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

**FULL PUBLIC REPORT**

**Styrene acrylate copolymer in Kyocera Mita 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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## TABLE OF CONTENTS

<u>FULL PUBLIC REPORT</u> .....	3
1. APPLICANT AND NOTIFICATION DETAILS.....	3
2. IDENTITY OF CHEMICAL .....	3
3. COMPOSITION.....	3
4. PHYSICAL AND CHEMICAL PROPERTIES.....	4
5. INTRODUCTION AND USE INFORMATION.....	5
6. HUMAN HEALTH IMPLICATIONS.....	5
6.1 Exposure assessment.....	5
6.1.1 Occupational exposure.....	5
6.1.2 Public exposure.....	6
6.2 Human health effects assessment.....	6
6.3 Human health risk characterisation.....	6
6.3.1 Occupational health and safety .....	7
6.3.2 Public health.....	7
7. ENVIRONMENTAL IMPLICATIONS .....	7
7.1 Environmental Exposure & Fate Assessment.....	7
7.1.1 Environmental Exposure.....	7
7.1.2 Environmental fate.....	7
7.1.3 Predicted Environmental Concentration (PEC) .....	8
7.2 Environmental effects assessment .....	8
7.2.1 Predicted No-Effect Concentration.....	8
7.3 Environmental risk assessment.....	8
8. CONCLUSIONS AND REGULATORY OBLIGATIONS.....	8
Hazard classification .....	8
Human health risk assessment .....	8
Environmental risk assessment .....	8
Recommendations.....	8
Regulatory Obligations .....	9
<u>APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES</u> .....	11
<u>APPENDIX B: TOXICOLOGICAL INVESTIGATIONS</u> .....	12
B.1. Genotoxicity – bacteria.....	12
<u>BIBLIOGRAPHY</u> .....	12

**FULL PUBLIC REPORT****Styrene acrylate copolymer in Kyocera Mita toner****1. APPLICANT AND NOTIFICATION DETAILS**

## APPLICANT(S)

Kyocera Mita Australia Pty Limited (ABN 77 003 852 444)  
Level 3, 6 - 10 Talavera Road, NORTH RYDE NSW 2113

## NOTIFICATION CATEGORY

Limited: Synthetic polymer with  $M_n \geq 1000$  Da.

## EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical names, Other names, CAS Number, Molecular formula, Structural Formula, Molecular weight, Spectral data, Identity and concentration of impurities, Import volume

## VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Melting Point, Vapour Pressure, Hydrolysis as a Function of pH, Partition Co-efficient, Adsorption/Desorption, Dissociation Constant, Flash Point, Flammability Limits, Explosive Properties

## PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

## NOTIFICATION IN OTHER COUNTRIES

USA (2007), Canada (2007)

**2. IDENTITY OF CHEMICAL**

## MARKETING NAME(S)

Kyocera Mita toner (product containing the notified polymer)

## MOLECULAR WEIGHT (MW)

Number Average Molecular Weight ( $M_n$ ) > 1000 Da

## ANALYTICAL DATA

Reference IR and GC spectra were provided.

**3. COMPOSITION**

DEGREE OF PURITY 99-100%

## HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

<i>Chemical Name</i>	Benzene, ethenyl-		
<i>CAS No.</i>	100-42-5	<i>Weight %</i>	0.02
<i>Hazardous Properties</i>	<u>Classification</u>		
	R10 (Flammable)		
	Harmful: R20 (Harmful by inhalation)		
	Irritant: R36/38 (Irritating to eyes and skin)		
	<u>Concentration cutoffs</u>		
	Conc $\geq$ 12.5%: Xn; R20; R36/38 (HSIS, 2008)		

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

ADDITIVES/ADJUVANTS           None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

The notified polymer is not expected to easily degrade, decompose or depolymerise.

DEGRADATION PRODUCTS

None known.

