

File No PLC/462

18 May 2004

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

FULL PUBLIC REPORT

NT-26

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
National Occupational Health and Safety Commission
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1161 or + 61 2 6279 1163.

This Full Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

**Director
Chemicals Notification and Assessment**

TABLE OF CONTENTS

1.	APPLICANT AND NOTIFICATION DETAILS	Error! Bookmark not defined.
2.	IDENTITY OF CHEMICAL	Error! Bookmark not defined.
3.	COMPOSITION.....	Error! Bookmark not defined.
4.	INTRODUCTION AND USE INFORMATION.....	Error! Bookmark not defined.
5.	PROCESS AND RELEASE INFORMATION.....	Error! Bookmark not defined.
5.1.	Operation Description.....	Error! Bookmark not defined.
6.	EXPOSURE INFORMATION	Error! Bookmark not defined.
6.1.	Summary of Environmental Exposure.....	Error! Bookmark not defined.
6.2.	Summary of Occupational Exposure	Error! Bookmark not defined.
6.3.	Summary of Public Exposure	Error! Bookmark not defined.
7.	PHYSICAL AND CHEMICAL PROPERTIES.....	Error! Bookmark not defined.
8.	HUMAN HEALTH IMPLICATIONS.....	Error! Bookmark not defined.
8.1.	Toxicology.....	Error! Bookmark not defined.
8.2.	Human Health Hazard Assessment.....	Error! Bookmark not defined.
9.	ENVIRONMENTAL HAZARDS.....	Error! Bookmark not defined.
9.1.	Ecotoxicology	Error! Bookmark not defined.
9.2.	Environmental Hazard Assessment	Error! Bookmark not defined.
10.	RISK ASSESSMENT.....	Error! Bookmark not defined.
10.1.	Environment	Error! Bookmark not defined.
10.2.	Occupational health and safety	Error! Bookmark not defined.
10.3.	Public health	Error! Bookmark not defined.
11.	CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS.....	Error! Bookmark not defined.
11.1.	Environmental risk assessment	Error! Bookmark not defined.
11.2.	Human health risk assessment	Error! Bookmark not defined.
11.2.1.	Occupational health and safety.....	Error! Bookmark not defined.
11.2.2.	Public health.....	Error! Bookmark not defined.
12.	MATERIAL SAFETY DATA SHEET	Error! Bookmark not defined.
12.1.	Material Safety Data Sheet	Error! Bookmark not defined.
13.	RECOMMENDATIONS.....	Error! Bookmark not defined.
13.1.	Secondary notification	Error! Bookmark not defined.
14.	BIBLIOGRAPHY	Error! Bookmark not defined.

FULL PUBLIC REPORT**NT-31****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Hewlett-Packard Australia Pty Ltd of 31-41 Joseph St, Blackburn, Victoria, 3130

NOTIFICATION CATEGORY

Synthetic Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Manufacture/Import Volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

No

NOTIFICATION IN OTHER COUNTRIES

No

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

NT-31

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met (yes/no/not applicable)</i>
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
No Substantial Degradability	Yes
Not Water Absorbing	Yes
Low Concentrations of Residual Monomers	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
-------------	----------	----------	----------	----------	----------

<i>Tonnes</i>	30-100	>100	>100	>100	>100
---------------	--------	------	------	------	------

USE

The notified polymer will be used as an ingredient at 70-95% of toner for electrophoto-copying machines or electrophoto-graphic printers.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The toner containing 70-95% notified polymer will be imported, distributed and supplied to consumers in 0.2 to 4 L sealed cartridges or plastic bottles containing between 80 to 2500g of toner.

The toner is mainly used in offices for copying and printing. To refill the toner, the toner bottle is firmly fitted into the copying machine and the shutter opened. To change the cartridge, the seal tape is removed and the cartridge is placed into the copying machine or printer. The toner bottle and cartridge are designed not to release the toner until the shutter is opened or seal tape is removed.

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

6. EXPOSURE INFORMATION

6.1. Summary of Environmental Exposure

The notified polymer is not intended to be manufactured or reformulated in Australia. The toner containing the notified polymer is to be imported, distributed and supplied in Australia in a plastic bottle or cartridge for consumers. The toner bottle/cartridge is installed inside of the machine or printer and designed to prevent access to or leakage of toner. Therefore, no environmental release is expected when the toner bottle/cartridge is replaced.

The paper printed with the toner is deinked during the paper recycling process. The fibre material is refined and used for recycled paper. The toner including the notified polymer is collected as water insoluble sludge during the deinking process. The sludge containing the notified polymer is usually disposed of to landfill or incinerated as waste. The size of the bottle/cartridge and the residual amount remaining in the bottle/cartridge varies on the types of copying machines or printers. A 0.2-4 L cartridge/bottle would have <12.5% residual toner left in the bottle/cartridge. Therefore, the amount of notified polymer remaining corresponds to < 11.9% (<95% x 0.125). Spent bottles/cartridges collected by the recovery system are recycled or reused along with all residual toner in the recycling process. Spent bottles/cartridges that are not recycled are likely to be sent to landfill.

