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July 2000

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

NE-8963H

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

NE-8963H

1. APPLICANT

First Applicant

An Assessment Certificate for the notified chemical **NE-8963H** was granted to Minolta Business Equipment Australia Pty Ltd of Unit 9, 372 Eastern Valley Way CHATSWOOD NSW 2067.

The Assessment Report for NE-8963H is identified by the sequence number NA/609.

Second Applicant

Since granting of the abovementioned Assessment Certificate, Hitachi Koki Imaging Solutions Inc of 2/28 Rodborough Road FRENCHS FOREST NSW 2086 has submitted a notification statement in support of their application for an extension of the Assessment Certificate for NE-8963H.

Minolta Business Equipment Australia Pty Ltd has agreed to this extension.

No new information on the new chemical has been submitted by Hitachi Koki Imaging Solutions Inc since the original notification statement submitted by Minolta Business Equipment Australia Pty Ltd in matters affecting occupational, environmental or public exposure. The original assessment report (NA/609) is reproduced here in full and without amendment, for the record as EX/17 (NA/609).

2. IDENTITY OF THE CHEMICAL

Claims were made and accepted for the identity of NE-8963H to be exempt from publication in the Full Public Report. The data items were:

- chemical name
- other names
- CAS number
- molecular and structural formulae
- molecular weight
- spectral data
- purity
- identity of toxic or hazardous impurities
- weight percentage of toxic or hazardous impurities
- non-hazardous impurities
- identity of additives/adjuvants
- weight percentage of additives/adjuvants
- polymer constituents
- use and import volume.

NE-8963H is not considered to be hazardous based on the nature of the chemical and the data provided.

Trade Name: NE-8963H

Number-Average Molecular Weight (NAMW): 2 240

Maximum Percentage of Low Molecular Weight Species

Molecular Weight < 500:	5.88
Molecular Weight < 1 000:	12.76

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa: pale yellow powder

Melting Point: 142.0 to 155.0°C (softening point)
60.3°C (glass transition point)
(non-standard test, non-GLP)

Density: 1.185 (non-standard test, non-GLP)

Vapour Pressure: 1.7×10^{-7} Pa at 25°C - vapour pressure balance method
(non-GLP) (European Economic Community (EEC), 1992)

Water Solubility: < 0.35 mg.L⁻¹ at 20°C & pH ~6.5 -
column elution method

(European Economic Community (EEC), 1992)
(Mullee DM and Bartlett AJ, 1997)

Partition Co-efficient (n-octanol/water):	not determined - see comment below
Hydrolysis as a Function of pH:	not measured- see comment below
Adsorption/Desorption:	not determined - see comment below
Dissociation Constant:	not measured - see comment below
Particle size:	< 150 (13.7%) - 2 000 μm 5 - 15 μm (toner product)
Flash Point:	not applicable
Flammability Limits:	not flammable
Autoignition Temperature:	not auto-flammable
Explosive Properties:	non-explosive
Reactivity/Stability:	no oxidising properties based on chemical structure and experience in use
Polydispersity (M_w/M_n):	13.65

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 water solubility has been determined spectrophotometrically to be less than 0.35 mg.L⁻¹ using the column elution method. This is presumed to be the limit of detection.

The polymer contains some 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 was provided as the notifier claims that it is not possible to measure, i.e. according to OECD TG 112, because there is no mode of chemical dissociation for this compound. However, as the polymer molecule may contain a low amount of carboxylic acid functionality, it would be expected to display weakly acidic properties. Also,

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: high

5. USE, VOLUME AND FORMULATION

NE-8963H will not be manufactured in Australia. NE-8963H will be imported as a component of a formulated toner product ready for use in photocopying machines.

The notified polymer will constitute 52% of the imported toner product. Import volumes for the notified chemical are estimated to be less than 1 000 kg for the first year and expected to increase to approximately 4 000 kg over the following four years.

The toner bottles will be interchanged with spent ones in electrophotocopying machines, usually by office staff. The toner bottles are sealed and designed so that no release of the contents can occur till the shipping tape is removed.

6. OCCUPATIONAL EXPOSURE

Toner products containing the notified polymer will be imported in the form of pre-packed bottles, each containing 450 g of toner (234 g of the notified polymer). Waterside, warehouse and transport workers are unlikely to be exposed to the notified polymer unless the packaging were breached.

