

File No: NA/437

Date: October 1996

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

C-1743

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.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**C-1743****1. APPLICANT**

Kodak Australasia Pty Ltd of 173 Elizabeth Street COBURG VIC 3058 has submitted a limited notification statement in support of an application for an assessment certificate for C-1743.

2. IDENTITY OF THE CHEMICAL

C-1743 would be classified as hazardous in relation to eye irritant effects based on the *in vitro* and *in vivo* data provided by the notifier. According to the *National Model Regulations for the Control of Workplace Hazardous Substances*, (1) eye irritants are regarded as Type II ingredients in terms of ingredient disclosure. Hence a generic name can be used to identify the notified chemical, as the identity of C-1743 is regarded as commercially confidential. Given that a generic name can be used to identify the notified chemical, the chemical name, CAS number, molecular and structural formulae and the spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Generic Name:	disubstituted tetrazole
Other Names:	C-1743 (shipping name)
Trade Name:	not applicable; will not be marketed
Molecular Weight:	297
Method of Detection and Determination:	high performance liquid chromatography; UV detection

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white solid
Melting Point:	167-168°C (at 760 mm Hg); chemical decomposed when melting
Boiling Point:	not conducted in view of melting temperature

Specific Gravity:	1.499
Vapour Pressure:	< 5.3x10 ⁻⁵ kPa at 25°C
Water Solubility:	50.7 mg/L at 25°C (shake flask determination) 34.8 mg/L at 25°C (column elution)
Partition Co-efficient (n-octanol/water):	log P _{ow} = 1.9 at 23.5°C
Hydrolysis as a Function of pH:	estimated T _{1/2} at pH 9.0 = 709 hours at 25°C
Adsorption/Desorption:	

Soil Type	Spodosol	Alfisol	Entisol
Texture class	Loamy sand	Silt loam	Loam
% clay	6	24	14
% organic matter	2.4	3.0	1.2
pH	4.7	6.5	7.5
% adsorbed	35.6	40.3	17.7
% desorbed	27.0	-3.25	6.00
% retained	73.0	103	94.0
K'	2.90	3.59	1.18
K _{oc}	121	120	98.1

Dissociation Constant:	could not be determined
Particle Size:	median particle size: 619 µm range: 75 - 1680 µm
Flash Point:	not applicable
Flammability:	highly flammable
Autoignition Temperature:	not applicable
Explosive Properties:	not explosive
Reactivity/Stability:	not expected to be an oxidiser based on structure-activity relationships

Comments on Physico-Chemical Properties

The substance is a disubstituted tetrazole, moderately soluble in water from an environmental impact perspective, and significantly more soluble in dilute aqueous sodium hydroxide solution, the manner in which it will be prepared for use.

C-1743 is non-volatile under standard ambient conditions. The chemical contains an amide group which may be subject to hydrolysis under environmental conditions, but measured hydrolysis was slow even at pH 9.

The K_{oc} values indicate limited adsorption to soil organic matter, hence the substance may be mobile in soil or sediment, but it may coordinate with transition metals through the substituent on the tetrazole moiety and then partition to sludge.

4. PURITY OF THE CHEMICAL

Degree of Purity:	sample no.	purity (%)
	94-0087	98.5
	95-0110	99.9

Toxic or Hazardous impurities:	none reported
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Non-Hazardous Impurities (> 1% by weight):	sample 94-0087:	remaining 1.5% of total area consisted of 5 unidentified impurity peaks, one of which had an area % > 0.5%.
	sample 95-0110:	remaining 0.08% of total area was accounted for by 2 unidentified impurity peaks, having area percentages of 0.02% and 0.06%, respectively.

Additives/Adjuvants:	none
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5. USE, VOLUME AND FORMULATION

C-1743 will not be manufactured or reformulated in Australia. The notified chemical is intended for use in the manufacture of photographic film and paper. C-1743 is currently being imported under a Low Volume Chemical Permit, but increased usage requires that this assessment be prepared. In the future, the import volume is expected to be 150 kg per year for the first year, rising to 150-200 kg per year for the following 4 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 10 kg of C-1743.

Waterside, warehouse and transport workers will be handling unopened drums containing the notified chemical. These workers are only expected to come into contact with C-1743 in the event of an accident or leaking packaging.

