

File No: NA/742

23 April 2020

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

**1,3-naphthalenedisulphonic acid, 7-[[4-[[4,6-bis-[(3-sulfo-1-prop-1-yl)thio]-1,3,5-triazin-2-yl]amino]-3-methoxyphenyl]azo] tetrasodium salt
(YELLOW Y-1189)**

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

**1,3-naphthalenedisulphonic acid, 7-[[4-[[4,6-bis-[(3-sulfo-1-propenyl)thio]-1,3,5-triazin-2-yl]amino]-3-methoxyphenyl]azo] tetrasodium salt
(YELLOW Y-1189)**

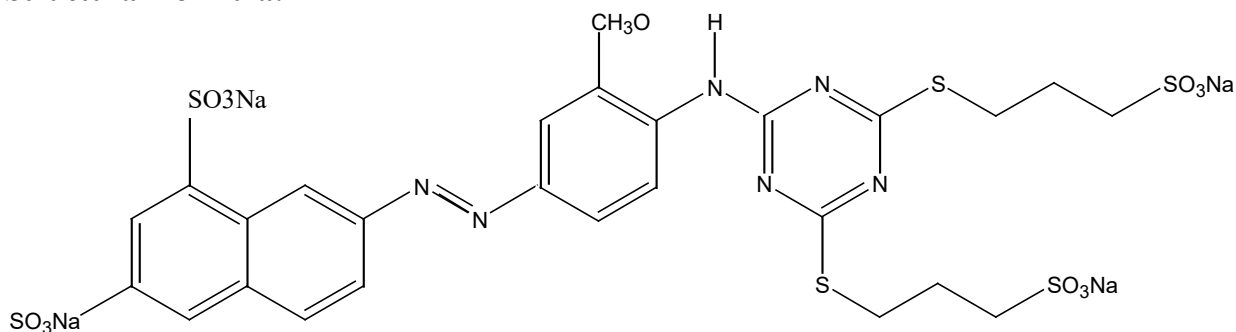
1. APPLICANT

Ilford Imaging (Australia) Pty Ltd of Foster & Ferntree Gully Roads, MT WAVERLEY, VICTORIA 3149 has submitted a limited notification statement in support of their application for an assessment certificate for Yellow Y-1189.

No claims for exempt information were made.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	1,3-naphthalenedisulphonic acid, 7-[[4-[[4,6-bis-[(3-sulfo-1-propenyl)thio]-1,3,5-triazin-2-yl]amino]-3-methoxyphenyl]azo] tetrasodium salt
Chemical Abstracts Service (CAS) Registry No.:	214559-61-2
Other Names:	Dye Y-1189 / Azo dye Y-1189 / Yellow Y-1189 / Yellow Y-1189L (L = liquid)
Marketing Names:	Yellow Y-1189; ILFOJET Yellow ink
Molecular Formula:	C ₂₆ H ₂₄ N ₆ O ₁₃ S ₆ Na ₄

Structural Formula:

Molecular Weight: 912.82

Method of Detection and Determination: Ultra-violet (UV), Infra-Red (IR) and High Performance Liquid Chromatography (HPLC)

Spectral Data: IR spectrum major absorbance peaks (approx): 1 600, 1 550, 1 500, 1 400, 1 200, 1 100, 700, 600 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C at 101.3 kPa: Dark yellow to orange powder;
Yellow to dark yellow solution.

Boiling Point: > 438°C (OECD Guideline 102)

Specific Gravity: Not determined (see comments below)

Vapour Pressure: Not determined (see comments below)

Water Solubility: > 1 000 g/L (OECD Guideline 105)

Partition Co-efficient (n-octanol/water): $\log P_{ow} = < -4$ (OECD Guideline 107)

Hydrolysis as a Function of pH: Not determined (see comments below)

Adsorption/Desorption: Not determined (see comments below)

Dissociation Constant: Not determined (see comments below)

Flash Point: Not appropriate as no ignition of the notified chemical observed

Particle Size Distribution (mm):	< 0.090:	17.60% (by weight)
	0.090 – 0.125:	8.30%
	0.125 – 0.160:	5.60%
	0.160 - 0.180:	2.20%
	0.180 – 0.250:	3.80%
	0.250 – 0.315:	1.90%
	0.315 – 0.355:	1.10%
	0.355 - 0.500:	3.40%
	0.500 - 0.710:	4.30%
	> 0.710:	51.80%
Flammability Limits:	Not appropriate as no ignition of the notified chemical observed (EEC Directive 92/69, Method A10)	
Autoignition Temperature:	Not appropriate as no ignition of the notified chemical observed (EEC Directive 92/69, Method A10)	
Explosive Properties:	Not appropriate as no ignition of the notified chemical observed	
Reactivity/Stability:	Not appropriate as no ignition of the notified chemical observed	

Comments on Physico-Chemical Properties

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

The specific gravity has not been measured as the dye is imported as a 20% aqueous solution.

As the notified chemical is a tetrasodium salt of a high molecular weight dye its vapour pressure is expected to be low.

Hydrolysis as a function of the pH was not measured as other similar azo dyes (Yellow Y104, NICNAS Assessment NA/523) have been found to be stable to hydrolysis from pH 4 to 9 and up to 50°C.

No data was provided for the adsorption/desorption behavior of the notified chemical. Based on the high water solubility, extremely low partition coefficient and the anionic nature of the molecular structure it is not expected to adsorb strongly to soils or sediment.

The notified chemical contains sulphonic acid groups that would be totally dissociated in water. The notified chemical also contains a secondary amine which is expected to have typical basicity.

4. PURITY OF THE CHEMICAL

Degree of Purity: 94.1%

Hazardous Impurities: None

**Non-hazardous Impurities
(> 1% by weight):**

<i>Chemical Name</i>	<i>Weight %</i>
Dimeric dye NR 1 formula Ja 7973	Not stated
Dimeric dye NR 2 formula Ja 7971	Not stated

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. The notified chemical, Yellow Y-1189, will be used as a component (3 to 5%) in aqueous coloured ink formulations for colour ink jet cartridges but will be imported in prepared inks in either ready to use cartridges or 1 L plastic refill bottles. Import volumes for Yellow Y-1189 are expected to be 200 kg in the first year, increasing to 600 kg in the fifth year.

The ready to use cartridges will generally last up to 18 months and may be refilled about two to three times during this period using refill bottles.

Yellow Y-1189 will be used in ink-jet printers Australia wide, by commercial and industrial users. The pigment loading on a given printed page will vary due to the wide variety in print density used.

6. OCCUPATIONAL EXPOSURE

Transport and Storage

Yellow Y-1189 will be imported in either ready to use sealed cartridges or plastic refill bottles. No reformulation or repackaging will take place. Hence, occupational exposure is not expected during transport and storage except in the event of a spill.

Customer Site (printers)

Occupational exposure to Yellow Y-1189 will primarily concern printer service personnel and to a lesser extent office workers.

Exposure to Yellow Y-1189 is expected to be minimal during normal handling by service technicians or printer users in replacing cartridges as the chemical is contained in a sealed cartridge except in the event of a container leak or spill. Some losses may be expected in the

refilling process and dermal exposure may occur. However the potential exposure would be low due to the small quantities involved and infrequent refilling of the cartridges.

Exposure may occur upon handling printed matter. However, very little ink is used per sheet of paper and it would not be separately available for exposure or dermal uptake as it is fused and fixed to the printed surface. These considerations indicate there would be no human exposure to the notified chemical during the handling of printed materials.

The notifier stated that impervious gloves and safety glasses are required during handling of the notified chemical.

Worker Education and Training

The notifier states that education is conducted by the technical service of the concerned selling companies on a regular base. Workers using inks are provided with the Material Safety Data Sheet (MSDS) and technical instruction before use.

7. PUBLIC EXPOSURE

The product containing 3 to 5% of Yellow Y-1189, is contained within sealed cartridges designed to be inserted into an inkjet printer. Refill bottles, designed to refill inkjet printer cartridges will also be available. As inkjet printers are commonly available, there is potential for public exposure to Yellow Y-1189 during routine home servicing of ink jet printers.

The ink is applied to special paper to form an image. Once dry, there would be minimal exposure, as very little ink is used per sheet of paper and the ink is fused and fixed to the paper surface, resulting in it not being available for exposure or dermal uptake.

Release to the environment of Yellow Y-1189 is expected from spills during transport, disposal of spills and waste of the product containing Yellow Y-1189 and disposal of empty packaging into landfill. Additionally, disposal of printed material would also occur. Ink residues within emptied refill bottles and cartridges are expected to remain within these containers. In the event of a spill the product is to be contained and prevented from entering drains prior to disposal in accordance with local regulations.

8. ENVIRONMENTAL EXPOSURE

Release

Environmental exposure will result from the disposal of printed paper and discarded cartridges or bottles. In addition, printed paper may also be subjected to a de-inking process and recycled. Waste paper is repulped using a variety of alkalis, dispersing agents, wetting agents, water emulsifiable organic solvents and bleaching agents. These chemicals enhance fibre separation, ink detachment from the fibres, pulp brightness and the whiteness of the paper. After pulping, the contaminants and the ink are separated from the fibres by pumping the stock through various heat washing, screening, cleaning, flotation and dispersion stages. De-inking wastes are expected to go to trade waste sewers. On combustion, water and oxides of carbon, nitrogen and sulphur will be released.

Ink residues contained in the emptied refill bottles and cartridges are expected to remain within these containers.

Fate

The high water solubility of Yellow Y-1189 indicates that unbound residues released directly to the aquatic compartment, for example, as a result of de-inking of paper, are likely to remain in solution where the low quantities will be rapidly diluted.

Yellow Y-1189 was examined for biodegradation potential using EEC Directive 92/69, Part C.4-C (Modified Sturm Test) and OECD Test Guideline 301B. Over the 28 day test, biodegradation reached 28.4%, indicating that Yellow Y-1189 is not readily biodegradable under the conditions of the test.

The bioaccumulation potential of the dye was not investigated. The high molecular weight (~900), extremely low partition coefficient ($\log P_{ow} = < -4$) and high water solubility (>1 000 g/L) of the notified chemical indicate that significant bioaccumulation is not likely.

9. EVALUATION OF TOXICOLOGICAL DATA

In support of their application for an assessment certificate the notifier provided the following toxicity studies using Yellow Y-1189.

9.1 Acute Toxicity

Summary of the acute toxicity of Yellow Y-1189

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
Acute oral toxicity	Rat	LD ₅₀ > 2 000 mg/kg	(Manciaux, 1998c)
Acute skin irritation	Rabbit	Slightly irritating	(Manciaux, 1998a)
Eye irritation	Rabbit	Slightly irritating	(Manciaux, 1998b)
Skin sensitisation	Guinea pig	Non sensitising	(Manciaux, 1998d)

9.1.1 Oral Toxicity (Manciaux, 1998c)

<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>	2 000 mg/kg of test material dissolved in water (dose volume 10 mL/kg) and administered by gavage
<i>Test method:</i>	OECD TG 401 and 92/69/EEC, B.1 – limit test
<i>Mortality:</i>	Nil
<i>Clinical observations:</i>	No clinical signs noted
<i>Morphological findings:</i>	No apparent abnormalities
<i>LD₅₀:</i>	LD ₅₀ > 2 000 mg/kg
<i>Result:</i>	The notified chemical was of very low acute oral toxicity in rats

9.1.2 Skin Irritation (Manciaux, 1998a)

<i>Species/strain:</i>	Rabbit/New Zealand White
<i>Number/sex of animals:</i>	3 males
<i>Observation period:</i>	72 hours
<i>Method of administration:</i>	A single, 4 hour semioccluded application of 0.5 g of test material applied to the flank
<i>Test method:</i>	OECD TG 404

Draize scores:

<i>Time after treatment (days)</i>	<i>Animal #</i>		
	<i>1</i>	<i>2</i>	<i>3</i>
<i>Erythema</i>			
1	^a 2	2	1
2	1	1	0
3	0	0	0
<i>Oedema</i>			
<i>All individual scores were zero</i>			

^a see Attachment 1 for Draize scales

Mean individual scores (24, 48 & 72 hours): Erythema: 1, 1, 0.3;
Oedema: 0, 0, 0;

Comment: Well-defined erythema was observed in two animals in days 1 and 2, with very slight erythema on day 3. The third animal had only very slight erythema on days 1 and 2.

A slight orange colouration of the skin was noted in all animals from day 1 to the end of the observation period.

Result: The notified chemical was slightly irritating to the skin of rabbits

9.1.3 Eye Irritation (Manciaux, 1998b)

<i>Species/strain:</i>	Rabbit/New Zealand White
<i>Number/sex of animals:</i>	3 males
<i>Observation period:</i>	72 hours
<i>Method of administration:</i>	100 mg of test material was introduced into the conjunctival

sac of the left eye of each animal; the right eye served as the control

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	<i>Time after instillation</i>											
<i>Animal</i>	<i>1 hour</i>			<i>24 hours</i>			<i>48 hours</i>			<i>72 hours</i>		
<i>Cornea</i>	<i>All individual scores were zero</i>											
<i>Iris</i>	<i>All individual scores were zero</i>											
<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	M	1 ¹	0	0	1	0	0	0	0	0	0	0
2	M	2	0	0	1	0	0	0	0	0	0	0
3	M	2	0	1	1	0	0	1	0	0	0	0

¹ see Attachment 1 for Draize scales

r = redness c = chemosis d = discharge

M = scoring masked by orange colouration of test material

Mean individual scores (24, 48, 72 hours):

Conjunctival chemosis: 0.3, 0.3, 0.7;
 Conjunctival redness: 0, 0, 0.3;
 Iris lesions: 0, 0, 0;
 Corneal opacity: 0, 0, 0.

Comment: Very slight or slight conjunctival reactions were observed in all animals from day 1. Very slight or slight chemosis and very slight redness of the conjunctiva were also observed and these reactions persisted up to day 3 at the latest.

No corneal or iridial reactions were noted during the study.

Result: The notified chemical was slightly irritating to the eyes of rabbits

9.1.4 Skin Sensitisation (Manciaux, 1998d)

Species/strain: Guinea pigs/Dunkin-Hartley

Number of animals: Control animals: 5/sex
 Test animals: 10/sex

Induction procedure: Intradermal Induction:
 Test animals:
 Day 1: three pairs of intradermal injections (0.1 mL) into the dorsal skin of the scapular region:

- Freund's complete adjuvant (FCA) 1:1 in saline;
- the test substance, at 20 % w/w in saline;

- the test substance at 20% w/v emulsified in a 50:50 mixture of FCA and saline;

Topical Induction:

Day 7 – A 24-hour application of 0.5 mL of sodium lauryl sulfate (10%w/w);

Day 8 – a 48 hour semi occlusive application of 500 mg of test substance;

Control animals:

Treated similarly to the test animals omitting the test substance from the intradermal injections and topical application

Challenge procedure:

Day 22

All animals were challenged by occlusive cutaneous application of 0.5 mL of the test substance at 10% in its original form to the posterior right flank (left flank served as control) for 24 hours;

Skin reactions were evaluated approximately 24 and 48 hours after removal of the dressing.

Test method:

OECD TG 406; Magnusson and Kligman maximisation method; EC Directive (92/69/EEC B.6)

Comment:

No clinical signs or deaths were observed over the study period. There was no adverse effect in body weight gain in test animals compared with controls. No necropsy was performed or skin samples taken.

No cutaneous reactions were observed in any animal.

An orange colouration of the skin, which could have masked a very slight erythema (grade 1), was noted at the 24 hour reading in almost all test and control animals.

Result:

The notified chemical was considered non-sensitising to the skin of guinea pigs

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (Haddouk, 1998)

<i>Strains:</i>	<i>Salmonella typhimurium</i> TA1535, TA1537, TA98 and TA100; <i>Escherichia coli</i> WP2 uvrA.
<i>Concentration range:</i>	0, 312.5, 625, 1 250, 2 500 and 5 000 µg/plate, dissolved in distilled water
<i>Metabolic activation:</i>	10% rat liver S9 fraction (Aroclor 1254) with standard cofactors
<i>Test method:</i>	OECD TG 471
<i>Positive controls:</i>	<u>Without S9</u> 1 µg/plate sodium azide: TA1535 and TA100 50 µg/plate 9-aminoacridine: TA1537 0.5 µg/plate 2-nitrofluorene: TA98 2 µg/plate 4-nitroquinoline-1-oxide: <i>E. coli</i> <u>With S9</u> 2 µg/plate 2-aminoanthracene: all <i>S typhimurium</i> strains 10 µg/plate 2-aminoanthracene: <i>E coli</i>
<i>Comment:</i>	<p>All five doses levels were tested in triplicate for each strain. Two experiments were performed in the absence of S9. In the presence of S9, one experiment was conducted as a standard plate incorporation, while the other was performed using the preincubation method.</p> <p>No precipitation was noted at any dose level. There was a moderate orange-yellow colouration at the highest dose level, which decreased at the lower doses.</p> <p>No significant increase in mutant frequency was noted for any of the tester strains, in the presence and absence of S9. All positive controls responded appropriately</p>
<i>Result:</i>	The notified chemical was non-mutagenic under the conditions of the assay

9.3 Overall Assessment of Toxicological Data

The notified chemical, Yellow Y-1189, has very low oral toxicity in the rat, with an LD₅₀>2 000 mg/kg.

It was a slight irritant to the rabbit skin but, on the basis of the mean scores for skin irritancy, no risk phrase is warranted. In the eye irritation study, very slight or slight conjunctival reactions were observed in all animals from day 1. Very slight or slight chemosis and very slight redness of the conjunctiva were also observed and these reactions persisted up to day 3 at the latest. In guinea pigs, the notified chemical was non sensitising. However, any mild reactions occurring at 24 hours after challenge were masked by skin discolouration.

Yellow Y-1189 did not induce mutations in *S typhimurium* or *E. coli* reversions assays when test under standard and preincubation conditions.

Based on the data provided, Yellow Y-1189 would not be considered hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicity studies performed on similar azo dyes have indicated that Yellow Y-1189 will be practically non-toxic to aquatic organisms. These test results were submitted for the very closely related dye, Yellow Y104, which was notified as NA/523. The tests were carried out to OECD Test Methods.

<i>Test</i>	<i>Species</i>	<i>Results</i>
Acute toxicity	rainbow trout	NOEC ≥ 100 mg/L
Acute toxicity	bluegill	NOEC ≥ 100 mg/L
Acute toxicity	<i>Daphnia magna</i>	NOEC ≥ 100 mg/L

* NOEC - no observable effect concentration

Limit tests were conducted for all test organisms. Some fish were observed swimming calmly towards the bottom of the tank in the fish acute toxicity test. No unusual observations were made during the duration of the ecotoxicity studies on *Daphnia* and algae.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Yellow Y-1189 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. Losses generated in the refilling process are expected to be low.

Recycling of treated paper could result in the release of a proportion of Yellow Y-1189 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 predicted low aquatic toxicity and low bioaccumulation potential of Yellow Y-1189.

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

Data submitted in support of this notification indicate that the notified chemical, Yellow Y-1189, has very low acute oral toxicity. It was slightly irritating to rabbit skin and eyes, but was not a skin sensitiser. Yellow Y-1189 was not mutagenic to bacteria.

