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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

C I DIRECT YELLOW 173

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services

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.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**C I DIRECT YELLOW 173****1. APPLICANT**

Epson Australia Pty Ltd of 70 Gibbes Street CHATSWOOD NSW 2067 has submitted a standard notification statement in support of their application for an assessment certificate for C I Direct Yellow 173.

2. IDENTITY OF THE CHEMICAL

The notified chemical is classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (11) in relation to eye irritancy and skin sensitisation. However, for commercial reasons, the identity of the notified chemical has been granted exemption from publication in the Full Public Report and the Summary Report. The conditions of this being permitted are:

- A descriptive generic name, C I Direct Yellow 173 be used to identify the substance in public reports and Material Safety Data Sheets (MSDS),
- The relevant employee unions shall be informed of the conditions of use of the notified chemical,
- The full chemical name shall be provided to any health professionals in the case of a legitimate need where exposure to the chemical may involve a health risk,
- The full chemical name shall be provided to those on site who are using the chemical and to those who are involved in planning for safe use, etc. in the case of a legitimate need,
- The Director of NICNAS will release the full chemical name etc in the case of a request from a medical practitioner,
- Confidentiality will expire after a 3 year period,
- The chemical be identified as an eye irritant and a skin in the Health Effects section, and that reference to assessment by NICNAS be made on the MSDS,

These conditions shall be published in the Chemical Gazette.

Other names:

Substance H113664
C I Direct Yellow 173

Trade name:

Pro-jet Fast Yellow 2
Pro-jet Fast Yellow 2 Liquid (formulation)

Molecular weight:

789

**Method of detection
and determination:**

HPLC separation with detection at 380nm and
infrared spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	orange powder
Melting Point:	> 300°C
Density:	1290 kg/m ³ 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: performed at pH 4 due to gel formation	< 10% at pH 7 and pH 9; test unable to be performed
Adsorption/Desorption:	test not performed
Dissociation Constant pK_a:	test not performed; dissociation constants can be predicted for the 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 a liquid formulation

Comments on Physico-Chemical Properties

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

By EEC definition, a chemical has surface activity when the surface tension is less than 60 mN m⁻¹, thus the substance is not considered surface active (EEC Directive

92/69, A5 "Surface Tension" (1992)).

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

The 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.

4. PURITY OF THE CHEMICAL

Degree of purity: 81.5% (range 80 - 85%)

Impurities (> 1% by weight):

. **Chemical name:** water
Weight percentage: 5.7%

. **Inorganics:** 3.9%

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as a component of a preparation used in ink-jet reprographic processes. It is to be imported as a 3-4% aqueous solution in sealed cartridges at a rate of < 1.5 tonnes per year for the first 5 years. The notified chemical will be used Australia wide, predominantly in the home and small office market.

6. OCCUPATIONAL EXPOSURE

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

7. PUBLIC EXPOSURE

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

exposure may occur through accidental rupture of a cartridge.

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

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

8. ENVIRONMENTAL EXPOSURE

Release

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

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

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

Fate

The relatively high water solubility of the notified chemical indicates that unbound residues released directly to the aquatic compartment are likely to remain in solution 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 ($BOD_5 < 0.082 \text{ g O}_2/\text{g}$, $COD 1.22 \text{ g O}_2/\text{g}$) 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 notified chemical was not investigated. The low partition coefficient ($\log P_{ow} = -1.39$), relatively high solubility (10 g/L) and low fat solubility (< 6.2 mg/kg) of the notified chemical indicate that significant bioaccumulation is not likely.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of C I Direct Yellow 173

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	(7)

9.1.1 Oral Toxicity (1)

<i>Species/strain:</i>	rat - Wistar-derived albino (AlpK:APfSD)
<i>Number/sex of animals:</i>	5 males, 5 females
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	gavage (corn oil)
<i>Clinical observations:</i>	no signs of toxicity
<i>Mortality:</i>	no deaths
<i>Morphological findings:</i>	no treatment-related findings
<i>Test method:</i>	directive 84/449/EEC (2)
<i>LD₅₀:</i>	> 2000 mg/kg
<i>Result:</i>	the notified chemical exhibited low acute oral toxicity in rats

9.1.2 Dermal Toxicity (3)

<i>Species/strain:</i>	rat - Wistar-derived albino (AlpK:APfSD)
<i>Number/sex of animals:</i>	5 males, 5 females
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	occlusive dressing (corn oil); 24 hour exposure

<i>Clinical observations:</i>	slight erythema and oedema in 2 males and 3 females regressed by day 5 but no other significant signs of toxicity
<i>Mortality:</i>	no deaths
<i>Morphological findings:</i>	no treatment-related findings
<i>Test method:</i>	directive 84/449/EEC (2)
<i>LD₅₀:</i>	> 2000 mg/kg
<i>Result:</i>	the notified chemical exhibited low acute dermal toxicity in rats

9.1.3 Skin Irritation (4)

<i>Species/strain:</i>	New Zealand White rabbits
<i>Number/sex of animals:</i>	3 males
<i>Method of administration:</i>	occlusive dressing, 500 mg of chemical in corn oil, 4 hour exposure

Draize scores (5):

<i>Time after treatment (days)</i>	<i>Animal #</i>		
	<i>1</i>	<i>2</i>	<i>3</i>
<i>Erythema</i>			
1	1 ⁱ	0	0
2	0	0	0
3	0	0	0
<i>Oedema</i>			
1	0	0	0
2	0	0	0
3	0	0	0