Inhalational, dermal and ocular exposure to the notified chemical may occur when workers weigh the pure chemical into an open topped plastic container. Inhalational exposure is expected to be minimised by the large particle size of the notified chemical (619 μm), which falls outside the range considered inspirable by the American Conference of Governmental Industrial Hygienists (cited in (2)). However, inhalational exposure to finer dust particles generated by handling the notified chemical may occur. The notifier states that exposure to C-1743 will be further reduced by carrying out these operations under air extractors with mechanical ventilation.

Following weighing, a slurry is prepared by mixing the chemical with solvent in an open mixing vessel to form a aqueous solution. A lid is fitted to the mixing vessel and it is wheeled to another area, where the solution is added (via a tap in the base of the vessel) to a mix tank, together with other addenda, 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 it is estimated that 400 batches will be made per year.

Worker exposure is expected to be minimal during the pumping of the dispersion, (containing the notified chemical at a concentration of less than 0.1 g/kg), into closely controlled automated equipment, where it will be incorporated into photographic film and paper. 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 notifier has indicated that C-1743 will not be manufactured or reformulated in Australia. It is to be imported in sealed shipping containers and used in the manufacture of photographic film and paper at only a single site in Australia.

The notifier states that C-1743 is a component which will be totally consumed within the notifier's plant during the manufacture of photographic articles. Practically all of the notified chemical will enter the public domain as a component of photographic film and paper. Once incorporated into such articles, the notified chemical will be under overcoat layers. As such, public exposure to C-1743, arising from its use in the production of photographic film and paper, is expected to be negligible.

8. ENVIRONMENTAL EXPOSURE

Transport, storage and disposal

C-1743 will be transported directly to the Kodak site and stored there sealed in the 10 kg containers (packaged in a plastic bag inside a fibre drum) in which it is imported. According to the Material Safety Data Sheet (MSDS), it should be stored in a tightly closed container, under cool (5-20°C) conditions in an area designated for flammable materials. According to the previous assessment for the sodium salt of C-1743 (NICNAS Assessment NA/354), the prepared aqueous solution will be used immediately, or stored for a few days only, and will not be transported off-site. The previous assessment also states that the dispersion containing C-1743 will be bagged and stored in a cold room for up to one week prior to use. It is expected that similar production procedures will currently apply in the Kodak plant.

The MSDS gives directions for clean-up of accidental releases (eliminate all ignition sources, sweep up and place in a container for chemical waste and clean surface thoroughly to remove residual contamination) and advice on disposal considerations. The notifier's submission states that accidental spills should be swept up, placed in a fibre carton, and disposed of by incineration. Shipping/storage containers, containing residual amounts of pure chemical, will be incinerated. These aspects are satisfactory.

Release

Release of the chemical during the film/paper manufacturing process described above is limited to the one site in Australia where that process occurs. Residues in various waste 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, there will be no potential direct exposure to the environment by the notified chemical, as the chemical will be present in very low concentrations under overcoat layers.

The notifier estimates that approximately 0.1% of the aqueous C-1743 solution (containing less than 1% C-1743) from the dissolving and dispensing tanks could be released to the municipal sewer. This would result in approximately 1 g per day release of the chemical. The notified chemical released as an aqueous solution to the municipal sewer is diluted initially in the sewer 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 megalitres, giving a maximum concentration in sewage effluent of 0.002 ppb. At 0.1% of total imports, total release by this means would be up to 0.2 kg per annum.

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. This part of the process is performed in the USA. Total release by this means would therefore be up to 10 kg per annum.

Additionally, the notifier estimates that up to 1% of dispersion waste, containing less than 0.1 g/kg C-1743, may be sent to a secured landfill. Total release by this means would therefore be up to 2 kg per annum.

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 dispersion is sent to a secured landfill. Waste trapped in filter cake is processed in the USA. Used shipping containers will be incinerated. Used or waste photographic film and paper would be incinerated, or buried in landfill.

9. EVALUATION OF TOXICOLOGICAL DATA

According to the Act, toxicological data are not required for a chemical with an import volume of less than 1 000 kg/year, although the data summarised below were submitted by the notifier to assist in the assessment of C-1743.

