File No: NA/32
Date:11 March 1992

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

G-1550

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

G-1550

1. IMPORTER

Oce-Australia Ltd., 89 Tulip Street, Cheltenham, Vic., 3192

2. IDENTITY OF THE CHEMICAL

Marketing name: G-1550

Other name: Polyester grafted copolymer

3. PHYSICAL AND CHEMICAL PROPERTIES

G-1550 is a light yellow coloured powder with no odour and negligible vapour pressure under ambient conditions (20^{o}C and 101.3 kPa). Its physical and chemical properties include:

Softening Point: 90-110^{o}C

Glass transition point: 61^{o}C

Density: 1.19 x 10^{3} kg/m^{3}

Vapour pressure: Negligible since G-1550 is a solid, high molecular weight polymer.

Water solubility: Insoluble (column elution method with limit of detection 1.5 ppm).
Soluble in Toluene and Tetrahydrofuran (>2g/l)
Insoluble in n-octanol and n-heptane.

Flash Point: Cleveland Open Cup Method: 278^{o}C
Closed Cup Method: 176^{o}C

Autoignition temperature: 500^{o}C (ASTM E659-78(1984))

Degree of hydrolysis: Non-hydrolysable (no changes observed in Infra-Red spectrum or Gel Permeation Chromatography profile at pH 1.2, 4.0, 7.0, or 9.0.

Partition Coefficient: Not obtainable as G-1550 is insoluble in both water and n-octanol.

Soil adsorption/desorption: Not measured. The polymer would be expected to be immobile in soils.

Dissociation constant: Not available, as the polymer is insoluble in water.

Particle size distribution:

Table 1. Particle size distribution of G-1550.

Particle size (µm)	Weight %
>350	97.8
250 - 350	0.9
150 - 250	0.6
<150	0.7

Note: The particle size distribution of Minolta CF Toner (mixture of Yellow, Magenta, Cyan and Black), which contains G-1550 and is used in the acute inhalational toxicity testing, is different to that shown in Table 1. Data cited in Section 6.2.3 indicates that approximately 40% of CF Toner (mixture of Yellow, Magenta, Cyan and Black) particles were smaller than 9.8µm aerodynamic diameter, and that 8% were of respirable size (<6µm).

4. INDUSTRIAL USES

G-1550 is intended to be used exclusively as a binder resin in colour toners for electrostatic photocopying (Minolta CF Toners). The toner formulations will contain >80% (w/w) (CF Toner Black) or >90% (w/w) (CF Toner Yellow, Cyan, Magenta) G-1550.

Minolta CF Toners containing G-1550 will be imported into Australia in sealed 375g bottles.

5. PUBLIC AND OCCUPATIONAL EXPOSURE

CF Toner formulations containing G-1550 will be imported and distributed in sealed containers ready for fitting to photocopiers. No reformulation, packaging, bottling, filling or refilling of containers is to be carried out in Australia.

It is expected that there will be low public and occupational exposure to toners containing G-1550 under proper use conditions. It is estimated that around 100 photocopier maintenance workers and 500 photocopier operators may be exposed to toners containing G-1550. Maintenance workers will experience the highest exposure via skin contact and inhalation during cleaning of the developing unit, collecting of waste toner and maintenance of the photocopier. Photocopier operators may be exposed to a lesser extent while exchanging toner bottles and possibly during copying. The filter fitted to the Minolta copier should reduce exposure during copier operation.

Once used in the copier, toners containing G-1550 will be fused to paper as a water insoluble polymer matrix, causing very low public and occupational exposure.

6. EVALUATION OF TOXICOLOGICAL DATA

6.1 Absorption

The key factors which appear to determine absorption of a chemical by an organism are its molecular weight and lipophilicity. It is generally believed that as molecular weight increases, absorption decreases. Although it is not possible to identify any single molecular weight limit above which no absorption will occur, the available information suggests that substances with molecular weights greater than 400 are generally not readily absorbed through the intact skin and that substances

with molecular weights greater than 1000 are generally not readily absorbed through the intact gastrointestinal tract (3).

Given its high molecular weight and polydispersity (maximum percentage of low molecular weight species (molecular weight < 1000 = 3.6%), it is anticipated that G-1550 would not be readily absorbed through the intact skin and gastrointestinal tract, and therefore, should not pose a significant acute toxicity risk.

6.2 **Acute Toxicity**

Tests of oral toxicity, dermal toxicity, inhalation toxicity, skin irritation and eye irritation were not conducted using G-1550, but using a mixture of the Minolta CF Toners (mixture of 25% of each of Yellow, Magenta, Cyan and Black). These toners contain 80 - 95% (w/w) G-1550 and 5 - 20% (w/w) of two or four kinds of organic pigment (confidential). Table 2 summarises the acute toxicity tests performed on the toner mixture.

Table 2. Summary of acute toxicity of Minolta CF Toner (mixture of Yellow, Magenta, Cyan and Black).

Test	Species	Outcome	Ref.
Oral	Rat	LD_{50} > 5000 mg/kg (M&F)	(4)
Dermal	Rabbit	LD_{50} > 2000 mg/kg (M&F)	(5)
Inhalation	Rat	LC_{50} > 1630 mg/m^3 (4h, M&F)	(6)
Skin irritation	Rabbit	non irritant	(7)
Eye irritation	Rabbit	slight irritation	(8)

6.2.1 **Acute Oral Toxicity**

A limit test (4) was carried out in a group of 5 male and 5 female CD rats, each treated with 5000 mg/kg of the Minolta CF Toner (mixture of Yellow, Magenta, Cyan and Black) by gavage in 1% (w/v) aqueous methylcellulose. None of the animals died within 15 days of the treatment. The only clinical sign observed in the animals was piloerection within five minutes of dosing, which subsided after one day. Terminal autopsy revealed no macroscopic

abnormalities. The oral LD_{50} for Minolta CF Toner (mixture of Yellow, Magenta, Cyan and Black) was greater than 5000 mg/kg.

6.2.2 **Acute Dermal Toxicity**

A limit test (5) was carried out in a group of 5 male and 5 female New Zealand White Rabbits. Each animal was treated with 2000 mg/kg of the Minolta CF Toner (mixture of Yellow, Magenta, Cyan and Black), which was moistened with water and applied to the skin for 24 hours. None of the animals died within 15 days following treatment. There were no clinical signs of systemic toxicity in response to treatment, but there was a purple staining of the skin at the site of application. Terminal autopsy revealed no macroscopic abnormalities. The dermal LD_{50} for Minolta CF Toner (mixture of Yellow, Magenta, Cyan and Black) was greater than 2000 mg/kg.

6.2.3 **Acute Inhalation Toxicity**

A limit test (6) was carried out in a group of 5 male and 5 female Sprague-Dawley rats. These animals were exposed to air containing Minolta CF Toner (mixture of Yellow, Magenta, Cyan and Black), at a concentration of 1630 mg/m^3, for 4 hours. Approximately 60% (w/w) of the airborne particles were larger than 9.8 µm diameter, while only 8% of the particles were of respirable size (< 6µm aerodynamic diameter). None of the animals died within 14 days following treatment. The only clinical sign observed during the 14 day observation period was staining of the tails of all animals with test substance. Food consumption by both male and female rats, and water consumption by male rats, was slightly reduced for 1 day following exposure. Bodyweight gain of male rats was slightly reduced for 1 day following exposure. Terminal autopsy revealed no macroscopic abnormalities. The 4-hour inhalation LC_{50} for Minolta CF Toner (mixture of Yellow, Magenta, Cyan and Black) was greater than 1630 mg/m^3.

6.2.4 **Skin Irritation**

Three female New Zealand White Rabbits were each treated with 0.5g doses of Minolta CF Toner (mixture of Yellow, Magenta, Cyan and Black), which were moistened with water and applied to the skin for four hours. The skin at the site of application was then observed at 30 minutes and 1, 2 and 3 days after removal of the

test substance. No erythema or odema was observed in any animal throughout the observation period. However the report (7) makes no mention of purple staining of the skin, which was observed when a higher dose was applied in the dermal toxicity study (5). On the basis of these results, it can be concluded that Minolta CF Toner (mixture of Yellow, Magenta, Cyan and Black) is not a skin irritant in rabbits.

6.2.5 **Eye Irritation**

Eye irritation was measured by instilling 0.05g of Minolta CF Toner (mixture of Yellow, Magenta, Cyan and Black) into the lower conjuntival sac of one eye in each of three female New Zealand White rabbits (8). The other eye of each animal was not treated and served as a control. Examination of the eyes was made after 1 hour and 1, 2, 3, 4 and 7 days after instillation. Mild inflammation of the conjunctiva was evident one hour after instillation in all three animals, but this had subsided after 1 day. On the basis of these results it can be concluded that Minolta CF Toner (mixture of Yellow, Magenta, Cyan and Black) is a slight eye irritant in rabbits.

