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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

ORGANO POLYSILOXANE

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For Enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA

Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA

Telephone: (61) (02) 565-9466 **FAX (61) (02) 565-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**ORGANO POLYSILOXANE****1. APPLICANT**

Canon Australia Pty Ltd, of 1 Thomas Holt Drive, North Ryde, Sydney, NSW 2113.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, organo polysiloxane is not considered to be hazardous. Therefore, the details of chemical name, CAS number, molecular formula, structural formula and spectral data have been exempted from publication in the Full Public Report and summary report.

Other name: Organo polysiloxane

Marketing name: C96E

Molecular formula: Not known

Number-average molecular weight: Not determined, the polymer is not soluble in the solvent used in GPC measurement. Expected to be very large.

Method of detection and determination:

The polymer is identified by infrared spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Light yellow to brown solid
Melting Point:	Not stable >200°C
Specific Gravity/Density:	1320 kg/m ³
Vapour Pressure:	9x10 ⁻⁴ kPa at 25°C
Water Solubility:	<1.5 x 10 ⁻³ g/L at 20°C Estimated value
Fat Solubility:	Not applicable
Partition Co-efficient (n-octanol/water) log P_{o/w}:	Not applicable
Hydrolysis as a function of pH: Adsorption/Desorption:	Not applicable
Dissociation Constant pK_a:	Not applicable
Flash Point:	Not flammable
Flammability Limits:	Not flammable
Decomposition Temperature:	>200°C
Decomposition Products:	Not determined
Autoignition Temperature:	>370°C
Explosive Properties:	Non-explosive
Reactivity/Stability:	Non-reactive, it is stable at operating temperature
Particle size distribution:	range 30-100 µm

. **Comments on physico-chemical properties**

The polymer contains some free amines which could increase the solubility in acid. There are no groups in the polymer which are expected to hydrolyse under environmental conditions.

4. **PURITY OF THE CHEMICAL**

Degree of purity : 100%

5. **INDUSTRIAL USE**

The notified polymer is used as a coating, on carrier (ferrite) particles to carry toners in electrophoto-copying machines. The product contain $\leq 0.5\%$ of the notified polymer.

The projected imported volume of the notified polymer is less than one tonne per annum for the next five years.

6. **OCCUPATIONAL EXPOSURE**

The notified polymer containing the developer is imported in sealed plastic bottles which will be placed directly into the photocopier machine.

The exposure to the notified polymer is possible as part of the following activities:

- . fixing of plastic bag to the photocopier;
- . transfer of the used developer from the photocopier;
and
- . refilling of phocopier with new developer.

It is envisaged that personnel involved in the above activities will be exposed the notified polymer for very short periods.

7. **PUBLIC EXPOSURE**

The public may be exposed to the polymer during the addition or removal of the developer container from the photocopier.

8. **ENVIRONMENTAL EXPOSURE**

. **Release**

The notified polymer coats a ferrite particle (30-100 μm), the carrier, which is a component of the developer will be imported into Australia in sealed plastic bottles. The developer is to be changed by a service technician using a specially designed plastic bag to prevent spills during transfer of the used developer and the new developer. The notifier does not expect release of the polymer during this process. The risk of environmental exposure is minimal when the developer is changed according to the services manual.

When the photocopier is in use, there should not be any release of the ferrite particle onto the paper used during photocopying, thus the environmental exposure on disposal or recycling of paper would be very low.

During transport risk of environmental release is limited to accident where the plastic bottles or the plastic bags containing the used developer are ruptured.

. **Fate**

No information was presented on the environmental fate of the polymer. As there are no groups that should hydrolyse in the polymer it will not readily degrade in the environment nor in landfill (1). The used polymer, coating the carrier, will most likely be disposed of by landfill.

It has a large molecular weight and therefore unlikely to cross biological membranes, with the result it is unlikely to bioaccumulate.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

No toxicology data are required under the *Industrial Chemicals (Notification and Assessment) Act 1989* for polymers introduced in volumes < one tonne or have NAMW >1000. However, the following studies, carried out on organo polysiloxane (C96E) and product Cu-Zn Ferrite, were submitted. These are evaluated below.

Table1 Summary of the acute toxicities of C96E and Cu-Zn Ferrite.

