

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

POLYMER OF LOW CONCERN PUBLIC REPORT

ATLAS™ Silica Composite

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government 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 Australian Government 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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Public Report

This assessment report is for an extension of original assessment certificate for ATLAS™ Silica Composite. Based on the submission of new information by the extension notifiers, some sections of the original assessment report have been modified. These modifications have been made under the heading 'Extension Application' in the respective sections.

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
EX/203 (PLC/1314)	Canon Australia Pty Ltd HP PPS Australia Pty Ltd	ATLAS™ Silica Composite	No	< 10 tonnes per annum	Component of printer and photocopier toners

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

- Where a suitable and sufficient workplace risk assessment indicates that control measures are necessary, these should be implemented to prevent, or where this is not practicable, minimize the risks to human health. Adequate control of exposure to workers should be in accordance with the hierarchy of controls. In particular, the following control measures should be used during dry blending and filling of toner cartridges:
 - Automated and enclosed processes, where possible
 - Adequate local and general ventilation
 - Personal protective equipment, including respiratory protection if inhalation exposure may occur

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Service personnel should wear 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 (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 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;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component of printer and photocopier toners, 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 (M)SDS of the notified polymer was provided by the applicant. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

Extension Application:

One of the two applicants for the extension application (Canon Australia Pty Ltd) has provided an MSDS for a product containing the notified polymer. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants

Holder of Original Assessment Certificate (PLC/1314)

Axieo Operations (Australia) Pty Ltd (ABN: 88 602 074 322)
Level 3, 35 Cotham Road
KEW VIC 3101

Applicants for an Extension of the Original Assessment Certificate:

Canon Australia Pty Ltd (ABN: 66 005 002 951)
Building A, The Park Estate, 5 Talavera Road
MACQUARIE PARK NSW 2113

HP PPS Australia Pty Ltd (ABN: 16 603 480 628)
Level 5, 1 Homebush Bay Drive,
RHODES NSW 2138

Exempt Information (Section 75 of the Act)

Original application

Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities and import volume

Extension Application

Data items and details claimed exempt from publication: use details and import volume

2. IDENTITY OF POLYMER

Marketing Name(s)

ATLAS™ Silica Composite

Other Name(s)

2-Alkanoic acid, 2-alkyl-, 3-(trimethoxysilyl)propyl ester, homopolymer, hydrolysis products with silica and 1,1,1-trimethyl-N-(trimethylsilyl)silaneamine
Treated Colloidal Silica/Poly(Methacryloxypropylsiloxane) Composite Particle

Molecular Weight

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

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
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	White or slightly off white powder
Melting Point	Decomposes at > 230 °C
Density	1,670 kg/m ³ at 20 °C
Water Solubility	Insoluble
Dissociation Constant	Not determined. The notified polymer does not contain any functional groups that are expected to dissociate in water
Particle Size	~ 80 nm
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

Original application

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
Tonnes	< 1	< 1	0.5-5	0.5-5	0.5-5

Total introduction volume for both extension applicants

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
Tonnes	0-3	1-10	1-10	1-10	1-10

Use

Original application

The notified polymer will not be manufactured in Australia. The notified polymer will be imported into Australia a) in the neat form as a powder for reformulation; b) as a component of end-use printer toners at ≤ 5% concentration (typically at 1% concentration); c) a component of end-use toners contained in cartridges at ≤ 5% concentration (typically at 1% concentration).

Extension application

The notified polymer will not be manufactured, reformulated or repackaged in Australia. The notified polymer will be imported into Australia in sealed toner containers. The notified polymer will be used as a component of a toner at up to 10% concentration in photocopier machines or printers.

6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer is a high molecular weight polymer (> 70,000 Da) with low water solubility. Inhalation of polymers with molecular weights > 70,000 Da has been linked with irreversible lung damage due to lung overloading and impaired clearance of particles from the lung, particularly following repeated exposure. If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs.

The notified polymer is also a nanomaterial. The notified polymer is expected to have a similar hazard profile to synthetic amorphous silica (SAS) that is one of the major components. Furthermore, the amorphous silica component is predominantly located at the surface. It is the surface characteristics that generally define the toxicity of nanoparticles.

SAS is considered to be of low toxicity. A report by the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC, 2006) concludes that in humans, SAS is essentially non-toxic by

mouth, skin or eyes, and by inhalation. The International Agency for Research on Cancer (IARC) did not identify SAS as either an animal or human carcinogen (IARC, 2007). Systemic toxicity after repeated exposure to SAS could not be detected in various studies via the oral, dermal and inhalation route (ECETOC 2006; OECD 2004). The inhalation of respirable particles of SAS produced a time- and dose-related local inflammation response of the lung tissue in animal studies (OECD 2004). However, it was observed in experimental investigations that these responses are transient and reversible after termination of exposure and during the recovery periods.

The notifier has also provided toxicological data for the notified polymer for the following endpoints (study reports were not provided):

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Rat, acute oral	LD50 > 2000 mg/kg bw; low toxicity	yes	OECD TG 420
Rabbit, skin irritation	non-irritating	no	OECD TG 404
Rabbit, eye irritation	non-irritating	yes	OECD TG 405
Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD TG 471

Acute oral toxicity: no mortality, hunched posture was noted in 4 animals during day of dosing, there were no signs of toxicity noted in one animal. All animals showed expected gains in body weight. No abnormalities noted at necropsy.

Eye irritation: Single application of test item to the non-irrigated eye of two rabbits produced moderate conjunctival irritation. One treated eye appeared normal at the 48-hour observation and the other treated eye appeared normal at the 72-hour observation.

The results were indicative of low hazard further supporting the expected low toxicity for the notified polymer.

Occupational Health and Safety Risk Assessment

The greatest risk posed by the notifier polymer is as an inhalation hazard due to the potential for lung overloading effects.

Inhalation exposure to the neat powdered notified polymer may occur during dry blending with bare toner particles and other additives to form the formulated toner. Inhalation to the notified polymer at $\leq 5\%$ concentration may also occur during filling of the toner cartridges with the formulated toner. The notifier states that the dry blending and filling processes are usually performed in a closed system. The notifier also states that workers are expected to wear PPE including a certified particulate respirator. Therefore, given the expected low hazard of the notified polymer and expected control measures in place to limit exposure, the risk of the notified polymer to the health of workers during dry blending and cartridge filling operations is not considered to be unreasonable.

Toner cartridges filled with toner containing the notified polymer at $\leq 5\%$ concentration (typically 1%) will be used in commercial and office printers and photocopiers. Office workers are expected to have similar exposure to the notified polymer as public consumers (see below). Therefore, the risk of the notified polymer to the health of office workers is not considered unreasonable.

Public Health and Safety Risk Assessment

Toner cartridges filled with toner containing the notified polymer at $\leq 5\%$ concentration (typically 1%) will be available to the public. Given the toner containing the notified polymer will be contained within sealed cartridges and the printing process is largely enclosed, public exposure to the notified polymer is not expected during printing. The public may come into contact with the toner containing the notified polymer after it has been imprinted onto the paper. However once the toner is melted and

fused onto the paper, the notified polymer will be trapped within the toner polymer matrix and will not be available for exposure.

Therefore, the risk of the notified polymer to public health is not considered to be unreasonable given the expected low hazard of the notified polymer and the assessed use pattern.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Polymers without significant ionic functionality are generally of low concern to the environment.

The notified polymer will be imported as a component of printer ink in ready-to-use cartridges. Printing cartridges are designed to prevent release of its contents during transport, installation and removal. Accidental spills are expected to be contained and disposed of to landfill. The toner containing the notified polymer may be blended locally. Air emission control facilities (e.g. scrubber, electrostatic dust collector) will be used during manual operation to prevent environmental release. Estimated release amount of the product containing the notified polymer to air and water is expected to be below 100 g/day. Any wash waters, spills and residues resulting from the blending/cleaning operations are likely to be disposed of in accordance with local, State and Federal regulations.

The ink will be used on printing articles and the notified polymer, bound within the dried ink matrix, will share the fate of the article. It is anticipated that approximately half of these articles will be disposed of to landfill and the remainder will be recycled at the end of their useful lifetime. During the recycling process, waste paper will be repulped using a variety of alkaline dispersing and wetting agents, water emulsifiable organic solvents and bleaches. Aqueous wastes containing these agents are expected to be sent to sewage treatment plants (STPs) for processing. Under a worst case scenario it will be assumed that 50% of the notified polymer will be washed into sewers. Assuming 0% of the notified polymer will be removed *via* absorption to sludge in the STP, the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as 2.13 µg/L [$\text{PEC}_{\text{river}} = 9.62 \text{ kg notified polymer/day} \div (150 \text{ L/person/day} \times 22.613 \text{ million people}) \times 1$ (dilution factor)]. The PEC is below the EC50 for algae of the most toxic polymers ($\text{EC}_{50} > 1 \text{ mg/L}$). In sewage treatment plants, most of the notified polymer is expected to partition to sludge and sediments as it has high molecular weight.

Due to its high molecular weight, the notified polymer will not readily cross biological membranes and, therefore, bioaccumulation is not expected.

The proportion of the notified polymer that is adsorbed to STP sludge will be disposed of to landfill or may be used for soil remediation, where it is expected to slowly degrade to form water and oxides of carbon and silica.

Therefore, based on its assumed low hazard, the notified polymer is not considered to pose an unreasonable risk to the environment.

Extension application

The increase in volume due to use according to the extension applications would lead to a PEC of 6.35 µg/L, which is still below the EC50 for algae of the most toxic polymers ($\text{EC}_{50} > 1 \text{ mg/L}$).

8. RISK ASSESSMENT FOR EXTENSION APPLICATION

While the introduction volume will increase, the extension applications are not considered to increase the environmental risk substantially. The proposed use of the notified polymer will not change significantly under the proposed extensions. Therefore the circumstances in the extension application are not expected to impact on the original human health and environmental risk assessment and recommendations.

REFERENCES

ECETOC (2006) Synthetic Amorphous Silica (CAS No. 7631-86-9). ECETOC JACC Report No. 51. European Centre for Ecotoxicology and Toxicology of Chemicals, Brussels, Belgium.

IARC (1997) Monographs on the Evaluation of Carcinogenic Risks to Humans, Silica. Int Agency Res Cancer (IARC) 68:1–9.

OECD (2004) SIDS Initial Assessment Report on Synthetic amorphous Silica and Silicates – CAS 7631-86-9, 112945-52-5, 112926-00-8:Silicon Dioxide; CAS 1344-00-9: Silicic Acid, Aluminum Sodium Salt; CAS 1344-95-2: Silicic Acid, Calcium Salt. In.