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

PUBLIC REPORT

Fine Sphere FS-468

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 Department of Health, 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 Energy.

This 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:

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**Director
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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2048	Kyocera Document Solutions Australia	Fine Sphere FS-468	ND*	≤ 10 tonnes per annum	Component of toner in sealed cartridges

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

Human health risk assessment

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

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

Environmental risk assessment

On the basis of the assumed low hazard and reported use pattern, the notified polymer is not considered to pose an unreasonable 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 in sealed cartridges. 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 SDS should be easily accessible to employees.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

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 polymer 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(2) of the Act; if
 - the function or use of the polymer has changed from a component of toner in sealed cartridges, or is likely to change significantly;
 - the amount of polymer being introduced has increased, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

No additional secondary notification conditions are stipulated.

Safety Data Sheet

The SDS of a product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT

Kyocera Document Solutions Australia (ABN: 77 003 852 444)
Level 3, 6-10 Talavera Road
NORTH RYDE NSW 2113

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ g/mol

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, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physiochemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME

Fine Sphere FS-468

MOLECULAR WEIGHT

Number Average Molecular Weight (M_n) is $> 10,000$ g/mol (estimated).

ANALYTICAL DATA

Reference IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY

$> 98\%$

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White powder

Property	Value	Data Source/Justification
Melting Point	100-120 °C*	SDS
Boiling Point	Not determined	Expected to decompose before boiling
Density	1,200-1,400 kg/m ³ *	SDS
Vapour Pressure	Not determined	Expected to be low based on high molecular weight
Water Solubility	Not determined	Water immiscible due to extensive crosslinking and high molecular weight
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities, but not expected to hydrolyse due to water immiscibility
Partition Coefficient (n-octanol/water)	Not determined	Immiscible in either phase due to extensive crosslinking and high molecular weight

Adsorption/Desorption	Not determined	No expected to be mobile due to high molecular weight.
Dissociation Constant	Not determined	Contains terminal anionic functionalities, expected to remain ionised in the environmental pH range (4-9).
Particle Size	<u>Notified polymer</u> Inhalable fraction (< 100 µm): 100% Respirable fraction (< 10 µm): 95.7% MMAD** = 2.56 µm <u>Toner*</u> Inhalable fraction (< 100 µm): 100% Respirable fraction (< 10 µm): 98.7% MMAD** = 5.74-6.89 µm	Measured
Flash Point	> 200 °C	Estimated
Flammability	Not determined	Not expected to be flammable under normal conditions of use
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use
Explosive Properties	Not determined	Contained no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contained no functional groups that would imply oxidising properties

** MMAD = Mass Median Aerodynamic Diameter

* Data for the imported printer or copier toner containing ≤ 1% notifier polymer

DISCUSSION OF PROPERTIES

For details of the single physio-chemical test refer to Appendix A.

Reactivity

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

Physical hazard classification

Based on the limited submitted physico-chemical data depicted in the above table, the notified polymer is cannot be recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured or reformulated in Australia. The notified polymer will be imported into Australia as a component of printer/photocopier toners at a concentration of ≤ 1% in purpose built 1.44 L sealed cartridges.

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

Year	1	2	3	4	5
Tonnes	≤ 10	≤ 10	≤ 10	≤ 10	≤ 10

PORT OF ENTRY

Sydney

IDENTITY OF RECIPIENTS

Kyocera Document Solutions Australia

TRANSPORTATION AND PACKAGING

The notified polymer will be imported as a component of printer/photocopier toners at $\leq 1\%$ concentration in purpose built 1.44 L sealed cartridges. The sealed toner cartridges will primarily be transported throughout Australia by road.

USE

The notified polymer will be used as a component of printer/photocopier toners at $\leq 1\%$ concentration.

OPERATION DESCRIPTION

The notified polymer will not be manufactured, reformulated or repackaged in Australia.

Sealed cartridges containing the notified polymer will be handled by service technicians, office workers or the public, who will replace spent cartridges in the photocopiers and printers as necessary. The cartridges containing the notified polymer will not be refilled within Australia.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	2-4	12-24
Wholesale/retail printer suppliers	8	200
Service technicians	4-8	200
Office workers (during cartridge changing)	0.25	12
Office workers (during printing)	4-8	200

EXPOSURE DETAILS

Transport, storage and wholesale/retail workers

Transport, storage and wholesale/retail workers may come into contact with the toner containing the notified polymer at $\leq 1\%$ concentration, only in the unlikely event of accidental rupture of the sealed toner cartridges.

Service technicians

Service technicians may be exposed to the toner containing the notified polymer at $\leq 1\%$ concentration when replacing toner cartridges and during printer/photocopier maintenance or repairs. The principal route of exposure is expected to be dermal. Inhalation exposure is not expected due to the sealed nature of the toner cartridges. Exposure is expected to be minimised through following the safe replacement procedures recommended by the manufacturer and the expected use of cotton disposable gloves.