Test	Species	Outcome	Reference
Oral (C96E)	rat	LD50 >5000 mg/kg	(1)
Oral (Cu-Zn Ferrite)	rat	LD50 >5000 mg/kg	(4)
Skin (C96E)	rabbit	non-irritant	(6)
Skin (Cu-Zn Ferrite)	rabbit	non-irritant	(7)
Eye (C96E)	rabbit	slight irritant	(9)
Eye (Cu-Zn Ferrite)	rabbit	slight irritant	(10)

9.1.1 Oral Toxicity

These studies were carried out according to OECD Guidelines for Testing of Chemicals No.: 401 (2)

9.1.1.1 C96E (3)

A single dose of 5000 mg/kg of C96E in maize oil (20% w/v) was administered by gavage to Wistar outbred rats (5/sex). The

animals were observed at 1 and 4 hours after dosing and subsequently once daily for 14 days. No deaths were noted during the study. All animals showed the expected gain in body weight over the study period. No gross abnormalities were noted at necropsy.

The results of this study indicate an oral LD₅₀ of >5000 mg/kg for C96E in rats.

9.1.1.2 Cu-Zn Ferrite (4)

A single dose of 5000 mg/kg of Cu-Zn Ferrite in aqueous suspension (25% w/v) was applied by gavage to Wistar outbred rats (5/sex). The animals were observed at 4 hours after dosing and subsequently once daily for 14 days. No deaths were noted during the study. All animals showed the expected gain in body weight over the study period. No gross abnormalities were noted at necropsy.

The results of this study indicate an oral LD₅₀ of >5000 mg/kg for Cu-Zn Ferrite in rats.

9.1.2 Skin Irritation

These studies were carried out according to OECD Guidelines for Testing of Chemicals No.: 404 (5).

9.1.2.1 C96E (6)

A single dose of 1.25 g of the test mixture (0.5 g of C96E and 0.75 g of vaseline) was applied by occlusive application to the shaven flank of three male New Zealand White rabbits for four hours. The site of application was examined approximately 60 minutes, 1, 2 and 3 days after removal of the dressing in all three animals. Skin reactions were assessed according to Draize (11). There were no signs of erythema or oedema in any of the animals.

The results of this study indicate that C96E is non-irritant to the skin of rabbit.

9.1.2.2 Cu-Zn Ferrite (7)

A single dose of 0.5 g of Cu-Zn Ferrite moistened with 0.25 g tap water was applied by occlusive application to the shaven flank of three male New Zealand White rabbits for four hours. The site of application was examined approximately 60 minutes, 1, 2, and 3 days after removal of the dressing in all three animals. Skin reactions were assessed according to Draize (11). There were no signs of erythema or oedema in any of the animals.

The results of this study indicate that Cu-Zn Ferrite is non-irritant to the skin of rabbit.

9.1.3 Eye Irritation

These studies were carried out according to OECD Guidelines for Testing of Chemicals No.: 405 (8).

9.1.3.1 C96E (9)

Three male New Zealand White rabbits were used in the study. Initially, a single dose of 0.075 g (0.1 ml) of C96E was instilled into the conjunctival sac of the right eye of each rabbit. The other eye which remained untreated, served as the control. Ocular reactions were assessed according to Draize (11) after 1 hour and 1, 2, and 3 days post-exposure. In all three animals slight erythema and slight chemosis of the conjunctivae, and slight ocular discharge were observed at 1 hour post-exposure with slight erythema persisting up to 24 hours. At 48 hours all treated eyes appeared normal.

The results of this study indicate that C96E is a slight eye irritant in rabbits.

9.1.3.2 Cu-Zn Ferrite (10)

Three male New Zealand White rabbits were used in the study. Initially, a single dose of 0.26 g (0.1 ml) of Cu-Zn Ferrite was instilled into the conjunctival sac of the right eye of each rabbit. The other eye which remained untreated, served as the control. Ocular reactions were assessed according to Draize (11) after 1 hour and 1, 2, and 3 days post-exposure. In all three animals slight erythema and chemosis were observed at 1 hour post-exposure which persisted up to 48 hours. On day 3 all treated eyes appeared normal.

The results of this study indicate that Cu-Zn Ferrite is a slight eye irritant in rabbits.

9.2 Genotoxicity

9.2.1 Bacterial Reverse Mutation Assay

This study was carried out according to OECD Guidelines for Testing of Chemicals No.: 471 (12).