6.3 **Genetic Toxicity**

The four toners containing G-1550 were tested for their genetic toxicity in bacterial mutation assays (9-12) and the mouse micronucleus test (13-16). These toners are: Minolta CF Toner Yellow (D-3F-Y); Minolta CF Toner Magenta (D-3F-M); Minolta CF Toner Cyan (D-3F-C); and Minolta CF Toner Black (D-3F-BK). The toners contain between 80 and 95% G-1550. None of the toners displayed genetic toxicity in either assay.

6.3.1 ***In vitro* Bacterial Mutation Assay**

Each of the four toners were tested for mutagenic effects on the histidine dependent *Salmonella typhimurium* strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100, and the tryptophan dependent *Escherichia coli* strain WP2 uvrA (9-12). The toners, dissolved in dimethylsulphoxide, were tested at doses of up to 5000 µg/plate. Dimethylsulphoxide served as the negative control. All tests were performed with and without metabolic activation systems, which were provided by liver preparations from Aroclor 1254-induced rats and (for the yellow and magenta toners) uninduced Syrian Hamsters. Positive control compounds (including 2-aminoanthracene and N-ethyl-N'-nitro-N-nitrosoguanidine) demonstrated the

sensitivity of the assay and the metabolising activity of the liver preparations. No evidence of mutagenic activity was seen at any dose level of any of the four toners. It can be concluded that the four Minolta CF Toners containing G-1550 are not mutagenic in these bacterial tests, at doses of up to 5000 µg/plate in dimethylsulphoxide.

6.3.2 *In vivo* Mouse Micronucleus Test

Each of the four toners were administered as an oral dose of 5000 mg/kg bodyweight to mice. Negative controls were dosed orally with the vehicle, 1% aqueous methylcellulose, while positive controls were dosed orally with mitomycin C at 12 mg/kg bodyweight. At 24 hours after dosing, mitomycin C produced large, highly significant increases in the frequency of micronucleated polychromatic erythrocytes. However, at 24, 48, and 72 hours after dosing, all four toners and the negative control produced no significant increases in the frequency of micronucleated polychromatic erythrocytes or micronucleated normochromatic erythrocytes, nor were significant decreases seen in the ratio of polychromatic to normochromatic erythrocytes. It can be concluded that the four Minolta CF Toners produced no mutations or bone marrow toxicity when administered at an oral dose of 5000 mg/kg in this test procedure (13-16).

6.4 Overall Assessment of Toxicological Data

Minolta CF Toner (mixture of Yellow, Magenta, Cyan and Black), containing 80 - 95% w/w G-1550, has low acute oral, dermal and inhalational toxicity and is not a skin irritant. It is, however, a slight eye irritant. In the absence of test data on the eye irritation potential of G-1550, it should be assumed that products containing G-1550 will be slight eye irritants, at least.

Minolta CF Toners (Black, Cyan, Magenta, Yellow) are not genotoxic when tested in *in vitro* (reverse mutation) and *in vivo* (mouse micronucleus) assays.

7. ENVIRONMENTAL ASSESSMENT

7.1 Environmental Release

G-1550 will be imported at a level of 80-95% in toner products pre packed in plastic bottles ready for immediate installation in

photocopiers. The polymer will not be released to the environment during use as the bulk will become fused to paper and filters are installed to prevent leakage of unfixed toner outside the machine. Spills can be readily swept up for disposal as the product is a powder. No formulation or repacking will be carried out in Australia, and spillages, empty toner bottles and dirty filters will presumably be consigned to landfill.

7.2 **Environmental Fate**

The bulk of the polymer will be fused to paper as a water insoluble matrix, and enter the environment in this form. Waste paper may be landfilled, incinerated or recycled. The polymer is expected to remain immobile in landfill and to be destroyed by incineration. If paper is recycled, the polymer is expected to remain bound to fibres or to become associated with sludge which will be landfilled.

7.3 **Environmental Effects**

Environmental effects testing is not required for small volume polymers. Polymers of this nature do not generally exhibit toxic characteristics as they are not readily absorbed by biota. Consideration of the polymer's structure does not give rise to any obvious toxicological concerns, and tests on rats and rabbits revealed it to be essentially nontoxic by acute oral and dermal administration.

7.4 **Environmental Hazard**

Minolta CF Toners containing 80-95% (w/w) G-1550 will be imported in sealed bottles ready for immediate installation into photocopiers, where the polymer becomes fixed to paper as an insoluble matrix. It has no obvious toxic potential and the annual import volume is low. Accordingly, the predicted environmental hazard is low.

8. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Public and occupational exposure to G-1550 is likely to be low under normal conditions, since the chemical is to be imported, distributed and supplied in a sealed plastic bottle. The bottle is designed to prevent user access, and bottle disposal is by incineration/landfill. Since the only known toxic effect of G-1550 (when tested as formulated Minolta CF Toners) is slight eye irritation, exposure to Minolta CF Toners should not pose a significant acute health and safety hazard to the public and workers.

9. MATERIAL SAFETY DATA SHEETS

The Material Safety Data Sheets (MSDS) for G-1550 and the four Minolta CF Toners containing G-1550 are at Attachments 1 to 5. These MSDSs were supplied by Oce-Australia Ltd. as part of their notification statement. They are reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Oce-Australia Ltd.

10. RECOMMENDATIONS FOR THE CONTROL OF PUBLIC AND WORKER EXPOSURE

To minimise public and worker exposure to the toner products, in general the following guidelines and precautions should be observed:

. as a good work practice, photocopiers and laser beam printers should be located in a well-ventilated area to control the accumulation of any dusts, gases or fumes;

. copies of the Material Safety Data Sheets for G-1550 and products containing G-1550 should be made available to all personnel who may have exposure to the toner; and

. photocopier and printer maintenance workers who frequently come into direct contact with the toner powder should:

  - wear appropriate gloves (for example, cotton or impervious gloves);

  - avoid contact of toners with the eyes;

- avoid the generation of a dust cloud; and

- observe good personal hygiene practices at work.

11. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of G-1550 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

12. REFERENCES

(1) Standards Australia, AS 3640-1989 *Workplace Atmospheres - Method for Sampling and Gravimetric Determination of Inspirable Dust*, Standards Australia, Sydney, 1989.

(2) Standards Australia, AS 2985-1987 *Workplace Atmospheres - Method for Sampling and Gravimetric Determination of Respirable Dust*, Standards Australia, Sydney, 1987.

(3) United States Federal Register, 40 CFR Part 723, *Premanufacture Notification Exemptions; Exemptions for Polymers*, 1984.

(4) Acute Oral Toxicity to Rats of D-3F-YMCBK, Huntingdon Research Centre, U.K., HRC Report No. 90922D/DIC 178/AC, 1990.

(5) Acute Dermal Toxicity to Rabbits of D-3F-YMCBK, Huntingdon Research Centre, U.K., HRC Report No. 901021D/DIC 179/AC, 1991.

(6) D-3F-YMCBK Acute Inhalation Toxicity Study in Rats 4 Hour Exposure, Huntingdon Research Centre, U.K., HRC Report No. DIC 182/9184, 1991.

(7) Irritant Effects on Rabbit Skin of D-3F-YMCBK, Huntingdon Research Centre, U.K., HRC Report No. 90973D/DIC 180/SE, 1990.

(8) Irritant Effects on the Rabbit Eye of D-3F-YMCBK, Huntingdon Research Centre, U.K., HRC Report No. 90974D/DIC 181/SE, 1990.

(9) D-3F-Y: Bacterial Mutation Assay, Huntingdon Research Centre, U.K., HRC Report No. DIC 175C/90823, 1991.

(10) D-3F-M: Bacterial Mutation Assay, Huntingdon Research Centre, U.K., HRC Report No.DIC 175B/90822, 1990.

(11) D-3F-C: Bacterial Mutation Assay, Huntingdon Research Centre, U.K., HRC Report No. DIC 175A/90781, 1990.

(12) D-3F-BK: Bacterial Mutation Assay, Huntingdon Research Centre, U.K., HRC Report No. DIC 177/901269, 1991.

(13) Mouse Micronucleus Test on D-3F-Y Toner, Huntingdon Research Centre, U.K., HRC Report No. DIC 183D/901610, 1991.

(14) Mouse Micronucleus Test on D-3F-M Toner, Huntingdon Research Centre, U.K., HRC Report No. DIC 183C/901609, 1991.

(15) Mouse Micronucleus Test on D-3F-C Toner, Huntingdon Research Centre, U.K., HRC Report No. DIC 183B/901608, 1991.

(16) Mouse Micronucleus Test on D-3F-BK Toner, Huntingdon Research Centre, U.K., HRC Report No. DIC 183A/901607, 1991.