Based on the data provided, Yellow Y-1189 would not be considered hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

Occupational Health and Safety

Transport and storage workers will be only be exposed to Yellow Y-1189 in the event of an accident or damage to packaging. The occupational health risk to these workers is negligible, considering the low quantities (3-5%) in ink jet printer cartridges or refill bottles and the low hazard presented by the chemical.

The main exposure will be to service personnel who will generally be responsible for changing printer cartridges or during refill. The design of the cartridge is such that skin contact to the notified polymer should be minimal during change over or replenishment.

Office workers are not expected to come into contact with Yellow Y-1189 under normal circumstances. Infrequent dermal exposure of end users to the toner containing Yellow Y-1189 may occur during servicing or clearing paper jams, but the high molecular weight of the Yellow Y-1189 indicates that percutaneous absorption would be minimal. Exposure to Yellow Y-1189 is not expected to occur once the toner is bound to paper.

Based on the low toxicological hazard presented by Yellow Y-1189 and the expected very low exposures, the health risk posed to service personnel and office workers by the notified Yellow Y-1189 is very low.

Public Health

Public exposure to Yellow Y-1189 is expected to be minimal, based on the low concentration of the chemical in the ink and in the use pattern associated with cartridges and refills for use in inkjet printers. The low oral toxicity indicates that the chemical is unlikely to pose an acute hazard. Slight eye and skin irritancy is of minimal concern, given the use pattern and strong colour of the product containing the notified chemical. Based on the toxicity profile and use pattern of Yellow Y-1189, it is considered that the Yellow Y-1189 will not pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to Yellow Y-1189 the following guidelines and precautions should be observed:

- Safety glasses should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);
- Impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia, 1998). The notifier recommends natural latex gloves.
- Spillage of the notified chemical should be avoided. Spillages 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 MSDS should be easily accessible to employees.

If the conditions of use are varied, particularly if the product is marketed outside of its use in inkjet printer cartridges, greater exposure of the public to the product may occur. In such circumstances, further information may be required to assess the hazards to public health.

14. MATERIAL SAFETY DATA SHEET

The MSDS for Yellow Y-1189 was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 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.

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

Haddouk, H. (1998). Y-1189: Bacterial Reverse Mutation Test. Report No. 17085 MMJ. Centre International de Toxicologie: Evreux.

Manciaux, X. (1998a). Y-1189: Acute Dermal Irritation in Rabbits. Report No. 16678 TAL. Centre International de Toxicologie: Evreux.

Manciaux, X. (1998b). Y-1189: Acute Eye Irritation in Rabbits. Report No. 16679 TAL. Centre International de Toxicologie: Evreux.

Manciaux, X. (1998c). Y-1189: Acute Oral Toxicity in Rats. Report No. 16676 TAR. Centre International de Toxicologie: Evreux.

Manciaux, X. (1998d). Y-1189: Skin Sensitisation Test in Guinea Pigs. Report No. 16680 TSG. Centre International de Toxicologie: Evreux.

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Standards Australia. (1994). AS 1336-1994, Australian Standard Eye protection in the Industrial Environment. Standards Australia: Sydney.

Standards Australia. (1998). AS/NZS 2161.2:1998, Australian/New Zealand Standard Occupational Protective Gloves Part 2: General Requirements. Standards Australia and Standards New Zealand: Sydney/Wellington.

Standards Australia/Standards New Zealand. (1992). AS/NZS 1337-1992, Australian/New Zealand Standard Eye Protectors for Industrial Applications. Standards Australia and Standards New Zealand: Sydney/Wellington.

Attachment 1

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

<i>Erythema Formation</i>	<i>Rating</i>	<i>Oedema Formation</i>	<i>Rating</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>Opacity</i>	<i>Rating</i>	<i>Area of Cornea involved</i>	<i>Rating</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>Redness</i>	<i>Rating</i>	<i>Chemosis</i>	<i>Rating</i>	<i>Discharge</i>	<i>Rating</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>Values</i>	<i>Rating</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