March 2010, Fuji Xerox Australia Pty Ltd, an ingredient of a toner used in printers/photocopiers

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer SP-03 in Magenta Toner

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, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also 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:

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Director
NICNAS

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Polymer SP-03 in Magenta Toner

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Fuji Xerox Australia Pty Ltd
101 Waterloo Rd
North Ryde NSW 2015

NOTIFICATION CATEGORY
Limited-small volume: Synthetic polymer with Mn < 1000 Da (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Chemical name, molecular formula, structural formula, weight percentage and ingredients, number average molecular weight, low molecular weight polymer, means of identification, degree of purity, hazardous/non-hazardous impurities/residual monomers, additive/adjuvants, import volume, use details.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Nil

NOTIFICATION IN OTHER COUNTRIES
Nil

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Magenta Toner (product containing polymer SP-03)

OTHER NAME(S)
None

MOLECULAR WEIGHT
>500 Da

ANALYTICAL DATA
Reference NMR, IR, GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
The notified polymer contains a hazardous impurity classified as carcinogenic. However, the impurity is present at a concentration lower than the cut-off concentration for carcinogenic potentials (see Secondary Notification).

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Nil

DEGRADATION PRODUCTS
No degradation products are expected to form under the proposed use of the notified polymer.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Extremely pale yellow powder

Property	Value	Data Source/Justification
Melting Point/Range	68.85 to 72.85°C	Measured
Boiling point	Not determined	--
Density	1.06 x 10^3 kg/m^3 at 21°C	Measured
Vapour Pressure	<1.2 x 10^{-6} kPa at 25°C	Measured
Water Solubility	< 1.1 mg/L at 20°C	Visually estimated
Hydrolysis as a Function of pH	Not determined	No hydrolysable functionalities are present in the notified polymer.
Partition Coefficient (n-octanol/water)	log $P_{OW} \geq 12.2$	Estimated by an atom fragment/constant methodology for a representative low molecular weight oligomer.
Adsorption/Desorption	log $K_{oc} > 5.63$	Measured.
Dissociation Constant	Not determined	No dissociable functionalities are present in the notified polymer.
Particle Size	Inhalable fraction (<100 μm): 12.8% Respirable fraction (<10 μm): 0.335%	Measured
Flammability (solids)	Not highly flammable	Measured
Autoignition Temperature	Not expected to self-ignite below its melting temperature	Measured
Explosive Properties	Not expected to be explosive	Estimated (based on structural indication of explosive properties)
Oxidizing Properties	Not expected to have oxidising properties	Estimated (based on structural indication of oxidising properties)

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
The polymer is expected to be stable under normal conditions of use.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia and will be imported into Australia as a component of fully finished toner cartridge.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<1	<1	<1	<1	<1

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Fuji Xerox Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The toner cartridge containing the notified polymer (<5% conc.) will be imported into Australia packaged in plastic bags housed inside cardboard boxes. Toner cartridges will be transported to industrial vendors for sale to industrial customers.

USE
The notified polymer will be used as an ingredient of a toner used in printers and photocopiers at a concentration of <5%.

OPERATION DESCRIPTION
The notified polymer will not be manufactured in Australia and will be imported into Australia as a component (<5% concentration) of a toner, sealed within a cartridge. No reformulation or repackaging of the product containing the notified polymer will occur in Australia. The cartridges are designed exclusively for Fuji Xerox printers and photocopiers, and sold to customers (general public, office workers, and industrial workers).

The customer opens the cardboard box and then opens the foil containing the cartridge. The toner cartridge will fit directly into the printing machine and the toner cartridge is designed not to allow release of the toner containing the notified polymer, unless during printing operation. Printing will be mostly closed process and dermal exposure is only possible if the printed pages are touched before the toner has dried. The cartridge containing the toner will be installed and/or replaced by service technicians, office workers, general public, or industrial workers.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Storage and Transport	>10	1 hour/day	50 days/year
Printing Machine Operators and Technicians	1-3/workplace	~7 hrs	Each working day
End users, Office workers	>100	1 hour/day	50 days/year

EXPOSURE DETAILS
Worker exposure to the notified polymer during the importation, transport and storage of the toner cartridges is not expected, except in the unlikely event of an accident where the cartridge and its packaging may be breached.

Dermal exposure to the notified polymer may occur when replacing spent cartridges containing the notified polymer. Replacement of printing cartridges involves removal of the old printing cartridge from the printing machine and directly loading the new cartridge. Dermal exposure could also occur when handling faulty or ruptured cartridges.

However, as the concentration of the notified polymer in the ink is low (<5%), the ink is contained within the cartridge, replacement of spent cartridge is done infrequently, exposure to the notified polymer during replacement of cartridge is expected to be low. Users will avoid contact with the cartridge ink where possible, to avoid staining of their skin/or clothing.