9.1 Acute Toxicity

Summary of the acute toxicity of C-1743

Test	Species	Outcome	Reference
acute oral toxicity	rat	LD ₅₀ > 2 000 mg/kg	(3)
acute dermal toxicity	rat	LD ₅₀ > 2 000 mg/kg	(4)
skin irritation	rabbit	non-irritant	(5)
eye irritation	EYTEX <i>in vitro</i> assay	potential for severe to extreme irritancy	(6)
skin sensitisation	rabbit	irritant	(7)
	guinea pig	non-sensitiser	(8)

9.1.1 Oral Toxicity (3)

<i>Species/strain:</i>	rat; CD [®] (SD)BR VAF/Plus [®]
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	gavage; 2000 mg/kg test substance administered in 0.5% aqueous suspension of guar gum
<i>Clinical observations:</i>	none
<i>Mortality:</i>	none

<i>Morphological findings:</i>	none
<i>Test method:</i>	according to OECD guidelines (9)
<i>LD₅₀:</i>	> 2 000 mg/kg
<i>Result:</i>	low oral toxicity in rats in a limit test with a single dose of 2 000 mg/kg

9.1.2 Dermal Toxicity (4)

<i>Species/strain:</i>	rat; CD [®] (SD)BR VAF/Plus [®]
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	2 000 mg of test substance was moistened with water and applied under a fibre pad to one intact skin site on each animal; treatment site occluded for 24 hours; dressing removed and site washed with water; observations made during the exposure period and daily for duration of experiment
<i>Clinical observations:</i>	none
<i>Mortality:</i>	none
<i>Morphological findings:</i>	none
<i>Test method:</i>	according to OECD guidelines (9)
<i>LD₅₀:</i>	> 2 000 mg/kg
<i>Result:</i>	low dermal toxicity in rats in a limit test with a single dose of 2 000 mg/kg

9.1.4 Skin Irritation (5)

<i>Species/strain:</i>	rabbit; Hra:(NZW)SPF
<i>Number/sex of animals:</i>	3/not determined
<i>Observation period:</i>	3 days
<i>Method of administration:</i>	0.5 g of test substance was moistened with water and applied under a fibre pad to one

intact skin site on each animal; treatment site occluded with adhesive dressing for 4 hours; dressing removed and site washed with water; observations made at 60 min, 2, 3 and 4 days after removal of dressing and scored according to the method of Draize (10)

Test method: according to OECD guidelines (9)

Result: there were no Draize scores greater than 0; the test substance was found not to be irritating to intact rabbit skin

9.1.5 Eye Irritation (6,7)

9.1.5.1 In vitro assay (6)

The notifier has submitted results of an EYTEX bioassay, which was used to assess the potential irritancy of the test material. The bioassay consists of a highly organised protein matrix which undergoes conformation and hydration changes when tested with a test material which is an eye irritant. These changes are considered relevant to *in vivo* irritation, as disturbance of protein conformation and hydration have been identified as components of corneal injury and ocular irritation. Changes in turbidity of the EYTEX reagent are correlated with expected Draize scores.

Assay: EYTEX Upright Membrane Assay

Doses: 20, 30, 40, 50 and 70 mg (10% suspension of the test material)

Test method: SOP No. CB 199 (EYTEX™ Test Procedure) (11)

Result: test material may have the potential to produce severe to extreme eye irritation

9.1.5.2 *In vivo* assay (7)

Based on the results of an *in vitro* test (EYTEX Assay - see above), only two animals were initially dosed. The treated eye of one animal was washed with water immediately after the test material was administered, the treated eye of the second animal was not washed. Based on the significant irritation observed in the single unwashed eye, further testing in additional animals was not performed.

<i>Species/strain:</i>	rabbit; Hra:(NZW)SPF
<i>Number/sex of animals:</i>	2; not determined
<i>Observation period:</i>	7 days
<i>Method of administration:</i>	100 mg dose of the test substance placed in conjunctival sac of one eye; treated eye of one rabbit was immediately washed with running distilled water; treated eye of the other rabbit was not irrigated

Draize scores (10) of treated 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	o ^a	a ^b	o ^a	a ^b	
not irrigated	0 ¹	-	0	-	0	-	-	-	-	-	0	-			
irrigated	0	-	0	-	0	-	-	-	-	-	0	-			
Iris															
not irrigated	1		1		0		-				0				
irrigated	0		0		0		-				0				
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
not irrigated	3	2	-	3	1	-	2	0	-	-	-	-	0	0	-
irrigated	0	0	-	0	0	-	0	0	-	-	-	-	0	0	-

¹ see Attachment 1 for Draize scales

^a opacity ^b area (no observations made) ^c redness ^d chemosis ^e discharge (no observations made)

