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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

H112287

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

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

H112287

1. APPLICANTS

Canon Australia Pty Ltd of 1 Thomas Holt Dr, North Ryde, Sydney, NSW 2113 and ICI Australia (Operations) Pty Ltd of 1 Nicholson St, Melbourne, VIC 3000 have submitted a standard notification for assessment of H112287.

2. IDENTITY OF THE CHEMICAL

Other names: Substance H112287
C I Direct Black 195

Trade names: Pro-ject Fast Black 2
Pro-ject Fast Black 2 Liquid (formulation)

Methods of detection and determination:

HPLC separation using a gradient solvent system (acetonitrile and distilled water containing 1.0% w/v ammonium acetate) with detection at 570 nm

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	dark brown powder
Melting Point:	> 300°C
Density:	1450 kg/m^3
Vapour Pressure:	1.3 x 10^{-6} kPa (20-50°C)
Water Solubility:	> 27 g/L at 23°C
Surface Tension (of aqueous solution):	70.8 N/m at 23°C
Fat Solubility:	**<** 0.11 mg/100 g standard fat HB 307 at 37°C
Partition Co-efficient (n-octanol/water) log P_{ow}:	- 1.6 at 25°C
Hydrolysis as a function of pH:	10% hydrolysis after 120 h at pH 4, 7 or 9
Adsorption/Desorption:	Not determined

Dissociation Constant
pKa**:** Not determined

Flash Point: not applicable

Flammability Limits: does not propagate combustion

Autoignition Temperature: 363°C

Explosive Properties: not explosive

Reactivity/Stability: non-oxidising

• Comments on the physico-chemical properties

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

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

4. PURITY OF THE CHEMICAL

Degree of purity: > 60%

Additives/Adjuvants: none

5. INDUSTRIAL USE, FORMULATION AND IMPORT VOLUME

The notified chemical will be used as a component of an ink in printers. It is imported at a rate > 1 tonne for the next five years. The notified chemical will be used Australia wide, predominantly in the home and small office market.

6. OCCUPATIONAL EXPOSURE

The voulme of ink in a cartridge will vary depending on the design of the printer. It is stated that normal handling, involving replacement of the spent ink cartridge by service technicians or office workers will not result in exposure to the ink and such exposure should only result if the cartridge is faulty and ruptures. Under normal conditions of use, several milligrams of notified substance are expected on each printed page.

7. PUBLIC EXPOSURE

The public may come in contact with paper printed with the formulated ink, but the potential for public exposure is expected to be minimal. 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.

8. ENVIRONMENTAL EXPOSURE

. Release

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

Cartridges will be replaced by the user as required. Empty cartridges will be disposed of with normal office refuse and home garbage.

. Fate

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

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

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 (particularly in alkaline sewers) where they will be rapidly diluted.

Results from biochemical oxygen demand tests (BOD_5 < 0.1 g/L, COD 1.29 g O_2/g) indicate that significant biodegradation is unlikely under aerobic conditions. In a modification of the Zahn-Wellens test (OECD TG 302B) colorimetric analysis showed a 52% mean colour reduction over 28 days, indicating significant bioelimination has occurred.

The bioaccumulation potential of the notified chemical was not investigated. The low partition coefficient (log P_{OW} = -1.6), low fat solubility (<1.1 $mg.kg^{-1}$) and the relatively high water solubility (2.70 % w/w) of the notified chemical indicate that significant bioaccumulation is not likely.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of H112287

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	moderate irritant	(6)
Skin sensitisation	Guinea-pig	mild sensitiser	(8)

9.1.1 Oral Toxicity (1)

LD_{50}: > 2000 mg/kg ***Species/strain:*** Wistar-derived albino rats (Alp K:APF SD)

Number/sex of animals: 5 M, 5 F ***Observation period:*** 14 days

Method of administration (vehicle): gavage (de-ionised water)

