	infrared spectroscopy

## 3. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance at 20°C &amp; 101.3 kPa:</b>	white powder
<b>Particle Size:</b>	9.7% < 100 µm (sieve); 28.1% < 10 µm (cascade impactor) (see comments below)
<b>Melting Point:</b>	104°C (decomposition temperature)
<b>Specific Gravity:</b>	1.17 at 19.5°C
<b>Vapour Pressure:</b>	< 4.9 x 10 <sup>-8</sup> kPa at 25°C
<b>Water Solubility:</b>	2.18 x 10 <sup>-4</sup> g/L at 20°C
<b>Partition Co-efficient (n-octanol/water):</b>	log P <sub>ow</sub> = 5.07 at 20°C
<b>Hydrolysis as a Function of pH:</b>	not determined (see comments below)
<b>Adsorption/Desorption:</b>	not determined (see comments below)
<b>Dissociation Constant:</b>	not determined (see comments below)
<b>Flash Point:</b>	not determined
<b>Flammability Limits:</b>	not highly flammable (EC method), combustible
<b>Autoignition Temperature:</b>	> 400°C
<b>Explosive Properties:</b>	non-explosive
<b>Reactivity/Stability:</b>	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. Full test reports were provided.

The water solubility of the chemical is very low. Accordingly, the OECD test procedures for hydrolysis, adsorption/desorption and dissociation constant were not applicable. The OECD Guidelines for Testing of Chemicals, Method 107 and Commission Directive 92/69/EEC, Method A8, were used to determine the partition coefficient of the chemical. The resultant log  $P_{ow}$  indicates that the chemical is hydrophobic.

The chemical is unlikely to have any hydrolysable functionality in the environmental pH range 4 - 9. Due to the low water solubility and the high log  $P_{ow}$ , the chemical would be expected to associate with soil/sediment and thus become immobilised.

The notifier has submitted that the pKa for a structurally similar compound (1-methyl-cyclohexanecarboxylic acid) is 5.13.

There was some apparent conflict between the sieve and cascade impactor results for particle size distribution. For small particles, the cascade impactor method is usually more reliable. Factors such as static charge build-up can hinder sieve testing.

#### **4. PURITY OF THE CHEMICAL**

<b>Degree of Purity:</b>	100%
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<b>Toxic or Hazardous Impurities:</b>	none
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<b>Non-hazardous Impurities (&gt; 1% by weight):</b>	none
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<b>Additives/Adjuvants:</b>	none
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#### **5. USE, VOLUME AND FORMULATION**

The notified chemical will not be manufactured in Australia. It will be imported as a component (< 1%) of a toner for electrophotocopiers or electrophotographic printers in 350 g plastic bottles or toner cartridges at less than 1 tonne per year for the first five years for each applicant.

## 6. OCCUPATIONAL EXPOSURE

The notified chemical is a component ( $< 1\%$ ) of an imported toner product, which is in powder form. The mean particle size of the toner is  $5 - 10\ \mu\text{m}$  (range  $1 - 30\ \mu\text{m}$ ). The toner is to be imported in toner cartridges or 350 g toner bottles. No reformulation or repackaging will take place. Hence, no exposure to the notified chemical in the toner is expected during transportation and storage other than for accidental spillage.

Typically, occupational exposure to the toner would be experienced by copier/ printer service personnel and office or printing staff using the machines when replacing or inserting new toner cartridges or bottles when a sealing tape is removed prior to insertion into the machine. When in use, the toner is completely sealed in the developing unit of the printer. Protective equipment is not used by persons exposed to the toner.

Typically, the amount of general airborne dust, including toner dust, around the printer would be approximately  $0.02\ \text{mg}/\text{m}^3$ .

Inhalation, ocular or dermal exposure to the toner powder may occur during toner replacement, particularly in the event of a container leak or spill, but this would rarely happen. More commonly, occasional dermal exposure to toner residues inside the machine may occur during machine servicing or paper feed problems.

Exposure may occur upon handling printed matter with the toner applied. However, less than 50mg of toner is used per legal sheet of paper, and it becomes heat fixed once applied to the printed surface. These considerations indicate there would be no human exposure to the notified chemical during the handling of printed materials.

## 7. PUBLIC EXPOSURE

It is expected that during transport and storage of the imported toner, exposure of the general public to the notified chemical will be minimal except in the event of an accidental spill.