#### 4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Glass transition temperature	60-70°C	Estimated
Density	Approximately 1100 kg/m <sup>3</sup> at 25°C	MSDS
Vapour Pressure	Not determined	Expected to be extremely low due to the high molecular weight of the notified polymer.
Water Solubility	0.023 g/L at pH 7 at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	Due to the low water solubility of the notified polymer. The notified polymer contains hydrolysable functionalities, but hydrolysis is unlikely to occur over the environmental pH range of 4 – 9.
Partition Coefficient (n-octanol/water)	Not determined	A high value of P <sub>OW</sub> is expected based on the hydrophobic structure and low water solubility of the notified polymer.
Adsorption/Desorption	Not determined	A high value of K <sub>OC</sub> is expected based on the both the hydrophobic structure and the cationic nature of the notified polymer.
Dissociation Constant	Not determined	The notified polymer contains cationic functionalities and is expected to be ionised in the environmental pH range 4 – 9.
Particle Size	Inhalable fraction (<100 µm): approximately 0.48% Respirable fraction (<10 µm): not detected MAD* = 601 µm	Measured
Flash Point	Not determined	High molecular weight polymer.
Autoignition Temperature	482°C (pressure unspecified)	MSDS
Explosive Properties	Not determined	High molecular weight polymer without any chemical moieties that would contribute to the polymer being explosive.

\*MAD = Mean Aerodynamic Diameter

DISCUSSION OF PROPERTIES

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

*Reactivity*

Not expected to be oxidising, based on chemical composition.

*Dangerous Goods classification*

Based on the available data the notified polymer is not classified according to the Australian Dangerous Goods Code (FORS, 1998). However it is combustible if the surrounding temperature is sufficiently high enough (Autoignition temperature 482°C).

## 5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as a component of toner at concentrations of 2-5% in sealed toner cartridges, which are ready to use in photocopiers and printers.

### 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>	0-1	0-1	1-3	1-3	1-3

### PORT OF ENTRY

Sydney

### IDENTITY OF RECIPIENTS

The toner cartridges containing the notified polymer will be delivered to warehouses and distribution centers before they are distributed to offices and retailers nationwide.

### TRANSPORTATION AND PACKAGING

Transportation will be by ship in containers. Individual toner cartridges of 1.44 L capacity will be packed in cardboard boxes and would normally be transported by road.

### USE

The notified polymer will be used as a component of toner cartridges for photocopiers and printers, at a concentration of 2-5%. The function of the notified polymer is an electrostatic charge control agent.

### OPERATION DESCRIPTION

The notified polymer will not be manufactured or reformulated in Australia. It will be imported as a component of sealed toner cartridges. The toner will be imported and supplied in sealed toner cartridges, which are inserted inside the photocopiers and printers and replaced when empty.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1 Exposure assessment

#### 6.1.1 Occupational exposure

##### NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Transport and storage	15-25	6-8 hours/day	125-225 days/year
Wholesale printer supplies	> 1000	8 hours/day	200 days/year
Service technicians	50-75	4-8 hours/day	150-225 days/year
Photocopier and printer users	> 1000	0.5 hour/day	5-20 days/year

##### EXPOSURE DETAILS

###### *Transport and warehousing*

Workers are not expected to be exposed to the imported notified polymer, as they will be handling closed containers. Exposure is possible in the event of an accident where the packaging is breached.

###### *Wholesale Workers*

These workers will be involved in opening cardboard cartons, removing the toner cartridges (the toner cartridges are contained within an outer cardboard box) and stacking the individual boxes onto shelves. These workers are expected to have minimal contact with the toner cartridge and therefore to the notified polymer.

###### *Service technicians*

Service technicians will come in contact with the sealed toner cartridges during photocopier and printer maintenance. Any empty cartridges or waste toner box will be replaced with new ones. Cartridges will not be refilled or replaced. The most likely route of exposure is dermal. Inhalation or oral exposure is not expected to

be significant. Photocopier and printer maintenance personnel often wear cotton disposable gloves. Worker exposure to the toner would be minimised further by the use of the replacement procedures recommended by the manufacturer.

Increased potential for dermal and/or inhalation exposure to toner containing the notified polymer will occur in the event of a spill. It is expected that toner containers and waste toner boxes are replaced in well-ventilated areas.

#### *Photocopier and printer users*

Office workers using photocopiers and printers might be exposed to the notified polymer when changing toners, however the exposure would be less frequent than for service technicians.

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

### **6.1.2. Public exposure**

The exposure of the public to the notified polymer through the use of photocopier and printer toner is expected to be similar to that experienced by office workers during the changing of cartridges, printing onto paper and other media, and handling dried, printed pages. Members of the public may be expected to change photocopier and printer cartridges less frequently than would office workers, as domestic applications are often smaller. Therefore exposure would be less frequent.

Public exposure through importation, transportation or storage is expected to be negligible. Such exposure could only occur in the extremely unlikely event of an accident where crates, boxes, packaging and cartridges were ruptured, liberating toner containing the notified polymer.

## **6.2. Human health effects assessment**

The results from toxicological investigation conducted on the notified polymer are summarised in the table below. Details of the study can be found in Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Mutagenicity – bacterial reverse mutation	non mutagenic

#### *Toxicokinetics and Distribution*

Based on the high molecular weight ( $M_n > 1000$ ) and low percentage of low molecular weight species  $< 1000$  Da ( $< 1\%$ ), absorption across biological membranes is expected to be very low. Systemic toxicity after dermal exposure to the notified polymer is therefore expected to be low.

The particle size distribution of the notified polymer indicates that the mean aerodynamic diameter is  $601 \mu\text{m}$ , with no particles having a diameter less than  $10 \mu\text{m}$  (respirable range). Therefore, the risk of significant respiration of the polymer powder into the lungs is low.

#### *Mutagenicity*

The notified polymer was not mutagenic in bacteria reverse mutation.

Information was also available for two analogue polymers containing similar monomers as the notified polymer: Analogue polymer 1 was of very low acute oral toxicity, was not a skin irritant, not an eye irritant and was not genotoxic as measured by induction of mutations in bacteria.

Analogue polymer 2 exhibited low acute oral toxicity in rats, was non-irritating to rabbit skin and slightly irritating to rabbit eyes. No bacterial mutagenicity was observed when the polymer was tested with or without metabolic activation.

Both analogue polymers were not classified as hazardous.

#### **Health hazard classification**

Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

## **6.3. Human health risk characterisation**

### 6.3.1. Occupational health and safety

Based on the available toxicological data (primarily on analogues), the notified polymer is considered to be of low oral toxicity, was non-irritating to skin and slightly irritating to eyes, and not mutagenic to bacteria.

The notified polymer will be imported as a component of the finished toner for photocopiers and printers at a concentration of 2-5%. The toner will be imported in a purpose-built cartridge.

Considering the likely low exposure of the workers at each step of use, the risk of adverse effects for workers involved in transport, storage, printing and servicing is low.

However, there is a possibility of inhalation and/or dermal exposure to the notified polymer during maintenance and servicing of the printing equipment. Safe work practises and good ventilation would minimise exposure. The NOHSC exposure standard for atmospheric dust is 10 mg/m<sup>3</sup>.

Once deposited onto the paper, the notified polymer is expected to remain bound to the paper or the cured print matrix and therefore not bioavailable. Overall, the release of the notified polymer and therefore exposure will be low. Therefore, the risk to workers from exposure to the notified polymer is considered to be low, based on expected low hazard and low exposure.

### 6.3.2. Public health

Overall, risk for the public from the use of the notified polymer is expected to be low, due to the likely low exposure and the low hazard of the notified polymer.

## 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 as a component in final toner products, in plastic cartridges that will be packed in sturdy cardboard boxes. Therefore, no environmental release is expected from manufacture or reformulation in Australia.

##### RELEASE OF CHEMICAL FROM USE

Toner cartridges containing the notified polymer will be installed in equipment for paper printing and will be removed after the containers are empty. Based on this intended use pattern, release of the notified polymer is not expected from the use.

##### RELEASE OF CHEMICAL FROM DISPOSAL

The overwhelming majority of the notified polymer will stay with paper after printing application, and share the fate of the paper. The paper may be either disposed of directly to landfill or be recycled. In the case of recycling, the fused toner containing the notified polymer is designed to be separated from the paper in one of the treatment processes. Based on the expected low water solubility, the notified polymer is anticipated to remain in the sediment sludge and end up with landfill.

The residual notified polymer in empty toner containers or waste toner boxes will be disposed of to landfill with the associated containers or boxes.

It is estimated that 60 – 70% of the notified polymer will be directly disposed of to landfill, either bound to paper or as residues in empty containers. It is anticipated that the remaining 30 – 40% of the notified polymer will be landfilled in sludge from paper recycling.

Collectively, minor release of the notified polymer to aquatic ecosystems is expected.

#### 7.1.2 Environmental fate

The notified polymer is expected to end up with landfill, where it will not leach based on its hydrophobic structure and cationic nature. It will undergo slow degradation to oxides of carbon, nitrogen and water through biotic and abiotic pathways.

### 7.1.3 Predicted Environmental Concentration (PEC)

The calculation of a PEC has not been undertaken since no release to the aquatic environment is expected based on both the reported use pattern and the nature of the notified polymer.

## 7.2. Environmental effects assessment

No ecotoxicity data were submitted. The notified polymer contains cationic functionalities that may be of high risk to aquatic compartment. However, this is not an issue given minor release to water environment is predicted based on the reported use pattern.

### 7.2.1 Predicted No-Effect Concentration

No ecotoxicity data were submitted, therefore, it is impossible to predict the PNEC of the notified polymer.

## 7.3. Environmental risk assessment

The notified polymer is not expected to enter the aquatic environment during normal use except via paper recycling. Most of the polymer is likely to be adsorbed on to sludge during wastewater treatment. Any polymer residues entering the aquatic environment are expected to associate with the sediments therefore, not remain in the water compartment and be available for assimilation by aquatic organisms.

As no ecotoxicity data are available, a PNEC and resultant PEC/PNEC ratio were not able to be calculated. However, given the low volume and diffuse release pattern, there should be an adequate safety margin and the overall environmental risk is expected to be acceptable.

## 8. CONCLUSIONS AND REGULATORY OBLIGATIONS

### Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the *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 and the low potential for aquatic exposure, the notified polymer is not considered to pose a risk to the environment.

### Recommendations

#### CONTROL MEASURES

#### Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as used in the product inks:
  - Printers should be located in well-ventilated areas;
  - Avoid spillage of toner and generating of dust particles during maintenance
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as used in the product inks:
  - Protective gloves



- Specific engineering controls, work practices or personal protective equipment required for safe use 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.

- Atmospheric monitoring should be conducted by employers to measure workplace concentrations of dust during use of the products containing the notified polymer. The NOHSC exposure standard for atmospheric dust is 10 mg/m<sup>3</sup>.
- 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.
- If products and mixtures containing the notified polymer 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.

#### 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(2) of the Act; if
  - the function or use of the chemical has changed from as a component of toner cartridges for photocopiers and printers, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 3 tonne per annum, or is likely to increase, significantly;
  - if 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 Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

#### *Material Safety Data Sheet*

The MSDS of the notified polymer and product containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

**APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**

**Water Solubility** 0.029 g/L (pH 2), 0.023 g/L (pH 7), 0.024g/L (pH 9) at 20°C

**Method** 10 g of the sample of particle size between 125- 250 µm was suspended in deionised water (1 L) in a 2 L flask. The suspension was stirred at 20°C for 24 hours using a constant low temperature water bath. The suspension was filtered by filter paper (185 mm in diameter) and dried at 40°C to constant weight. The determination was carried out 3 times at pH values of 2, 7 and 9, and the averaged result was determined at each pH.

**TEST FACILITY** Fujikura Kasei Co., Ltd (2007)

**Particle Size** Mean Aerodynamic diameter = 601 µm

<i>Range (µm)</i>	<i>Mass (%)</i>
< 500	< 34
< 100	Approximately 0.482
< 50	Not detected
< 10	Not detected

**Remarks** Laser diffraction particle size analyser was used.

**TEST FACILITY** Unspecified

**APPENDIX B: TOXICOLOGICAL INVESTIGATIONS****B.1. Genotoxicity – bacteria**

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Pre incubation procedure
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA
Metabolic Activation System	S9 mix
Concentration Range in Main Test	a) With metabolic activation: 0, 39, 78, 156, 313, 625, 1250, 2500, 5000 µg/plate b) Without metabolic activation: 0, 0.61, 1.2, 2.4, 4.9, 10, 20, 39, 78, 156, 313, 625, 1250 µg/plate
Vehicle	Acetone
Remarks - Method	Original study in Japanese and summary in English was provided.

## RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>	> 5000			
Test 1		> 1250	> 1250	negative
Test 2		> 1250	> 1250	negative
<i>Present</i>	> 5000			
Test 1		> 5000	> 5000	negative
Test 2		> 5000	> 5000	negative

Remarks - Results In this study, neither any increase in the number of relevant colonies more than twice in comparison with that of the negative control, nor any dose-related response was observed with or without metabolic activation.

CONCLUSION The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY BML, Inc. (2007)

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