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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

NT-21

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**Director
Chemicals Notification and Assessment**

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FULL PUBLIC REPORT**NT-21****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Canon Australia Pty. Ltd (ABN 66 005 002 951)
PO Box 313 North Ryde NSW 1670

NOTIFICATION CATEGORY

Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Part B: Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae,
Molecular Weight, Spectral Data.

Part D: Identity and Composition of Polymer, Degradation Products and Loss of Monomers, Other
Reactants, Additives, Impurities.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Hydrolysis as a function of pH, Dissociation constant, and Flashpoint

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Not applicable

NOTIFICATION IN OTHER COUNTRIES

Japan and USA (March 1994).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

NT-21

3. COMPOSITION

Details of the composition of the notified polymer have been exempted from publication in the full public report.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

The notified polymer will be imported as a component (binder resin) of a toner formulation in sealed plastic bottles and cartridges. The notified polymer will not be manufactured in Australia.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

| Year | 1 | 2 | 3 | 4 | 5 |
|--------|------|--------|--------|--------|--------|
| Tonnes | 1-10 | 10-100 | 10-100 | 10-100 | 10-100 |

USE

A component (40-60%) of a toner formulation for use in photocopying machines or graphic printers.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY

Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS

Canon Australia Pty. Ltd

TRANSPORTATION AND PACKAGING

The notified polymer will be transported and distributed as a component of an end-use product in sealed plastic bottles and cartridges. No repackaging will occur in Australia.

5.2. Operation Description

No manufacturing, reformulation, filling or refilling of containers will be carried out in Australia. The toner is mainly used in office copying and printing. For replacement of toner, the toner bottle is to be fitted firmly to the copying machine, and the shutter open to allow the transfer of the toner into the machine. To change the cartridge, after removing the seal-tape the cartridge is inserted into the copying machine or printer.

5.3. Release

RELEASE OF CHEMICAL AT SITE

Not applicable

RELEASE OF CHEMICAL FROM USE

Release of the toner containing the notified polymer to the environment is not expected under normal use as the cartridge is designed to prevent leakage. However, if leakage does occur, the toner will be contained and disposed of in landfill. Environmental exposure will result from the disposal of printed paper and discarded cartridges as well as the possibility of accidental leakage of the cartridges during use. Toner residues contained in the empty cartridges are expected to be about 2% of the import volume (up to 2 tonnes per annum) and to remain within these containers, although release could occur from deterioration of the cartridge. The total import volume of the notified polymer will ultimately be disposed of either in landfill or be incinerated or recycled with paper.

5.4. Disposal

The notified polymer, toner bottles and cartridges are disposed of either in landfill or by incineration subject to federal, state and local laws.

6. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa

White powder with no specific odour.

MELTING RANGE

83.9-88.9 ± 0.5°C

METHODS

OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.

Remarks

By the capillary method

TEST FACILITY

SafePharm Laboratories Limited, UK (2001a)

DENSITY

1.17 x 10³ kg/m³ at 20.5 ± 0.5°C

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks By a gas comparison pycnometer.
TEST FACILITY SafePharm Laboratories Limited, UK (2001a)

VAPOUR PRESSURE < 0.53 kPa at 25°C

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Linear regression analysis was used to calculate vapour pressure at 25 °C. The low value indicates that the notified chemical is classified as being very slightly volatile.
TEST FACILITY SafePharm Laboratories Limited, UK (2001b)

WATER SOLUBILITY < 1.3 x 10⁻³ g/L at 20.0 ± 0.5°C

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks By visual assessment using a modified flask method. The notified polymer is classified as being slightly soluble which is consistent with its predominantly hydrocarbon structure.
TEST FACILITY SafePharm Laboratories Limited, UK (2001a)

HYDROLYSIS AS A FUNCTION OF PH No data available.

Remarks Due to the negligible water solubility of the notified polymer and the absence of a satisfactory method for analysis for such aqueous samples.

PARTITION COEFFICIENT (methanol/water) > 1.59 x 10⁶ log Pow > 6.20 at 30°C

METHOD OECD TG 117 Partition Coefficient (n-octanol/water), HPLC Method.
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks The retention time was longer than that of the reference standard DDT. The low water solubility is consistent with the high log P_{ow}, indicating a very high affinity for the organic component of soils and sediments.
TEST FACILITY SafePharm Laboratories Limited, UK (2001a)

ADSORPTION/DESORPTION (via QSAR calculation) Koc > 2.59 x 10³, log Koc > 3.41, calculated from
log Koc = 0.47 log Pow + 0.5 (alcohols, organic acids)
log Koc = 0.49 log Pow + 1.05 (esters)

METHOD EC Directive 93/67/EEC Risk Assessment for New Notified Substances.
Remarks With a high log Koc, the notified polymer is classified as being immobile in soil.
TEST FACILITY SafePharm Laboratories Limited, UK (2001a)

DISSOCIATION CONSTANT 3.33-4.5 (carboxylic acids)
12.76-14.63 (alcohols)

Remarks No test is conducted due to the negligible water solubility of the notified polymer.
The above ranges are estimated for the polymer using the specialist computer software.

PARTICLE SIZE

METHOD EC TG Particle Size Distribution/Fibre Length and Diameter Distribution

| Range (µm) | Mass (%) |
|------------|--------------------------------|
| < 100 | 12.8 (Sieve method) |
| < 10 | 10.7 (Cascade Impactor method) |

Remarks The results indicate that the proportion by mass of particles which, if inhaled, can be expected to achieve an alveolar deposition in man of 10.7%.

TEST FACILITY SafePharm Laboratories Limited, UK (2001a)

FLASH POINT Not applicable

Remarks The notified polymer is a solid.

FLAMMABILITY LIMITS Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).

Remarks The notified polymer failed to support combustion in the preliminary screening test.

TEST FACILITY SafePharm Laboratories Limited, UK (2001c)

AUTOIGNITION TEMPERATURE None below its melting temperature

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.

Remarks The notified polymer was heated in an oven up to 100°C (approx 10°C higher than the melting temperature).

TEST FACILITY SafePharm Laboratories Limited, UK (2001c)

EXPLOSIVE PROPERTIES Not determined

Remarks No test was conducted as the result could be predicted negative based on the chemical structure.

REACTIVITY Not determined

Remarks No test was conducted as the result could be predicted negative based on the chemical structure.

7. TOXICOLOGICAL INVESTIGATIONS

7.1. Acute toxicity – oral

TEST SUBSTANCE NT-21

METHOD OECD TG 423 Acute Oral Toxicity - Acute Toxic Class Method.

EC Directive 96/54/EC B.1 tris Acute Toxicity (Oral).

Species/Strain Rat/Sprague-Dawley CD

Vehicle Arachis oil BP

Remarks - Method

RESULTS

| <i>Group</i> | <i>Number and Sex of Animals</i> | <i>Dose mg/kg bw</i> | <i>Mortality</i> |
|--------------|--------------------------------------|--------------------------|------------------|
| 1 | 3 females | 2000 | 0 |
| 2 | 3 males | 2000 | 0 |

LD50 > 2500 mg/kg bw

Signs of Toxicity None

Effects in Organs None

Remarks - Results

CONCLUSION The notified polymer is of low toxicity via the oral route.

TEST FACILITY SafePharm Laboratories Limited, UK (2001d)

7.2. Irritation – skin

TEST SUBSTANCE NT-21

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals Three
Vehicle Distilled water
Observation Period 72 hours
Type of Dressing Semi-occlusive
Remarks - Method 4 hour exposure

RESULTS

| <i>Lesion</i> | <i>Mean Score* Animal No.</i> | | | <i>Maximum Value</i> | <i>Maximum Duration of Any Effect</i> | <i>Maximum Value at End of Observation Period</i> |
|------------------------|-----------------------------------|---|---|----------------------|---|---|
| | 1 | 2 | 3 | | | |
| <i>Erythema/Eschar</i> | 0 | 0 | 0 | 0 | 0 | 0 |
| <i>Oedema</i> | 0 | 0 | 0 | 0 | 0 | 0 |

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results A primary irritation index is 0.

CONCLUSION The notified polymer was classified as non-irritant to rabbit skin.

TEST FACILITY SafePharm Laboratories Limited, UK (2001e)

7.3. Irritation – eye

TEST SUBSTANCE NT-21

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals Three
Observation Period 72 hours
Remarks - Method The pH of a 10% w/w aqueous solution of ST593MO was 9.2.

RESULTS

| <i>Lesion</i> | <i>Mean Score* Animal No.</i> | | | <i>Maximum Value</i> | <i>Maximum Duration of Any Effect</i> | <i>Maximum Value at End of Observation Period</i> |
|-------------------------------|-----------------------------------|---|---|--------------------------|---|---|
| | 1 | 2 | 3 | | | |
| <i>Conjunctiva: redness</i> | 0 | 0 | 0 | 1 | 1 hour | 0 |
| <i>Conjunctiva: chemosis</i> | 0 | 0 | 0 | 1 | 1 hour | 0 |
| <i>Conjunctiva: discharge</i> | 0 | 0 | 0 | 1 | 1 hour | 0 |
| <i>Corneal opacity</i> | 0 | 0 | 0 | 0 | -- | 0 |
| <i>Iridial inflammation</i> | 0 | 0 | 0 | 0 | -- | 0 |

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results Minimal conjunctival irritation with cream coloured residual test material was noted in all treated eyes one hour post treatment.

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY SafePharm Laboratories Limited, UK (2001f)

7.4. Genotoxicity - bacteria

| | |
|-----------------------------|--|
| TEST SUBSTANCE | NT-21 |
| METHOD | Japanese OH&S Law. Standards for mutagenicity test using microorganisms. |
| Species/Strain | <i>S. typhimurium</i> : TA100, TA1535, TA98, TA1537. <i>E. coli</i> : WP2 uvrA (pKM101). |
| Metabolic Activation System | Rat liver microsome S9 fraction. |
| Concentration in Test 1 | a) With metabolic activation: 19.53-5000 µg/plate. b) Without metabolic activation: 19.53-5000 µg/plate. |
| Concentration in Test 2 | a) With metabolic activation: 9.77-5000 µg/plate. b) Without metabolic activation: 625-10000 µg/plate. |
| Concentration in Test 3 | a) With metabolic activation: 312.5-5000 µg/plate. b) Without metabolic activation: 312.5-10000 µg/plate. |
| Vehicle | DMSO |
| Remarks - Method | Test 2 was conducted with TA1537 only. |

RESULTS

| <i>Metabolic Activation</i> | <i>Cytotoxicity</i> | <i>Test Substance Concentration (µg/plate)</i> | <i>Resulting in:</i> |
|-----------------------------|---------------------|--|--|
| | | <i>Precipitation</i> | <i>Genotoxic Effect</i> |
| <i>Present</i> | | | |
| Test 1 | Not observed | Not observed | A slight increase beyond spontaneous reversion (TA1537: 19.53-312.5 µg/plate) |
| Test 2 | Not observed | Not observed | Not observed |
| Test 3 | Not observed | Not observed | Not observed |
| <i>Absent</i> | | | |
| Test 1 | Not observed | Not observed | Twofold increase beyond spontaneous reversion (TA1537: 312.5-5000 µg/plate) |
| Test 2 | Not observed | Not observed | Not observed |
| Test 3 | Not observed | Not observed | Not observed |

Remarks - Results

CONCLUSION The notified polymer was non-mutagenic to bacteria under the test conditions.

TEST FACILITY Canon Inc., Japan (2001)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted which is acceptable for limited notifications.

8.1. Environmental effects

No results or test reports were submitted which is acceptable for limited notifications.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Release of the toner containing the notified polymer to the environment is not expected under normal use as the cartridge is designed to prevent leakage. However, if leakage does occur, the

toner will be contained and disposed of in landfill. Environmental exposure will result from the disposal of printed paper and discarded cartridges as well as the possibility of accidental leakage of the cartridges during use. Toner residues contained in the empty cartridges are expected to be about 2% of the import volume and to remain within these containers, although release could occur from deterioration of the cartridge. The total import volume of the notified polymer will ultimately be disposed of in either landfill or be incinerated or recycled with paper.

Some waste paper may be disposed of directly to landfill with the notified polymer strongly bound to the paper. It is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified substance. Incineration of waste paper will destroy the compound with the generation of water vapour and oxides of carbon.

In addition to landfill, some of the toner printed on paper will enter 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. De-inking wastes are expected to go to trade waste sewers. Trade sources estimate the washing process will recover 30-60% of the total amount of toner and therefore at least 30% of the notified chemical in the recycled paper will be disposed of with sludge in landfill. The substance is not expected to bioaccumulate due to its high molecular weight and limited release to water (Connell 1990).

9.1.2. Environment – effects assessment

Not relevant as the data is not required by the Act and there will be limited release to the aquatic compartment.

9.1.3. Environment – risk characterisation

The notified polymer will enter environmental compartments indirectly by disposal of waste paper (for recycling, to landfill or for incineration) and by direct release from discarded printer cartridges at landfill sites. Based on the import volume, method of packaging and low concentration of the notified chemical in printer ink, release of the notified chemical to the environment is expected to be low but widespread. Waste from the recycling process includes sludge which is dried and disposed of to landfill, and very little of the notified chemical will partition to the supernatant water which is released to the sewer.

Abiotic or slow biotic processes are expected to be largely responsible for the degradation of the notified chemical as it is unlikely to be readily biodegradable. As a consequence of its low water solubility, the notified chemical is likely to be immobilised through adsorption onto soil particles and sediments.

Releases to the sewer will be low because very little of the notified chemical is expected to reach water and partition to supernatant water. Furthermore, the substance is not expected to bioaccumulate due to its high molecular weight and limited release to water.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and storage workers are unlikely to be exposed to the notified polymer under normal circumstances as it will be imported as a toner component contained within plastic bottles or cartridges that are designed not to release the toner until the seal tape is removed.

Office workers may come into contact with small amounts of toner containing the notified polymer when replacing cartridges and toner bottles. Dermal exposure would be the main route of exposure. Minimal inhalation and ocular exposure may occur if low levels of toner are present around operating printing equipment.

Printer service personnel may be dermally exposed to minimal amounts of toner dust while cleaning the inside and exterior of printer units. Exposure by inhalation may also occur, although the amount of dust around printers is expected to be minimal. The service personnel

are trained in servicing techniques and often wear disposable gloves during servicing machines.

There will be frequent and widespread worker contact with paper printed with the toner containing the notified polymer. However, the polymer once fixed to the paper as part of the toner product will not be bioavailable.

9.2.2. Public health – exposure assessment

The notified polymer will be imported only as an ingredient of toner powder for copying and printing machines. The toner powder is sealed in toner bottles or cartridges for consumer use. Upon use a toner bottle or cartridge is inserted directly into the appropriate machine. Members of the public may be exposed to the toner containing the notified polymer following transport accidents involving breakage of the toner bottles or cartridges or following environmental contamination or during the recycling of cartridges. Such exposure is unlikely. Exposure may also occur following accidental spillage of toner powder when replacing spent bottles or cartridges. This type of exposure, although more likely to occur, is not expected to be common or involve anything more than very small amounts of toner powder. During printing or copying, the toner powder will be fixed to paper by heat. The notified polymer on printed paper is likely to be inaccessible to human contact. The potential for public exposure is therefore minimal.

9.2.3. Human health - effects assessment

The notified polymer is of low toxicity via the oral route ($LD_{50} > 2500$ mg/kg). It is not irritant to rabbit skin. It is slightly irritant to the rabbit eye. It is not mutagenic to bacteria in the reverse mutation bacterial assay using four strains of *S typhimurium* and one of *E coli* at concentrations of up to 10000 µg/plate, with or without metabolic activation.

SUMMARY OF TOXICOLOGICAL INVESTIGATIONS

| <i>Endpoint and Result</i> | <i>Assessment Conclusion</i> |
|---|------------------------------|
| Rat, acute oral $LD_{50} > 2500$ mg/kg bw | low toxicity |
| Rabbit, skin irritation | non-irritating |
| Rabbit, eye irritation | slightly irritating |
| Genotoxicity - bacterial reverse mutation | Non mutagenic |

9.2.4. Occupational health and safety – risk characterisation

The occupational health risk to transport and storage workers is considered to be negligible, as they will be only be exposed to the notified polymer in the event of an accident or damage to packaging.

Office workers are not expected to come into contact with the notified polymer under normal circumstances. Design of the toner cartridges and bottles are such that exposure to the notified polymer should be minimal. Minor dermal exposure may occur during changing of toner cartridges if a small quantity of toner is present around the printer. There may be a low level of toner dust in the immediate vicinity of printers when they are operating, although inhalation and eye exposure to the notified polymer is expected to be low. Exposure to the notified polymer is not expected to occur once the toner is bound to paper. Based on the expected low toxicity of the polymer and the expected low exposure, the health risk posed to office workers is negligible. Employers are responsible for maintaining the NOHSC exposure standard for nuisance dust of 10 mg/m³ TWA (NOHSC, 1995).

Maintenance workers may be exposed to the toner dust repeatedly when servicing photocopiers and printers. Exposure is anticipated predominantly by the dermal route, hence the wearing of cotton or disposable gloves is recommended. They are also likely to encounter inhalation exposure to dust containing approximately 10% respirable particles. It is recommended that printers/photocopiers be placed in well-ventilated areas. Given the training they receive, the low anticipated toxicity of the notified polymer and PPE worn, the risk of adverse health effects is likely to be low.

9.2.5. Public health – risk characterisation

Public exposure to the toner powder containing the notified polymer following transport accidents, environmental contamination or the recycling of bottles and cartridges is unlikely. Public exposure to the toner powder during the replacement of spent bottles or cartridges is more likely but is not expected to be common. Contact with the notified polymer on printed paper is likely to be negligible. Exposure is most likely to be dermal but ocular or respiratory contact is also possible. Exposure is likely to be of an infrequent or transient nature. The very low likelihood of contact with the notified polymer and the low toxicity of the notified polymer suggest that the notified polymer will not pose a significant hazard to public health when used in the proposed manner.

10. CONCLUSIONS

10.1. Environment

On the basis of the available information, the polymer is not considered to pose a risk to the environment when used in the reported pattern.

10.2. Health hazard

Based on the available data the notified polymer is not classified as hazardous under the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC, 1999).

10.3. Human health

10.3.1. Human health – Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Human health – public

There is Negligible Concern to public health when used in the proposed manner.

11. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure to the new toner product containing the notified polymer:
 - Adequate induction and training programs for service personnel.
- Employers should ensure that the following personal protective equipment is used by maintenance workers to minimise occupational exposure to the new toner product:
 - Wearing of cotton or disposable gloves when servicing printers or removing spent cartridges.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Employers are responsible for maintaining dust levels around printers and photocopiers below the NOHSC exposure standard for nuisance dust of 10 mg/m³ TWA. Printers and photocopiers should be located in well-ventilated areas.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of either through recycling, landfill or incineration.

Emergency procedures

- Spills/release of the notified polymer should be contained as described in the MSDS (ie sweep onto paper and transfer to a sealable waste container) and the resulting waste is disposed of in landfill.

11.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

12. MATERIAL SAFETY DATA SHEET

The MSDS for the toner product which contains 40-60% of the notified polymer was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

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.

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SafePharm Laboratories Ltd (2001d) Acute oral toxicity in the rat – acute toxic class method (Project number 1091/037). Derby, UK. (Unpublished report submitted by Canon Inc)

SafePharm Laboratories Ltd (2001e) Acute dermal irritation in the rabbit (Project number 1091/038). Derby, UK. (Unpublished report submitted by Canon Inc)

SafePharm Laboratories Ltd (2001f) Acute eye irritation in the rabbit (Project number 1091/039). Derby, UK. (Unpublished report submitted by Canon Inc)