Office workers and copier maintenance workers may be exposed to the notified polymer contained in the toner products during the operation and/or servicing of photocopier machines. The pre-packed toner bottles are sealed and worker exposure to the contained toner product will be controlled by the use of the replacement procedures recommended by the manufacturer. The toner bottles are designed so that no release of the contents can occur until the seal tape is removed. However, dermal or inhalation exposure may occur if the toner is accidentally spilt while replacing spent toner bottles. Spent toner bottles are expected to retain approximately 10 g of toner. When replenishing the toner, the operator fits the toner bottle into the machine then peels off the seal tape, which allows the transfer of toner contents to storage within the photocopy machine. The particle size of the notified polymer ranges from less than 150 to 2 000 μm . The particle size of the toner product (5 to 15 μm) has been provided in the MSDS. This is within the respirable size range. Given that the notified polymer contains 13.7 % of particle size less than 150 μm , exposure to inspirable and respirable dust is possible. Contact with paper printed with toners containing the notified polymer will result in dermal exposure. However, as the notified chemical will be bound in the structure of the paper such exposure would not result in transfer of the chemical to the skin.

Maintenance workers for photocopiers would experience more frequent contact with the notified chemical. The design of the toner bottles and the fact that the toner powder is separately located within the photocopy machines means that maintenance workers should not become overly contaminated with toner powder during machine servicing.

7. PUBLIC EXPOSURE

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

Residual toner in toner bottles will be disposed of together with spent toner bottles as office wastes. It is estimated that 18 to 90 kg of the notified polymer will be disposed of as uncured toner. Cured toners printed on paper are likely to be disposed of as domestic or office wastes. Public exposure from disposal is expected to be negligible.

8. ENVIRONMENTAL EXPOSURE

Release

The toner product containing the notified polymer is fixed to the paper following application, which offers little potential for release. When the copier requires more toner, the empty bottle is replaced. The exchange process is designed to minimise toner losses. The majority of empty 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 notifier estimates the amount of toner residue remaining in the bottle to be 5 to 10 g of the notified polymer.

The majority of the notified polymer will be associated with the toner, which is strongly bound to the paper. Its release will be associated with the fate of the waste paper.

The notifier claims that filters installed in the copiers prevent leakage to the outside of the machine. Accidental spills 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 products containing the notified polymer (either from a spillage during toner bottle replacement 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 into 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 DW, 1989).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

NE-8963H has been notified under a limited notification category. According to the Act, no toxicological data are required under the limited notification; however, the notifier has provided results of a number of toxicological tests, which are summarised below. The tests were performed on the toner product, containing 52% of the notified polymer, NE-8963H.

Summary of acute toxicity

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	rat	> 2 000 mg.kg ⁻¹	(Sanders A, 1996)
skin sensitisation	guinea pig	non-sensitiser	(Sanders A, 1997)

9.1.1 Oral Toxicity (Sanders A, 1996)

<i>Species/strain:</i>	rat/Sprague-Dawley Crl:CD [®] BR
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	single dose of 2 000 mg.kg ⁻¹ administered by gavage in arachis oil
<i>Clinical observations:</i>	no signs of systemic toxicity observed
<i>Mortality:</i>	nil
<i>Morphological findings:</i>	none
<i>Test method:</i>	similar to OECD guidelines (European Economic Community (EEC), 1993c)
<i>LD₅₀:</i>	> 2 000 mg.kg ⁻¹
<i>Result:</i>	the test material was of very low acute oral toxicity in rats

9.1.2 Skin Sensitisation (Sanders A, 1997)

<i>Species/strain:</i>	guinea pig/Dunkin Hartley
<i>Number of animals:</i>	30/unspecified (20 tests; 10 controls)
<i>Induction procedure:</i>	<u>Test</u> Day 0: <ul style="list-style-type: none">• 50 % concentration of test material in 80% aqueous ethanol applied to the left flank of each test animal by occlusive dressing• patch was held by surgical adhesive tape and covered with aluminium foil• occlusive dressing was removed after 6 hours and test sites decontaminated using diethyl ether Day 7 and 14: <ul style="list-style-type: none">• similar dose as on day 0 applied to the same test area <u>Control</u>

similar topical application procedure using 80% aqueous ethanol alone

Challenge procedure:

Day 28:

- 50 % (w/w) concentration of test material in 80% aqueous ethanol applied to the left flank of test and control animals by occlusive dressing
- 25% (w/w) concentration of test material in 80% aqueous ethanol also was applied to the right flank of test and control animals by occlusive dressing
- patches were held by surgical adhesive tape and covered with aluminium foil
- occlusive dressing was removed after 6 hours and test sites decontaminated using diethyl ether

challenge was evaluated at 24 and 48 hours after dressing removal

Challenge outcome:

<i>Challenge concentration</i>	<i>Test animals</i>		<i>Control animals</i>	
	<i>24 hours*</i>	<i>48 hours*</i>	<i>24 hours</i>	<i>48 hours</i>
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: similar to OECD guidelines (European Economic Community (EEC), 1993b)

Result: the test material was not a skin sensitiser in guinea pigs

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Thompson, 1993)

Strains: *Salmonella typhimurium* TA1535, TA100, TA1537, TA1538, TA98;
Escherichia coli WP2uvrA⁻

Concentration range: 0, 50, 150, 500, 1 500 and 5 000 µg.plate⁻¹ with or without metabolic activation (rat liver S9 mix)

Test method: similar to OECD guidelines (European Economic Community (EEC), 1993d), (European Economic Community (EEC), 1993a)

Result: the test material was not mutagenic in the bacterial strains tested in the presence or absence of metabolic activation

9.4 Other data

The notifier summarised a literature study on chronic inhalation exposure to a commercial toner (Xerox 9000) in rats (Muhle et al, 1991). Nine hundred F - 344 rats of each sex were exposed by inhalation to the commercial toner with respirable size particles of 35% (respirable according ACGIH criteria) for 6 hours per day, 5 days per week for a period of 24 months. The extent of lung fibrosis increased with both duration and exposure to toner. The summary reports mild to moderate lung fibrosis was observed in 92% of rats at a dose of 16 mg/m³ (high dose). At 4 mg/m³ dose (mid dose), 22% of the animals had minimal to mild lung fibrosis. There was no pulmonary change observed at 1 mg/m³ dose (low dose). Muhle et al indicated that the low dose level was most relevant in regard to potential human exposures but did not explain the basis for this assertion. The authors also suggest that the lung

alterations observed in high dose exposure were associated with chronic lung overloading, a generic response of the respiratory system to saturation of its detoxification capacity. The inhalation of the commercial toner and appropriate control materials did not show any signs of overt toxicity. NICNAS obtained the full study for the purposes of this assessment. The above summary is an accurate reflection of the adverse effects seen in the lungs of rats exposed to the commercial toner. Exposure to the toner did not result in an increased frequency of lung tumours, compared with the air only and titanium oxide control groups.

9.5 Overall Assessment of Toxicological Data

There is only limited toxicological data submitted for the notified polymer, NE-8963H. This is acceptable under the requirements for a limited notification. All tests were performed on the toner preparation, which contains 52% of the notified polymer. The product exhibited very low oral acute toxicity in rats with an LD₅₀ greater than 2 000 mg.kg⁻¹. Acute dermal or inhalation toxicity data was not provided for the product. Skin and eye irritation data were also not provided. The product was not a skin sensitiser when tested using a modified Buehler test in guinea pigs. The product was found to be not mutagenic when tested in a bacterial reverse mutation assay.

The toner product containing 52% of the notified polymer would not be classified as hazardous according to the NOHSC Approved Criteria (National Occupational Health and Safety Commission, 1994a), considering only the toxicology information provided by the notifier.

The 24-months inhalation study of a commercial toner (Xerox 9000) with respirable size particles of 35% (respirable according ACGIH criteria), in rat by Muhle et al (1991) indicated that the lowest dose where lung fibrosis was seen was 4 mg/m³. There was no pulmonary change observed in animals treated with 1 mg/m³. The authors also suggest that lung alterations observed in high dose exposure were associated with chronic lung overloading, which is a generic response of the respiratory system to saturation of its detoxification capacity. The inhalation of the commercial toner did not result in any signs of overt toxicity or increased frequency of lung tumours, when compared to the appropriate control animals.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicology data were provided, which is acceptable for polymers of NAMW > 1000 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. 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 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.

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

Waterside, warehouse and transport workers will only be exposed to the notified polymer in the event of an accident or damage to packaging. The occupational health risk to these workers is negligible, particularly considering the physico-chemical properties of the notified chemical and the low hazard presented by the toner product containing the notified polymer.

Office workers may need to handle the notified chemical within the container when replacing the spent toner powder. The design of the toner bottles is such that exposure to the notified polymer should be minimal when undertaking this task; however, some dermal or inhalation exposure may occur if toner is accidentally spilt. Maintenance workers regularly servicing office machines may frequently come in contact with small amounts of residual toner. In general however, the separate location of toner and the design of toner bottles should control incidental contact. Should either office workers or maintenance workers come into contact with the toner product or notified polymer, the risk of adverse health effects is low. Firstly, the chemical has a large molecular weight, therefore absorption across biological membranes would be limited. The toner product containing the notified polymer was not a skin sensitizer when tested using a modified Buehler test in guinea pigs. There may be low levels of toner dust in the immediate vicinity of photocopy machines when the machines are operating. Inhalation of the notified chemical (with 13.7 % of particle size less than 150µm) is possible but is expected to be minimal. Separate transfer of the notified polymer from paper to the skin is not expected to occur once the toner is bound in the structure of the paper after the copying process.

The notifier submitted a summary of a 24-month study of chronic inhalation exposure to commercial toner (Xerox 9000) containing 35% of particles of respirable size (respirable according ACGIH criteria), in rats (Muhle et al, 1991). The summary provided indicates that 92 % of rats had mild to moderate lung fibrosis at 16 mg/m³ dose (high dose) and 22% had

minimal to mild lung fibrosis at 4 mg/m³ dose (mid dose). There was no pulmonary change observed at 1 mg/m³ dose (low dose). Muhle et al indicated that the low dose level was most relevant in regard to potential human exposures but did not provide the basis for assertion. The authors also suggest that the lung alterations observed in high dose exposure were associated with chronic lung overloading, a generic response of the respiratory system to saturation of its detoxification capacity. The inhalation of the commercial toner did not produce signs of overt toxicity or increased frequency of lung tumours outside the control values.

Consequently, based on the low toxicological hazard presented by the chemical and the expected minimal exposure, the health risk posed to office workers and maintenance workers by the notified polymer is low.

Some toxicological data was provided in the MSDS for the toner product containing the notified polymer. Carbon black is present in the toner product at a concentration of 1 to 5 %. Should the toner product be formulated in Australia, employers will need to ensure that the exposure standard for carbon black of 3 mg/m³ (TWA) (National Occupational Health and Safety Commission, 1995) is not exceeded. Photocopy machines should be located in well-ventilated areas. It is unlikely that exposure monitoring would be necessary in the normal office environment.

Minimal public exposure is expected to occur during transport, handling or use, or from disposal. The general public may come in contact with cured toner on photocopied paper. However, the cured toner is bound strongly to the paper and the notified polymer is not expected to be dermally absorbed.

13. RECOMMENDATIONS

To minimise occupational exposure to NE-8963H the following guidelines and precautions should be observed:

- Work areas around the photocopy machines should be well ventilated. Workers using the product should implement good work practices to avoid spillage or the generation of dusts;
- Spillages should be cleaned up promptly and placed into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion; and
- A copy of the Material Safety Data Sheet (MSDS) for NE-8963H and/or information about the toners containing NE-8963H should be easily accessible to employees.

Employers need to ensure that the exposure standard for carbon black of 3 mg/m³ (TWA) (National Occupational Health and Safety Commission, 1995), which is a component of the toner product, is not exceeded in the workplace.

14. MATERIAL SAFETY DATA SHEET

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

This MSDS was provided by the applicant as part of the notification statement. It is 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

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Thompson P (1993) LR-147: Reverse Mutation Assay 'Ames Test' Using *Salmonella typhimurium* and *Escherichia coli*, Project No. 256/53, SafePharm Laboratories Limited, UK.