9.2.1.1 C96E (13)

C96E in carboxymethylcellulose at dose levels of 12. 0, 37, 111, 333 and 1000 µg/plate was tested for gene mutation using *Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537 both in the presence or absence of metabolic activation (S9-mix). The experiment was repeated using the same dose levels. Dimethyl sulphoxide was used as the negative control. Positive controls used were sodium azide with TA1535 and TA100 (without S-9 mix), 2-nitrofluorene with TA98 (without S-9 mix), 9-aminoacridine with TA1537 (without S-9 mix)) and 2-aminoanthracene with TA98, TA100, TA1535, TA1537 and TA1538 (with S-9 mix).

In both experiments the test substance did not induce statistically significant dose-related increases in the number of revertant colonies of *Salmonella typhimurium* strains both in the absence or presence of S-9 mix. The positive controls induced the expected increases in revertant colonies.

The results of this study indicate that C96E is not mutagenic.

9.2.1.2 Cu-Zn Ferrite (14)

Cu-Zn Ferrite in dimethyl sulfoxide at dose levels of 10, 50, 100, 500, 1000 and 5000 µg/plate was tested for gene mutation using bacterial strains TA98, TA100, TA1535, TA1537, TA1538 and WP2 uvrA both in the presence or absence of metabolic activation (S9-mix). Positive controls used were sodium azide with TA1535, 2-(2-furyl)-3-(5-nitro-2-furyl)acrylamide with TA98, TA100 and WP2 uvrA, 9-aminoacridine with TA1537 and 2-nitrofluorene with TA1538 (without S-9 mix) and 2-aminoanthracene with TA98, TA100, TA1535, TA1537, TA1538 and WP2 uvrA (with S-9 mix).

The test substance did not induce statistically significant dose-related increases in the number of revertant colonies of bacreial stains both in the absence or presence of S-9 mix. The positive controls induced the expected increases in revertant colonies.

The results of this study indicate that Cu-Zn Ferrite is not mutagenic.

9.3 Overall Assessment of Toxicological Data

Both C96E and Cu-Zn ferrite have low acute oral toxicities in rats (LD₅₀s >5000 mg/kg and >5000 mg/kg respectively). They were slight eye irritants but not skin irritants in rabbits. C96E and Cu-Zn ferrite were found to be non mutagenic in the bacterial reverse mutation assay.

10 ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided, which is acceptable for polymers of NAMW > 1000 according to the Act.

There are a small but undefined amount of free amines in the polymer that could confer some aquatic toxicity (15). However, due to the polymers low solubility and the present proposal's low environmental exposure there should be no effect on aquatic organisms.

11. ASSESSMENT OF ENVIRONMNETAL HAZARD

The polymer is not expected to reach the environment apart from that which is released in accidents. In the event of an accident in which the developer, either fresh or used, is released clean up according to the MSDS sheets will prevent significant releases, with the minor amount left after clean-up being inert and not effecting biological systems. Due to the large molecular weight of the polymer, these minor amounts are not expected to effect biological systems or cause an environmental hazard. The environmental hazard of the notified polymer is expected to be minimal.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

C96E has been shown in animal studies to have low acute oral toxicity. It is not a skin irritant. However, it is a slight eye irritant. Therefore, eye contact with the developer should be avoided.

The notified polymer coated carrier has a non-respirable particle size distribution.

As the notified chemical in toner will be imported in cartridges which are inserted directly into the photocopier, the occupational exposure is expected to be low.

Under normal use conditions, given the toxicological profile and physico-chemical properties of the notified polymer and low exposure, the notified chemical is unlikely to pose a significant risk to occupational and public health.

13. RECOMMENDATIONS

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

- . Good work practices should be implemented to avoid spillages and generation of dust.
- . Atmospheric levels of C 96E dust levels in the workplace should be kept below 10 mg/m^3 (16).
- . If engineering controls and work practices are insufficient to significantly reduce exposure to a safe level, then personal protective devices which conform to and are used in accordance with Australian Standards (AS) for safety goggles {(AS 1336; AS 1337) (17,18)}, dust masks {(AS 1715; AS AS 1716) (19,20)} and gloves {AS 2161 (21)}.
- . Good personal hygiene should be observed.
- . a copy of the Material Safety Data Sheet (MSDS) for product containing the the notified polymer should be easily accessible to all employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for organo polysiloxane (C96E) and developer containing the notified polymer (Attachments 1A and 1B) were provided in Worksafe Australia format (22). This MSDS was provided by Canon Australia Pty Ltd as part of their notification statement. It is reproduced here as a matter of public record. 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* (the Act), secondary notification of organo polysiloxane 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

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