

File No: NA/294

Date: 5 December 1995

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

C96E

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.

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.

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**C96E****1. APPLICANT**

Gestetner Office Systems Pty Ltd of 108 Old Pittwater Road Brookvale NSW 2100 has submitted a limited notification statement in support of their application for an assessment certificate for C96E.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, C96E is considered to be non-hazardous. Therefore, the chemical identity and composition have been exempted from publication in the Full Public Report and Summary Report.

Trade name: C96E

3. PHYSICAL AND CHEMICAL PROPERTIES

The following data refer to the notified polymer and not to the product containing it.

Appearance at 20°C and 101.3 kPa:	Light yellow to brown powder
Odour:	Odourless
Melting Point:	Approximately 110°C (resin component). Minor decomposition occurred at 400°C
Glass-transition Temperature:	Not provided
Density:	1311 kg/m ³ at 22.5°C
Vapour Pressure:	Not determined
Water Solubility:	The water extractable portion of C96E was determined to be 0.2 g/kg at 20°C
Partition Co-efficient (n-octanol/water) log P_{ow}:	Due to the low water solubility of the polymer in different solvents, no appropriate analytical method could be used (or developed) to determine log P _{ow}
Hydrolysis as a function of pH:	Not determined
Adsorption/Desorption:	Not provided. The low water solubility of the notified polymer prevented the determination of adsorptive/desorptive characteristics

Dissociation Constant pKa:	>14	
Flash Point:	Not determined	
Flammability Limits:	Not highly flammable	
Combustion Products:	Not provided	
Pyrolysis Products:	Oxides of carbon, nitrogen oxides, silicon oxides and water. This information is derived from the structure.	
Autoignition Temperature:	> 400°C	
Explosive Properties:	Not considered to present any risk of explosion	
Stability:	non-oxidising	
Particle size distribution:	< 7 µm	4.6% (w/w)
	7-< 14 µm	3.4% (w/w)
	14-<28 µm	5.0% (w/w)
	28-<63 µm	15.4% (w/w)
	63-<100 µm	15.0% (w/w)
	100-<200 µm	33.1% (w/w)
	>200 µm	23.8% (w/w)

Comments on physico-chemical properties

The above comments provided by the notifier are supported by test reports and are adequate.

The literature indicates that siloxane polymers are resistant to hydrolysis or oxidative breakdown under ambient conditions. Although considered generally stable in the environment, siloxanes can undergo significant hydrolysis in dry soils (< 5% moisture content), resulting in the formation of low-molecular weight oligomers. The clay constituents of soils promote this rearrangement process and degradation is inhibited by moisture in the soils [1]. Abundant soil water seems to prevent the hydrophobic siloxane polymers from contacting the clay surfaces, thus slowing the reaction in moist soil [2]. Siloxanes are tightly sorbed to sediment particles and forms an organo-silica layer around the particles [3]. Therefore, the notified polymer is likely to adsorb to soil/sediment and organic matter.

4. PURITY OF THE CHEMICAL

Degree of purity : >99.9%

5. INDUSTRIAL USE

The notified polymer will not be manufactured in Australia, but imported as a component of photocopier developers in pre-packaged cartridges.

The projected import volume will be less than one tonne per annum for the next 5 years.

C96E is used as a component (coating resin of carrier particles) of formulated photocopy developer product for use in dry process photocopiers. The concentration of the notified chemical in the formulated product is reported as < 1%.

6. OCCUPATIONAL EXPOSURE

The main category of workers potentially exposed to the formulated products containing C96E are, photocopier service engineers, who will be involved in the installation and maintenance of dry photocopiers. There are approximately 150-160 service engineers involved in these tasks in Australia. Office workers and workers in office photocopy rooms will also be exposed to notified chemical.

The total number of employees likely to be exposed to formulated products containing the notified chemical cannot be specified with any great certainty, as this will depend on the number of machines used (which is dependent on market share) and the amount of photocopying carried out on each individual machine will vary, which will mean that the toner cartridge will need replacing more often or less often.

7. PUBLIC EXPOSURE

Developers containing C96E are provided to users in the form of pre-packaged cartridges which are inserted into the copiers as required. The design of the cartridge allows for minimal contact with the developer during the loading operation.

The potential for public exposure to C96E is low. The chemical is present in products at a low concentration (<1%), and is contained in prepacked cartridges which allow for minimal exposure to the formulated product. The public may be exposed through contact with residues on photocopied paper, but such residues are likely to be very low.

8. ENVIRONMENTAL EXPOSURE

Release

The notified polymer is a component of a toner that is contained within a cartridge. When the photocopier indicates that it requires more toner, the operator removes a toner cartridge and replaces it with another. Therefore, release of the notified polymer under normal conditions of use is expected to be negligible, as practically no waste is generated.

Releases to the environment as a result of accidents (during transport or in the workplace) are expected to be negligible.

The toner cartridge and any spills of toner can be disposed of as domestic waste, in accordance with government regulations (e.g. landfill, incineration).

Releases to the environment may occur through processing of waste paper. This possibility is explored further below.

Fate

Disposal of the notified polymer to landfill is unlikely to result in contamination of surface and ground. Its low water solubility and high molecular weight and large molecular size indicate it is unlikely to leach.

Combustion of the notified polymer in presence of excess air will result in products of oxides of carbon and water.

Unless incinerated, the polymer is likely to arrive in a dispersed manner in landfill bound to waste paper. As such, it will be immobile, and no leaching from landfill would be expected despite the polymer's expected persistence.

Paper recycling is a growing industry in Australia. Wastepaper 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 polymer during the recycling process. The polymer is likely to survive the above conditions, either remaining bound to the pulp or becoming associated with the sludge. In the latter case, the polymer will either arrive in landfill or be destroyed through incineration. Any degradation under landfill conditions will result in the formation of oligomers which are likely to be either volatilised from the soil, incorporated into humus, or to a lesser extent, evolved as CO₂ [4].

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological data are not required for polymers of number-average molecular weight (NAMW) >1000 according to the *Industrial Chemicals (Notification and Assessment) Act, 1989* as amended. However, the following studies on acute oral toxicity, skin irritation, eye irritation and skin sensitisation were submitted for the notified polymer.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of C96E

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD ₅₀ > 5000 mg/kg	(5)
Skin Irritation	Rabbit	non-irritant	(7)
Eye irritation	Rabbit	slight irritant	(9)
Skin sensitisation	Guinea-pig	non-sensitiser	(10)

9.1.1 Oral Toxicity (5)

LD₅₀: > 5000 mg/kg

Species/strain: rats, Wistar Crl:
WI(WU)BR

Number and sex of animals: 5/sex

Method of administration (vehicle): orally by gavage (5000 mg/kg) in maize oil

Clinical observations: No signs of systemic toxicity were noted during the study. The animals did not show any signs of abnormal behaviour or abnormal appearance that could be ascribed to treatment with the test substance.

Mortality: no deaths

Morphological findings:
no abnormalities were
noted at necroscopy

Test Method: OECD 401, 84/449/EEC (6) Test B1

9.1.2 Skin Irritation (7)

Result: The notified chemical has no skin irritation potential in rabbits

Species/strain: Male New Zealand White rabbits

Number of animals: 3

Method of administration: 500 mg test substance semi-occlusive dressing. Vehicle:
vaseline

Test Method: directive OECD 404; 42/449/EEC (5) Test B4

Draize (8) Scores

i:

Animal	Time after decontamination			
	60 min	1 day	2 days	3 days
ERYTHEMA/ ESCHAR FORMATION				
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0
OEDEMA				
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0

9.1.3 Eye Irritation (9)

Result: The notified chemical is a slight irritant to the rabbit eye

Species/strain: Male New Zealand White rabbits

Number of animals: 3

Method of administration: 75mg = 0.1 ml powdered test substance

Test Method: OECD 405; 84/449/EEC (5) Test B5

Draize (8) Scoresii

	Time after instillation			
	1 Hour	1 day	2 days	3 days
CORNEAL OPACITY				
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0
IRIDIAL INFLAMMATION				
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0
CONJUNCTIVAL REDNESS				
1	1	1	0	0
2	1	1	0	0
3	1	1	0	0
CONJUNCTIVAL CHEMOSIS				
1	1	0	0	0
2	1	0	0	0
3	1	0	0	0
OCULAR DISCHARGE				
1	1	0	0	0
2	1	0	0	0
3	1	0	0	0

9.1.4 Skin Sensitisation (10)

Result: non-sensitiser to guinea pig skin

Species/strain: Albino guinea pig

Number of animals: 10/sex in test group,

CrI:(HA)BR

5/sex in control group

Concentration for the induction and challenge phases:

Intradermal induction: 1% in maize oil
1% in FCA + maize oil (1:1)

Topical induction: 30% in vaseline

Topical challenge: 30% in vaseline

Skin reactions after topical induction: Slight to moderate signs of skin irritation were observed in 9 out of the 10 controls.

The 30% test dilution induced slight to moderate signs of skin irritation in the 20 test animals.

Skin reactions after topical challenge: No adverse reactions were noted at the test material and vehicle control sites of the test or control animals at the 24-hour and 48-hour observations.

Test Method: directive 84/449/EEC (5) Test B6

9.2 Genotoxicity

9.2.1 Induction of Point Mutations (11)

Result: No toxicity was exhibited to any of the strains of bacteria used. No significant increases in the number of revertant colonies of bacteria were recorded for any of the strains of bacteria used, at any dose level, either with or without metabolic activation. The positive control substances all produced marked increases in the number of revertant colonies with and without metabolic activation.

Strains: *Salmonella typhimurium* TA 1535, TA 1537, TA 98, TA 100

Concentration range: 12 - 1000µg/plate

Toxicity to bacteria: >1000 µg/plate

Metabolic activation: Aroclor 1254-induced rat liver S9-mix

Solvent: DMSO

Test Method: directive 92/69/EEC (5) Test B13, B14

9.4 Overall Assessment of Toxicological Data

The notified polymer has been shown in animal studies to have low acute oral toxicity (LD50: > 2000mg/kg). It is not a skin irritant or a sensitiser to guinea pig skin. However, it is a mild eye irritant to the rabbit eye. C96E was not mutagenic in an Ames *Salmonella* reverse mutation assay in the presence or absence of metabolic activation.

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 irritant effects (skin and eye), acute lethal effects (oral) and sensitising effects (skin).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

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

The notified polymer is not likely to exhibit toxic characteristics in the environment because large polymers of this nature are not readily absorbed by biota.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

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

Environmental exposure to the notified substance could occur when paper containing the polymer is recycled or disposed of. In each case, the final destination is likely to be landfill where the polymer can be expected to persist but remain immobile, being either bound to paper or to the sludge from the recycling process. Any degradation under landfill conditions will result in the formation of oligomers which are unlikely to present a hazard to the environment.

Accidental spillage of the polymer should result in negligible hazard as it will be marketed in cartridges for direct insertion into photocopier machines.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer is not expected to be a health hazard as the high number-average molecular weight (>1000) should preclude absorption of the molecules across biological membranes. The purity of the notified polymer is reported as $>99.9\%$, and residual monomers and other reactants are estimated to be present at $<0.01\%$. Levels of the residual monomers should not render the polymer a health hazard. The notified polymer is a slight eye irritant to the rabbit eye. Therefore, eye contact with the products containing C96E should be avoided.

