

File No: NA/ 233

Date: 4 August, 1995

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

SUBSTANCE H113664

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989*, 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 Human Services and Health.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

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) 565-9466 **FAX (61) (02) 565-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**SUBSTANCE H113664****1. APPLICANT(S)**

Canon Australia Pty Ltd of 1 Thomas Holt Dr, North Ryde, Sydney, NSW 2113 and ICI Australia (Operations) Pty Ltd of 1 Nicholson St, Melbourne, Vic 3000 have submitted a standard notification for assessment of Substance H113664.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the chemical and the data provided, Substance H113664, is considered to be non-hazardous. Therefore, the chemical name, CAS number, molecular formula, structural formula, molecular weight and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Other names: Substance H113664
C I Direct Yellow 173

Trade names: Pro-jet Fast Yellow 2
Pro-jet Fast Yellow 2 Liquid

Method of detection and determination:

HPLC separation and infrared spectroscopy.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: Orange powder

Melting Point/Boiling Point: > 300°C

Density: 1290 kg/m³ at 20°C

Vapour Pressure: < 0.0013 Pa

Water Solubility: > 10g/L at 22°C

Surface Tension of Aqueous Solution: 68.5 mN/m at 23°C

Fat Solubility: 0.62 mg/100g solvent

Partition Co-efficient (n-octanol/water) log P_{ow}: -1.39 at 25°C

Hydrolysis as a function of pH: < 10% at pH 7 and pH 9. Test unable to be performed at pH 4 due to gel formation

Adsorption/Desorption:	Test not performed. The notified chemical is a mixed sodium/ammonium salt which contains aromatic carboxylic acid groups, and a basic nitrogen. The chemical is expected to have dissociation constants typical for these functionalities.
Dissociation Constant pK_a:	Test not performed. The notified chemical is a mixed sodium/ammonium salt which contains aromatic carboxylic acid groups, and a basic nitrogen. The chemical is expected to have dissociation constant typical for these functionalities.
Flammability Limits:	Does not propagate combustion
Autoignition Temperature:	270°C
Explosive Properties:	Non-explosive
Reactivity/Stability:	Non-reactive
Particle size distribution:	100% <115 µm (Aerodynamic equivalent diameter). The notified substance will be imported in the powder form.

• Comments on the physico-chemical properties

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

Adsorption/desorption :

The notifier's comments 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: > 80%

5. INDUSTRIAL USE

The notified chemical will be used as a component of a preparation used in ink-jet reprographic processes. It is imported as a 3-4% aqueous solution in a sealed cartridge at a rate of 1 tonne for the first year and 1-10 tonnes per year for the following 4 years. The notified chemical will be used Australia wide, predominantly in the home and small office market.

6. OCCUPATIONAL EXPOSURE

The notified chemical is to be imported in sealed cartridges each containing 50 mL of the ink formulation. 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. Under normal conditions of use, several milligrams of the notified chemical is expected on each printed paper.

7. PUBLIC EXPOSURE

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

8. ENVIRONMENTAL EXPOSURE

. Release

Spills that occur during transport or handling will be absorbed onto earth, sand or other suitable absorbent materials, transferred to waste containers and consigned to secure landfill in accordance with the MSDS. The occurrence and size of spills should be minimised due to the small volumes contained in the cartridges and the protection offered by the cartridge housing.

Cartridges will be replaced by the user. Empty cartridges will be disposed with normal office refuse and domestic garbage.

. Fate

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 empty cartridges are expected to remain within the cartridge housing.

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 where they will be rapidly diluted.

The ready biodegradability of the notified chemical was assessed using the modified MITI test (OECD TG 301C). Analysis of BOD at the end of the test indicated only slight biodegradation (<10%). Biochemical and chemical oxygen demand test results (BOD₅ < 0.082 g O₂/g, COD 1.22 g O₂/g) indicate that no significant biodegradation is likely

under aerobic conditions . Colorimetric analysis showed significant colour removal (79%) over 28 days, indicating that primary biodegradation takes place.

