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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

MLT-8723

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

MLT-8723

1. APPLICANT

Minolta Business Equipment Australia Pty Ltd of Unit 9, 372 Eastern Valley Way CHATSWOOD NSW 2067 and Mita Copiers Australia Pty Ltd of 25 Sirius Road LANE COVE NSW 2066 have submitted a limited notification statement in support of their application for an assessment certificate for MLT-8723.

2. IDENTITY OF THE CHEMICAL

Marketing Name:	MLT-8723
Number-Average Molecular Weight (NAMW):	4 100
Polydispersity (M_w/M_n):	3.85
Method of Detection and Determination:	detection by infrared (IR) spectroscopy and determination by gel-permeation chromatography, differential thermal analysis and differential scanning calorimetry

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	cream crystalline solid
Softening Point:	101 - 105°C
Specific Gravity:	1.2
Vapour Pressure:	not measured
Water Solubility:	< 0.5 mg/L at 20°C

Partition Co-efficient (n-octanol/water): not determined (see comments below)

Hydrolysis as a Function of pH: not measured

Adsorption/Desorption: not determined (see comments below)

Dissociation Constant: not measured

Flash Point: > 300°C

Flammability Limits: Upper Explosive Limit = not determined
Lower Explosive Limit = 28 $g.m^{-3}$

Particle Size:

particle size (μm)	*%*
10	0.5
45	3.0
100	9.0
250	28.5
500	62.5
1 018	86.5

Explosive Properties: not explosive

Reactivity/Stability: stable

Comments on Physico-Chemical Properties

Tests were performed according to OECD/EEC test guidelines at facilities complying with OECD Principles of Good Laboratory Practice (GLP), except where stated.

The vapour pressure of the notified polymer is expected to be negligible due to its high molecular weight.

The water solubility has been determined spectrophotometrically to be less than 0.5 $mg.L^{-1}$ using the column elution method. This is assumed to be the limit of detection.

The polymer contains some ester linkages that could be expected to undergo hydrolysis under extreme pH conditions. However, due to the very low water solubility, this is unlikely in the environmental pH range of between 4 and 9.

The determination of partition coefficient and adsorption/desorption could not be undertaken as the notified polymer was determined to be insoluble in both n-octanol and water, and the HPLC methods employed are not applicable to polymeric materials. Due to its very low

water solubility, the polymer is expected to become associated with the organic component of soils and sediments.

No dissociation constant data were provided. However, as the polymer molecule may contain a very low amount of aromatic carboxylic acid functionality, it would be expected to display weakly acidic properties and to have a pKa similar to that of phthalic acid (approximately 3). However, the very low water solubility should preclude manifestation of the inherent weakly acidic nature of the polymer.

4. PURITY OF THE CHEMICAL

Degree of Purity:	99.7%
Toxic or Hazardous Impurities:	none
Non-hazardous Impurities (> 1% by weight):	none
Maximum Content of Residual Monomers:	0.1%
Additives/Adjuvants:	0.30%

5. USE, VOLUME AND FORMULATION

The notified chemical is to be used as a component of colour toner products imported ready for use in electrostatic photocopying systems. It will be imported at a rate of less than 10 tonnes per year by the fifth year.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported as a component of toner products at a concentration of greater than 90% in 295 g plastic bottles. Exposure to the notified chemical during transport and handling is only likely in the event of an accident.

Office workers will replenish toner by attaching the toner bottle to a removable hopper containing receptacles for a number of different coloured toners. This is accomplished by removing the bottle lid and screwing the bottle to the hopper to allow the toner to enter the hopper by gravity feed. Once empty the bottle is removed and the lid replaced for disposal. There is potential for accidental spillage during this procedure in which case dermal, inhalational and ocular exposure are possible.

Photocopier maintenance workers may be exposed to toner residues during machine repair via the dermal and inhalation routes.

7. PUBLIC EXPOSURE

Public exposure to the notified polymer will occur through the use of photocopiers. Although no exposure during normal use of the photocopiers is expected, intermittent public exposure to the notified polymer is possible during changing toner bottles or from clearing paper jams. A filter is installed in the copiers to prevent leakage to the outside of the machine. Public contact with the notified polymer will occur when handling printed paper but no exposure is expected as the toner is bound in the structure of the paper.

8. ENVIRONMENTAL EXPOSURE

Release

The toner (with the notified polymer) is fused to the paper following application, which offers little potential for release. When the copier requires more toner of a particular colour, a new bottle of toner is added to the toner hopper. The filling process is designed to minimise toner losses. The majority of emptied bottles are expected to be disposed of with general office waste and placed into landfill where release of toner should occur only after destruction of the integrity of the bottle.

The major avenue for release to the environment will be through disposal of waste paper.

