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## **NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME**

### **FULL PUBLIC REPORT**

**P-102**

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

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

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Director  
Chemicals Notification and Assessment

**FULL PUBLIC REPORT****P-102****1. APPLICANT**

Gestetner Office Systems Pty Ltd of 108 Old Pittwater Road BROOKVALE NSW 2100, has submitted a limited notification statement accompanying their application for an assessment certificate for the polymer, P-102.

**2. IDENTITY OF THE CHEMICAL**

P-102 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, exact molecular weight, molecular and structural formulae, composition data (including spectra) and details of volume of import have been exempted from publication in the Full Public Report and the Summary Report.

<b>Trade name:</b>	P-102
<b>Other names:</b>	Polyester resin
<b>Molecular weight:</b>	> 1,000

**3. PHYSICAL AND CHEMICAL PROPERTIES**

The following data refer to the notified polymer (P-102) and not to the toner product.

<b>Appearance at 20°C and 101.3 kPa:</b>	pale yellow granules
<b>Melting Point:</b>	~ 330°C (softens > 77°C)
<b>Glass-transition Temperature:</b>	77°C to 110°C
<b>Density:</b>	1190 - 1210 kg/m <sup>3</sup> at 20°C
<b>Vapour Pressure:</b>	< 2.3 x 10 <sup>-38</sup> Pa at 25°C (estimated using the modified Watson correlation)
<b>Water Solubility:</b>	0.14 g/L at 20°C
<b>Partition Co-efficient (n-octanol/water) log P<sub>ow</sub>:</b>	> 6 (estimated)

<b>Hydrolysis as a function of pH:</b>	could not be determined (according to existing guidelines)
<b>Adsorption/Desorption:</b>	could not be determined (according to existing guidelines)
<b>Dissociation Constant</b> pKa:	3.8 (estimated)
<b>Flash Point:</b>	not determined
<b>Flammability Limits:</b>	not flammable
<b>Combustion Products:</b>	carbon oxides (various) and water
<b>Pyrolysis Products:</b>	various (as detected by pyrolysis GC-MS)
<b>Decomposition Temperature:</b>	330-350°C
<b>Autoignition Temperature:</b>	> 400°C
<b>Explosive Properties:</b>	none
<b>Reactivity:</b>	has no oxidising properties; no incompatible compounds known
<b>Particle size distribution:</b>	mean - 550µm (96.4% > 200µm)

### **Comments on physico-chemical properties:**

Based on the notified polymer's low water solubility and high (estimated) log  $P_{ow}$  it is likely to adsorb to soil/sediment and organic matter or to be immobile in soils. The level of entry into soil is expected to be low.

The notified polymer is not likely to bioaccumulate in the environment because large polymers of this nature are not readily absorbed by biota.

No data were supplied for hydrolysis, on the grounds that low water solubility prevented testing of this characteristic. The presence of ester linkages in the structure of the polymer indicate that hydrolysis is possible, but this is unlikely under typical environmental conditions.

#### **4. PURITY OF THE CHEMICAL**

**Degree of purity :** >95%

The notified chemical contains no hazardous impurities at levels necessary to classify it as a hazardous substance (1). Therefore, information on the purity of the polymer has been exempted from publication in the Full Public Report and the Summary Report.

**Maximum content of residual monomers:** < 0.1%

#### **5. USE, VOLUME AND FORMULATION**

The notified polymer is a polyester resin to be used as a component of formulated photocopier toner and developer products for use in dry process photocopiers.

The notified polymer will not be manufactured in Australia, but will be imported in formulated developer products. The projected import volume (of the notified polymer) is > 1 tonne per annum for the first 5 years.

#### **6. OCCUPATIONAL EXPOSURE**

Formulated products are imported in ready-to-use sealed cartridges and distributed by road to various establishments throughout the country. Exposure during transportation will result only in the event of accidental spill and damage to cartridges.

There are two categories of workers likely to be exposed to formulated products containing the notified polymer:

- photocopier service engineers involved in the installation and maintenance of dry process photocopiers. Approximately 150-160 service engineers will be involved in these tasks in Australia and will be servicing machines on a daily basis; and
- office workers who add toner to photocopiers *in situ* including workers involved in full time photocopying and machine upkeep. The total number of employees likely to be exposed will be large, depending on the number of machines in use and the quantity of photocopying carried out.