ⁱ see Attachment 1 for Draize scales

<i>Test method:</i>	directive 84/449/EEC (2)
<i>Result:</i>	slight skin irritant in rabbits

9.1.5 Eye Irritation (6)

Species/strain: New Zealand White rabbits

Number/sex of animals: 3 males

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

Draize scores (5) of unirrigated eyes:

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

ⁱ see Attachment 1 for Draize scales * terminated 2 days after instillation due to severity of iridal response

^a opacity ^b area ^c redness ^d chemosis ^e discharge

Test method: directive 84/449/EEC (2)

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

9.1.6 Skin Sensitisation (7)

Species/strain: albino guinea-pigs (Alpk: Dunkin-Hartley)

Number of animals: 20 test, 10 control

Induction procedure: 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

Challenge procedure: two weeks after topical induction 0.05-0.1 mL of test substance in corn oil at 3% or 10% (w/v) was applied under occlusive dressing

Challenge outcome:

Challenge concentration	Test animals		Control animals	
	24 hrs*	48 hrs*	24 hrs	48 hrs
3%	1/20**	1/20	0/10	0/10
10%	5/20	5/20	0/10	1/10

* time after patch removal

** number of animals exhibiting positive response

Test method: directive 84/449/EEC (2)

Result: the notified chemical was a skin sensitizer in guinea pigs; the net percentage response was 30% with challenge at 10% (w/v) and 5% with 3% (w/v)

9.2 Repeated Dose Toxicity (8)

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

Number/sex of animals: 5/ sex at each dose plus an additional 5/ sex in control and high dose animals

Method of administration: gavage (corn oil)

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

Clinical observations: none

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

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)

Result:

the target organs for toxicity of the notified chemical were the kidney and the liver; histopathological changes were only observed at 1000 mg/kg/day but urine clinical chemistry changes in females at 250 mg/kg/day indicated renal involvement

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (9)

Strains:

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

Concentration range:

200 - 6135 µg/ plate

Test method:

directive 84/449/EEC (2)

Result:

weakly mutagenic; 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

9.3.2 *In Vitro* Cytogenetic Assay in Human Lymphocytes (10)

<i>Doses:</i>	1 - 500 µg/mL
<i>Cell Culture:</i>	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 (male donor)
<i>Test method:</i>	directive 84/449/EEC (2)
<i>Result:</i>	one isolated statistically significant (small) increase in aberrant cells at 100 µg/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

9.4 Overall Assessment of Toxicological Data

The notified chemical was of low toxicity via the oral and dermal routes in the rat with both LD₅₀s > 2000 mg/kg. It was a slight irritant to the skin and a severe irritant to the eye of the rabbit. It was a skin sensitiser in guinea pigs. 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. These effects were not observed at dose levels of 50 and 250 mg/kg/day although at the latter dose level urine clinical chemistry changes in females indicated renal involvement. C I Direct Yellow 173 was found to be weakly mutagenic *in vitro* in Escherichia coli WP2uvrA(pKM101) and non-clastogenic in PHA-stimulated human peripheral blood lymphocytes.

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

The table below summarises the ecotoxicity tests provided by the notifier for C I Direct Yellow 173. These tests were performed in accordance with OECD guidelines and principles of GLP.

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
Daphnia, <i>Daphnia magna</i>	48 hour immobilisation OECD TG 202	EC ₅₀ > 20 mg/L
Algae <i>Selenastrum</i> <i>capricornutum</i>	Growth Inhibition OECD TG 201	Biomass: NOEC = 12.5 mg/L EbC ₅₀ = 73 mg/L Growth rate : NOEC = 12.5 mg/L ErC ₅₀ > 100 mg/L
Activated sludge	ETAD Method 103	8% inhibition of respiration at 1000 mg/L nominal

The fish study reported the mean measured concentration as 67% of the nominal value of 180 mg/L. 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. 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 notified chemical on sewage treatment were investigated under aerobic and anerobic conditions. Under aerobic conditions a 1000 mg/L 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.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

C I Direct Yellow 173 is not expected to present a hazard to the environment. During normal use the chemical will be bound to the treated substrate.

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

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

Spills of the dye should not present an environmental hazard when cleaned up according to the Material Safety Data Sheets (MSDS).

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The toxicologic profile of C I Direct Yellow 173 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 and is likely to be weakly genotoxic. 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).

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

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 C I Direct Yellow 173 the following guidelines and precautions should be observed:

- in the event of a spill or during routine cleaning or maintenance, if engineering controls or work practices are insufficient to reduce exposure to a safe level, personal protective devices which conform to and are used in accordance with Australian Standards (AS) or Australian/ New Zealand Standards (AS/NZS) for eye protection (AS 1336, AS/NZS 1337) (14,15), impermeable gloves (AS 2161) (16) and overalls (AS 2919) (17) should be worn; and
- a copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the ink containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of a Material Safety Data Sheets* (18).

This MSDS was provided by the applicant as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of 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

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.
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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. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australia Government Publishing Service, Canberra, Australia.
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, 1994, *Australian Standard 1336-1994, Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, Australia.
15. Standards Australia, Standards New Zealand 1992, *Australian/ New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

16. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ., Sydney, Australia.
17. Standards Australia, 1987, *Australian Standard 2919 - 1987 Industrial Clothing*, Standards Association of Australia Publ., Sydney, Australia.
18. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*, AGPS, Canberra, Australia.

Attachment 1

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

Erythema Formation	Rating	Oedema Formation	Rating
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising)	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

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

CORNEA

Opacity	Rating	Area of Cornea involved	Rating
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	Rating	Chemosis	Rating	Discharge	Rating
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

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