The notifier's claim that environmental release of the toner will be very low during use. Filters will prevent dust emissions escaping from the machine during copying. Accidental spills, if they do occur, will be collected and disposed of to landfill or incinerated.

Fate

The majority of the notified polymer will be associated with the fused toner and will be strongly bound to the paper. Waste paper disposal is effected either through high temperature incineration, recycling or deposition into landfill.

High temperature incineration will destroy the compound, with production of water vapour and carbon oxides.

The notifiers have provided no data on the likely behaviour of the polymer during the paper recycling process. During such processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, ink detachment from the fibres, pulp brightness and the whiteness of paper. It is expected that during this process the material would be either destroyed chemically or, if it survives, be incorporated into waste sludge due to its low solubility. Waste sludge from the recycling plants will be either incinerated or disposed of to landfill,

while aqueous waste would be comprehensively treated before discharge.

Some waste paper may be disposed of directly to landfill, and it is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified substance. The same considerations will apply to waste sludge from paper recycling if disposed of to landfill.

Toner (either from a spillage during filling or as residue in toner bottles) will be disposed of to landfill or by incineration. Leaching of the polymer from landfill is unlikely from these sites, given the low solubility of the substance. Hydrolysis, although theoretically possible, is unlikely.

Should the polymer be spilt into waterways, it is not expected to disperse into the water column, but settle out onto sediments. The polymer is not expected to cross biological membranes, due to the low solubility and high molecular weight, and as such should not bioaccumulate (1).

9. EVALUATION OF TOXICOLOGICAL DATA

All of the toxicity studies were conducted on coloured toner preparations containing greater than 90% of the notified chemical.

9.1 Acute Toxicity

The acute toxicity studies were conducted on a mixture of cyan, magenta, yellow and black toners.

Summary of the acute toxicity of MLT-8723

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	$LD_{50} > 2\ 000$ mg.kg^{-1}	(2)
acute inhalation toxicity	rat	$LC_{50} > 5.02$ mg.L^{-1}	(3)
skin irritation	rabbit	not irritant	(4)
eye irritation	rabbit	not irritant	(5)
skin sensitisation	guinea pig	non-sensitiser	(6)

9.1.1 Oral Toxicity (2)

Species/strain: rat/Sprague-Dawley

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration:	gavage; vehicle: arachis oil
Clinical observations:	none
Mortality:	none
Morphological findings:	none
Test method:	according to OECD guidelines (7)
LD_{50}:	> 2 000 $mg.kg^{-1}$
Result:	the notified chemical was of low acute oral toxicity in rats

9.1.2 Inhalation Toxicity (3)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	4 hour nose-only exposure; mean particle size: 10.1 µm
Clinical observations:	hunched posture, pilo-erection, increased or decreased respiratory rate and laboured, gasping and noisy respiration
Mortality:	none
Morphological findings:	one male and two females showed dark foci on the lungs
Test method:	according OECD guidelines (7)
LC_{50}:	> 5.02 $mg.L^{-1}$
Result:	the notified chemical was of low acute inhalational toxicity in rats

9.1.3 Skin Irritation (4)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	2 males, 1 female
Observation period:	72 hours
Method of administration:	0.5 g of test substance under semi-occlusive dressing for 4 hours
Test method:	according to OECD guidelines (7)
Result:	the notified chemical was not a skin irritant in rabbits; no erythema or oedema was observed in any animal at any time point from 1 to 72 hours

9.1.4 Eye Irritation (5)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 females
Observation period:	72 hours
Method of administration:	62 mg of the test substance was placed into the conjunctival sac of the right eye of each animal
Test method:	according to OECD guidelines (7)
Result:	the notified chemical was a slight eye irritant in rabbits; no corneal or iridal effects were seen at any time point (1, 24, 48 or 72 hours post-instillation); the only conjunctival effect was slight redness at 1 hour post-instillation in all animals

9.1.5 Skin Sensitisation (6)

Species/strain:	guinea pig/Dunkin Hartley
Number of animals:	10 test, 5 control
Induction procedure:	0.1 mL intradermal injections into the scapular region as follows: - 5% w/v formulation of the test substance

in arachis oil;
- 5% w/v formulation of the test substance in a 1:1 preparation of Freund's Complete Adjuvant (FCA) in distilled water;
- FCA 1:1 in distilled water

topical induction on day 7 was with 50% w/w test substance in arachis oil under occlusive dressing for 48 hours

Challenge procedure: on day 21 with 10% w/w test substance in arachis oil under occlusive dressing for 24 hours

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
5%	0/10**	0/10	0/5	0/5
10%	0/10	0/10	0/5	0/5

* time after patch removal
** number of animals exhibiting positive response

Test method: according to OECD guidelines (7)

Result: the notified chemical was not a skin sensitiser in guinea pigs

9.3 Genotoxicity

The genotoxicity experiments were repeated with cyan, magenta, yellow or black toners. Similar negative results were obtained in each assay for each toner. The results of typical studies designed to detect induction of either bacterial mutation or micronuclei in mouse bone marrow cells are reported below.

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (8, 9, 10, 11)

Strains: TA 1535, TA 1537, TA 1538, TA 98 and TA 100

Concentration range: 50 - 5 000 $\mu g.plate^{-1}$

Test method: according to OECD guidelines (7)

Result:	the test substance was not mutagenic in *S. typhimurium* either in the presence or absence of metabolic activation provided by rat liver S9 fraction

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (12, 13, 14, 15)

Species/strain:	mouse/CD-1
Number and sex of animals:	5/sex/sampling group
Doses:	5 000 $mg.kg^{-1}$
Method of administration:	intraperitoneal
Test method:	according to OECD guidelines (7)
Result:	the test substance did not induce micronuclei in mouse bone marrow polychromatic erythrocytes at either 24, 48 or 72 hours after dosing

9.4 Overall Assessment of Toxicological Data

Toxicological studies on acute toxicity, skin and eye irritation and skin sensitisation were conducted on a mixture of similar cyan, magenta, yellow and black toners containing greater than 90% of the notified chemical whereas genotoxicity studies were conducted on the individual toners. The toner mixture was of low acute oral (LD_{50} > 2 000 $mg.kg^{-1}$) and inhalation toxicity (LC_{50} > 5.02 $mg.L^{-1}$) in rats, was not a skin or eye irritant in rabbits and was not a skin sensitiser in guinea pigs. Each of the individual toners was not genotoxic as judged by negative results in *in vitro* mutagenicity studies in bacteria and *in vivo* clastogenicity studies in mouse bone marrow polychromatic erythrocytes.

The notified chemical would not be classified as hazardous according to NOHSC's *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (16) in relation to the toxicological data provided.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicology data were provided, which is acceptable for polymers of NAMW greater than 1 000 according to the Act.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of notified polymer should not enter the environment until it is incorporated into a polymer matrix when the toner is cured and fixed to paper. Environmental exposure and the overall environmental hazard should therefore be low.

Disposal of the waste paper containing the cured toner is normally through landfill, incineration or recycling. In all three cases it is anticipated that the polymer will be destroyed either through the agency of a vigorous chemical environment, or through slow biological or abiotic processes. Even in the absence of substantial degradation, the diffuse nature of disposal patterns would indicate slow release into the wider environment.

Accidental spillage of the toner, either during filling of toner hoppers or during transport, should result in powder wastes being sent to either landfill or incineration facilities. Empty bottles containing residues of toner are also likely to be sent to landfill or for incineration. Movement of the polymer by leaching from landfill sites is not expected.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Toxicological studies suggest that the notified polymer would not be acutely toxic via the oral or inhalation routes, would not be irritating to skin or eyes, would not be a skin sensitiser and would not be genotoxic. As the toners containing the notified chemical at greater than 90% were used in these studies, the other components of the toners also are unlikely to present a hazard in terms of these endpoints. The notified polymer would not be classified as hazardous according to the Approved Criteria in terms of the toxicological data provided.

Exposure to toner containing the notified polymer during transport and handling of containers should not result in exposure except in the event of an accident.

Exposure of office workers will potentially occur when toner is recharged. Spillage is possible when the bottle in which the toner is imported is screwed into a hopper after it is removed from the photocopier. It is possible that some dermal and inhalation exposure may occur. As photocopiers are expected to be installed in well-ventilated areas dust buildup in the atmosphere from machine operation or toner spillage should be low.

Dermal exposure of workers to toner residues is possible during routine maintenance but is expected to be low unless spillage occurs.

It is concluded that the risk of adverse health effects to workers involved in transport, storage, use or disposal of the notified polymer is minimal. Similarly, the risk of public health effects is also considered to be minimal.

13. RECOMMENDATIONS

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

- Spillage of the notified chemical should be avoided; spillage should be cleaned up promptly using a vacuum cleaner and disposed of;
- The NOHSC exposure standard for nuisance dusts of 10 $mg.m^{-3}$ (17) should be adhered to;
- Good personal hygiene should be practised to minimise the potential for secondary ingestion;
- A copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for products containing the notified chemical were provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (18).

These MSDS were provided by the applicant as part of the notification statement. They are reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicants.

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

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8. Thompson, P. W. 1995, *M31F Cyan Toner: Reverse Mutation Assay "Ames Test" Using Salmonella typhimurium*, Project No. 635/027, Safepharm Laboratories Limited, Derby, U. K.

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