Public exposure to the notified chemical during use is expected to be occasional, but widespread, and would include changing toner bottles or cartridges, attending to minor faults such as paper feed jams, and handling printed matter. Inhalation, ocular or dermal exposure to toner could occur in the event of a spill. More commonly, dermal exposure to toner residues inside the machine may occur on an infrequent basis during machine servicing or paper feed problems.

Exposure may occur upon handling printed matter with the toner applied. However, less than 50mg of toner is used per legal sheet of paper, and it becomes heat fixed once applied to the printed surface. These considerations indicate there would be no human exposure to the notified chemical during the handling of printed materials.

## **8. ENVIRONMENTAL EXPOSURE**

### **Release**

Since the notified chemical will not be manufactured or repackaged, potential release to the environment would only occur during use or disposal.

The design of the bottle will mean that only a minimal amount of toner will be released from the unit during use. A very small amount of the notified chemical may enter the air, or be washed down the drain during hand washing. The notifier advises to sweep any spills onto a sheet of paper and discard it into a bin. During the operation of a photocopier or printer, a very small amount of toner will remain on the drum together with paper dust. This mixture is scraped off and collected in a waste reservoir. The amount of toner involved is likely to be less than 0.1%. At the time the machine is serviced the reservoir is either replaced or emptied. Presumably the waste from all sources will go to landfill or for incineration.

The notifier has advised that less than 4 mg of toner (approximately 1% of the contents and less than 0.04 mg of notified chemical) will remain in the empty bottle. The bottle will not be recycled but will be disposed of to landfill or incinerated.

Printed paper will either be disposed of to landfill, incinerated, or recycled. During the recycling process the paper will be deinked, resulting in the production of sludge. It is presumed that the notified chemical will be contained in the sludge because of its very low solubility. The sludge will be disposed of to landfill or incinerated.

### **Fate**

Spilt drum waste and residue toner in disposed bottles is likely to amount to a maximum of 22 kg per year of unfixed chemical that will be landfilled or incinerated. Only a very small amount will be washed down drains, generally resulting from hand washing.

Once the toner is fixed, the notified chemical will be bound in the print matrix and immobilised. Thus, the fate of used notified chemical will depend on the fate of the paper, and be sent to landfill, for incineration or recycling. If the paper is recycled the notified chemical is likely to end up in the resultant sludge. This sludge will then either go to landfill or for incineration.

## 9. EVALUATION OF TOXICOLOGICAL DATA

No studies were provided for the notified chemical. However, studies were provided for a toner containing the chemical (TT037) and the masterbatch comprising 10% notified chemical and 90% pigment (ST063). TT037 is a toner containing magenta pigment.

### 9.1 Acute Toxicity

Summary of the acute toxicity of ST063 or #983 (10% notified chemical, 90% pigment) and TT037 magenta toner (0.5% notified chemical, 4.5% pigment, 95% polyester resin)

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	rat	LD <sub>50</sub> > 2 000 mg/kg (ST063 and TT037)	(Hempstock, 1997c) (Allen, 1998c)
skin irritation	rabbit	slight to moderate skin irritant (ST063) slight skin irritant (TT037)	(Hempstock, 1997a) (Allen, 1998a)
eye irritation	rabbit	slight to moderate eye irritant (ST063) slight eye irritant (TT037)	(Hempstock, 1997b) (Allen, 1998b)

### Oral Toxicity

#### 9.1.2.1 ST063 (Hempstock, 1997c)

<i>Species/strain:</i>	rat/Sprague-Dawley
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	oral gavage; vehicle arachis oil
<i>Clinical observations:</i>	red/pink staining of faeces on day 1; slight red/pink staining of fur up to day 5
<i>Mortality:</i>	none
<i>Morphological findings:</i>	none
<i>Test method:</i>	OECD TG 401
<i>LD<sub>50</sub>:</i>	> 2 000 mg/kg



*Result:* a formulation containing 10% notified chemical was of very low acute oral toxicity in rats

#### **9.1.2.1 TT037 (Allen, 1998c)**

*Species/strain:* rat/Sprague-Dawley

*Number/sex of animals:* 5/sex

*Observation period:* 14 days

*Method of administration:* oral gavage; vehicle arachis oil

*Clinical observations:* red staining of faeces one to two days after dosing

*Mortality:* none

*Morphological findings:* none

*Test method:* OECD TG 401

*LD<sub>50</sub>:* > 2 000 mg/kg

*Result:* a formulation containing 0.5% notified chemical was of very low acute oral toxicity in rats