Considering the low water solubility, the polymer is unlikely to hydrolyse in the environmental pH range of 4-9 and should associate with the organic or soil/sediment phases. There are no dissociable groups.

6.2. Summary of Occupational Exposure

Office workers and printer maintenance workers may be intermittently exposed to the notified polymer when replacing the spent cartridge or bottle, and during maintenance and cleaning of printers or photocopiers. Maintenance workers may potentially come in contact with the notified polymer more often than office workers. Exposure would be principally by skin contamination, however, inhalation exposure could also occur, particularly if spillage occurs. The notified polymer consists of a small proportion of inhalable particles (5.5% less than 75µm) but no respirable particles (<10µm). In addition, exposure is expected to be controlled through the design of the toner cartridge or bottles and the printing and photocopier machines. Printer and photocopier maintenance personnel often wear cotton disposable gloves. Toner cartridges and bottles are sealed and worker exposure to the toner is minimised by the use of the replacement procedures recommended by the manufacturer.

Waterside, warehouse and transport workers are unlikely to be exposed to the notified polymer unless the packaging is breached.

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

6.3. Summary of Public Exposure

The public may be intermittently exposed to the notified polymer when replacing the spent cartridge or bottle, and during maintenance and cleaning of home printers or photocopiers. Exposure would be principally by skin contamination, however, inhalation exposure could also occur, particularly if spillage occurs. The notified polymer consists of a small proportion of inhalable particles (5.5% less than 75µm) but no respirable particles (<10µm). Exposure is expected to be controlled through the design of the toner cartridge or bottles and the printing and photocopier machines. Toner cartridges and bottles are sealed and public exposure to the toner is minimised by the use of the replacement procedures recommended by the manufacturer.

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

7. PHYSICAL AND CHEMICAL PROPERTIES

Test reports were provided for the following physico-chemical properties: Melting temperature, relative density, water extractivity, flammability, explosive properties, self-ignition temperature and particle size distribution (Huntingdon, 2003) and stability (Kurume, 2003)

Appearance at 20°C and 101.3 kPa	White Powder
Melting Point/Glass Transition Temp	The notified polymer softens at temperatures above 85 °C, forming a gel at 110 °C, before becoming less viscous from approximately 200°C and decomposing above 290 °C.
Density	900 kg/m ³ at 21°C
Water Solubility	The notified polymer was determined to have water extractivity values of 0.3 and 0.5 mgC/L at the low and high test concentration, respectively, indicating a low water solubility.
Particle Size	% < 75 µm: 5.5 % < 10 µm: 0
Flammability	Not highly flammable
Explosive Properties	Not explosive in thermal, shock and friction tests. Fine powder can form explosive dust-air mixtures.
Self Ignition Temperature	>400 °C
Oxidising Properties	Non-oxidising
Stability Test	Polymer stable in buffer solutions under the test conditions of the range from pH1.2 to pH9
Reactivity	Polymer is not designed to degrade by oxidation, hydrolysis, attack by solvents, heat light, or microbial action. Polymer considered to be stable under the conditions in which it is used.
Degradation Products	Oxides of Carbon

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

Study reports were submitted for the following toxicological end-points:

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>	<i>Reference</i>
Rat, acute oral	low toxicity, LD50 >2500 mg/kg bw	no	no	SafePharm (2003a)
Rabbit, skin irritation	very slightly irritating	no	yes	SafePharm (2003b)

Rabbit, eye irritation	very slightly irritating	no	yes	SafePharm (2003c)
Guinea pig, skin sensitisation – Bühler test.	no evidence of sensitisation.	no	no	RCC (2003)
Genotoxicity - bacterial reverse mutation	non mutagenic	no	no	Canon (2003)

All results were indicative of low hazard.

8.1.1 Discussion of Observed Effects

Rabbit, skin irritation

Very slight erythema was noted at 2 out of 3 treated skin sites one hour after patch removal. The other treated site appeared normal. All treated sites appeared normal at the 24 hour observation.

Rabbit, eye irritation

Minimal conjunctival irritation was noted in 2 out of 3 treated eyes one hour after application of the test material. The other treated eye appeared normal. All treated eyes appeared normal at the 24 hour observation.

8.2. Human Health Hazard Assessment

Acute toxicity.

The notified polymer was of low oral toxicity in an acute rat study.

Irritation and Sensitisation.

The notified polymer was found to be very slightly irritating to skin and eyes in rabbits. The notified polymer was negative in a skin sensitisation test in guinea pigs.