Once the ink dries, the notified polymer would be trapped in the printed paper and is not expected to be readily bioavailable. Therefore, dermal exposure to the notified polymer from contact with the dried ink is expected to be low.

6.1.2. Public exposure

Dermal and ocular exposure of the public to the notified polymer may occur when replacing spent cartridges. However, as the concentration of the notified chemical in the toner is low (<5%), the ink is contained within the cartridge, replacement of spent cartridge is done infrequently, exposure to the notified polymer during replacement of cartridge is expected to be low. Furthermore, users will avoid contact with the toner where possible, to avoid staining of their skin/or clothing.

6.2. Human health effects assessment

As no toxicological data were submitted for the notified polymer, human health hazards associated with the notified polymer can not be identified.

Based on the relatively low molecular weight (< 1000) and the presence of a significant amount of low MW species, the notified polymer has some potential to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure. Inhalation may lead to direct absorption across the epithelium of the respiratory tract.

The MSDS states that the following characteristics of the notified polymer, however the relevant studies were not provided: Acute oral toxicity (LD50 >2000 mg/kg bw in rat), Skin irritation (non-irritant in rabbit), Eye irritation (mild irritant in rabbit).

Health hazard classification

As no toxicological data were submitted, the notified polymer cannot be classified according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

As no toxicological data were submitted for the notified polymer, human health hazards associated with the use of notified polymer can not be identified.

There is a potential for exposure to the notified polymer during importation, transportation, storage, replacing spent cartridges, printing applications, handling faulty or ruptured cartridges, and during servicing and maintenance. However, considering that the concentration of the notified polymer in the ink is low (<5%), the ink is contained within the cartridge, replacement of spent cartridge is done infrequently, and use of closed printing systems, the level of risks to workers presented by the use of notified polymer is expected to be low and is not considered to be unacceptable. Furthermore, users will avoid contact with the cartridge ink where possible, to avoid staining of their skin/or clothing.

Once the ink dries, the notified polymer would be trapped in the printed paper and is not expected to be readily bioavailable. Therefore, the risk of dermal exposure to the notified polymer from contact with the dried ink is also expected to be low and considered acceptable. During transport and storage, the risk to workers is also minimal and acceptable as workers will only be exposed to the notified polymer in the case of an accident involving damage to the packaging and to wrapping.

Overall, the risk presented by the notified polymer to the health and safety of workers is not considered to be unacceptable.

6.3.2. Public health

There is potential public exposure to the notified polymer during printing applications such as replacing cartridges and printing. However, exposure is expected to be low and only for a brief period of time. Therefore, considering the exposure level and the low concentration of the notified polymer (<5%) in the toner, the risk from exposure is expected to be low and considered acceptable.

The public will be exposed to the paper or other types of material printed with toner ink containing the notified polymer. In this case, the exposure will be minimal as the notified polymer will be bound to the paper or other print substrates once the ink has dried. Therefore, the risk is not considered unacceptable, given that exposure is expected to be very low.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia as a component of a final product in ready-to-use cartridges. No manufacturing and reformulation of the notified polymer will take place in Australia. Environmental release of the notified polymer is unlikely to occur during importation, storage and transportation.

RELEASE OF CHEMICAL FROM USE

The toner cartridges will be designed to prevent leakage and will not be opened during transport, use, installation or replacement. Therefore, release of toner containing the notified polymer to the environment is not expected under normal conditions of use. If leakage or spillage does occur, the toner will be physically contained with absorbent material and disposed of to landfill.

Cartridges will be contained within the printer until the contents are consumed and then they will be removed and sent for recycling or disposed of to landfill. Approximately 0.1% of the toner containing the notified polymer will remain in "empty" cartridges.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the notified polymer will be bound to printed paper, which will be either disposed of to landfill or recycled. It is assumed that 50% of the waste paper will end up in landfill and the rest will undergo paper recycling processes. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of toner from the fibres. Very little of the notified polymer is expected to partition to the supernatant water, due to its highly hydrophobic nature, which is released to the sewer. Sludge generated during the washing process will be sent to landfill for disposal.

7.1.2 Environmental fate

No environmental fate data were submitted. The notified polymer is not expected to be bioavailable or bioaccumulative due to its molecular weight.

Most of the notified polymer will be sent to landfill via either direct disposal of waste paper containing the notified polymer or disposal of sediment sludge produced from the waste paper recycling processes. In landfill, the notified polymer will be bound to soil based on its hydrophobicity and will be slowly degraded, eventually forming water and oxides of carbon.

7.1.3 Predicted Environmental Concentration (PEC)

The PEC for the notified polymer has not been calculated since no significant release to the environment is expected based on its reported use pattern.