<i>Irrigated eye:</i>	slight erythema of the conjunctiva and nictitating membrane 1 hour after dosing; eye appeared clinically normal one day after dosing
<i>Test method:</i>	according to OECD guidelines (9)
<i>Result:</i>	irritant to the rabbit eye

9.1.6 Skin Sensitisation (8)

<i>Species/strain:</i>	guinea pig; Crl:(HA)BR VAF/Plus®
<i>Number of animals:</i>	30 males; 10 control, 20 test
<i>Induction procedure:</i>	<p>day 0: 3 pairs of intradermal injections:</p> <ul style="list-style-type: none"> - 0.1 mL of 5% concentration of test material in corn oil - 0.1 mL Freund's Complete Adjuvant (FCA):water (1:1) - 0.1 mL of 5% concentration of test material in FCA:water (1:1) <p>day 6: 0.5 mL 10% sodium lauryl sulphate applied</p> <p>day 7: occluded application of 25% concentration of test material in petrolatum for 48 hours</p>
<i>Challenge procedure:</i>	day 21: occluded administration of 25% concentration of test material in petrolatum for 24 hours
<i>Comments:</i>	one test animal was removed from the study due to a prolapsed rectum

Challenge outcome:

Challenge concentration	Test animals		Control animals	
	24 hours*	48 hours*	24 hours	48 hours
25%	0/19**	0/19	0/10	0/10

* time after patch removal

** number of animals exhibiting positive response (one test animal was removed from the study for reasons unrelated to exposure to the test material)

<i>Test method:</i>	according to OECD guidelines (9)
<i>Result:</i>	test material is not considered a sensitiser when tested in guinea pigs

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (12)

<i>Strains:</i>	<i>Salmonella typhimurium</i> TA 1535, TA 1537, TA 98, TA 100 and <i>Escherichia coli</i> strain WP2uvrA(pKM101)
<i>Concentration range:</i>	100, 333, 667, 1 000, 3 300, 5 000 µg/plate
<i>Test method:</i>	according to OECD guidelines (9)
<i>Result:</i>	not mutagenic in the bacterial strains tested in the presence or absence of metabolic activation provided by rat liver S9 fraction

9.4 Overall Assessment of Toxicological Data

The notified chemical exhibited low acute oral toxicity in rats (LD₅₀ > 2 000 mg/kg). It was not a skin irritant when tested in rabbits, or sensitiser to guinea pig skin. The notified chemical was found not to be mutagenic in bacteria in the presence or absence of metabolic activation.

The notified chemical was considered to have the potential to cause severe to extreme eye irritation in an *in vitro* EYTEX assay. Based on the result of this assay, a single animal test was performed, according to the method of OECD guideline 405 (9). This test showed the notified chemical to be an eye irritant in one rabbit when the eye was not washed. Given this result, no further animals were tested.

On the basis of submitted data, the notified chemical would be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (13) in relation to eye irritant effects.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

According to the Act, no ecotoxicological data needs to be provided when the notified chemical has an annual import volume of < 1 000 kg per year, and none were provided by the notifier.

Biodegradation

The Act also states that no biodegradation data needs to be provided when the notified chemical has an annual import volume of < 1 000 kg per year. However, the notifier has provided a Ready Biodegradability Study (CO₂ evolution test according to OECD Test Guideline 301B - EEC Method C.4-C, substance added directly to test carboys due to sparing solubility). Over the 28 day test, biodegradation reached 35% and 24% in the two replicates, indicating moderate biodegradability of at least part of the molecule. Biodegradation reached 10% after a 7 day lag phase, although

it did not reach 60% within the following 10 days. Based on this result the substance would not be declared 'Readily Biodegradable'.

Bioaccumulation

According to the Act, no bioaccumulation data needs to be provided when the notified chemical has an annual import volume of <1 000 kg per year. Moderate water solubility and low environmental exposure should preclude bioaccumulation.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Production of a 200 L batch of the aqueous solution containing less than 1 kg of the notified chemical, with an expected waste of 0.1%, would result in release of approximately 1 g of the chemical to sewer. This quantity will be diluted by 500 ML at Werribee, giving a concentration of approximately 0.002 ppb.

Additionally, less than 1% of dispersion wastes may be sent to a secured landfill. This would equate to less than 2 kg of C-1743 per annum.