Clinical observations: no significant signs of toxicity

Mortality: no deaths ***Morphological findings:*** no macroscopic abnormalities detected at necropsy

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

9.1.2 Dermal Toxicity (3)

LD_{50}: > 2000 mg/kg ***Species/strain:*** Wistar-derived albino (Alp K:APF SD)

Number/sex of animals: 5 M, 5 F ***Observation period:*** 14 days

Method of administration (vehicle): as a paste with de-ionised water

Clinical observations: no significant signs of toxicity; slight skin irritation overall

Mortality: no deaths ***Morphological findings:*** no macroscopic abnormalities detected at necropsy

Test Method: directive 84/449/EEC (2) Test B3

9.1.4 Skin Irritation (4)

Result: slight irritant to rabbit skin **Species/strain:** New Zealand White rabbits

Number/sex of animals: 3 M

Method of administration: sample moistened with de-ionised water applied under occlusive gauze dressing for four hours.

Test Method: directive 84/449/EEC (2) Test B4

Draize (5) Scores[i]:

Animal	Time after decontamination				
	30-60 min	1 day	2 days	3 days	7 days
ERYTHEMA					
1	2	1	0	0	0
2	2	1	0	0	1
3	1	0	0	0	0
OEDEMA					
1	2	1	0	0	0
2	4	3	2	0	0
3	1	1	0	0	0

9.1.5 Eye Irritation (6)

Result: moderate irritant to the rabbit eye

Species/strain: Female New Zealand White rabbits **Number of animals:** 3

Method of administration: test substance (100 mg) instilled in conjunctival sac of one eye

Test Method: directive 84/449/EEC (2) Test B5

Draize (5) Scores[ii]

Animal	Time after instillation														
	1 day			2 days			3 days			4 days			7 days		
CORNEA:	opacity area			opacity area			opacity area			opacity area			opacity area		
1	3	1		2	2		2	2		1	1		1	1	
2	1	2		1	2		1	2		1	1		1	1	
3	1	1		1	1		1	1		1	1		1	1	
IRIS															
1	1			1			0			0			0		
2	0			0			0			0			0		
3	1			0			0			0			0		
CONJUNCTIVA	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]
1	2	2	1	2	1	0	2	0	0	2	0	0	0	0	0
2	2	2	1	2	1	0	2	1	0	1	0	0	0	0	0
3	2	2	1	2	1	0	1	1	0	1	0	0	0	0	0

[a] redness [b] chemosis [c] discharge

9.1.6 Skin Sensitisation (7)

Result: Mild Sensitiser

Species/strain: Albino male guinea-pigs/ AlpK:Dunkin Hartley **Number of animals:** 20 in test group, 10 in control group

Induction: 1% (w/v) in de-ionised water and 1% (w/v) in FCA plus de-ionised water (1:1)

Results:

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

Test Method: directive 84/449/EEC (2) Test B6

9.2 Repeated Dose Toxicity (8)

Species/strain: Rat/ AlpK: APfSD (Wistar derived) **Number/sex:** 6 males and females

Method of administration (vehicle): orally by gavage (de-ionised water)

Dose/ Duration of administration: 0, 50, 200 or 1000 mg/kg/day for 28 days plus 14 day recovery

Toxicologically Significant Observations:

1. Clinical

Clinical signs of toxicity in 1 male of the high dose group. Two males and females in the high dose group died of causes unrelated to administration of the notified chemical.

2. Clinical Chemistry/Haematology

One male in the high dose group exhibited slight anaemia.

3. Necropsy Findings/ Histopathology

The kidneys were identified as the target organ. Tubular degeneration was observed in all rats in the 200 and 1000 mg/kg/day dose groups. The severity of the lesions was similar in both sexes but less severe at the lower dose level. Tubular degeneration was correlated with changes in kidney function in severely affected rats manifested as proteinuria and increases in absolute kidney weight and kidney to bodyweight ratio. Tubular degeneration was not resolved during the recovery period but the other changes were resolved.

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

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (9)

Result: No significant dose-related induction of mutations above background in the presence or absence of metabolic activation provided by rat liver S9.

Strains: *Salmonella typhimurium* TA 1537, TA 1538, TA 98, TA 100 and *Escherichia coli* WP2*uvrA* (pKM101)

Concentration range: 8.0 to 6250 μg/ plate

Test Method: directive 84/449/EEC (2) Test B4

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (10)

Result: No significant increases in the incidence of micronucleated polychromatic erythrocytes over vehicle control values were observed at either dose level in either sex at any of the sampling times investigated.

Species/strain: Mouse/ C57BL/ 6J fCD-1/AlpK

Number and sex: 5 males and females **Doses:** 1460 and 2330 mg/kg (F)
3130 and 5000 mg/kg (M)

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

Test Method: directive 84/449/EEC (2) Test B12

9.4 Overall Assessment of Toxicological Data

H112287 is non-toxic via the oral and dermal routes in the rat with both LD_{50} > 2000 mg/kg. It is a moderate irritant to the eye and a slight irritant to the skin of the rabbit. It is a mild sensitiser to the skin of the guinea-pig. When rats were treated orally with up to 1000 mg/kg/day for 28 days, irreversible tubular degeneration of the kidney was observed in 200 and 1000 mg/kg/day dose groups. However, there was no treatment related effects at the lowest dose level of 50 mg/kg/day. H112287 was found to be non-mutagenic in *vitro* to *Salmonella typhimurium* TA 1537, TA 1538, TA 98 and TA 100 and to *Escherichia coli* WP2*uvrA* (pKM101). Non-clastogenic in the bone marrow cells *in vitro* from the mouse.

On the basis of submitted data, the notified chemical would not be classified as hazardous in accordance with Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)] in relation to acute lethal effects (oral, dermal); irritant effects (skin, eye); sensitising effects (skin) and mutagenic effects nor can it be classified as hazardous from repeated or prolonged exposure (oral route).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Table 1 summarises the ecotoxicity tests provided by the notifier for Substance H112287. These tests were performed in accordance with OECD guidelines and principles of GLP.

Table 1. Ecotoxicity test results (nominal concentrations)

Species	Test	Result
Rainbow Trout, *Oncorhynchus mykiss*	96 hour acute EEC Directive 84/449/EEC Test C1	LC_{50} = >100 $mg.L^{-1}$
Daphnia, *Daphnia magna*	48 hour immobilisation EEC Directive 84/449/EEC Test C2	EC_{50} > 100 $mg.L^{-1}$
Activated sludge	ETAD Method 103 (aerobic)	19% inhibition of respiration in 100 $mg.L^{-1}$

Results are reported in terms of nominal concentrations as the mean measured concentrations were found to be within 97% of the nominal value. No mortalities were reported in either aquatic study. In the fish study, the intense colour of the test solutions prevented observations of toxicity symptoms. Similar observations were not noted in the *Daphnia* report. These results show that the notified chemical is practically non-toxic to the fish and daphnia species studied.

Algal growth inhibition testing was not performed on the basis of the low toxicity shown by the other aquatic studies. Testing of similar chemicals submitted by the same notifier have shown slight algistatic effects. However, these results may be attributed to the colouration of the test solution and the resultant reduction in light transmittance as opposed to any inherent chemical toxicity.

The potential effects of the active on sewage treatment were investigated under aerobic and anaerobic conditions. Under aerobic conditions a 100 $mg.L^{-1}$ (nominal) of the notified substance in activated sludge caused a 19% inhibition in the respiration rate of the microorganisms (ETAD Method 103). While this may indicate slight inhibition, significant effects on sewage treatment systems are considered unlikely as the actual concentration will be significantly lower. The active had no effect on nitrification (Department of the Environment, UK 1980. The Assessment of the Nitrifying Ability of Activated Sludge (Tentative Methods). HMSO London). Under anaerobic conditions, concentrations of up to 1.5% w/w of the active were reported to have had no significant effects on the levels of gas production. Colorimetric studies indicated a mean colour removal of 88% at the conclusion of digestion experiments.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Substance H112287 is not expected to present a hazard to the environment. During normal use the chemical will be bound to the treated substrate. 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 MSDS sheets.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

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

The toxicologic profile of H112287 suggests that it is unlikely to produce acute toxic effects upon ingestion and dermal contact and neither mutagenic nor clastogenic. However, it is moderately irritating to the eye, slightly irritating to the skin and a weak skin sensitiser. H112287 is not classified as a hazardous substance according to Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)].

Consequently the occupational health risk is expected to be minimal.

The potential for public exposure to the notified chemical by handling the ink 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 and its insolubility on the surface of paper.

13. RECOMMENDATIONS

To minimise occupational exposure to H112287 the following guidelines and precautions should be observed:

. in the event of a spill to reduce exposure of H112287 to a safe level, personal protective devices which conform to and are used in accordance with Australian Standards (AS) for eye protection (AS 1336, AS 1337) (11,12), impermeable gloves (AS 2161) (13) and overalls; and

. a copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for H112287 was provided in Worksafe Australia format (14).

This MSDS was provided by Canon Australia Pty Ltd as part of their notification statement. The accuracy of this information remains the responsibility of Canon Australia Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of H112287 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 AR5204, January 1991. *Acute Oral Toxicity Study with H112287 in Rats*. ICI 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 CR2752, June 1990. *Acute Dermal Toxicity Study with H112287 in Rats.* ICI Toxicology Laboratory, Cheshire, United Kingdom.

4. ICI Project EB3791, June 1990. Primary Skin Irritation Study with H112287 in Rabbits. ICI 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 FB3791, June 1990. *Primary Eye Irritation Study with H112287 in Rabbits*. ICI Toxicology Laboratory, Cheshire, United Kingdom.

7. ICI Projects GG4944 and GG4763 July 1990. *Contact Hypersensitivity to H112287 in Albino Guinea Pigs, Maximisation Test*, ICI Toxicology Laboratory, Cheshire, United Kingdom.

8. ICI Project KR1116, June 1990. *Subacute 28-Day Oral Toxicity Gavage Study with H112287 in Rats*. ICI Toxicology Laboratory, Cheshire, United Kingdom.

9. ICI Projects YV2738, YV2739 and YV2763, June 1990. *Salmonella typhimurium and Escherichia coli Reverse Mutation Assay for Azo dyes with H112287*. ICI Toxicology Laboratory, Cheshire, United Kingdom.

10. ICI Project SM0441, June 1990. *Micronucleus Assay in the Bone Marrow Cells of the Mouse*. ICI Toxicology Laboratory, Cheshire, United Kingdom.

11. Standards Australia, 1982. Australian Standard 1336-1982, *Eye Protection in the Industrial Environment,* Standards Association of Australia Publ, Sydney,.

12. Standards Australia, 1982. Australian Standard 1337-1984, *Eye Protectors for Industrial Applications,* Standards Association of Australia Publ, Sydney,.

13. Standards Australia, 1982. Australian Standard 2161-1978, *Industrial Safety Gloves and Mittens and Mittens (excluding Electrical and Medical Gloves),* Standards Association of Australia Publ, Sydney,.

14. Worksafe Australia, February 1990, *Guidance Note for Completion of a Material Safety Data Sheet.* Australian Government Publishing Service, Canberra.

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

Erythema Formation	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 by definite raising)	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

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

CORNEA			
Opacity	**rating**	**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 translu cent 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 severe	3 severe	Swelling with lids half-closed	3 mod.	Disharge with moistening of lids and hairs and considerable area around eye	3
		Swelling with lids half-closed to completely closed	4 severe		

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