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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

S161629

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

S161629

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 S161629.

2. IDENTITY OF THE CHEMICAL

Other names: Substance S161629
C I Direct Violet 107

Trade names: Pro-jet Fast Magenta 2
Pro-jet Fast Magenta 2 Liquid (formulation)

Methods of detection and determination:

HPLC separation using a gradient solvent system (methanol containing 1% tetrabutylammonium phosphate, pH 7) with detection at 520 nm

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: dark brown powder at 20°C and 101.3 kPa

Melting Point: > 300°C

Density: 1480 kg/m^3

Vapour Pressure: < 1.0 x 10^{-6} kPa (20-50°C)
(based on comparative estimates)

Water Solubility: > 34 g/l at 19-22°C
(based on comparative estimates)

Surface Tension (of aqueous solution): 73.0 N/m at 23°C

Fat Solubility: Not determined

Partition Co-efficient (n-octanol/water) log P_{ow}: < - 3.3 at 25°C

Hydrolysis as a function of pH: <10% hydrolysis after 120 h (25°C) at pH 4, 7 or 9

Adsorption/Desorption:	Not determined. The notifier states due to the products insolubility at low pH (not specified) that it is likely to exhibit low mobility in soils
Dissociation Constant pKa**:**	Not determined. The notified chemical is a mixed sodium/ammonium salt which contains aromatic carboxylic and sulphonic acid groups, and several basic nitrogens. The chemical is expected to have dissociation constants typical for these functionalities.
Flash Point:	not applicable
Flammability Limits:	does not propagate combustion
Autoignition Temperature:	381°C
Explosive Properties:	not explosive
Reactivity/Stability:	non-oxidising
Particle Size:	Not applicable

. 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.

The notifiers comments indicate strong absorption 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 absorption.
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. PROPOSED INDUSTRIAL USE, FORMULATION AND IMPORT VOLUME

The notified chemical will be used as a component of ink formulations for colour printers. It is imported in a sealed cartridge at a rate > 1 tonne for the next 5 years. The notified chemical will be used Australia wide, predominantly in the home and small office markets.

6. OCCUPATIONAL EXPOSURE

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

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 because the printed paper will contain only milligram quantities of the notified chemical per sheet and the notified chemical becomes insoluble on contact with the surface paper.

8. ENVIRONMENTAL EXPOSURE

. Release

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. Empty cartridges will be disposed with normal office refuse and domestic 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.

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

The relatively high water solubility of the notified chemical indicates that unbound residues released directly to the aquatic compartment are likely to remain in solution where they will be rapidly diluted.

The biodegradation potential of the notified substance was assessed using a manometric respirometer (OECD TG 301F). Results for biological and chemical oxygen demand (BOD_5 < 0.01 g O_2/g, COD 0.72 g O_2/g) indicate that rapid biodegradation is considered unlikely under aerobic conditions.

The bioaccumulation potential of the dye was not investigated. The high molecular weight, low partition coefficient (log P_{OW} < -3.3) and high water solubility (>34 g/L) of the notified chemical indicate that significant bioaccumulation is not likely.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Overall Assessment of Toxicological Data

S161629 is non-toxic via the oral and dermal routes in the rat with both LD_{50} > 2000 mg/kg. It is a slight irritant to the skin and eye of the rabbit. It is a sensitiser to the skin of the guinea-pig. When rats were treated orally with up to 1096 mg/kg/day for 28 days no results of toxicological significance were observed. S161629 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 vitro* cytogenetic assay in human lymphocytes .

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), mutagenic effects and severe effects after repeated or prolonged exposure (oral route).