The notified polymer is of low acute oral toxicity to rats ($LD_{50}>5000$ mg/kg), was not a skin irritant but was a slight eye irritant in rabbits, and did not result in skin sensitisation in guinea pigs. Although these results do not suggest any specific toxicological concerns for the polymer, eye contact should be avoided as a precautionary measure.

As the notified polymer will be imported in cartridges which are inserted directly into the photocopier, occupational exposure is expected to be low. Potential for exposure occurs during loading of cartridges, but is controlled by simple work practices to minimise dust generation and good hygiene practices. As the formulated products containing C96E is only used by a restricted group of trained and experienced personnel, exposure through inhalation and skin contact is minimal.

Formulated products which contain C96E, may contain additional components which require the following exposure standards to be observed (carbon black - TWA 3 mg/m^3 and iron oxide - TWA 5 mg/m^3) in the event of an accident.

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

The potential for public exposure to C96E is low. The chemical is present in products at a low concentration ($<1\%$), and is contained in prepacked cartridges which allow for minimal exposure to the formulated product. The public may be exposed through contact with residues on photocopied paper, but such residues are likely to be very low.

In the case of accidental spillage during transport, the public may be exposed to C96E. This is minimised by the recommended practices for storage and transportation. Emergency procedures for the containment and clean up of accidental spills are available and should be followed.

13. RECOMMENDATIONS

To minimise occupational exposure to C96E the following guidelines and precautions should be observed:

- . when changing toner cartridges containing the notified polymer, care should be taken to avoid exposure to the toner adhering to the plastic tape which seals the cartridge. Should exposure occur, the toner should be removed immediately by washing.
- . in the event of an accidental spill, effective decontamination, vacuuming dust and cleaning of contaminated walls and surfaces must be carried out.
- . avoid generation of dust 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 attached Material Safety Data Sheet (MSDS) for Ricoh Color Developer Type E Black containing the notified chemical was provided in an acceptable format (12).

This MSDS was provided by Gestetner Office Systems 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 Gestetner Office Systems Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of C96E 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. Carpenter JC, et al, Study of the degradation of polydimethylsiloxanes on soil, *Environ. Sci. Technol.* 1995, 29, pp864-868.
2. Lehmann RG, et al, Degradation of silicone polymers in soil, 1994, *Environ. Toxicol. Chem.*, Vol 13, No 7, pp1061-1064.
3. Kukkonen J & Landrum PF, 1995, Effects of sediment-bound polydimethylsiloxane on the bioavailability and distribution of benzo[a]pyrene in lake sediment to *Lumbriculus variegatus*, *Environ. Toxicol. Chem.*, Vol 14, No 3, pp523-531.

4. Lehman RG, Varaprath S & Frye CL 1994. Fate of silicone degradation products (silanols) in soil., *Environ. Toxicol. Chem.*, Vol 13, No 7, pp1753-1759.
5. TNO Nutrition and Food Research, Acute oral toxicity study (limit study) with C96E in rats, Project No. 352060/15, Powdertech Co., Ltd., Japan
6. 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).
7. TNO Nutrition and Food Research, Acute dermal irritation/corrosion study with C96E in albino rats, Project No. 352061/22, Powdertech Co., Ltd., Japan
8. 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.
9. TNO Nutrition and Food Research, Acute eye irritation/corrosion study with C96E in albino rabbits, Project No. 352069/17, Powdertech Co., Ltd., Japan
10. TNO Nutrition and Food Research, Sensitization study with C96E in guinea pigs (maximization test), Project No. 352063/05, Powdertech Co., Ltd., Japan
11. TNO Nutrition and Food Research, Examination of C96E for mutagenic activity in the Ames test, Project No. 352064/012, Powdertech Co., Ltd., Japan
12. Worksafe Australia, February 1990, Guidance Note for a Completion of a Material Safety Data Sheet, Australian Publishing Service, Canberra.

iThe 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. 1mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

iiThe 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	1 slight	Any swelling above normal	1 slight	Any amount different	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 moderate	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.	Discharge 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