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June 1999

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

NE-8143

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

NE-8143

1. APPLICANT

Minolta Business Equipment Australia Pty Ltd of Unit 9, 372 Eastern Valley Way CHATSWOOD NSW 2067 and Lexmark International (Australia) Pty Ltd of 12A Rodborough Road FRENCHS FOREST NSW 2086 have submitted a limited notification statement in support of their joint application for an assessment certificate for NE-8143.

2. IDENTITY OF THE CHEMICAL

Other Names:	Tuftone NE-8143
Trade Name:	NE-8143
Number-Average Molecular Weight (NAMW):	> 1 000
Maximum Percentage of Low Molecular Weight Species	
Molecular Weight < 500:	5.9%
Molecular Weight < 1 000:	7.7%
Method of Detection and Determination:	infrared (IR) spectroscopy, gel permeation chromatography, differential thermal analysis, differential scanning calorimetry

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white powder
Softening Point:	111 – 115°C
Specific Gravity:	1.2

Vapour Pressure:	not measured – see comment below
Water Solubility:	< 0.0249 mg/L at 20°C
Partition Co-efficient (n-octanol/water):	not determined – see comment below
Hydrolysis as a Function of pH:	not determined – see comment below
Adsorption/Desorption:	not determined – see comment below
Dissociation Constant:	not determined – see comment below
Flash Point:	> 300°C (open cup)
Flammability Limits:	explosive limits in air: LEL, 28 g/m^3 (UEL not determined); not "highly flammable" in the EEC flammability of solids test (Method A10 of Commission Directive 92/69/EEC); based on the chemical structure and experience in use, the substance is not pyrophoric or flammable in contact with water; the substance is combustible and will burn if involved in a fire, evolving noxious fumes (eg carbon dioxide and phenol derivatives)
Autoignition Temperature:	none below melting temperature
Explosive Properties:	the substance is not explosive under the influence of a flame, to shock, or to friction
Reactivity/Stability:	the notified chemical does not have oxidising properties based on its chemical structure and experience in use; it does not react with water; the chemical is considered to be stable

Particle Size:

Size Range (μm)	*%*
< 850	88
< 500	60
< 350	40
< 250	26
< 150	12

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 for density and softening point.

The vapour pressure of the polymer is predicted to be very low due to the high molecular weight.

The water solubility has been determined to be less than 0.025 mg/L using the column elution method with recirculating pump.

The polymer contains ester linkages which 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. Measurement according to OECD TG 112 is not possible because there is no mode of chemical dissociation for this compound.

4. PURITY OF THE CHEMICAL

Degree of Purity: 99.8%

Toxic or Hazardous Impurities: none

Non-hazardous Impurities (> 1% by weight): none

Maximum Content of Residual Monomers: the notifier states there is virtually no residual monomer present (no test report submitted)

Additives/Adjuvants:

Chemical Name	*CAS No.*	*Weight %*
di-n-butyltin oxide	818-08-6	0.2%

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/printing systems. Only the toner cartridges are to be imported into Australia. Import volumes are expected to be less than 20 tonnes per year for the first five years. The toner contains greater than 90% notified polymer with the remainder being pigments and other components.

6. OCCUPATIONAL EXPOSURE

The notified polymer will be imported in toner cartridges containing approximately 151 g of toner. As the toner is a fine powder, potential exposure may be by skin contact or by inhalation of the dust. Exposure of transport and storage workers should only occur in the event of accidental spillage.

The notifier estimates that up to 100 maintenance workers and 500 operators of electrostatic photocopiers or printers are potentially exposed to the notified polymer. Operators replace toner cartridges as required and may be exposed to residues in the copier/printer. Additionally, some exposure may occur clearing page jams. Exposure may occur during disposal of the cartridges. Normally operators do not wear personal protective equipment.

Maintenance workers clean the developing unit of copiers/printers, collect waste toner and maintain the machines. Some exposure to residual toner may be possible during these operations. Maintenance workers may wear disposable gloves.

7. PUBLIC EXPOSURE

The potential for public exposure from transport of the toner cartridges is anticipated to be low. Public exposure may arise through contact with dust particles during maintenance of photocopiers or printers or through contact with cured toner on photocopied or printed papers. These are not regarded as significant as in most cases (except for people employed for photocopying or printing) photocopying or printing is carried out infrequently and the packaging of the product in cartridges will markedly reduce exposure potential. The cured toner is bound strongly to the paper, and the notified polymer is not expected to be dermally absorbed.

Residual toner in toner cartridges will be disposed of together with toner cartridges as office waste. Cured toner printed on paper is likely to be disposed of as domestic or office waste. Public exposure from disposal is expected to be negligible.

8. ENVIRONMENTAL EXPOSURE

Release

The toner (with the notified polymer) is fused to the paper following application, which offers little potential for release. Its release will be associated with the fate of the waste paper.

When the copier requires more toner, the empty cartridge is replaced. The exchange process is designed to minimise toner losses. The majority of empty cartridges 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 container. The notifier estimates the amount of toner residue remaining in the bottle to be 5 g of the notified polymer.

