File No: LTD/1875

February 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in TK-8XXX toners

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.

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
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1875	Kyocera Document Solutions Australia Pty Ltd	Polymer in TK-8XXX toners	ND*	≤ 1.0 tonne per annum	Component of printer toner

*ND = not determined

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, 2004).

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 PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer [as introduced, as diluted for use, in the printer cartridges:
  - Printers should be located in well-ventilated areas;
  - Avoid spillage of toner and generation of dust particles during maintenance

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

- Service personnel should ensure adequate ventilation is present when removing spent printer cartridges containing the notified polymer and during routine maintenance and repairs.

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

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 containment, physical 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 component of printer toner, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 1 tonne per annum, 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.

(Material) Safety Data Sheet
The (M)SDS of the notified polymer (and products containing the notified chemical) provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicant(s)
Kyocera Document Solutions Australia Pty Ltd (ABN: 77 003 852 444)
Level 3, 6–10 Talavera Road
NORTH RYDE NSW 2113

Notification Category
Limited: Synthetic polymer with Mn ≥ 1,000 Da.

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, use details, manufacture/import volume, site of manufacture/reformulation and identity of manufacturer/recipients.

Variation of Data Requirements (Section 24 of the Act)
Variation to the schedule of data requirements is claimed for all physico-chemical properties except water solubility.

Previous Notification in Australia by Applicant(s)
None

Notification in Other Countries
Korea (2014)
Taiwan (2015)

2. IDENTITY OF CHEMICAL

Marketing Name(s)
F-763
Cyan Toner for TK-8XXXC toners (product containing the notified polymer)
Black Toner for TK-8XXXK toners (product containing the notified polymer)
Magenta Toner for TK-8XXXM toners (product containing the notified polymer)
Yellow toner for TK-8XXXY toners (product containing the notified polymer)

Analytical Data
Reference IR and GPC spectra were provided.

3. COMPOSITION

Degree of Purity
> 95%

Molecular Weight (MW)
Number Average Molecular Weight (Mn) > 10,000 Da

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White solid (non-fibrous)

Property	Value	Data Source/Justification
Melting Point	Not determined	Polymer is expected to decompose before melting.
Boiling Point	Not determined	Polymer is a solid, no determination of boiling point due to expected decomposition prior to boiling.

Density	1,000–1,200 kg/m^3 at 25 °C	SDS
Vapour Pressure	Not determined	Based on the high molecular weight of the polymer, the vapour pressure is expected to be low.
Water Solubility	Insoluble at 25 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities; however, not expected to hydrolyse under environmental conditions (pH 4–9) based on low water solubility.
Partition Coefficient (n-octanol/water)	Not determined	Expected to be high based on low water solubility.
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on high molecular weight and low water solubility.
Dissociation Constant	Not determined	Expected to be ionised under environmental conditions (pH 4–9).
Particle Size	Not determined	Not supplied
Flash Point	Not determined	Not supplied
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	Contains no functional groups that imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties

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

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not 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 be imported as a component of toner at concentrations ≤ 1.0 wt%, inside sealed toner cartridges, for use with devices such as photocopiers and multifunction printers.

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
The notified polymer will be manufactured in Japan and exported to Australia. The notified polymer will be received in Australia by the sales distributer for distribution throughout Australia to offices and other workplaces.

Transportation and Packaging
Six to 12 units of toner-filled cartridges are packed in a master carton made of cardboard. Transportation from Japan to Australia is by sea; the main transportation in Australia is by truck. The master cartons are stored and delivered by the pallet. The master cartons are used to store the toner in the warehouse of each retailer.

Use
The notified substance will be used as a toner additive for use in printers.

Operation description
The notified polymer will be imported as a component of a toner preparation (present at less than <1.0 wt%) inside sealed toner cartridges for use with devices such as photocopiers and multifunction printers. No reformulation or repackaging will occur in Australia. Toner cartridges will be distributed to offices and other similar workplaces throughout Australia where they will be loaded into multifunction devices for use in workplace printing purposes.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport workers	0	0
Maintenance workers	0.5	240
Office workers/End-users	0.1	12

EXPOSURE DETAILS
No occupational exposure during repackaging or reformulation will occur in the country as no reformulation will take place in Australia.

Transport and warehousing
Transport and distribution workers handling the cartridges containing the notified polymer will be involved in loading and unloading of packages containing numerous cartridges. 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
Wholesale workers will not come into contact with the toner containing the notified polymer as the toner cartridge is designed to prevent spiller of the toner. As such, these workers are not expected to be exposed to the notified polymer.

