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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Silicate

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

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**Silicate****1. APPLICANT**

Canon Australia Pty Ltd of 1 Thomas Holt Drive NORTH RYDE NSW 2113 has submitted a limited notification statement in support of their application for an assessment certificate for Silicate.

2. IDENTITY OF THE CHEMICAL

Silicate is not considered 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, spectral data and details of impurities have been exempted from publication in the Full Public Report and the Summary Report.

Trade name: Silicate

Molecular weight: < 500

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: white powder

Melting Point: 366.85°C

Relative Density: 3.9643 at 21°C

Vapour Pressure: 1.1×10^{-16} Pa at 25°C

Water Solubility: 3.88×10^{-3} g/L at 20°C

Partition Co-efficient (n-octanol/water): not determined due to insolubility

Hydrolysis as a Function of pH: not determined due to insolubility

Adsorption/Desorption: not determined due to insolubility

Dissociation Constant: not determined

Flash Point: not applicable for a solid

Flammability Limits: not highly flammable

Autoignition Temperature: > 400°C

Explosive Properties: non-explosive

Reactivity/Stability: non-reactive

Comments on Physico-Chemical Properties

Hydrolysis, partition coefficient and adsorption/desorption were not determined for the notified chemical because it is insoluble in water. Chemicals of this type are insoluble in water and acids (except hydrofluoric) but are soluble in hot alkaline hydroxide solutions. Due to the type of chemical and its low solubility, the notified chemical is not expected to cross biological membranes. The dissociation constant could not be determined by the methods outlined in OECD Guideline 112.

4. PURITY OF THE CHEMICAL

Degree of purity: > 93%

Toxic or hazardous impurities: none

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia, but imported as a component of photocopier and electrophotographic toners in prepackaged bottles packed in cardboard boxes and distributed by road to various establishments throughout Australia.

The estimated import volume for the notified chemical will be less than one tonne per annum for the first five years.

6. OCCUPATIONAL EXPOSURE

Silicate will not be manufactured in Australia. The notified chemical will be imported as a component of a photocopier and electrophotographic toner. The concentration of the notified chemical in the formulated toner is less than 3%.

The main category of workers potentially exposed to the formulated products containing Silicate are photocopy service engineers who will be involved in the installation and maintenance of photocopiers and electrophotographic equipment. Within Australia there may be greater than one hundred such personnel. Office workers and workers in office photocopy rooms may be exposed to the notified chemical during the handling of toner bottles.

7. PUBLIC EXPOSURE

There is negligible potential for public exposure to Silicate during normal printing/ photocopying operations. There may be widespread public contact with the notified chemical on the surface of printed/ photocopied paper, but its adhesion to the substrate and physico-chemical properties preclude absorption across the skin or other biological membranes.

8. ENVIRONMENTAL EXPOSURE

Release

The notified chemical, as a component of a pre-formulated toner, will be imported in small sealed plastic bottles. The toner contains the notified chemical at a concentration of < 3% w/w. These bottles are designed to prevent release of the toner until the removal of sealing tape. Under normal use (ie photocopying) the toner is transferred onto a sheet of paper where it is firmly fixed to the surface of the paper by heat. As such, the chemical has the potential for wide distribution on copy paper, but at very low levels.

Release of the notified chemical will also occur through the disposal of the bottles containing residuals of the toner. As the toner contains less than 3% of the new chemical and the expected residual remaining in the bottle would be less than 0.1%, the quantity of the new chemical released in this fashion would be minimal and diffuse.

Environmental release during transport due to accidental spillage will be limited due to the toner being supplied in discrete, small volume, plastic containers.

Fate

The notified chemical will most likely share the fate of its paper substrate, and be disposed of to landfill, incinerated or recycled. Small quantities, as residual toner in empty containers, will also be disposed of by landfill. Chemical disposed of to landfill is unlikely to leach or contaminate surface water because of its low water solubility.

Incineration of paper and combustion of the notified chemical in the presence of excess air will result in products of oxides of carbon and water and metal salts.

Paper recycling is a growing industry in Australia. 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 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.

The notifier has provided no data on the likely behaviour of the notified chemical during the recycling process. The chemical is likely to survive the above conditions, either remaining bound to the pulp or becoming associated with the sludge. In the latter case, the chemical will either arrive in landfill or be disposed of with product of incineration.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological data are not required for a limited notification according to the Act. However, the following studies on acute oral toxicity, acute dermal irritation, acute eye irritation and mutagenicity were submitted on a toner similar to that which is to be imported containing less than 3% of the notified chemical.

9.1 Acute Toxicity

Summary of the acute toxicity of toner mixture containing < 3% Silicate

Test	Species	Outcome	Reference
acute oral toxicity	rat	>5000 mg/kg	1
skin irritation	rabbit	slight irritant	3
eye irritation	rabbit	slight irritant	5

9.1.1 Oral Toxicity (1)

<i>Species/strain:</i>	Sprague-Dawley rats
<i>Number/sex of animals:</i>	5 male/ 5 female
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	all animals received 5000 mg/kg of the toner mixture in arachis oil once by gavage at 10 mL/kg
<i>Clinical observations:</i>	none
<i>Mortality:</i>	none
<i>Morphological findings:</i>	no abnormalities were noted at necropsy
<i>Test method:</i>	according to OECD guidelines (2)
<i>LD₅₀:</i>	> 5000 mg/kg
<i>Result:</i>	the toner containing < 3% of the notified chemical was of low toxicity by acute oral administration