The main exposure to the notified polymer is likely to be from skin contact with the toner product, with little inhalational exposure to airborne dust due to the relatively large particle size (96% > 200µm). The design of the toner cartridge is such that contents are contained in a semi-sealed system. In addition, dry process photocopiers are designed as low maintenance machines, with installation of cartridge taking less than 5 minutes. As such minimal exposure to the notified polymer will occur during cartridge installation operations.

## **7. PUBLIC EXPOSURE**

The notified polymer will be imported into Australia in sealed cartridges. These cartridges are wholly enclosed within a compartment of the photocopier machine. Public exposure is unlikely during cartridge installation. Public exposure is also unlikely during use, as the toner will be heat fixed to paper. Minor public exposure to the notified polymer may result from accidental spillage during transport or disposal of used cartridges as waste. Clean-up of spills and disposal of wastes will be carried out in the appropriate manner by licensed contractors.

## **8. ENVIRONMENTAL EXPOSURE**

### **Release**

The notified polymer is a component of a toner that is contained within a cartridge. When the photocopier requires more toner, the operator removes the toner cartridge and replaces it with another. Therefore, release of the notified polymer under normal conditions of use is expected to be negligible, as practically no waste is generated.

Releases to the environment as a result of accidents (during transport or in the workplace) are expected to be negligible.

The toner cartridge and any spills of toner can be disposed of as domestic waste, in accordance with government regulations (e.g., landfill, incineration).

Releases to the environment may occur through processing of waste paper. This possibility is explored further below.

### **Fate**

Disposal of the notified polymer to landfill is unlikely to result in contamination of surface and ground. Its low water solubility and high log  $P_{ow}$  indicates it is unlikely to leach.

Combustion of the notified polymer in presence of excess air will result in products of oxides of carbon and water.

Unless incinerated, the polymer is likely to arrive in a dispersed manner in landfill bound to waste paper. As such, it will be immobile, and no leaching from landfill would be expected despite the polymer's expected persistence.

Paper recycling is a growing industry in Australia. Wastepaper is repulped using a variety of alkalis, dispersing agents, wetting agents, water emulsifiable organic solvents and bleaching agents. These chemicals enhance fibre separation, ink detachment from the fibres, pulp brightness and whiteness of the paper. After pulping, the contaminants and the ink are separated from the fibres by pumping the stock through various heat washing, screening, cleaning, flotation and dispersion stages. The notifier has provided no data on the likely behaviour of the polymer during the recycling process. The polymer is likely to survive the above conditions,

either remaining bound to the pulp or becoming associated with the sludge. In the latter case, the polymer will either arrive in landfill where it can be expected to remain intact, or be destroyed through incineration. The presence of one acid proton per molecule may produce some acidity in such landfill, however, would be expected to be of low concentration due to the large molecular weight of the compound.

## 9. EVALUATION OF TOXICOLOGICAL DATA

Under the *Industrial Chemicals (Notification and Assessment) Act, 1989*, (the Act), toxicity data are not required for polymers with a NAMW >1,000. Data for acute oral toxicity, skin irritation, sensitisation and mutagenicity in bacteria were supplied and are evaluated below.

### 9.1 Acute Toxicity

**Table 1** Summary of the acute toxicity of P-102

<b>Test</b>	<b>Species</b>	<b>Outcome</b>	<b>Reference</b>
acute oral toxicity	rat	LD <sub>50</sub> > 5000 mg/kg	(1)
skin irritation	rabbit	non-irritant	(3)
skin sensitisation	guinea pig	not sensitising	(4)

#### 9.1.1 Oral Toxicity (2)

*Species/strain:* rat/Sprague-Dawley

*Number/sex of animals:* 5 M, 5 F      *Observation period:* 14 days

*Method of administration:* P-102 in corn oil (250 mg/ml) was administered by gavage at a single dose of 5000 mg/kg

*Clinical observations:* no significant signs of toxicity

*Mortality:* no deaths

*Morphological findings:* no gross lesions observed at necropsy

*Test method:* OECD Guidelines for Testing of Chemicals No 401 (5)

*Result:* LD<sub>50</sub>: > 5000 mg/kg

### **9.1.2 Skin Irritation (3)**

*Species/strain:* rabbit/New Zealand White

*Number/sex of animals:* 3 M, 3 F

*Method of administration:* 0.5 g of test material (moistened with water) was placed under a gauze pad then entire trunk of the animal wrapped in elastic bandage for four hours; test terminated after 72 hours

*Test method:* OECD Guidelines for Testing of Chemicals No 404 (6).

*Draize scores (7):* no scores > 1 for either erythema or oedema up to 72 hours; (See Attachent 1 for Draize Scales)

*Result:* non-irritant

### **9.1.3 Skin Sensitisation (4)**

*Species:* guinea pig

*Number of animals:* 20 test and 20 control animals

*Induction:* a concentration of 25% w/v in paraffin oil was selected for the induction phases; slight to moderate erythema was seen in test group - slight erythema in control group (skin reactions (erythema) were assessed according to a 4 point scale)

*Test Method:* OECD Guidelines for Testing of Chemicals No: 406 (8); the test used was the guinea pig maximisation test of Magnusson and Kligman (9)

*Observations:* When challenged with 25% P-102 (in paraffin oil vehicle), no erythema or oedema was elicited in either test or control animals for up to 48 hours (after patch removal). Two animals died (unrelated to treatment) prior to challenge.

*Result:* not sensitising

## **9.2 Genotoxicity**

### **9.2.1 Salmonella typhimurium Reverse Mutation Assay (10)**

*Strains:* *Salmonella typhimurium* TA 98, TA 100, TA 1535, TA 1537 and TA 1538

*Concentration range:* 33, 100, 333, 1000, 3333 and 10,000 µg/ plate

*Test method:* OECD Guidelines for Testing of Chemicals No: 471 (11); Maron and Ames (12)

*Result:* the notified polymer (dissolved in acetone) did not induce point mutations by base-pair changes, or frameshifts in the genome of any of the five strains used, either with or without metabolic activation (provided by rat liver S9); results obtained from positive control groups were in the normal ranges expected for each bacterial strain

### **9.3 Overall Assessment of Toxicological Data**

The notified polymer exhibited a low acute oral toxicity ( $LD_{50} > 5000$  mg/kg) and was neither a skin irritant nor a skin sensitiser. The notified polymer was not mutagenic (with or without metabolic activation) in *Salmonella typhimurium*. The notified polymer is not classified as a hazardous substance (1) with respect to the available toxicological information.

## **10. ASSESSMENT OF ENVIRONMENTAL EFFECTS**

No ecotoxicological data were provided, which is acceptable for polymers of NAMW > 1000 according to the Act.

The notified polymer is not likely to exhibit toxic characteristics or to bioaccumulate in the environment because large polymers of this nature are not readily absorbed by biota.

## **11. ASSESSMENT OF ENVIRONMENTAL HAZARD**

The low environmental exposure of the polymer as a result of normal use indicates that the overall environmental hazard should be negligible.

Environmental exposure to the notified polymer could occur when paper containing the polymer is recycled or disposed of. In each case, the final destination is likely to be landfill where the polymer can be expected to persist but remain immobile, being either bound to paper or to the sludge from the recycling process.

Accidental spillage of the polymer should result in negligible hazard as it will be marketed in cartridges for direct insertion into photocopier machines.

## **12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS**

No data on effects on humans (for the notified polymer) were available for assessment.

Based on the results of animal studies provided, the polymer is unlikely to present a risk of skin irritation or sensitisation to workers. In addition, adverse systemic effects (from dermal absorption) are unlikely due to the high number-average molecular weight (NAMW) of the notified polymer (which should preclude transmission of



molecules across biological membranes). In addition, the level of residual monomers, impurities and low molecular weight species in the notified polymer are unlikely to present a health hazard. There are no hazardous impurities present in sufficient concentrations to render the polymer hazardous (1).

Although there is a possibility of dust generation during photocopier servicing procedures, < 4% of notified polymer dust is of inspirable size of which < 0.1% is respirable and therefore the notified polymer is unlikely to present a respiratory hazard. Provided atmospheric dust levels are kept below the Worksafe (TWA) exposure standard (13) for nuisance dusts (10 mg/m<sup>3</sup>), exposure standards for hazardous impurities/ingredients in the toner product - Nashuatec Toner Black - will not be exceeded (ie., 3 mg/m<sup>3</sup> (TWA) for carbon black and 0.1 mg/m<sup>3</sup> (TWA) for dibutyltin oxide. Dust levels approaching these standards would however not be expected under normal conditions of use. Chronic effects are similarly unlikely due to the low maintenance requirements for dry process photocopiers.

There exists little possibility for public exposure to the notified polymer during normal use of the photocopier or from exposure to photocopied pages due to the semi-sealed nature of the toner cartridge and the fixing of the toner to paper. Risks of exposure via spillage during transport and disposal will be minimised by adherence to recommended practices.

The risk of adverse occupational or public health effects resulting from transport, storage, disposal or use of the notified polymer is expected to be minimal.

### **13. RECOMMENDATIONS**

To minimise occupational risks from exposure to P-102, the following guidelines and precautions should be observed:

- When changing toner cartridges containing the notified polymer, care should be taken to avoid exposure to the toner adhering to the plastic tape which seals the cartridge. Should exposure occur, the toner should be removed immediately by washing.
- Good industrial hygiene practices should be implemented during storage and handling.
- Atmospheric dust levels should be kept below 10 mg/m<sup>3</sup> (TWA) in accordance with Worksafe exposure standards for nuisance dusts (13).
- If engineering controls and/or work practices are insufficient to reduce exposure to the notified polymer to a safe level, the following personal protective equipment should be used:
  - Respiratory protection should be chosen according to Australian Standard/New Zealand Standard (AS/NZS) 1715 (14) and Australian Standard (AS) 1716 (15).
  - Chemical-type goggles conforming to AS 1336 (16) and AS/NZS 1337 (17).
  - Impervious gloves conforming to AS 2161 (18).
  - Protective clothing conforming to AS 2919 (19).

- A copy of the MSDS for the toner product (Nashuatec Toner Black) and other products containing the notified polymer should be easily accessible to all employees.

#### **14. MATERIAL SAFETY DATA SHEET**

The attached Material Safety Data Sheet (MSDS) for Nashuatec Toner Black (containing the notified polymer) was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (20).

This MSDS was provided by Gestetner Office Systems Pty Ltd as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Gestetner Office Systems Pty Ltd.

#### **15. REQUIREMENTS FOR SECONDARY NOTIFICATION**

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of P-102 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

#### **16. REFERENCES**

1. National Occupational Health and Safety Commission, *Approved Criteria for Classifying Hazardous Substances*, Australian Government Publishing Service, Canberra, Australia, 1994.
2. *Acute Oral Toxicity (Limit) Test in Rats (P-102)*, IRI Report No. 5244, Inveresk Research International Ltd, Scotland, July 1988.
3. *Primary Skin Irritation Test in Rabbits (P-102)*, IRI Report No. 5255, Inveresk Research International Ltd, Scotland, July 1988.
4. *Modified Magnusson-Kligman Maximisation Test in Guinea Pigs (P-102)*, IRI Report No. 5256, Inveresk Research International Ltd, Scotland, July 1988.
5. OECD Guidelines for Testing of Chemicals - Acute Oral Toxicity No: 401, 1987.
6. OECD Guidelines for Testing of Chemicals - *Acute Dermal Irritation/Corrosion No: 404*, 1981.
7. Draize J H. 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US*, **49**, 1959.
8. OECD Guidelines for Testing of Chemicals - *Skin Sensitisation No: 406*, 1981.

9. Magnusson B & Kligman AM. *Allergic Contact Dermatitis in the Guinea-Pig: Identification of Contact Allergens*, published by CC Thomas, Springfield, Illinois, USA. 1970.
10. *Testing for Mutagenic Activity with Salmonella typhimurium in P-102, (TA 1535, TA 1537, TA 1538, TA 98 and TA 100)*. IRI Report No. 4675, Inveresk Research International Ltd, Scotland, July 1988.
11. OECD Guidelines for Testing of Chemicals - *Salmonella typhimurium*, *Reverse Mutation Assay No: 471*, 1983.
12. Maron DM and Ames BN. *Revised methods for the Salmonella mutagenicity test*. Mutation Research, 113: 173-215, 1983.
13. National Occupational Health and Safety Commission, *Exposure Standards for Atmospheric Contaminants in the Occupational Environment*, Australian Government Publishing Service, Canberra, 1995.
14. Australian Standard/New Zealand Standard AS/NZS 1715-1994. *Selection, use and maintenance of respiratory protective devices*, Standards Australia, Sydney.
15. Australian Standard AS 1716-1994. *Respiratory protective devices*, Standards Australia, Sydney.
16. Australian/ New Zealand Standard AS/NZS 1336-1994. *Recommended Practices for Occupational Eye Protection*, Standards Australia, Sydney.
17. Australian Standard AS/NZS 1337-1992. *Eye Protectors for Industrial Applications*, Standards Australia, Sydney.
18. Australian Standard AS 2161-1978. *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Australia, Sydney.
19. Australian Standard AS 2919-1987. *Industrial Clothing*, Standards Australia, Sydney.
20. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets*, Australian Government Publishing Service, Canberra.

## Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

<b>Erythema Formation</b>	<b>rating</b>	<b>Oedema Formation</b>	<b>rating</b>
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising)	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4