Office workers

Office workers may be exposed to the toner containing the notified polymer at $\leq 1\%$ concentration when replacing toner cartridges. Exposure may be minimised by the use of safe replacement procedures recommended by the manufacturer.

After application to the paper substrate and once dried, the toner containing the notified polymer is expected to be bound to the substrate and will not be available for exposure.

6.1.2. Public Exposure

Similar to office workers, the public may be exposed to the toner containing the notified polymer at $\leq 1\%$ concentration when replacing toner cartridges. Exposure may be minimised by the use of safe replacement procedures recommended by the manufacturer.

After application to the paper substrate and once dried, the toner containing the notified polymer is expected to be bound to the substrate and will not be available for exposure.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer.

Based on the expected high molecular weight ($> 10,000$ g/mol) and absence of low molecular weight species ($< 1,000$ g/mol) of the notified polymer, absorption across biological membranes is not expected.

The notified polymer contains a structural alert for corrosion. However irritation effects are not expected given the expected high molecular weight and absence of low molecular weight species of the notified polymer.

Health hazard classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the available information, the notified polymer is expected to be of low hazard.

However, the notified polymer is a high molecular weight water insoluble polymer ($M_n > 10,000$ g/mol). Inhalation of respirable particles of polymers with molecular weights $> 70,000$ g/mol has been linked with irreversible lung damage due to lung overloading and impaired clearance of particles from the lung, particularly following repeated exposure. While there is also a concern for polymers with molecular weights between 10,000 and 70,000 g/mol, it is acknowledged that there is a data gap for this range. Therefore, there is uncertainty for the potential for lung overloading effects with respect to the notified polymer. If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs.

The particle size of the toner containing the notified polymer at $\leq 1\%$ concentration indicates that it is largely respirable ($< 10 \mu\text{m}$). However given the toner will be contained within sealed cartridges and the low concentration of the notified polymer, lung overloading effects are not expected.

Overall, given the low concentration of the notified polymer in the imported toner cartridges and limited potential for exposure, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

Similar to office workers, given the low concentration of the notified polymer in the imported toner cartridges and limited potential for exposure, the notified polymer is not expected to pose an unacceptable risk to public health.

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 in purpose-designed sealed printer cartridges at a concentration of $\leq 1\%$. It will not be reformulated. Accidental spillage of the toner containing the notified polymer will only occur if the cartridge is breached, and in such circumstances the toner is expected to be collected for disposal to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The printing process is fully enclosed and automated. It is estimated that 90% of toner in a cartridge is transferred to paper, 5% stays in the cartridge, while the remainder is retained in the interior of the printer. During maintenance of the printer, the small amount of residual notified polymer therein may be removed and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Used toner cartridges with residual toner may be recycled to form low grade plastics, but eventually all of the notified polymer from used toner cartridges will be disposed of to landfill. Paper containing the notified polymer adhered to its surface will be disposed of either to landfill or be recycled. During recycling, the notified polymer will be removed and likely end up in liquid waste. A recent Australian waste report states that the average paper recycling rate is 60% (Blue Environment Ltd., 2016). In the worst case scenario, up to 60% of the notified polymer used on paper, which is equivalent to 54% (90 % on paper x 0.6) of the annual import volume of the notified polymer, could be released to the aquatic environment from paper recycling processes.

7.1.2. Environmental Fate

Based on its use as a material for printing, most of the notified polymer is expected to share the fate of the printed paper, which will either be recycled or disposed of to landfill. In landfill, based on its high molecular weight and presumptive low water solubility, the notified polymer will be neither bioavailable nor mobile. In landfill the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and sulfur.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume 90% of the import volume of the notified polymer will be used on paper substrate and 60% of this would be potentially released to sewers through paper recycling processes (Blue Environment Ltd., 2016). As paper recycling occurs at facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume. It is also assumed under the worst-case scenario that there is no removal of the notified polymer during wastewater treatment processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	54	%
Annual quantity of chemical released to sewer	5,400	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	20.8	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0	%
Daily effluent production:	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	4.26	µg/L
PEC - Ocean:	0.43	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 4.26 µg/L may potentially result in a soil concentration of approximately 28.4 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymer in the applied soil in 5 and 10 years may be approximately 142 µg/kg and 284 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. Polymers without significant ionic functionality are generally considered not to be harmful to aquatic organisms.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated as the notified polymer is not considered to be harmful to aquatic organisms due to its presumptive low water solubility.

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) has not been calculated as the notified polymer is not expected to be harmful to aquatic organisms. Therefore, based on the assumed low hazard and use as a polymer in printing, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Particle Size Inhalable fraction (< 100 µm): 4.34%
Respirable fraction (< 10 µm): 95.63%

Method Not stated

<i>Range (µm)</i>	<i>Mass (%)</i>
< 100	4.34
< 10	20.5
< 5	75.13

Remarks Dry method

Test Facility Not stated

BIBLIOGRAPHY

Blue Environment Pty Ltd (2016) Australian National Waste Report 2016. Canberra, Australia.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >