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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Yellow Y-104

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Director Chemicals Notification and Assessment

FULL PUBLIC REPORT

Yellow Y-104

1. APPLICANT

Ilford Australia Pty Ltd of Cnr Forster and Ferntree Gully Roads MT WAVERLEY VIC 3149 has submitted a standard notification statement in support of their application for an assessment certificate for Yellow Y-104.

2. IDENTITY OF THE CHEMICAL

Yellow Y-104 is considered not to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Other Names: sulfonated azo-dye

Trade Name: Yellow Y-104 (product containing < 10% of notified

chemical), Dye Y-104 (product containing < 10%

of notified chemical)

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C

and 101.3 kPa: yellow powder

Melting Point: > 350°C decomp.

Specific Gravity: $D_4^{20} = 880 \pm 0.017$

Vapour Pressure: not determined (see comments below)

Water Solubility: > 365g.L⁻¹ at 30°C

Partition Co-efficient

(n-octanol/water): $log P_{ow} = -4.98$

Hydrolysis as a Function $T_{1/2}$ at pH 4.0 > 1y⁻¹

of pH: $T_{1/2}$ at pH 7.0 > 1 y^{-1}

 $T_{1/2}$ at pH 9.0 > 1 y^{-1}

Adsorption/Desorption: not determined (see comments below)

Dissociation Constant: not determined (see comments below)

Flash Point: not determined

Flammability Limits: not considered as highly flammable

Autoignition Temperature: > 380°C

Explosive Properties: non-explosive

Surface Activity: 72.6mN.m⁻¹ at a concentration of 0.25g.L⁻¹

72.6mN.m⁻¹ at a concentration of 0.50g.L⁻¹ 72.4mN.m⁻¹ at a concentration of 1.00g.L⁻¹

Reactivity/Stability: not considered to be reactive

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice (1).

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

The results of the study on abiotic degradation of the notified chemical indicate that it is stable to hydrolytic decomposition.

No data were provided for the adsorption/desorption behaviour of the notified chemical. Based on the high water solubility and extremely low partition coefficient it is not expected to adsorb strongly to soils or sediment.

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

The notified chemical is not expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 mN.m⁻¹ (2).

4. PURITY OF THE CHEMICAL

Degree of Purity: 96.0%

Toxic or Hazardous

Impurities: none

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

Chemical name: dimeric dye

Weight percentage: 3.0%

CAS No.: not available

Chemical name: unidentified dyes

Weight percentage: 1.0%

CAS No.: not available

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It will be imported into Australia at a concentration of less than 10% in prepared inks in either ready to use cartridges (~50 mL) or 100 to 500 mL plastic refill bottles. Import volumes of the notified chemical are expected to be between 100 and 1 000 kg per annum between 1997 and 2000.

6. OCCUPATIONAL EXPOSURE

Exposure of transport workers to the notified chemical is unlikley under normal working conditions.

The notified chemical will be used in ink-jet printers Australia wide, for predominantly commercial and industrial uses. The life span of the ready-to-use cartridge is dependent upon the amount of use but generally is for up to 18 months. During this time the cartridges may be refilled on average once every 2 months.

Normal handling, involving replacement of the spent ink cartridge by service technicians or office workers will not result in exposure to the notified chemical as it is contained within the sealed cartridge. Exposure during refill of the cartridges by office workers will vary dependent upon the office printing requirements but as the cartridges are likely to be filled infrequently the potential for exposure is minimal. If accidental exposure occurs it will be intermittent and most likely via the dermal route.

Once printed onto the paper the ink is bound to the paper thus preventing exposure to the notified chemical.

7. PUBLIC EXPOSURE

Infrequent dermal exposure to inks may occur when refilling empty ink cartridges. Public exposure to the notified chemical is possible in the event of an accident during transport and storage, but the likelihood of a substantial spill occurring is low in view of the packaging.

8. ENVIRONMENTAL EXPOSURE

Release

Environmental exposure will result from the disposal of printed paper and discarded cartridges or bottles. In addition to landfill, printed paper may also be recycled after first being subjected to a de-inking process. Waste paper is repulped using a variety of alkalis, dispersing agents, wetting agents, water emulsifiable organic solvents and bleaching agents. These chemicals enhance the 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 sulfur 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 the notified chemical 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 they will be rapidly diluted due to low quantities expected.

The substance 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 15%, indicating that Yellow Y-104 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 Pow = -4.98) and high water solubility (365 g.L⁻¹) 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 Yellow Y-104

Test	Species	Outcome	Reference
acute oral toxicity	Rat	> 2 000 mg.kg ⁻¹	(3)
acute dermal toxicity	Rat	> 2 000 mg.kg ⁻¹	(4)
skin irritation	Rabbit	non-irritant	(5)
eye irritation	Rabbit	slight irritant	(6)
skin sensitisation	Guinea pig	non-sensitiser	(7)

9.1.1 Oral Toxicity (3)

Species/strain: rat/Sprague-Dawley ICO:OFA-SD (IOPS Caw)

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: oral gavage at a concentration of 2 000mg.kg⁻¹

of test material in distilled water

Clinical observations: none

Mortality: nil

Morphological findings: no abnormalities detected

Test method: OECD test guidelines (1)

 LD_{50} : > 2 000 mg.kg⁻¹

Result: the notified chemical was of low acute toxicity

in an oral limit test in rats

9.1.2 Dermal Toxicity (4)

Species/strain: rat/Sprague-Dawley ICO:OFA-SD (IOPS Caw)

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: the notified chemical was applied as a paste in

distilled water at a dose level of 2 000 mg.kg⁻¹ under a semi-occluded dressing for 24 hours, after which excess test material was removed

by washing the site with distilled water

Clinical observations: a slight decrease in body weight gain was

noted in females in the first week only: no other

treatment related effects were observed

Mortality: nil

Morphological findings: no abnormalities detected

Test method: OECD test guidelines (1)

LD50: $> 2000 \text{ mg.kg}^{-1}$

Result: the notified chemical was of low acute dermal

toxicity when tested dermally in rats

9.1.3 Inhalation Toxicity

This test was not conducted as it is considered not to be an appropriate route of exposure

9.1.4 Skin Irritation (5)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3/male

Observation period: 13 days

Observations: very slight or slight erythema was observed

> one hour after treatment in 2 out of 3 animals; this persisted in one animal for 24 hours; no other signs of skin irritation were observed

Method of administration: 500 mg of neat test material moistened with

> distilled water was applied to the shaved flank of each rabbit and secured by means of a semi-occlusive dressing; the test material was

removed after 4 hours

Test method: OECD test guidelines (1)

Result: the notified chemical is a non-irritant to the

rabbit skin

9.1.5 Eye Irritation (6)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3/male

3 days Observation period:

Observations: an orange colouration of the conjunctiva was

> noted 1 hour after treatment only, in all animals; redness of conjunctiva was marked by this colouration; slight corneal opacity was noted only at the 24 hour reading in one animal: no other ocular lesions were observed

during the study

Method of administration: 100 mg of the test material was instilled into

> the conjunctival sac of the left eye of each rabbit, the right eye serving as control; the eyes were not irrigated after administration of

the test material

Test method: OECD test guidelines (1)

Result: the notified chemical caused slight ocular

irritation when tested in rabbits

9.1.6 Skin Sensitisation (7)

Species/strain: guinea pig/Dunkin-Hartley

Number of animals: 20/test and 10/control group

Induction procedure: Day 1: 3 pairs of intradermal injections:

> 0.1mL Freund's complete adjuvant (FCA):isotonic saline (1:1(v/v))

> 0.1mL of 10% concentration of test

material in isotonic saline

0.1mL of 10% concentration of test

material in FCA:isotonic saline

(1:1(v/v))

Day 7: test area treated with 0.5mL per injection site of 10% (w/w) sodium

lauryl sulfate (10%w/w) in vaseline

Day 8: occluded application of 20%

concentration of test material for 48

hours

Challenge procedure: Day 22: occluded application of 5%

concentration of test material for 24

hours

Day 33: occluded application of 5%

concentration of test material for 24

hours

Challenge outcome:

	Test a	nimals	Control animals	
Challenge concentration	24 hours*	48 hours*	24 hours	48 hours
25%	0/20**	0/20	0/10	0/10
50%	0/20	0/20	0/10	0/10

^{*} time after patch removal

Re-challenge outcome:

	Test a	nimals	Control animals	
Re-challenge concentration	24 hours*	48 hours*	24 hours	48 hours
5%	0/20**	0/20	0/10	0/10

^{*} time after patch removal

Test method: OECD test guidelines (1)

Observations: no cutaneous reactions were observed after

both challenge applications

Result: the notified chemical was not a skin sensitiser

in guinea pigs

9.2 Repeated Dose Toxicity (8)

Species/strain: rat/Sprague-Dawley

Number/sex of animals: 5/sex in low and mid dose groups, 10/sex in

high dose group

^{**} number of animals exhibiting positive response

^{**} number of animals exhibiting positive response

Method of administration: the notified chemical was administered by

gavage

Dose/Study duration:: the test material was administered daily for a

period of 28 days:

control: vehicle only (purified water)

low dose: 150 mg kg⁻¹ mid dose: 450 mg.kg⁻¹ high dose: 1 350mg.kg⁻¹

on completion of the treatment period, the five animals/sex in the control and high dose group were kept for a 2 week reversibility

period

Clinical observations: no signs of systemic toxicity were observed;

during the dosing period the faeces were coloured yellow or reddish orange in animals in mid and high dose groups, the extremities and were also coloured in most animals in the

mid and high dose group; during the

reversibility period, only couloured tails were noted in females in the high dose group; colouration was considered to be related to the elimination of the test material or its

metabolites;

body weight gain and food consumption were similar in control and treated animals during

the study;

Clinical

chemistry/Haematology no treatment related effects were observed

Organ weights: no significant differences were observed

between treated and control animals

Histopathology: orange or yellowish deposits observed in

some parts of digestive tract were due to the dyeing properties of the test substance; at microscopic examination no treatment related

findings were noted

Test method: OECD test guidelines (1)

Result: administration of doses up to 1 350 kg.kg⁻¹

daily for 28 days did not induce changes of

toxicological significance in the rat

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (9)

Strains: TA 98, TA 100, TA 102, TA 1535 and

TA 1537

Concentration range: 30, 100, 300, 1 000, 3 000 µg/plate; assays

were carried out in the presence or absence of

S9 mix

Test method: according to OECD test guidelines (1)

Result: the notified chemical was found not to be

mutagenic in the bacterial strains tested under

the conditions of the assay

9.3.2 Salmonella typhimurium Reverse Mutation Assay (10)

Strains: TA 98, TA 100, TA 1535, TA 1537 and

Escherichia coli WpuvrA

Concentration range: 312.5, 625, 300,1 250, 2 500, 5 000 µg/plate;

assays were carried out in the presence or

absence of S9 mix

Test method: according to OECD test guidelines (1)

Result: the notified chemical was found not to be

mutagenic in the bacterial strains tested under

the conditions of the assay

9.3.3 Chromosome Aberration Assay in Human Lymphocytes (11)

Experiment 1

Concentration range: for treatment: 30, 100, 300, 1 000, 3 000 and

5 000 μ g.mL⁻¹ (with or without S9 mix) for chromosome aberration scoring: 1 000, 3 000 and 5 000 μ g.mL⁻¹ (with or without S9 mix); cells were incubated for 48 hours and then harvested 20 hours after the beginning of

treatment

Test method: OECD test guidelines (1)

Result: the notified chemical was considered not to be

clastogenic when tested in cultured human

lymphocytes under the conditions of this assay

Experiment 2

Concentration range: for treatment: 300, 1 000, 3 000 and

5 000 $\mu g.mL^{-1}$ (without S9 mix, for all harvest times), 1 000, 3 000 and 5 000 $\mu g.mL^{-1}$ (with

S9 mix, for all harvest times)

for chromosome aberration scoring: 1 000, 3 000 and 1 000 μg.mL⁻¹ (with or without S9

mix, for the 20 hour harvest time),

 $5~000~\mu g.m L^{-1}$ (with or without S9 for the 44

hour harvest time)

as indicated above cells were incubated for 48 hours and then harvested 20 hours and 44 hours after the beginning of treatment

Test method: OECD test guidelines (1)

Result: the notified chemical was considered not to be

clastogenic when tested in cultured human lymphocytes under the conditions of this

assay

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse

This study was not conducted by the notifier on the basis that negative responses were obtained in 2 other genotoxicity assays. This was considered to be acceptable.

9.4 Overall Assessment of Toxicological Data

The notified chemical was found to be of low acute toxicity in rats when administered by the oral and dermal routes ($LD_{50} > 2\,000\,\text{mg.kg}^{-1}$ in both studies). The notified chemical did not cause skin irritation but caused slight eye irritation when tested in rabbits. The results of a guinea pig maximisation test indicate that the chemical is not a skin sensitiser.

Findings in a 28 day repeat-dose oral toxicity study indicate that no significant toxicological effects were observed at high dose levels (1 350 mg.kg⁻¹ daily).

The notified chemical was not mutagenic in bacteria in the presence or absence of metabolic activation, and it was not clastogenic when tested *in vitro* in human lymphocytes.

Based on the results of the toxicity studies summarised above, the notified chemical would not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (12).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicological data is not required for chemicals with import volumes less than one tonne per year according to the Act. However, the following ecotoxicity studies have been supplied by the notifier. The tests were carried out to OECD Test Methods (1).

