File No PLC/1035

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in MX series 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. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government 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 Australian Government Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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

February 2012

Table of Contents

SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1035	Sharp Corporation of Australia Pty Ltd	Polymer in MX series Toner	No	< 10 tonnes per annum	Ingredient for toners in printing cartridges

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

Environmental Risk Assessment
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Health and Safety Recommendations

- 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 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.

Environmental Recommendations

- No specific control measures are required to minimise release of the notified polymer to the environment.

Disposal

- The notified polymer should be disposed of to landfill.

Storage

- The following precautions should be taken by workers regarding storage of the notified polymer:
  - Store in a segregated and approved area.
  - Store in original container protected from direct sunlight in a dry, cool and well ventilated area, away from incompatible materials (oxidising substances, strong acids, strong bases).

Emergency Procedures

- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.
- Spills and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

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 polymer 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 polymer, 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(1) of the Act; if
- the notified polymer is introduced in a chemical form that does not meet the PLC criteria.
- the polymer is imported other than in sealed cartridge.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the notified polymer has changed from ingredient for toners in printing cartridges at < 50%, or is likely to change significantly;
- the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
- the notified polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the notified 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.

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants
Sharp Corporation of Australia Pty Ltd (ABN 40 003 039 405)
1 Huntingwood Drive, HUNTINGWOOD NSW 2148

Exempt Information (Section 75 of the Act)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities, use details and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)
Polymer in MX series Toner

Molecular Weight
Number Average Molecular Weight (Mn) is > 1,000 Da

Reactive Functional Groups
The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Yellowish-brown power
Glass Transition Temp	59.7°C
Density	1110 kg/m^3 at 24.6°C
Water Solubility	0.075 g/L at 25°C. Measured by an in-house method. Notified polymer (2000 mg) was dissolved in water (1 L), agitated for 1 hr at 37°C and kept for 24 hrs at 25°C. The solution was filtered with a membrane filter and the residual polymer weight was measured. The mean of duplicate tests was reported.
Dissociation Constant	Not determined. The notified polymer contains functionality that is expected to ionise in the environmental pH range (4 - 9). However, it constitutes a minor proportion of the notified polymer.
Particle Size	The polymer is a resinous substance with no fine particulate or granular material present.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 10	< 10	< 10	< 10	< 10

Use
The notified polymer will not be manufactured in Australia and it will be imported as ingredient for toners in printing cartridges at < 50%.

6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by tests submitted on the following toxicological endpoint.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
1. Skin sensitisation, guinea pig, adjuvant test (product containing < 50% polymer)	no evidence of sensitisation	no	Similar to OECD TG 406
2. Genotoxicity - bacterial reverse mutation (notified polymer)	non mutagenic	no	OECD TG 471

All results were indicative of low hazard.

One monomer of the notified polymer is classified as a skin sensitiser because of its potential to form sensitising oxidation products. The level of residual monomer is below the cut-off concentration for classification. The polymer itself contains a moderate level of low molecular weight species and while the potential for sensitisation of the notified polymer cannot be ruled out, it will be reduced by the overall high molecular weight and the fact that the polymer contains only a limited percentage of the monomer.

Occupational Health and Safety Risk Assessment
Due to the classification of one of the monomers, the potential for skin sensitisation of the polymer cannot be ruled out. However, as the polymer is imported in sealed cartridges at < 50% and no reformulation or repackaging occurs in Australia, exposure of technicians while servicing printers and photocopiers, including replacing empty toner cartridges, is expected to be low. The monomer has been reacted to reduce saturation, and this may further reduce the hazard. In addition an adjuvant test for skin sensitisation on the imported product containing the notified polymer was negative. The risk to workers is not considered unreasonable.

Public Health and Safety Risk Assessment
The exposure of the public during use of photocopiers or printers is considered to be similar to that of workers, but is expected be less frequent. Therefore the risk to the public posed by the notified polymer is not considered unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. This does not

apply to the notified polymer and it is therefore unlikely to be an over-chelation hazard to algae. Furthermore, only a small proportion of the notified polymer has anionic functionality.

The notified polymer will be imported into Australia as an ingredient of toner in printer cartridges. Approximately 50% of the paper on which the products will be printed will be recycled. Most of the notified polymer will reach landfill as a result of disposal of used paper, empty cartridges, or sludge waste from paper recycling processes. In landfill the notified polymer will be slowly degraded, eventually forming water and oxides of carbon. The notified polymer is moderately water soluble and may not be fully recovered by on site waste water treatment at paper recycling facilities. Small quantities of the polymer may therefore be released to surface waters as a result of the de-inking process. However, the notified polymer is not expected to be a toxic hazard to aquatic organisms and, based on its high molecular weight, has a low potential to bioaccumulate. The notified polymer is therefore not expected to pose an unreasonable risk to the environment based on the assessed use pattern.