The powder may cause mechanical irritation to the eyes, and to the respiratory tract if inhaled.

Mutagenicity

The notified polymer was negative in an Ames test.

In addition, the notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No toxicological data were submitted.

9.2. Environmental Hazard Assessment

No test results were included for biodegradability or ecotoxicity studies of the notified polymer. Polynonionic polymers which have MW > 1000 are generally of low concern.

10. RISK ASSESSMENT

10.1. Environment

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 bottles/cartridges at landfill sites. The substance is not expected to bioaccumulate due to its high molecular weight. In landfills abiotic or slow biotic processes are expected to be largely responsible for the degradation of the notified polymer. Considering the low water solubility, the polymer is likely to be immobilised through adsorption onto soil particles and sediments. Based on the above and the widespread and diffuse use of the notified polymer, release to the environment is expected to be low and is unlikely to pose an environmental risk.

10.2. Occupational health and safety

The OHS risk presented by the notified polymer is expected to be low due to its expected low

toxicity and low potential for exposure. Nevertheless, the notified polymer is a slight skin and eye irritant and due to its particulate nature may cause irritation of the respiratory tract if inhaled. Therefore, skin eye and respiratory exposure should be avoided. Individuals with the potential for prolonged exposure i.e. service personnel should wear cotton or disposable gloves. Photocopiers and printers should be located in well-ventilated areas. The NOHSC exposure standard for atmospheric dust is 10 mg/m³ (TWA).

10.3. Public health

The risk to public health presented by the notified polymer is expected to be low due to its expected low toxicity and low potential for exposure. Nevertheless, the notified polymer is a slight skin and eye irritant and due to its particulate nature may cause irritation of the respiratory tract if inhaled. Therefore, skin eye and respiratory exposure should be avoided. Photocopiers and printers should be located in well-ventilated areas

11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

11.1. Environmental risk assessment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

11.2. Human health risk assessment

11.2.1. Occupational health and safety

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

11.2.2. Public health

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

12. MATERIAL SAFETY DATA SHEET

12.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

13. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.
 - Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- Service personnel should wear cotton or disposable gloves and ensure adequate ventilation is present when removing spent printer cartridges containing the notified polymer and during routine maintenance and repairs.
- A copy of the MSDS should be easily accessible to employees.

Disposal

- The notified polymer should be disposed of to landfill or by incineration.
- DO NOT put toner or toner container or cartridge into fire; heated toner may cause

severe burns. DO NOT shred a toner container holding remaining toner or toner cartridge, unless dust-explosion preventing measures are taken. Finely dispersed particles form explosive mixtures in air. Disposal should be subject to federal, state or local laws.

Emergency procedures

- No toner spillage occurs in normal operations of handling. If it should occur, avoid inhalation of the dust. Sweep material onto paper and carefully transfer to a sealable waste container. Clean remainder with wet paper, wet cloth or a vacuum cleaner. If a vacuum cleaner is used, it must rate as a dust explosion-proof type. Fine powder can form explosive dust-air mixtures.

13.1. 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 subsection 64(1) of the Act; if
 - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.
- or
- (2) Under subsection 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.

14. BIBLIOGRAPHY

Canon (2003) Report of Mutagenicity Test using Microorganisms (Report No. 679), Canon Inc, Shizuoka, Japan (Unpublished report submitted by notifier)

Huntingdon Life Sciences (2003) ST1090MO Physicochemical Properties (Report number CNN533/033204), Huntingdon Life Sciences Ltd, Huntingdon, UK (Unpublished report submitted by notifier)

Kurume Laboratory (2003) Study of "Safety Evaluation Flow Scheme for Polymer" of ST1116MO (Study Number 82297), Kurume Laboratory Chemicals Evaluation and Research Institute, Japan (Unpublished report submitted by notifier)

RCC Ltd (2003), ST1161KH: Contact Hypersensitivity in Albino Guinea Pigs, Bühler Test (RCC Study Number 849934), RCC Ltd, Füllinsdorf, Switzerland (Unpublished report submitted by notifier)

SafePharm Laboratories (2003a) ST1161KH: Acute Oral Toxicity in the Rat - Acute Toxic Class Method (SPL Project Number 897/324), SafePharm Laboratories Limited, Derby, UK (Unpublished report submitted by notifier)

SafePharm Laboratories (2003b) ST1161KH: Acute Dermal Irritation in the Rabbit (SPL Project Number 897/325), SafePharm Laboratories Limited, Derby, UK (Unpublished report submitted by notifier)

SafePharm Laboratories (2003c) ST1161KH: Acute Eye Irritation in the Rabbit (SPL Project Number 897/326), SafePharm Laboratories Limited, Derby, UK (Unpublished report submitted by notifier)