Service technicians
Service technicians will come in contact with the sealed toner cartridges during multifunctional device and printer maintenance. Any empty or defective cartridges will be replaced with new ones. The most likely route of exposure is dermal. Inhalation exposure is unlikely due to the sealed nature of the cartridges. Similarly, accidental oral exposure is not expected to be significant. Multifunctional device and printer maintenance personnel exposure to the toner will be minimised by following the replacement procedures recommended by the manufacturer. The only increased potential for dermal and/or inhalation exposure to toner containing the notified polymer during toner container and waste toner box replacement operations will occur in the event of a spill.

Photocopier and printer users
Multifunctional devices and printer users in the office might be exposed to the notified polymer when changing toners; however, the exposure is less frequent than service technicians. After application to paper substrate and once dried, the toner containing the notified polymer is expected to be bound to the paper or the cured print matrix 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.

Public exposure through importation, transportation or storage is expected to be negligible. Such exposure could only occur in the unlikely event of an accident.

The formulated toner is contained inside a sealed cartridge, which is also wholly contained within a compartment of the machine during normal use. Public exposure to the notified polymer is expected to be minimal under normal conditions of use. During the printing process the toner is instantaneously printed onto paper following its release from the toner cartridge. The toner is immediately melted during printing and the notified polymer is irreversibly bound to the paper matrix under normal conditions of use.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Mutagenicity – bacterial reverse mutation	Non-mutagenic

Toxicokinetics, metabolism and distribution
Based on the high molecular weight (Mn > 1000) and low percentage of low molecular weight species < 1,000 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.

Mutagenicity/Genotoxicity
The notified polymer was not mutagenic in bacteria in a bacterial reverse mutation assay.

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, or 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 information, the notified chemical is expected to be of low hazard. Limited dermal absorption of the notified chemical is expected. The notified polymer will be imported as a component of finished toner for photocopiers and printers at a concentration < 1.0 wt %. These exposures are expected to be lowered by the enclosed nature of the toner cartridges and personal protective equipment.

Once deposited onto the paper, the notified polymer is expected to remain bound to the paper or the cured print matrix and, therefore, not be bioavailable. Overall, the release of the notified polymer and exposure will be low. Therefore, when used in the proposed manner, the risk to workers from exposure to the notified polymer is not considered to be unreasonable.

6.3.2. Public Health
There is the potential for direct dermal exposure of the public to the notified chemical during maintenance of printers. The public may come into contact with products that have been printed with the notified chemical; however, once cured, the notified chemical will not be bioavailable.

Therefore, when used in the proposed manner, the risk to public health from exposure to the notified polymer is not considered to be unreasonable.

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 printer toner in sealed ready-to-use cartridges. Release of the toner solution to the environment is not expected, as manufacturing and reformulation of the toner containing the notified polymer will not take place in Australia. Environmental release of the notified polymer during importation, transport and storage is likely to be limited to accidental spills and leaks.

RELEASE OF CHEMICAL FROM USE

During use, the majority of the notified polymer will be cured within an inert matrix and bound to paper substrates, and will not be released from printed paper substrates. Environmental release of the notified polymer is possible during paper recycling and from the disposal of used printer cartridges.

RELEASE OF CHEMICAL FROM DISPOSAL

Following use, spent cartridges containing residues of the notified polymer will be collected for recycling by the distributor, or be disposed of to landfill in accordance with local government regulations. Residues containing the notified polymer separated from the spent cartridges will be disposed of in accordance with local government regulations, most likely to landfill.

The notified polymer will be used in printer toner for printing onto paper substrates. The majority of the notified polymer is expected to share the fate of the printed articles to which it is bound. It is assumed that 50% of the printed paper will be disposed of to landfill, and the remainder will undergo paper recycling processes. During paper recycling processes, waste paper is repulped using a variety of chemical treatments which, amongst other things, will enhance toner detachment from the fibres. Waste water containing the notified polymer will be released to sewer.

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified polymer. The majority of the notified polymer is expected to enter the environment from disposal of printed paper products to which the printer toner containing the notified polymer is bound. Approximately 50% of the notified polymer is expected to be disposed of to landfill as part of printed waste paper. Based on its high molecular weight and low water solubility, the notified polymer in landfill is not expected to be mobile or bioavailable. The remaining 50% of the notified polymer has the potential to be released to sewer after the de-inking of printed paper during recycling processes. During the de-inking process, the notified polymer is unlikely to be released to supernatant waters. Based on its high molecular weight and cationic properties, up to 90% of the cured toner containing the notified polymer is expected to adsorb to sludge and sediment (Boethling & Nabholz, 1997), with the sludge eventually disposed of to landfill or re-used for soil remediation.