Test	Species	Results
Acute Toxicity	Rainbow trout	NOEC <u>≥</u> 100 mg.L ⁻¹
(96 h, static)	Oncorhynchus mykiss	
(OECD Guideline 203)		
Acute Toxicity	Daphnia magna	NOEC <u>></u> 100 mg.L ⁻¹
(48 h, static)		
(OECD Guideline 202)		
Growth Inhibition	Algae	NOEC \geq 100 mg.L ⁻¹
(72 h)	Scenedesmus	
(OECD Guideline 201)	subspicatus	

^{*} 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.

The ecotoxicity data for the notified chemical indicate that Yellow Y-104 can be considered practically non-toxic to fish, *Daphnia* and algae.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Yellow Y104 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 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 occupational health risk associated with importation, storage, use or disposal of the notified chemical is expected to be minimal.

The toxicological profile of Yellow Y-104 suggests that it is unlikely to be acutely toxic via the oral and dermal routes and is likely to be neither mutagenic nor clastogenic. It is unlikely to cause skin irritation but may cause slight eye irritation. It was not a skin sensitiser and it is unlikely to exhibit significant toxic effects on repeated or prolonged exposure.

The notified chemical will be used in ink-jet reprographic processes and will be imported in sealed ink-jet cartridges which are inserted directly into ink-jet printers for commercial and industrial use. Exposure to the notified chemical during normal handling is not expected other than in the unlikely event that the cartridge is faulty and ruptures. Refill bottles containing the ink will also be imported and may be used every 2 months during the life of the cartridge (18 months). During refill there is minimal potential for occupational exposure as the cartridges will be filled infrequently and the notified chemical is present in the ink at low percentages (<10%).

The notified chemical has low dermal toxicity in rats it is not a skin irritatant or skin sensitiser in animal studies. Infrequent, minor dermal exposure from refilling ink cartridges is unlikely to pose a health hazard to the public.

Based on the information provided and the intended use, the notified chemical does not appear to pose a significant hazard to public health.

13. Recommendations

To minimise occupational exposure to Yellow Y-104 the following guidelines and precautions should be observed:

- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then 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.

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* (13).

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

- 1. Organisation for Economic Co-operation and Development 1995-1996, *OECD Guidelines for the Testing of Chemicals on CD-Rom*, OECD, Paris.
- 2. European Economic Community (EEC), E.D. December 1992, *A.5 Surface Tension Methods for the determination of physico-chemical properies*, vol. EEC Publication No. L383.
- 3. de Jouffrey, S. 1995, *Acute Oral Study in Rats*, Project no., CIT/Study No. 12988 TAR/M-377/Ilford, C.I.T., Evreux.
- 4. de Jouffrey, S. 1995, *Acute Dermal Toxicity in Rats*, Project no., CIT/Study No. 13675 TAR/M-377Ilford, C.I.T., Evreux.
- 5. de Jouffrey, S. 1995, *Skin Irritation Study in Rabbit*, Project no., CIT/Study No. 12990 TAL/M-377/Ilford, C.I.T., Evereux, France.
- 6. de Jouffrey, S. 1995, *Occular Irritation Study in the Rabbit*, Project no., CIT/Study No. 12989 TAL/M-377/Ilford, C.I.T., Evreux.
- 7. de Jouffrey, S. 1995, *Skin Sensitisation Study in Guinea Pigs*, Project no., CIT/Study No. 12991 TSG/M-377/Ilford, C.I.T., Evreux.
- 8. Fabreguettes, C. 1996, 4-Week Toxicity Study by Oral Administration (Gavage) in Rats Followed by a 2-Week Reversibility Period, Project no., CIT/Study No. 13709 TSR/M-377/Ilford, C.I.T., Evreux.
- 9. Molinier, B. 1995, *Bacterial Reverse Mutation Test*, Project no., CIT/Study No. 12994 MMO/M-377/Ilford, C.I.T., Evreux.
- 10. de Jouffrey, S. 1996, *Bacterial Reverse Mutation Test*, Project no., CIT/Study No. 13859 MMJ/M-377/Ilford, C.I.T., Evreux.

- 11. de Jouffrey, S. 1996, *In Vitro Mammalian Chromosome AberrationTest in Cultured Lymphocytes*, Project no., CIT/Study No. 13694 MLH/M-377/Ilford, C.I.T., Evreux.
- 12. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australian Government Publishing Service, Canberra.
- 13. 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	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
easily discernible Diffuse beefy red	3	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and	3 severe
	severe	Swelling with lids half-closed to completely closed	4 severe	hairs and considerable area around eye	

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