The bioaccumulation potential of the dye was not investigated. The low partition coefficient ($\log P_{ow} < -1.39$) relatively high solubility (10 g/L) and low fat solubility ($<6.2 \text{ mg.kg}^{-1}$) of the notified chemical indicate that significant bioaccumulation is not likely.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Substance H113664

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD ₅₀ > 2000 mg/kg	(1)
Acute dermal toxicity	Rat	LD ₅₀ > 2000 mg/kg	(3)
Skin Irritation	Rabbit	slight irritant	(4)
Eye irritation	Rabbit	severe irritant	(6)
Skin sensitisation	Guinea-pig	sensitiser	(8)

9.1.1 Oral Toxicity (1)

LD₅₀: > 2000 mg/kg

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

Number/sex of animals: 5M, 5F

Observation period: 14 days

Method of administration (vehicle): gavage (corn oil)

Clinical observations: no signs of toxicity

Mortality: no deaths

Morphological findings: no treatment-related findings

Test Method: directive 84/449/EEC (2) Test B1

9.1.2 Dermal Toxicity (3)

LD₅₀: > 2000 mg/kg

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

Number/sex of animals: 5M, 5F

Observation period: 14 days

Method of administration (vehicle): occlusive dressing (corn oil), 24 hour exposure

Clinical observations: slight erythema and oedema in 2 males and 3 females
regressed by day 5 but no other significant signs of toxicity

Mortality: no deaths

Morphological findings: no treatment-related findings

Test Method: directive 84/449/EEC (2) Test B1

9.1.3 Skin Irritation (4)

Result: slight irritant

Species/strain: New Zealand White rabbits

Number/sex of animals: 3 M

Method of administration: occlusive dressing, 500 mg of chemical in corn oil, 4 hour exposure

Test Method: directive 84/449/EEC (2) Test B1

Draize (5) Scores¹:

Animal	Time after decontamination			
	30-60 min	1 day	2 days	3 days
ERYTHEMA				
1	2	1	0	0
2	1	0	0	0
3	1	0	0	0
OEDEMA				
1	2	0	0	0
2	1	0	0	0
3	2	0	0	0

9.1.5 Eye Irritation (6)

Result: severe irritant

Species/strain: New Zealand White rabbits

Number of animals: 3 M

Method of administration: 100 mg of the notified chemical applied into the conjunctival sac of the left eye

Test Method: directive 84/449/EEC (2) Test B1

Draize (5) Scoresⁱⁱ

Animal	Time after instillation											
	1 day			2 days			3 days			4 days		
CORNEA:	opacity area			opacity area			opacity area			opacity area		
1	2	3		2	3		2	3		2	3	
2	2	2		2	2		2	2		2	2	
3*	2	2		2	2							
IRIS												
1	1			1			1			1		
2	2			1			1			1		
3*	2			2								
CONJUNCTIVA	^a	^b	^c	^a	^b	^c	^a	^b	^c	^a	^b	^c
1	3	2	3	2	1	1	2	1	0	2	0	0
2	2	1	2	2	1	2	2	0	2	2	0	2
3*	2	2	3	2	0	2						

^a redness ^b chemosis ^c discharge * terminated 2 days after instillation due to due to severity of iridal response

9.1.6 Skin Sensitisation (7)

Result: sensitiser

Species/strain: Albino guinea-pigs *Number of animals:* 20 test, 10 control
(Alpk: Dunkin-Hartley)

Induction: Injections of 0.05 - 0.1 mL FCA plus corn oil (1:1); 1% (w/v) notified chemical in corn oil; 1% (w/v) notified chemical in FCA plus corn oil (1:1).
Topical induction at day 8: 75% (w/v) notified chemical in corn oil

Results:

Challenge Concentration	24 hrs		48hrs	
	test	control	test	control
3%	1/20	0/10	1/20	0/10
10%	5/20*	0/10	5/20*	1/10

All positive responses were scattered mild redness

* only 2 animals exhibited a positive response at both 24 and 48 hours so that 8 animals in all were sensitised - a rate of 30%

Test Method: directive 84/449/EEC (2) Test B1

9.2 Repeated Dose Toxicity (8)

Species/strain: Rat - Wistar derived (AlpK: APFSD) *Number/sex:* 5 M, 5 F per dose with additional 5/sex in control and high dose groups

Method of administration (vehicle): gavage (corn oil)

Dose/ Duration of administration: 0, 50, 250 and 1000 mg/kg/day; 7 days per week with a 14 day recovery period for control and high dose groups

Toxicologically Significant Observations:

1. Clinical

None

2. Clinical Chemistry/Haematology

At 250 mg/kg/day urine clinical chemistry changes suggestive of renal involvement were seen. At 1000 mg/kg/day there was a slightly raised platelet count at day 28. Urine clinical chemistry changes (reduced urine volume and raised specific gravity and/or increases in urinary protein) in females indicated renal involvement. Blood clinical chemistry changes (increased plasma cholesterol and reduced plasma total protein and albumin levels, reduced plasma alkaline phosphatase, alanine transaminase and/or aspartate transaminase activities) were seen for males and/or females and indicated liver involvement.

3. Necropsy Findings/ Histopathology

The kidney and liver were identified as target organs for toxicity. No effects were observed at 50 or 250 mg/kg/day.

At 1000 mg/kg/day kidney weight changes were observed for females and histopathological changes in the kidney for males and females were seen at day 28 (tubular basophilia, tubular vacuolation and glomerular vacuolation). Following the recovery period minimal changes indicative of previous renal injury were apparent. Liver weight changes apparent in females persisted through the recovery period. However, histopathological findings in the liver (periportal hepatocyte fat vacuolation and epithelial vacuolation of the intrahepatic bile duct) were only seen at day 28.

Test Method: directive 84/449/EEC (2) Test B1

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (9)

Result: weakly mutagenic

Comments: positive result in *Escherichia coli* WP2uvrA(pKM101) at a maximum of 1.9 times background and 2×10^{-2} mutants per μg with indications of a dose-response relationship

Strains: *Salmonella typhimurium* TA 1535, TA 1537, TA 98 and TA 100 and *Escherichia coli* WP2uvrA(pKM101) and WP2 (pKM101)

Metabolic activation: rat liver S9 *Solvent:* dimethylsulfoxide

Concentration range: 200 - 6135 μg / plate

Test Method: directive 84/449/EEC (2) Test B1

9.3.2 In Vitro Cytogenetic Assay in Human Lymphocytes (10)

Result: non-clastogenic

Cell Culture: PHA-stimulated peripheral blood lymphocytes in RPMI-1640 tissue culture medium, 48 hour growth prior to treatment. Sampling times: 68 hours (male and female donors) and 92 hours (female donor)

Metabolic activation: rat liver S9 *Doses:* 1 - 500 $\mu\text{g}/\text{mL}$

Comments: one isolated statistically significant (small) increase in aberrant cells at 100 $\mu\text{g}/\text{mL}$ was observed for the female donor at 68 hours but was judged not to be biologically significant in the absence of a dose-response

Test Method: directive 84/449/EEC (2) Test B1

9.4 Overall Assessment of Toxicological Data

The notified chemical is non-toxic via the oral and dermal routes in the rat with both $\text{LD}_{50} > 2000 \text{ mg/kg}$. It is a slight irritant to the skin and a moderate irritant to the eye of the rabbit. It is a sensitiser to the skin of the guinea-pig. When rats were treated orally with up to 1000 mg/kg/day for 28 days, reversible tubular and glomerular changes of the kidney was observed in 1000 mg/kg/day dose group. However, there was no treatment related effects at the dose levels of 50 and 200 mg/kg/day. Substance H113664 was found to be weakly mutagenic *in vitro* to *Escherichia coli* WP2uvrA(pKM101). Non-clastogenic in the PHA-stimulated peripheral blood lymphocytes in RPMI-1640 tissue.

On the basis of submitted data, the notified chemical would be classified as hazardous in accordance with Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (11) in relation to irritant effects (eye) and sensitising effects (skin).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Table 1 summarises the ecotoxicity tests provided by the notifier for Substance H113664. These tests were performed in accordance with OECD guidelines and principles of GLP.