9.2 Acute Toxicity

Table 1 Summary of the acute toxicity of S161629

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	slight irritant	(6)
Skin sensitisation	Guinea-pig	sensitiser	(8)

9.2.1 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

9.2.2 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

9.2.3 Skin Irritation (4)

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

Number/sex of animals: 3 F

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	*	*	0	0	0
2	*	*	0	0	0
3	*	*	*	*	0
OEDEMA					
1	0	0	0	0	0
2	0	0	0	0	0
3	1	0	0	0	0

* unable to assess due to staining

9.2.4 Eye Irritation (6)

Result: slight 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	*	*		*	*		*	*		*	*		*	*	
2	*	*		*	*		*	*		*	*		*	*	
3	*	*		*	*		*	*		*	*		0	0	
IRIS															
1	*			*			*			*			*		
2	*			*			*			*			*		
3	*			*			*			*			*		
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	*	1	0	*	0	0	*	0	0	*	0	0	*	0	0
2	*	1	0	*	0	0	*	0	0	*	0	0	*	0	0
3	*	0	0	*	0	0	*	0	0	*	0	0	0	0	0

*unable to assess due to staining
[a] redness [b] chemosis [c] discharge

9.2.5 Skin Sensitisation (7)

Result: 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	Histopathogical Findings			
	Induction-solvent only		Induction-test substance	
	test	control	test	control
3%	6/10	10/10	13/20	20/20
10	8/10	10/10	17/20	20/10

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

9.3 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, 16.4, 164 or 1096 mg/kg/day for 28 days plus 14 day recovery

Toxicologically Significant Observations:

1. Clinical

No clinical signs of toxicity observed in any of the animals.

2. Clinical Chemistry/Haematology

There were no significant observations

3. Necropsy Findings/ Histopathology

There were no significant changes

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

9.4 Genotoxicity

9.4.1 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* WP2P and WP2P*uvrA* (pKM101)

Concentration range: 200 to 7580 μg/ plate

Test Method: directive 84/449/EEC (2) Test B10

9.4.2 In Vitro Cytogenetic Assay in Human Lymphocytes (10)

Result: No significant increases in the percentage of aberrant cells, over control values at dose levels in treated cultures from either sex in the presence or absence of S9 -mix were observed at any of the sampling times investigated.

Species/strain: **Homo sapiens**

Number and sex (Donors): male and female *Doses:* 10, 100 and 250 μg/ml at 68 hour sampling time (M and F)
250 μg/ml, at 92 hour sampling (F)

Method of administration (vehicle): Dosing suspension of the test material was prepared in supplemented RPMI-1640 culture medium followed by serial dilutions. The culture medium was used as the medium control.

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

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Table 1 summarises the ecotoxicity tests provided by the notifier for Substance S161629. These tests were performed in accordance with OECD guidelines and principles of GLP.

The fish study made no comment on NOEC. However, the test solutions were observed to be opaque and dark pink in colour, and presumably this prevented observations of toxicity symptoms. The mean measured concentrations ranged from 89-100% of the nominal value.

In the *Daphnia* study the mean measured concentration ranged from 15-18% of nominal. Since the test media reacted with the notified chemical to form a gelatinous precipitate at the bottom of the test solution, the supernatant solution was decanted and used as the test solution. Spectral comparisons of the supernatant with a solution of the notified chemical in deionised water showed no significant differences. Therefore, the integrity of the test solution was maintained. No immobilisation of *Daphnia* was observed.

No mortalities were reported in either aquatic study. The results show that the notified chemical is practically non-toxic to the fish and daphnia species studied.

Algal growth inhibition testing indicated the active was slightly to practically non-toxic to algae. The test solution was observed to be clear, with a pink to red colouration. The mean measured concentration ranged from 98-108% of nominal values. The slight algicidal activity measured may be attributed to the reduced light transmittance through the test solution and the possible reduction in photosynthetic activity resulting from the colouration of the test solution by the notified chemical.

The potential effects of the active on sewage treatment were investigated under aerobic conditions. 1000 $mg.L^{-1}$ (nominal) of the notified substance caused < 5% inhibition in the respiration rate of the microorganisms in activated sludge (ETAD Method 103). No significant effects on sewage treatment systems are considered likely.