Based on its high molecular weight and low water solubility, the notified polymer is not expected to be biodegradable. Bioaccumulation of the notified polymer is not likely as it is not expected to cross biological membranes due to its high molecular weight and low water solubility. In landfill, the notified polymer is expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with 50% of the paper products containing the notified polymer undergoing recycling, and the notified polymer to be released into sewers with no removal during recycling or STP processes. As the notified polymer bound to paper substrates is to be processed at paper recycling facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	500	kg/year

Days per year where release occurs	260	days/year
Daily chemical release:	1.92	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.425	µg/L
PEC - Ocean:	0.043	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m^2/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 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.425 µg/L may potentially result in a soil concentration of approximately 2.835 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 14.17 µg/kg and 28.35 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data for the notified polymer were submitted. Ecotoxicological endpoints for the notified polymer were calculated based on structure-activity relationship (SAR) equations, assuming a worst case cationic charge density for the polymer (Boethling & Nabholz, 1997). The endpoints are summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Acute Toxicity		
Fish Toxicity	96 h LC50 = 8.92 mg/L	Not harmful to fish up to water solubility limit
Daphnia Toxicity	48 h EC50 = 148.19 mg/L	Not harmful to *Daphnia*
Algal Toxicity	96 h E_rC50 = 10.62 mg/L	Not harmful to algae up to water solubility limit
Chronic Toxicity		
Fish Toxicity	ChV = 0.5 mg/L	Potentially toxic to fish with long lasting effects
Daphnia Toxicity	ChV = 8.23 mg/L	Not harmful to *Daphnia* (chronic)
Algal Toxicity	ChV = 3.14 mg/L	Not harmful to algae (chronic)

Based on the above SARs estimation endpoints, the notified polymer is not expected to be acutely harmful to aquatic life up to the limit of its solubility in water, although it may be toxic to fish on a chronic basis. The SARs estimation procedure used is a standard approach and is considered reliable to provide general indications of the likely environmental effects of a polymer. However, this method is not considered sufficient to formally classify the hazard of the notified polymer to aquatic life under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009). Therefore, the notified polymer is not formally classified under the GHS for acute and chronic toxicities.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the most sensitive chronic endpoint for fish. A safety factor of 50 was used given modelled acute and chronic endpoints are available for three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish, ChV)	0.50	mg/L
Assessment Factor	50	
Mitigation Factor	1.00	
PNEC:	10.00	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.425	10.00	**0.043**
Q - Ocean	0.043	10.00	**0.004**

The Risk Quotients for discharge of treated effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. Whilst the notified polymer is not expected to be biodegradable, it is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual importation volume, and assessed use pattern in printing ink, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility Insoluble at 25 °C

METHOD	In-house flask method
Remarks	200 mg of the test substance was added to 100 mL of water and shaken in a 35–40 °C water bath for 1 h. They were placed at 25 ± 2 ºC for 24 h. Any insoluble components were then filtered, washed with solvents, dried and weighed.
TEST FACILITY	Toray Research Center (2015)

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	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2*uvrA*
Metabolic Activation System	S9 mix
Concentration Range in Main Test	a) With metabolic activation: 0, 10, 20, 39, 78, 156, 313 µg/plate (*S. typhimurium*); 0, 313, 625, 1250, 2500, 5000 µg/plate (*E. coli*) b) Without metabolic activation: 0, 0.61, 1.2, 2.4, 4.9, 10, 20 µg/plate (*S. typhimurium*); 0, 313, 625, 1250, 2500, 5000 µg/plate (*E. coli*)
Vehicle	Acetone
Remarks - Method	Original study in Japanese and a 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*
Absent	≥ 20		≥ 5,000	negative
Test 1		≥ 20	≥ 5,000	negative
Test 2		≥ 20	≥ 5,000	negative
Present	≥ 313		≥ 5,000	negative
Test 1		≥ 313	≥ 5,000	negative

Remarks - Results	In this study, neither an increase in the number of revertant colonies more than twice in comparison with that of the negative control, nor a dose-related response was observed in any strains of base-pair substitution type or frame-shift type, with or without metabolic activation.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BML, Inc. General Laboratory (2014)

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