C-1743 will enter the environment when the aqueous solution containing the notified substance is discharged to the sewer. C-1743 could undergo some microbial degradation in the sewerage system, although the degree to which this occurs would depend on the pH and other conditions of the system. Some of the chemical may also partition to sediment (sludge) on binding to metals. Any remaining chemical could remain dissolved in effluent and enter receiving water, where it would be further diluted, giving a final concentration well below 0.001 ppb, could partition to sludge during treatment, or could be retained in soil if the effluent undergoes tertiary treatment.

Residues in the dispersion going to secured landfill and those in film and paper going to landfill would presumably degrade at a slow rate, depending on conditions.

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 when 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 10 kg of 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 moderate health risk posed to workers in the Kodak plant who will be handling the pure chemical in powdered form. Inhalational, dermal and ocular exposure may occur while workers are weighing the chemical in solid form. Based on *in vitro* and *in vivo* studies, the main health risk is the potential for the notified

chemical to cause eye irritation, and eye contact should be avoided (see recommendations section). Inhalational exposure is expected to be minimal, due to the large particle size of the notified chemical in solid form, however, the exposure standard (2) for nuisance dusts (10 mg/m^3) should be observed if dust is generated while handling the C-1743 in pure form. Based on results from animal models, there is a low risk of skin irritation or sensitisation if dermal exposure does occur.

The risk of adverse health effects resulting from exposure to the notified chemical is reduced once the chemical is in aqueous or dispersion form. The concentration of the notified chemical is less than 1% in the aqueous solution, and less than 0.1% in the dispersion form. In addition, eye contact is expected to be limited to accidental drips or splashes. Other components of the aqueous solution and the dispersion may, however, cause skin irritation and may also cause eye irritation and/or damage.

The occupational health risk is low for workers involved in supervising the automated process where the notified chemical is incorporated into photographic film and paper, due to the expected very low exposures and the low concentration of C-1743 in the preparations. Once incorporated into articles, the health risk posed to workers by the notified chemical is negligible.

Workers involved in cleaning equipment used in these processes should wear appropriate personal protective equipment, as outlined in the section below.

There is also negligible potential for public exposure to C-1743 arising from its use in the manufacture of photographic film and paper. Once incorporated into such articles, the notified chemical will be under overcoat layers and public exposure is unlikely to occur.

In the case of accidental spillage during transport, the public may be exposed to C-1743. This is minimised by the recommended practices for storage and transportation. Emergency procedures for the containment and clean up of accidental spills are available and should be followed.

13. RECOMMENDATIONS

To minimise occupational exposure to C-1743 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (14) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (15);
- Industrial clothing should conform to the specifications detailed in AS 2919 (16);
- The Worksafe Australia document *Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards* (2) should be used as a guide in the control of any nuisance dusts generated while handling C-1743 in pure form;

- Spillage of 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 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. 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. National Occupational Health and Safety Commission 1994, *Control of Workplace Hazardous Substances* [NOHSC:1005(1994), 2007(1994)], Australian Government Publishing Service, Canberra, Australia.
2. National Occupational Health and Safety Commission 1995, 'Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment', [NOHSC:1003(1995)], in *Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards*, Australian Government Publishing Service Publ., Canberra.
3. Shepard KP, 1994, *C-1743 Acute Oral Toxicity Study in the Rat*, Project number 94-0033, data on file, Eastman Kodak Company, New York.
4. Shepard KP, 1994, *C-1743 Acute Dermal Toxicity Study in the Rat*, Project number 94-0033, data on file, Eastman Kodak Company, New York.
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8. Shepard KP, 1994, *C-1743 Skin Sensitisation Study (Maximisation Test) In the Guinea Pig*, Project number 94-0033, data on file, Eastman Kodak Company, New York.
9. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris.
10. Draize, JH 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US*, **49**.
11. In vitro International, *The EYTEX™ System Manual, Revision D*, In vitro International, USA
12. Lawler TE, 1994, *Mutagenicity Test With EK 94-0033, C-1743 In the Salmonella-Escherichia coli/Mammalian-Microsome Reverse Mutation Assay*, Project Number 16279-0-409, data on file, Eastman Kodak Company, New York.
13. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)], Australian Government Publishing Service, Canberra.
14. Standards Australia 1994, *Australian Standard 1336-1994, Eye protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney.
15. Standards Australia/Standards New Zealand 1992, *Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.
16. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing*, Standards Association of Australian Publ., Sydney.
17. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets* [NOHSC:2011(1994)], Australian Government Publishing Service, Canberra.

Attachment 1

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

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

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

CORNEA

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

CONJUNCTIVAE

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

IRIS

Values	Rating
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe