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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

NT-19

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Ageing.

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Chemicals Notification and Assessment

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FULL PUBLIC REPORT**NT-19****1. APPLICANT**

HP Australia Pty Ltd of 31-41 Joseph Street, Blackburn 3130 (ABN 74 004 394 763), has submitted a [limited](#) notification statement in support of their application for an assessment certificate for **NT-19**.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and details of the polymer composition have been exempted from publication in the Full Public Report and the Summary Report.

3. PHYSICAL AND CHEMICAL PROPERTIES

Tests were performed according to EEC/OECD Test Guidelines (SafePharm Laboratories Limited, 2001a, 2001b and 2000). Studies were conducted using ST 427 (identical to NT-19) in accordance with Good Laboratory Standards published as OECD principles on Good Laboratory Practice.

Appearance at 20°C & 101.3 kPa: Pale yellow crystalline solid with no specific odour

The toner is formed as a fine black powder

Melting point Decompose from approximately 58.6-65.5°C

Boiling Point: > 374.6°C at 101.32 kPa (see comments below)

Relative Density: 1.18 at 21 ± 0.5 °C (see comments below)

Vapour Pressure: < 2.5 x 10⁻⁴ Pa at 25°C (see comments below)

Water Solubility: 0.46 mg/L (at 20 ± 0.5°C) (See comments below)

Partition Co-efficient (n-octanol/water): log P_{ow}>10 (see comments below)

Hydrolysis as a Function of pH: Not determined (see comments below)

Adsorption/Desorption:	Log K_{oc} > 6.0
Particle size distribution	Proportion of material less than 100µm is 4.67% (Sieve method)
Dissociation Constant:	Not determined (see comments below)
Flash Point:	Not applicable for solids
Flammability Limits:	Not highly flammable (EC method A.10)
Autoignition Temperature:	None below 400°C (EC method A.15)
Explosive Properties:	Non-explosive (EC method A.14)
Reactivity/Stability:	Oxidising Properties: Non-oxidising (EC method A.17)

3.1 Comments on Physico-Chemical Properties

The boiling point of the notified polymer was determined in accordance with OECD Test Guideline 103 by differential scanning calorimetry (SafePharm Laboratories, 2001a). Decomposition or incomplete vaporisation of the polymer was suspected during the test; therefore, the boiling point of the polymer or some component of it was estimated by the computer software MPBP for Windows version 1.31 to be greater than 400°C.

The relative density of the notified polymer was determined in accordance with OECD Test Guideline 109 by the gas comparison pycnometer method (SafePharm Laboratories, 2001a).

The vapour pressure of the notified polymer was determined according to OECD Test Guideline 104 by the vapour pressure balance (SafePharm Laboratories, 2001b). The notified polymer is classified as slightly volatile (Mensink *et al.*, 1995).

The water solubility of the notified polymer was determined in accordance with OECD Test Guideline 105 by the flask method (SafePharm Laboratories, 2001a). The notified polymer may be regarded as slightly soluble in water (Mensink *et al.*, 1995).

The hydrolysis potential of the notified polymer was not determined due to its low solubility in water and common organic solvents including tetrahydrofuran and dimethylformamide. The polymer contains ester groups that have the potential for hydrolysis but are not expected to hydrolyse under normal environmental conditions (pH 4-9) due to the low water solubility.

The notifier was not able to provide the partition coefficient for the polymer due to its negligible solubility in n-octanol, water and reverse phase HPLC solvents. The partition coefficient was therefore estimated using computer software KOWWIN version 1.65.

The adsorption/desorption properties of the notified polymer were not determined by the OECD test method because it is not soluble in HPLC solvents. The notifier has provided an estimate of the adsorption coefficient using computer software PCKOCWIN, version 1.66.

The dissociation constant of the notified polymer was not determined due to its negligible water solubility. The notified polymer contains free carboxylic acid groups that are weakly acidic ($pK_a \sim 4$). The notified polymer also contains alcohol groups but these groups would not dissociate under environmental conditions (pH 4-9).