7.2. Environmental effects assessment

No ecotoxicity data for the notified polymer or any acceptable analogue polymer were submitted. The notified polymer is a relatively high molecular weight non-ionic polymer and is therefore not expected to be hazardous to the environment.

7.2.1 Predicted No-Effect Concentration

The PNEC has not been calculated since no ecotoxicity data are available for the notified polymer.

7.3. Environmental risk assessment

The notified polymer is unlikely to be released into aquatic ecosystems in environmentally significant concentrations based on the intended use pattern and the potential for removal of the notified polymer from waste water steams by physical processes, especially adsorption to solids. As there is very little potential for aquatic exposure to the notified polymer based on the reported use pattern, the polymer is not expected to pose a risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As no toxicological data were submitted, the notified polymer cannot be classified according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* [NOHSC: 1008(2004)].

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental risk assessment

On the basis of the reported use pattern, the notified polymer is not expected to pose a risk to the environment.

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.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- the importation volume exceeds one tonne per annum notified polymer;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from as an ingredient of a toner used in printers/photocopiers;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.
- the concentration of isoprene residual monomer is ≥ 0.1% in the notified polymer.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet
The MSDS of product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Physico-chemical properties were conducted on notified chemical with a purity of >99%.

Melting Point/Melting Range 68.85 to 72.85ºC

Method	OECD TG 102 Melting Point/Melting Range.
Remarks	Determination was carried out by differential scanning calorimetry (DSC).
Test Facility	SafePharm Laboratories Ltd (2008a)

Density 1.06 x 10^3 kg/m^3 at 21ºC

Method	OECD TG 109 Density of Liquids and Solids.
Remarks	Determined using a gas comparison pycnometer. Temperature and pressure readings were taken between 40 and 50˚C
Test Facility	SafePharm Laboratories Ltd (2008a)

Vapour Pressure <1.2 x 10^{-6} kPa at 25ºC

Method	OECD TG 104 Vapour Pressure.
Remarks	Determined using a vapour pressure balance. Balance readings were low and variable and thus statistical analysis was not meaningful. A regression slope was imposed on a chosen data point to provide an estimate of the maximum value for the vapour pressure at 25°C.
Test Facility	SafePharm Laboratories Ltd (2008b)

Water Solubility < 1.1 mg/L at 20ºC

Method	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Flask Method. A mixture of the notified polymer with water at a nominal loading level of 1.1 mg/L was prepared and then shaken at approximately 30ºC for 3 hours at 200 rpm. After equilibrating at 20 ± 0.5ºC, excess test material was present in the sample. The water solubility has also been estimated to be ≤ 1.2 × 10^{-7} mg/L for a representative low molecular weight oligomer at 25ºC by using an atom/fragment contribution method (WSKOW v 1.41).
Test Facility	SafePharm Laboratories Ltd (2008a)

Partition Coefficient (n-octanol/water) log P_{OW} ≥ 12.2

Method	KOWWIN, version 1.67 © 2000 US EPA
Remarks	Experimental determination of K_{OW} for the notified polymer was not feasible due to the low solubilities in both water and n-octanol. The log P_{OW} was estimated to be ≥ 12.2 by an atom fragment-constant methodology.
Test Facility	SafePharm Laboratories Ltd (2008a)

Adsorption/Desorption – screening test log K_{oc} > 5.63

Method	OECD TG 121 Estimation of the Adsorption Coefficient on Soil and on Sewage Sludge Using HPLC.
Remarks	The dead time was determined to be 3.23 min using formamide. The test substance eluted from the column after the reference substance DDT (log K_{OC} = 5.63), indicating a log K_{OC} of > 5.63 for the notified polymer.
Test Facility	SafePharm Laboratories Ltd (2008a)

Particle Size

Method OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (μm)	*Method*	*Result*
Proportion of test material having an inhalable particle size less than 100 μm	Sieve	12.8%
Proportion of test material having a thoracic particle size less than 10 μm	Cascade Impactor	0.335%
Proportion of test material having a thoracic particle size less than 5.5 μm	Cascade Impactor	0.246%

Remarks Screening test (sieve method) and definitive test (cascade impactor method) were used. MMAD (Mass Median Aerodynamic Diameter) could not be determined as there were too few particles of diameter > 10 μm.
Test Facility SafePharm Laboratories Ltd (2008a)

Flammability (Solids) Not highly flammable.

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The test material has been determined to be not highly flammable as it did not propagate combustion over 200 mm of the preliminary screening test.
Test Facility SafePharm Laboratories Ltd (2008b)

Autoignition Temperature Not expected to self-ignite below its melting temperature

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The test material was heated in an oven and the relative self ignition temperature determined. The oven temperature was programmed to be increased from ambient to 83°C (which was approximately 10°C higher than the melting temperature). The test material has been determined not to have a relative self-ignition temperature below its melting temperature.
Test Facility SafePharm Laboratories Ltd (2008b)

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