### **Skin Irritation**

#### **9.1.2.1 ST063 (Hempstock, 1997a)**

*Species/strain:* rabbit/New Zealand White

*Number/sex of animals:* 3/male

*Observation period:* 7 days

*Method of administration:* 4-hour, semi-occluded application

*Draize scores (Draize, 1959):*

<b>Time after treatment</b>					
	<i>1 hour</i>	<i>24 hours</i>	<i>48 hours</i>	<i>72 hours</i>	<i>7 days</i>
<b><i>Erythema</i></b>					
1	0 <sup>a</sup>	1	2	2	0*
2	0	1	0	0	0
3	0	2	2	2	0*
<b><i>Oedema</i></b>					
1	0	0	1	1	0
2	0	1	0	0	0
3	0	1	1	1	0

<sup>a</sup> see Attachment 1 for Draize scales; \* barely perceptible desquamation

*Test method:* OECD TG 404

*Result:* the test substance was a slight to moderate skin irritant in rabbits

**9.1.2.2 TT037 (Allen, 1998a)**

*Species/strain:* rabbit/New Zealand White

*Number/sex of animals:* 3/male

*Observation period:* 72 hours

*Method of administration:* 4-hour, semi-occluded application

*Draize scores (Draize, 1959):*

<b>Time after treatment</b>						
		<i>1 hour</i>	<i>24 hours</i>	<i>48 hours</i>	<i>72 hours</i>	<i>7 days</i>
<hr/>						
<b><i>Erythema</i></b>						
1	1 <sup>a</sup>	0	0	0	0	0
2	1	0	0	0	0	0
3	1	1	1	0	0	0
<hr/>						
<b><i>Oedema</i></b>						
1	1	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0

<sup>a</sup> see Attachment 1 for Draize scales

*Test method:* OECD TG 404

*Result:* the test substance was a slight skin irritant in rabbits

### 9.1.3 Eye Irritation

#### 9.1.3.1 ST063 (Hempstock, 1997b)

*Species/strain:* rabbit/New Zealand White

*Number/sex of animals:* 2 males, 1 female

*Observation period:* 72 hours

*Method of administration:* 0.1 mL (44 mg) into the conjunctival sac of the right eye

*Draize (Draize, 1959) scores:*

**Time after instillation**

<i>Animal</i>	<i>1 hour</i>			<i>24 hours</i>			<i>48 hours</i>			<i>72 hours</i>		
<i>Cornea</i>	no scores above zero											
<i>Iris</i>	no scores above zero											
<i>Conjunctiva</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>
1	2	1	2	1	0	0	0	0	0	0	0	0
2	1	0	0	0	0	0	0	0	0	0	0	0
3	1	0	0	0	0	0	0	0	0	0	0	0

<sup>1</sup> see Attachment 1 for Draize scales

o = opacity a = area r = redness c = chemosis d = discharge

*Test method:*

OECD TG 405

*Result:*

the test substance was a slight to moderate eye irritant in rabbits

**9.1.3.2 TT037 (Allen, 1998b)**

*Species/strain:*

rabbit/New Zealand White

*Number/sex of animals:*

3/male

*Observation period:*

72 hours

*Method of administration:*

0.1 mL (69 mg) into the conjunctival sac of the right eye

*Draize (Draize, 1959) scores:*

**Time after instillation**

<i>Animal</i>	<i>1 hour</i>			<i>24 hours</i>			<i>48 hours</i>			<i>72 hours</i>		
<i>Cornea</i>	no scores above zero											
<i>Iris</i>	no scores above zero											
<i>Conjunctiva</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>
1	1	1	1	0	0	0	0	0	0	0	0	0
2	1	1	1	0	0	0	0	0	0	0	0	0
3	1	0	1	0	0	0	0	0	0	0	0	0

<sup>1</sup> see Attachment 1 for Draize scales

o = opacity a = area r = redness c = chemosis d = discharge

*Test method:* OECD TG 405

*Result:* the test substance was a slight eye irritant in rabbits

## **9.2 Genotoxicity: *Salmonella typhimurium* Reverse Mutation Assay**

### **9.2.1 #983 (Andoh & Katoh, 1998b)**

*Strains:* TA 98, TA 100

*Concentration range:* 0, 19.53, 78.13, 312.5, 1 250 or 5 000 µg/plate (first experiment) and 0, 156.3, 312.5, 625 or 1 250 or 2 500 µg/plate (second experiment)

*Test method:* similar to OECD guidelines

*Comment:* negative controls were within acceptable limits and the positive control substances 2-(2-furyl)-3-(5-nitro-2-furyl) acrylamide and benzo[a]pyrene demonstrated the sensitivity of the assay; a less dense background lawn was observed in the first experiment at the top dose in both strains without or with S9 fraction and at 1 250 µg/plate in TA 98 on one plate in the absence of S9; in the second experiment similar results were observed at the top dose and also 1 250 µg/plate in TA 100 in the absence of S9

*Result:* the test substance was not mutagenic in bacteria either in the absence or presence of metabolic activation provided by rat liver S9 fraction

### **9.2.2 TT037 (Andoh & Katoh, 1998a)**

*Strains:* TA 98, TA 100

*Concentration range:* 0, 19.53, 78.13, 312.5, 1 250 or 5 000 µg/plate (first experiment); 0, 0.78, 1.56, 3.13, 6.25, 12.5, 25.0, 50.0, 312.5, 625, 1 250 or 5 000 µg/plate (second experiment); 0, 0.78, 1.56, 3.13, 6.25, 12.5, 25.0, 50.0 µg/plate (third experiment)

*Test method:* similar to OECD guidelines

*Comment:* negative controls were within acceptable limits and the positive control substances 2-(2-furyl)-3-(5-nitro-2-furyl) acrylamide and benzo[a]pyrene demonstrated the sensitivity of the assay; in the first experiment a less dense background lawn of bacterial growth was observed at the two lowest

doses in TA 98 in the absence of S9; in the second experiment, in the absence of S9 with TA 98 only doses up to 50 µg/plate were used and a less dense background lawn was observed at doses of 25 and 50 µg/plate; a similar effect was observed in the third experiment using TA 98 alone in the absence of S9

*Result:*

the test substance was not mutagenic in bacteria either in the absence or presence of metabolic activation provided by rat liver S9 fraction

### **9.3 Overall Assessment of Toxicological Data**

A formulation containing the notified chemical at a level of 10% was of very low acute oral toxicity in rats ( $LD_{50} > 2\,000$  mg/kg). The same formulation was a slight to moderate skin irritant and a slight to moderate eye irritant in rabbits. A toner containing 0.5% of the notified chemical was a slight skin irritant and a slight eye irritant in rabbits. Neither formulation was mutagenic in bacteria.

Studies on acute oral or dermal toxicity, skin or eye irritation, skin sensitisation, repeated dose toxicity or genotoxicity of the notified chemical were not provided. The data provided is insufficient to determine whether or not the notified chemical would be a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999).

## **10. ASSESSMENT OF ENVIRONMENTAL EFFECTS**

No ecotoxicological data were provided.

## **11. ASSESSMENT OF ENVIRONMENTAL HAZARD**

The majority of the notified chemical reaching the environment will be in a bound stable matrix form created by the heat fixing of the toner. It will not leach from landfill.

Assuming 1.1% of every bottle of toner is residue waste, then the 1 000 kg of imported toner will generate 11 kg of waste notified chemical per year. Due to the very low solubility and high  $\log P_{ow}$  of the notified chemical, it is very unlikely that the chemical will leach from landfill.

## 12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Toxicological data were provided for a masterbatch containing 10% notified chemical and 90% pigment and for a typical toner formulation containing 0.5% notified chemical. The masterbatch was of very low acute oral toxicity ( $LD_{50} > 2\,000$  mg/kg). Therefore, the toner also would be expected to exhibit low acute oral toxicity on the basis of its notified chemical content. The masterbatch was a slight to moderate eye irritant and a slight to moderate skin irritant in rabbits. The toner was a slight eye irritant and a slight skin irritant in rabbits. Neither the masterbatch nor the toner formulation was mutagenic or bacteria. Studies on acute oral or dermal toxicity, skin or eye irritation, skin sensitisation, repeated dose toxicity or genotoxicity of the notified chemical were not provided. The data provided is insufficient to determine whether or not the notified chemical would be a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999).

Although a substantial fraction of the notified chemical is respirable ( $28.1\% < 10\ \mu\text{m}$ ), it is present at less than 0.5% in the toner. However, the toner contains a high respirable fraction (particle size  $5 - 10\ \mu\text{m}$ ). Therefore, the toner can be considered a nuisance dust and employers are responsible for maintaining atmospheric levels of toner dust below the NOHSC exposure standard of  $10\ \text{mg}/\text{m}^3$  (National Occupational Health and Safety Commission, 1995). It is unlikely that the airborne concentration of toner dust in the workplace would warrant exposure monitoring and specific ventilation.

### Occupational Health and Safety

Exposure to toner containing the notified chemical can occur during machine operation (likely inhalation exposure of  $0.02\ \text{mg}/\text{m}^3$ ), during clearing paper feed problems and machine maintenance. Transport and storage of the toner bottles and cartridges is unlikely to result in worker exposure except in the event of accidental spillage.

Printing staff, who will perform additions of toner and replacement of a used toner container (cartridge or bottle), are expected to be exposed infrequently to the notified chemical as the toner container is sealed and loaded directly into a printing machine. Upon application to the paper, the toner is fused to the surface and release is unlikely to occur. Therefore, the risk of adverse health effects to printing personnel is low and no personal protective equipment is required. Nevertheless, any generation of dust should be avoided.

Service personnel may be exposed to the notified chemical when cleaning printer/copier equipment and replacing copier developer; however, as the toner product is not hazardous, the risk of adverse health effects is low. Disposable gloves may be worn to prevent skin irritation and workers should avoid any generation of dust when handling the toner.

Spilt residues should be swept up manually or using a dust explosion-proof vacuum cleaner and placed within a waste container.

Given these considerations, the chemical will not pose a significant health hazard in the occupational environment.

Workers handling printed paper are not at risk of adverse health effects because the polymer

is fixed to the paper and not available for exposure or dermal uptake.

### **Public Health**

Based on its use pattern, physico-chemical properties and low toxicity, the notified chemical will not pose a significant hazard to public health.

## **13. MATERIAL SAFETY DATA SHEET**

The Material Safety Data Sheet (MSDS) for a toner containing the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994).

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.

## **14. RECOMMENDATIONS**

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

- Avoid generation of dust clouds when handling the toner;
- Service operators should wear disposable, rubber gloves when handling toner;
- Spillage of the notified chemical should be avoided. Spillage should be cleaned up promptly with absorbents which should be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the appropriate MSDS should be easily accessible to employees.

If the conditions of use are varied, then greater exposure of the public may occur. In such circumstances, further information may be required to assess the hazards to public health.

## **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**



Allen DJ (1998a) TT037: Acute Dermal Irritation in the Rabbit, Project No. 1091/020, Safepharm Laboratories Limited, Derby, UK.

Allen DJ (1998b) TT037: Acute Eye Irritation in the Rabbit, Project No. 1091/021, Safepharm Laboratories Limited, Derby, UK.

Allen DJ (1998c) TT037: Acute Oral Toxicity (Limit Test) in the Rat, Project No. 1091/019, Safepharm Laboratories Limited, Derby, UK.

Andoh F & Katoh Y (1998a) Report of Mutagenicity Test Using Microorganisms, Report No. 619, Project No. 619, Chemicals Safety Division, Canon Inc, Tokyo, Japan.

Andoh F & Katoh Y (1998b) Report of Mutagenicity Test Using Microorganisms, Report No. 620, Project No. 620, Chemicals Safety Division, Canon Inc, Tokyo, Japan.

Draize JH (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49 : 2-56.

Hempstock C (1997a) ST063: Acute Dermal Irritation Test in the Rabbit, Project No. 897/014, Safepharm Laboratories Limited, Derby, UK.

Hempstock C (1997b) ST063: Acute Eye Irritation Test in the Rabbit, Project No. 897/015, Safepharm Laboratories Limited, Derby, UK.

Hempstock C (1997c) ST063: Acute Oral Toxicity (Limit Test) in the Rat, Project No. 897/013, Safepharm Laboratories Limited, Derby, UK.

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.

National Occupational Health and Safety Commission (1995) Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment, [NOHSC:1003(1995)]. In: ed. Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Australian Government Publishing Service, Canberra.

## Attachment 1

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

<i><b>Erythema Formation</b></i>	<i><b>Rating</b></i>	<i><b>Oedema Formation</b></i>	<i><b>Rating</b></i>
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***

<i><b>Opacity</b></i>	<i><b>Rating</b></i>	<i><b>Area of Cornea involved</b></i>	<i><b>Rating</b></i>
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***

<i><b>Redness</b></i>	<i><b>Rating</b></i>	<i><b>Chemosis</b></i>	<i><b>Rating</b></i>	<i><b>Discharge</b></i>	<i><b>Rating</b></i>
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><b>Values</b></i>	<i><b>Rating</b></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