The notifier claims that filters installed in the copiers prevent leakage to the outside of the machine. Accidental spills, if they do occur, will be collected and disposed of to landfill or incinerated.

Fate

Waste paper disposal is effected either through incineration, recycling or deposition into landfill. Incineration will destroy the compound with production of water vapour and carbon oxides.

The notifier has 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 will 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 will 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 will 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 toner cartridge replacement or as residue in toner cartridge) 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 also 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 (Connell, 1989).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

The investigations of acute oral toxicity and skin sensitisation were performed with a representative toner product (M32F) containing approximately 93% of the notified chemical.

Summary of the acute toxicity of M32F

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	(Allen, 1996a)
skin sensitisation	guinea pig	sensitiser (1 experiment); non-sensitiser (3 experiments)	(Allen, 1996b; Allen, 1996c; Allen, 1998a; Allen, 1998b)

9.1.1 Oral Toxicity (Allen, 1996a)

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:	OECD TG 401
LD_{50}:	> 2 000 mg/kg
Result:	a product containing approximately 93% notified chemical was of very low acute oral toxicity in rats

9.1.2 Skin Sensitisation (Allen, 1996b; Allen, 1996c; Allen, 1998a; Allen, 1998b)

The notifier originally submitted two studies performed with the either the Magnusson and Kligman method or the Buehler method, the first of these (listed below as experiment 1) being positive. The notifier claimed that the positive study was performed with an experimental batch of toner and provided two repeat studies using samples from production batches

subject to quality control. The additional studies are reported below as experiments 2 and 3. In experiment 3, the topical sighting study with potential challenge concentrations gave irritant responses above a concentration of 5% (w/v), therefore, this was the maximum challenge concentration used.

Magnusson and Kligman method: Experiment 1 **(Allen, 1996c)**

Species/strain: guinea pig/Dunkin Hartley

Number of animals: 20 test, 10 control

Induction procedure: 0.1 mL intradermal injections into the scapular region as follows:

- 1% w/v formulation of the test substance in arachis oil;
- 1% 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 50% and 25% 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***
25%	8/20**	0/20	0/10	0/10
50%	7/20	1/20	0/10	0/10

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

Test method: OECD TG 406

Result: the notified chemical was a skin sensitiser in guinea pigs under the test conditions

Magnusson and Kligman method: Experiment 2 **(Allen, 1998b)**

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:

- 1% w/v formulation of the test substance in arachis oil;
- 1% 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 50% and 25% 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***
25%	1/10**	0/10	0/5	0/5
50%	0/10	0/10	0/5	0/5

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

Test method: OECD TG 406

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

Magnusson and Kligman method: Experiment 3 **(Allen, 1998a)**

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:

- 1% w/v formulation of the test substance in arachis oil;
- 1% 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 5% and 2% 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***
2%	0/10**	0/10	0/5	0/5
5%	0/10	0/10	0/5	0/5

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

Test method: OECD TG 406

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

Buehler method **(Allen, 1996b)**

Species/strain: guinea pig/Dunkin Hartley

Number of animals: 20 test, 10 control

Induction procedure: 0.5 mL of the test substance at a concentration of 50% (w/w) in arachis oil under occlusive dressing for 6 hours on days 0, 7, and 14

Challenge procedure: on day 28, 0.5 mL of the test substance at concentrations of 50% (w/w) and 25% (w/w) in arachis oil under occlusive dressing were applied for 6 hours

Challenge outcome:

Challenge concentration	Test animals		Control animals	
	24 hours*	48 hours*	24 hours	48 hours
25%	0/20**	0/20	0/10	0/10
50%	0/20	0/20	0/10	0/10

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

Test method: OECD TG 406

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

9.2 Genotoxicity

Six genotoxicity experiments were conducted with cyan, magenta or yellow toners containing approximately 93% of the notified polymer. Similar negative results were obtained in each assay for each toner. The results of typical studies designed to detect induction of bacterial mutation are reported below.

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (Thompson, 1996a; Thompson, 1996b; Thompson, 1996c; Thompson, 1997a; Thompson, 1997b; Thompson, 1997c)

Strains: TA 1535, TA 1537, TA 1538, TA 98 and TA 100 (repeat studies were conducted with just TA 98 and TA 100)

Concentration range: 50 – 5 000 µg/plate

Test method: OECD TG 471

Result: the products tested were not mutagenic in *S. typhimurium* in either the presence or absence of metabolic activation provided by rat liver S9 fraction; a precipitate was observed at and above 1 500 µg/plate

9.3 Overall Assessment of Toxicological Data

Toners containing ca. 93% of the notified polymer exhibited very low acute oral toxicity in rats (LD_{50} > 2 000 mg/kg) and were not mutagenic in bacteria. In studies of skin sensitisation potential in guinea pigs, a toner product gave positive results using the Magnusson and Kligman protocol but negative results using the Buehler protocol. The Magnusson and Kligman protocol was used for repeat experiments with samples from recent production batches claimed by the notifier to be subject to quality control. In these experiments, the notified polymer was negative.

The notified polymer would not be determined to be hazardous according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a) on the basis of information submitted.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicology data were provided.