The fish study reported the mean measured concentration as 67% of the nominal value of 180 mg.L⁻¹. At the beginning of the study, the test solutions were observed to be orange in colour and slightly cloudy. The cloudiness increased during the course of the study. Observations of toxicity symptoms could not be made due to the colour and opacity of the test solutions. No mortalities were recorded.

For the *Daphnia* study, the mean measured concentration corresponded to only 11% of the nominal value of 180 mg.L⁻¹. This significant difference was attributed to the test material dropping out of solution from the *Daphnia* test medium. This effect was not observed when the test material was dissolved in deionised water. At the start of the study the test solutions were described as opaque, evenly distributed yellow suspensions. After 48 h settling of the suspension resulted in a clear yellow phase above a layer of gelatinous matter at the bottom of the test vessel. During the study none of the *Daphnia* were classified as immobile.

These results indicate that the notified chemical is practically non-toxic to fish and at worst slightly toxic to *Daphnia*.

Algal growth inhibition testing indicated that the notified chemical was slightly toxic in terms of biomass and practically non-toxic with respect to growth rate. Measured test concentrations at the start of testing ranged from 73-94% of nominal values. The slight activity measured may be attributed to the reduced light transmittance through the test solution and a 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 and anerobic conditions. Under aerobic conditions a 1000 mg.L⁻¹ nominal concentration of the notified substance in activated sludge caused a 8% inhibition in the respiration rate of the microorganisms (12). This result indicates that no significant effects on sewage treatment systems are considered likely. At the same concentration the active caused a 21% reduction in the nitrification ability of the activated sludge (13).

Under anerobic conditions, nominal concentrations of the notified chemical ranging from 0.1 to 2.5% w/w total dry solids, were reported to have had no inhibitory effects on gas production. This result indicating that no significant toxic effects are expected for anaerobic sewage treatment.

Table 1. Ecotoxicity test results (mean measured concentrations)

Species	Test	Result
Rainbow Trout, <i>Oncorhynchus mykiss</i>	96 hour acute OECD TG 203	LC ₅₀ = >120 mg.L ⁻¹
Daphnia, <i>Daphnia magna</i>	48 hour immobilisation OECD TG 202	EC ₅₀ > 20 mg.L ⁻¹
Algae <i>Selenastrum capricornutum</i>	Growth Inhibition OECD TG 201	Biomass: NOEC = 12.5 mg.L ⁻¹ EbC ₅₀ = 73 mg.L ⁻¹ Growth rate : NOEC = 12.5 mg.L ⁻¹ ErC ₅₀ > 100 mg.L ⁻¹
Activated sludge	ETAD Method 103	8% inhibition of respiration at 1000 mg.L ⁻¹ nominal

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Substance H113664 is not expected to present a hazard to the environment. During normal use the chemical will be bound to the treated substrate.

The disposal of uncured inks will be largely confined to residues contained in colour cartridge systems which do not allow the replacement of individual colours. These residues 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 dispersed in landfills around Australia where it 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.

Spills of the dye should not present an environmental hazard when cleaned up according to the MSDS sheets.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is to be used in ink-jet reprographic processes. Exposure during normal handling is not expected through the use of containment, other than in the unlikely event that the cartridge is faulty and ruptures.

The toxicologic profile of Substance H113664 suggests that it is unlikely to produce acute toxic effects upon ingestion and dermal contact. Although it is expected to be a slight skin irritant, irritation to the eye is expected to be severe. The notified chemical may be a skin sensitiser in certain individuals and is weakly mutagenic but not clastogenic. The results of the sub-acute 28-day oral toxicity test suggest the notified chemical has the potential to cause renal and liver damage on repeated or prolonged exposure. However, as organ

toxicity in rats in this test was only observed at 1000 mg/kg/day, the notified chemical would not be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (11).

Despite the intrinsic health hazard of the notified chemical, exposure from normal use is expected to be low and hence the occupational health risk arising from this use is expected to be minimal. However, in the event of a spill or an accident, skin contact should be avoided, since there is a potential for skin sensitisation, due to the presence of the notified chemical in excess of 1% in the ink formulation.

The potential for public exposure to the notified chemical by handling the 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 preparation and its insolubility on the surface of paper. Accidental rupture of the cartridge is unlikely to result in a significant health hazard due to the low level of the notified chemical in the ink, small quantities of the ink in a cartridge and the low toxicity of the notified chemical preparation.

13. RECOMMENDATIONS

To minimise occupational exposure to Substance H113664 the following guidelines and precautions should be observed:

- . in the event of a spill to reduce exposure of Substance H113664 to a safe level, personal protective devices which conform to and are used in accordance with Australian Standards (AS for eye protection (AS 1336, AS 1337) (14,15), impermeable gloves (AS 2161 (16) and overalls; and
- . a copy of the Material Safety Data Sheet should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Substance H113664 was provided in Worksafe Australia format (17).

This MSDS was provided by ICI (Operations) Pty Ltd as part of their notification statement. The accuracy of this information remains the responsibility of ICI (Operations) Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Substance H113664 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. ICI Project SI/93/0008, July 1993. *Acute Oral Toxicity Study with H113664 in Rats*. Zeneca Central Toxicology Laboratory, Cheshire, United Kingdom.
2. EEC Council 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. L251 (19 September 1984).
3. ICI Project SI/93/0008, July 1993. *Acute Dermal Toxicity Study with H113664 in Rats*. Zeneca Central Toxicology Laboratory, Cheshire, United Kingdom.
4. ICI Project SI/93/0008, June 1993. Primary Skin Irritation Study with H113664 in Rabbits. Zeneca Central Toxicology Laboratory, Cheshire, United Kingdom.
5. 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**.
6. ICI Project SI/93/0008, August 1993. *Primary Eye Irritation Study with H113664 in Rabbits*. Zeneca Central Toxicology Laboratory, Cheshire, United Kingdom.
7. ICI Projects SI/93/0008 July 1993. *Contact Hypersensitivity to H113664 in Albino Guinea Pigs, Maximisation Test*, Zeneca Central Toxicology Laboratory, Cheshire, United Kingdom.
8. ICI Project SH/93/0008, November 1993. *Subacute 28-Day Oral Toxicity Gavage Study with H113664 in Rats*. Zeneca Central Toxicology Laboratory, Cheshire, United Kingdom.
9. ICI Projects SH/93/0008 May 1993. *Salmonella typhimurium and Escherichia coli Reverse Mutation Assay for Azo dyes with H113664*. Zeneca Central Toxicology Laboratory, Cheshire, United Kingdom.
10. ICI Project SH/93/0008, November 1993. *Micronucleus Assay in the Bone Marrow Cells of the Mouse with H113664*. Zeneca Central Toxicology Laboratory, Cheshire, United Kingdom.
11. Worksafe Australia, March 1994, *Approved Criteria for Classifying Hazardous Substances*. Australian Government Publishing Service, Canberra.
12. ETAD (Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry). Ecological Test Method 103 - A screening test for the Assessment of the Possible Inhibitory Effect of the Chemical Substance on Aerobic Waste-Water Bacteria.
13. Department of the Environment, UK 1980. The Assessment of the Nitrifying Ability of Activated Sludge (Tentative Methods). HMSO London.

14. Standards Australia, 1982. Australian Standard 1336-1982, *Eye Protection in the Industrial Environment*, Standards Association of Australia Publ, Sydney,.
15. Standards Australia, 1982. Australian Standard 1337-1984, *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ, Sydney,.
16. Standards Australia, 1982. Australian Standard 2161-1978, *Industrial Safety Gloves and Mittens and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ, Sydney,.
17. Worksafe Australia, February 1990, *Guidance Note for Completion of a Material Safety Data Sheet*. Australian Government Publishing Service, Canberra.

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

Erythema Formation		Oedema Formation	
rating		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. 1mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

ii The Draize scale for evaluation of eye reactions is as follows:

CORNEA			
Opacity rating	rating	Area of Cornea involved	
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,	3 moderate	Greater than 75%	
4			
size of pupil barely discernible			
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 severe	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3
		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 slight	1
No reaction to light, haemorrhage, gross destruction severe	2