9.1.2 Skin Irritation (3)

<i>Species/strain:</i>	New Zealand White rabbit
<i>Number/sex of animals:</i>	2 females/ 1 male
<i>Observation period:</i>	7 days
<i>Method of administration:</i>	0.5 g of the test article moistened with 0.5 mL of distilled water was applied to the dorsal flank of each rabbit under a secured cotton gauze patch; four hours after application the patch was removed and any residual test article removed; one hour after the removal of the patches, and 24, 48 and 72 hours later, the test sites were examined for evidence of primary irritation in accordance with Draize (4)

Draize scores (4):

Time after treatment (days)	1 hour	Animal #			
		1	2	3	7
Erythema					
1	1*	0	0	0	0
2	0	0	0	0	0
3	0	1	1	1	0
Oedema					
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0

* see Attachment 1 for Draize scales

Test method: according to OECD guidelines (2)

Result: the toner containing < 3% of the notified chemical was a slight skin irritant in rabbits

9.1.3 Eye Irritation (5)

Species/strain: New Zealand White rabbit

Number/sex of animals: 2 females/ 1 male

Observation period: 72 hours

Method of administration: a volume of 0.1 g of the test material was placed in the conjunctival sac of the right eye; the left eye remained untreated and was used for control purposes; assessment of ocular damage/ irritation was made approximately 1 hour and 24, 48 and 72 hours following treatment

Draize scores (4) of unirrigated eyes:

	Time after instillation											
Animal	1 hour			1 days			2 days			3 days		
Cornea	o ^a	a ^b		o ^a	a ^b		o ^a	a ^b		o ^a	a ^b	
1	0*	0		0	0		0	0		0	0	
2	0	0		0	0		0	0		0	0	
3	0	0		0	0		0	0		0	0	
Iris												
1		0			0			0			0	
2		0			0			0			0	
3		0			0			0			0	
Conjunctiva	r ^c	c ^d	d ^e	r ^c	c ^d	d ^e	r ^c	c ^d	d ^e	r ^c	c ^d	d ^e
1	1	0	0	0	0	0	0	0	0	0	0	0
2	1	0	1	0	0	0	0	0	0	0	0	0
3	1	0	0	0	0	0	0	0	0	0	0	0

* see Attachment 1 for Draize scales

^a opacity ^b area ^c redness ^d chemosis ^e discharge

Test method: according to OECD guidelines (2)

Result: the toner containing < 3% of the notified chemical is a slight eye irritant

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (6)

Strains: TA 100 and TA 98

Concentration range: 19.5-5000 µg per plate with or without S9 rat liver metabolic activation

Test method: according to OECD guidelines (2)

Result: the toner containing < 3% of the notified was found not to be mutagenic in bacteria

9.3 Overall Assessment of Toxicological Data

The toner containing less than 3% of the notified chemical was of low acute oral toxicity in rats (LD₅₀ > 5000 mg/kg). It was a slight skin and eye irritant in rabbits and was not mutagenic in bacteria.

The notified chemical would not be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (7) based on the toxicological data provided.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided, which is acceptable for new chemicals imported at a rate of less than 1 tonne per year according to the Act.

The notified chemical is not likely to exhibit toxic characteristics in the environment because of its insolubility and expected low bioavailability.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Environmental exposure to the notified substance could occur when paper containing the chemical is recycled or disposed of. In each case, the final destination is likely to be landfill where the chemical can be expected to persist but remain immobile, being either bound to paper or in the sludge from the recycling process.

Accidental spillage of the chemical should result in negligible hazard as it will be marketed in small plastic bottles for direct insertion into photocopier machines.

The low environmental exposure of the notified chemical as a result of normal use indicates that the overall environmental hazard should be negligible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The toxicological data provided suggest that the toner to be imported containing the notified chemical is of low acute oral toxicity and may not be mutagenic but may be a slight skin and eye irritant.

As the notified chemical will be imported in bottles which are inserted directly into the photocopier or electroreprographic machine, occupational exposure is expected to be low under normal conditions of use.

Given the likely low intrinsic health hazard of the toner containing notified chemical together with expected low exposure, occupational and public health risks arising from transport, storage, use and disposal are expected to be low.

13. RECOMMENDATIONS

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

- When changing toner bottles containing the notified chemical, care should be taken to avoid exposure to the toner adhering to the plastic tape which seals the bottle; should exposure occur, the toner should be removed immediately by washing
- Spillage of the notified chemical should be avoided, spillages should be cleaned up with an industrial vacuum cleaner
- Dust generation should be avoided and good personal hygiene should be observed
- A copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical and a toner containing it were provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (8).

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. Allen, D J, 1995, *Acute Oral Toxicity (Limit Test) in the Rat*, Safepharm Laboratories Limited, Derby, U.K., Project No.: 480/59.
2. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris, France.
3. Allen, D J, 1995, *Acute Dermal Irritation Test in the Rabbit*, Safepharm Laboratories Limited, Derby, U.K., Project No.: 480/60.
4. 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**.
5. Allen, D J, 1995, *Acute Eye Irritation Test in the Rabbit*, Safepharm Laboratories Limited, Derby, U.K., Project No.: 480/61.
6. Andoh, F, 1996, *Report of Mutagenicity Test Using Microorganisms*, Chemical Safety Dept, Canon, Tokyo, Japan, Report No.:582.
7. Worksafe Australia, 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (1994)]*, AGPS, Canberra.
8. Worksafe Australia, 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*, AGPS, Canberra.

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