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. 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 without substantial degradation, the diffuse nature of disposal patterns would indicate slow release into the wider environment.

Accidental spillage of the toner, either during usage or transport, should result in powder wastes being sent to either landfill or incineration facilities. Empty cartridges 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.

Considering the above, environmental exposure and the overall environmental hazard is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer has a number-average molecular weight above 1 000 which is expected to preclude absorption across biological membranes and to minimise systemic effects. Levels of low molecular weight species and residual monomers are low and are unlikely to render the polymer hazardous according to NOHSC *Approved Criteria for Classifying Hazardous*

Substances (National Occupational Health and Safety Commission, 1994a). From the toxicological data provided by the notifier, the notified polymer would be expected to be of low acute toxicity via the oral route and not a mutagen *in vitro*. The notifier originally provided 2 skin sensitisation studies performed using either the Magnusson and Kligman method or the Buehler method, a positive result being obtained using the former. The notifier claimed that the batch of toner used was an experimental batch and submitted two further studies using the Magnusson and Kligman protocol. These studies were said to be from typical production batches subject to quality control and were negative. Therefore the notified polymer is, on balance, judged not to be a skin sensitiser when contained in production batches of the toner.

The risk of adverse health effects to transport and storage workers is expected to be minimal. Should accidental spillage occur, respiratory exposure may cause discomfort, but, as approximately 90% of the particles are above the inspirable range, respiratory effects should be limited.

During normal operation of photcopiers and printers, filters are used to prevent escape of toner particles into the air. When cartridges are changed by office workers minimal dermal exposure may occur. However, as this occurs infrequently and the notified polymer is expected not to be hazardous, the risk of adverse health effects is likely to be very low. Exposure of maintenance workers may be somewhat greater. Nevertheless, the risk of adverse health effects is still considered to be minimal given the likely low hazard of the notified polymer. Should a large quantity of toner be released into the air, respiratory effects are likely to be limited given that approximately 90% of the particles are greater than 150 μm in size. Nevertheless, dust generation of the toner should be avoided to minimise any respiratory discomfort. Maintenance workers are advised to wear disposable gloves to minimise skin contact with the toner.

Members of the public are likely to have minimal exposure to the notified polymer during transport, storage, use or disposal, or from contact with cured toners. Therefore, given the likely low hazard of the polymer, the risk of adverse health effects is negligible.

13. RECOMMENDATIONS

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

- Spillage of the notified chemical should be avoided. Spillage should be cleaned up promptly by vacuuming and put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the Material Safety Data Sheets should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical and for toners containing the notified chemical were provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994b).

The 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 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

Allen DJ (1996a) M32F: Acute Oral Toxicity (Limit Test) in the Rat, Project No. 635/043, Safepharm Laboratories Limited, Derby, U.K.

Allen DJ (1996b) M32F: Buehler Contact Hypersensitivity Study in the Guinea Pig, Project No. 635/045, Safepharm Laboratories Limited, Derby, U.K.

Allen DJ (1996c) M32F: Magnusson and Kligman Maximisation Study in the Guinea Pig, Project No. 635/044, Safepharm Laboratories Limited, Derby, U.K.

Allen DJ (1998a) M32F (10) Toner: Magnusson and Kligman Maximisation Study in the Guinea Pig, Project No. 635/083, Safepharm Laboratories Limited, Derby, U.K.

Allen DJ (1998b) M32F (20) Toner: Magnusson and Kligman Maximisation Study in the Guinea Pig, Project No. 635/085, Safepharm Laboratories Limited, Derby, U.K.

Connell DW (1989) General characteristics of organic compounds which exhibit bioaccumulation. In: D. W. Connell ed. Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton.

National Occupational Health and Safety Commission (1994a) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1994b) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

Thompson PW (1996a) M 32F-C: Reverse Mutation Assay "Ames Test" Using *Salmonella typhimurium*, Project No. 635/048, Safepharm Laboratories Limited, Derby, U.K.

Thompson PW (1996b) M 32F-M: Reverse Mutation Assay "Ames Test" Using *Salmonella typhimurium*, Project No. 635/047, Safepharm Laboratories Limited, Derby, U.K.

Thompson PW (1996c) M 32F-Y: Reverse Mutation Assay "Ames Test" Using *Salmonella typhimurium*, Project No. 635/046, Safepharm Laboratories Limited, Derby, U.K.

Thompson PW (1997a) M 32F-Cyan: Reverse Mutation Assay "Ames Test" Using *Salmonella typhimurium* Strains TA 98 and TA 100 - Single Experiment, Project No. 635/074, Safepharm Laboratories Limited, Derby, U.K.

Thompson PW (1997b) M 32F-Magenta: Reverse Mutation Assay "Ames Test" Using *Salmonella typhimurium* Strains TA 98 and TA 100 - Single Experiment, Project No. 635/073, Safepharm Laboratories Limited, Derby, U.K.

Thompson PW (1997c) M 32F-Yellow: Reverse Mutation Assay "Ames Test" Using *Salmonella typhimurium* Strains TA 98 and TA 100 - Single Experiment, Project No. 635/072, Safepharm Laboratories Limited, Derby, U.K.