Table 1. Ecotoxicity test results (mean measured concentrations)

Species	Test	Result
Rainbow Trout, *Oncorhynchus mykiss*	96 hour acute OECD TG 203	LC_{50} = >180 $mg.L^{-1}$
Daphnia, *Daphnia magna*	48 hour immobilisation OECD TG 202	NOEC > 82 $mg.L^{-1}$ EC_{50} > 82 $mg.L^{-1}$
Algal Growth Inhibition *Selenastrum capricornutum*	72 h OECD TG 201	results in terms of nominal concentrations biomass: E_bC_{50} = 31 $mg.L^{-1}$ NOEC = 6 $mg.L^{-1}$ growth rate: E_rC_{50} > 100 $mg.L^{-1}$ NOEC = 12 $mg.L^{-1}$
Activated sludge	ETAD Method 103	EC_{50} > 1000 $mg.L^{-1}$ (<5% inhibition of respiration)

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Substance S161629 is not expected to present a hazard to the environment. During normal use the chemical will be bound to the treated substrate.

The disposal of uncured inks will be largely confined to residues contained in colour cartridge systems which do not allow the replacement of individual colours. These residues are expected to remain in the cartridge housing.

Recycling of treated paper could result in the release of a proportion of the notified chemical to the aquatic compartment where it will be rapidly diluted to environmentally negligible levels. Where recycling does not occur, the notified chemical will be widely dispersed in landfills around Australia where it 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 as a component of ink in colour 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 S161629 suggests that it is unlikely to produce acute toxic effects upon ingestion and dermal contact and neither mutagenic nor clastogenic. However, it is slightly irritating to the skin and eye and a skin sensitiser.

Given the low intrinsic health hazard of the notified chemical together with expected low exposure, the occupational health risk arising from use is expected to be minimal.

The potential for public exposure to the notified chemical by handling the cartridges is expected to be negligible. Exposure by contact with the printed paper is also expected to be negligible because of the low level of the notified chemical used in the ink preparation and its insolubility on the surface of paper. Accidental rupture of the cartridge is unlikely to result in a significant health hazard due to the low level of the notified chemical in the ink, small quantities of the ink in a cartridge and the low toxicity of the notified chemical preparation.

13. RECOMMENDATIONS

To minimise occupational exposure to S161629 the following guidelines and precautions should be observed:

. in the event of a spill to reduce exposure of S161629 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 S161629 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 S161629 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. Project AR5633, January 1991. *Acute Oral Toxicity Study with S161629 in Rats*. ZENECA 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. Project CR3091, Jan 1994. *Acute Dermal Toxicity Study with S161629 in Rats.* ZENECA Toxicology Laboratory, Cheshire, United Kingdom.

4. Project EB4239, Dec 1993. Primary Skin Irritation Study with S161629 in Rabbits. ZENECA 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. Project FB4801, Feb 1994. *Primary Eye Irritation Study with S161629 in Rabbits*. ZENECA Toxicology Laboratory, Cheshire, United Kingdom.

7. Project GG6014, Feb 1994. *Contact Hypersensitivity to S161629 in Albino Guinea Pigs, Maximisation Test*, ZENECA Toxicology Laboratory, Cheshire, United Kingdom.

8. Project KR1196, April 1994. *Subacute 28-Day Oral Toxicity Gavage Study with S161629 in Rats*. ZENECA Toxicology Laboratory, Cheshire, United Kingdom.

9. Project YV3269, Oct 1993. *Salmonella typhimurium and Escherichia coli Reverse Mutation Assay for Azo dyes with S161629*. ZENECA Toxicology Laboratory, Cheshire, United Kingdom.

10. Project SV0701, Feb 1994. An Evaluation in the *in Vitro Cytogenetic Assay in Human Lymphocytes.* ZENECA 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

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[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	**rating**	**Area of Cornea involved**	
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