4. PURITY OF THE CHEMICAL

Degree of Purity: >96 %

Hazardous Impurities: <0.2%

**Non-hazardous Impurities
(> 1% by weight):** <2.1%

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

The notified polymer will be used as an ingredient of a toner for electrophoto-copying machine or electrophoto-graphic printer and will be present at 45-55% in toner.

The toner will be imported as consumer product into Australia. The notifier states in the notification dossier that there is no intention of importing the notified polymer at 100% or manufacturing the toner. It is to be imported in toner cartridges (300-1500 g) or toner bottles (500-2000 g).

The toner will be sealed up in a particular plastic bottle or cartridge outside Australia. The toner bottle is designed so that toner will not be released until the shutter or the seal tape is removed.

During copying or printing operation, the toner will be transferred on to the paper and firmly fixed by heat.

It is estimated that 1-10 tonnes will be imported in the first 12 months and 10-100 tonnes per year over the following four years.

6. OCCUPATIONAL EXPOSURE

The notified polymer is a component of an imported toner product (45-55% in toner), which is in powder form. The mean particle size is 5-10 μm (range 1-30 μm). No reformulation or repackaging will take place. Waterside, warehouse and transport workers are unlikely to be exposed to the notified chemical unless the packaging is breached.

The toner is mainly used in the offices for copying or printing. Airborne generated dust, including dust toner, around the printer may occur.

Inhalation, ocular or dermal exposure to the toner may occur during toner replacement, particularly in the event of a container leak or spill. More commonly, occasional dermal exposure to toner residues inside the machine may occur during machine servicing or paper feed problems.

Office workers and machine maintenance workers may be intermittently exposed to the notified polymer contained in the plastic toner bottle or cartridge when replacing the spent container, and during repair maintenance and cleaning of printers or photocopiers. Maintenance workers for printers or photocopiers may potentially come in contact with the notified polymer more often than office workers. Exposure is expected to be controlled through the design of the cartridges or bottles and the printing or photocopying machines. Printer or photocopier maintenance personnel often wear cotton disposable gloves. Pre-packed cartridges or bottles are sealed and worker exposure to the toner is minimised by the use of the replacement procedures recommended by the manufacturer.

Service personnel are trained for handling toner, and maintains a service manual.

Contact with paper printed with toner containing the notified polymer is unlikely to result in dermal exposure, as it will be bound in the structure of the paper.

7. PUBLIC EXPOSURE

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. However, such exposure is unlikely.

Inhalation, ocular or dermal exposure to the public during use is expected to be minimal but widespread and would include changing toner bottles, attending to minor faults and handling printed matter; accidental exposure to the notified polymer due to spillage of toner powder when replacing spent bottles or cartridges is not expected to be common or involve anything more than very small amounts of toner powder. More commonly, dermal exposure to toner residues inside the machine may occur on an infrequent basis during machine servicing or paper feed problems. During printing or copying, the toner paper will be fixed to paper by heat. These considerations indicate that public exposure is therefore minimal.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Transport

The notified polymer is contained in sealed cartridges or bottles designed to prevent release of the toner until it is required for use; therefore losses during transport should not occur.

End Use

The notifier does not anticipate release of the polymer during replacement of spent toner

bottles or cartridges. However, accidental spillage during this activity could result in toner waste being disposed of to landfill or incineration.

Release to the environment will result from the disposal of the spent cartridges and bottles. The toner residue in spent cartridges varies from 5-15% of the initial 300-1500 g capacity. For bottles, the toner residue varies from 1-5% of the 500-2000 g capacity. A proportion of the spent bottles and cartridges will be recycled. To estimate release, a case is assumed in which cartridges will be imported with a concentration of polymer in the toner of 55%, a residue of toner in the spent cartridge of 5%, and none of the cartridges recycled. According to this scenario some 5.0 tonnes of the notified polymer could be released per annum to landfill. This release would also be widely dispersed because the toner would be used throughout Australia.

Recycling and Disposal

The majority of the notified polymer released to the environment will be bound to paper during printing and photocopying. The waste paper generated will either be recycled or disposed of to landfill/incineration. According to current paper recycling trends in Australia, 70-92% of waste paper will be recycled (Australian Environmental Review, 2001). The recycling process involves repulping the waste paper and treating the pulp with alkalis, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. The de-inking of paper during this treatment is 30-60% efficient for inkjet/photocopying. Therefore a proportion of notified polymer will be released during paper recycling process as waste.

8.2 Fate

The majority of the notified polymer contained in the imported toner will be cured onto paper during photocopying and printing. Therefore the fate of most of the polymer will be determined by paper recycling trends in Australia. Given that 70-92% of waste paper is recycled (Australian Environmental Review, 2001) most of the polymer bound to paper waste will be subjected to this process. During paper recycling removal of the toner is 30-60% efficient. Thus a proportion of the polymer will be released into the waste water. Given the low solubility of the notified polymer it would be expected to partition with the sludge and be removed during waste-water treatment. Sludge from the waste water treatment would be disposed of to landfill where the notified polymer is expected to remain immobile until it eventually degrades through abiotic and biotic processes. The remainder of the notified polymer will be bound to the paper pulp and become integrated into the recycled paper.

The remainder of the paper to which the notified polymer is bound will be disposed of directly landfill or incineration. In landfill the notified polymer will eventually degrade through abiotic and biotic processes. Any incineration of waste paper to which the notified polymer is bound will destroy the polymer resulting in the production of water vapour and oxides of carbon.

Up to 5.0 tonnes per annum of the notified polymer could be disposed of to landfill as residue on spent toner cartridges. The poor water solubility of the notified polymer suggests that it will associate with the organic compartment if released to the environment, when spent cartridges are destroyed in landfill.

The notified polymer is not expected to bioaccumulate given its high molecular weight

(Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

No acute or repeat dose toxicity studies were submitted for assessment on the notified chemical. NT 19 was tested for mutagenicity using *Salmonella typhimurium* (TA98 and TA100) mutagenicity study.

9.4 Genotoxicity

9.4.1 Genotoxicity-Bacteria

TEST SUBSTANCE	NT-19
METHOD	Test methods of Japanese Occupational Safety and Health Law (according to 'Standards for mutagenicity test using microorganisms')
Species/Strain	TA98 and TA100
Metabolic Activation System	Liver induced by Phenobarbital and 5,6-benzoflavon (microsomal fraction, S9)
Concentration Range in Main Test	Expt (1): With and without metabolic activation: 19.53, 78.13, 312.5, 1250 and 5000 µg/plate. Expt (2): With and without metabolic activation: 312.5, 625, 1250, 2500 and 5000 µg/plate. Expt (3): (TA 98) with metabolic activation: 78.13, 156.25, 312.5, 625, 1250, 2500 and 5000 µg/plate.
Vehicle	Dimethyl sulphoxide
Remarks - Method	Two plates for each dose were used in the experiments.
RESULTS	
Remarks - Results	The number of revertant colonies in treated plates was less than twice that of the negative controls with and without S9 mix. Growth inhibition (cytotoxicity) was only observed in the second experiment in TA98 strain with S9 mix at 2500 and 5000 µg/plate. Precipitation of the test substance was seen at 1250-5000 µg/plate in each experiment
CONCLUSION	The notified chemical was not mutagenic to bacteria.

REFERENCE

Chemicals Safety Division, 2000: Report of Mutagenicity Test Using Micronucleus (Report No. 634).

9.5 Overall Assessment of Toxicological Data

Studies on acute oral, dermal or inhalation toxicity, skin or eye irritation, skin sensitisation, repeated dose toxicity or *in vivo* genotoxicity were not provided on the notified chemical. The notified chemical was non-mutagenic in an *in vitro* bacterial reverse mutation assay.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of the notified polymer will not be released to the environment until the paper to which it is bound during the printing/photocopying process is disposed directly to landfill or recycled. Paper recycling will release a proportion of the bound polymer to waste water where it is expected to associate with sludge and be disposed of to landfill. In addition a small amount of notified polymer will be disposed of to landfill as residue on spent cartridges or bottles.

In landfill the polymer is expected to associate with the soil and organic matter due to its poor solubility in water. The notified polymer is likely to persist in this environment and remain immobile until it eventually degrades through abiotic and biotic processes. Bioaccumulation of the notified polymer is not expected to occur given its high molecular weight.

Overall, the environmental hazard presented by the introduction of the notified chemical is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard assessment

In the only toxicological data provided, a mutagenicity study conducted using NT-19 was negative. No information was provided on the acute toxicity and topical hazards of the notified polymer.

The notified polymer has a NAMW of greater than 1000, contains low levels of residual monomers and low levels of low molecular weight species. The high molecular weight of the polymer indicates that it would be unlikely to cross biological membranes readily. Therefore, the toxicity of the polymer is anticipated to be low and it is unlikely to be a hazardous substance according to the *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission (NOHSC), 1999).

The technical dossier states that some symptoms coming from exposure of fine powder may be observed such as eye irritation or throat irritation (coughing). Respiratory irritation may occur due to exposure to large amounts of dust generated by the handling of the toner.

The material safety data sheet (MSDS) for the toner stated that minimal respiratory tract irritation may occur due to inhalation of large amounts of dust and that the toner is not classified as hazardous.

It is determined that 4.67% of the notified polymer has a particle size at less than 100 µm, and it is present in the toner at 45-55%. The form of the toner is powder and the average particle size is from 5 – 10 µm (respirable). The toner can be considered a nuisance dust and employers are responsible for maintaining atmospheric levels of toner dust below the NOHSC exposure standard of 10 mg/m³ TWA¹ (NOHSC, 1995). Australia does not have a national exposure standard for respirable dust, however, the ACGIH TLV² is 3 mg/m³ TWA (ACGIH, 2001).

Occupational Health and Safety

Exposure to toner containing the notified polymer can occur during machine operation, during clearing paper feed problems and machine maintenance. Transport and storage of the toner bottles and cartridges is unlikely to result in worker exposure except in the event of accidental spillage.

Office staff performing additions of toner and replacement of a used toner container (cartridge or bottle) are expected to be exposed infrequently to the notified polymer as the toner container is sealed and loaded directly into a printing machine. Upon application to the paper, the toner is fused to the surface and release is unlikely to occur. Therefore, the risk of adverse health effects to office personnel is low and no personal protective equipment is required. Nevertheless, any generation of dust should be avoided.

Service personnel may be exposed to the notified polymer when cleaning printer/copier equipment and replacing copier developer. However, as the polymer is not likely to be hazardous, the risk of adverse health effects is low. Cotton or disposable gloves may be worn to prevent skin irritation and workers should avoid any generation of dust when handling the toner.

It is unlikely that the airborne concentration of toner dust in the workplace would warrant exposure monitoring and specific ventilation.

Spilt residues should be swept up manually or using a dust explosion-proof vacuum cleaner and placed within a waste container.

Given these considerations, the polymer will not pose a significant health hazard in the occupational environment.

Workers handling printed paper are not at risk of adverse health effects because the polymer is fixed to the paper and not available for exposure or dermal uptake.

¹ Time Weighted Average

² Threshold Limit Value

Public Health

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.

13. RECOMMENDATIONS

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

- Avoid generation of dust clouds when handling the toner;
- Service operators should wear cotton or disposable gloves when handling the toner (ie when removing spent cartridges or bottles containing the notified polymer or when servicing printers or photocopiers);
- Spillage of the notified polymer should be avoided. Spillage should be cleaned up promptly with absorbents which should be put into containers for disposal;
- A copy of the appropriate MSDS should be easily accessible to employees.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with State and Territory hazardous Substances regulations must be in operation.

Secondary notification

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

Under Sub-section 64(1) of the Act:

If the conditions of use are varied, then greater exposure of the public may occur. In such circumstances, further information may be required to assess the hazards to public health.

Or

Under Sub-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.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the toner containing 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.

15. REFERENCES

ACGIH, 2001; The American Conference of Governmental Industrial Hygienists (ACGIH): Threshold Limit Values for Chemical Substances and Physical Agents and Biological Indices 2001; ACGIH Cincinnati, Ohio.

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