

File No PLC/790

August 2008

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

FULL PUBLIC REPORT

Polymer in BH35 series and B854

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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**Director
NICNAS**

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FULL PUBLIC REPORT**Polymer in BH35 series and B854****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT

Ciba (Australia) Pty Limited (ABN 97 005 061 469)
235 Settlement Road
THOMASTOWN VIC 3074

NOTIFICATION CATEGORY

Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name, CAS Number, Other Names, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Import Volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

NOTIFICATION IN OTHER COUNTRIES

USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

BH35-Y, BH35-M, BH35-C, BH35-K, B854

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >1000 Da

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION*Criterion*

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

Criterion met

Yes
Yes
Yes
Yes
Yes
Yes
Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Slightly yellow-coloured pellets
Melting Point ~130°C

Density	~1250 kg/m ³
Water Solubility	< 10 mg/L at 20°C based on limited laboratory testing. No test report available.
Dissociation Constant	Not determined. The notified polymer contains low amounts of carboxylic acid functionality and is expected to have typical acidity (pKa 3-5).
Particle Size	Mean particle size = 607.4 µm (2.1% ≤100 µm)
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 be used as a component of photocopier toner.

Mode of Introduction

The notified polymer will be imported either in powder form at 100% or in purpose-built sealed toner cartridges (typically, ~800 g, ~1230 g) at <90% for use in photocopying equipment.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

No toxicological data were submitted. The notified polymer meets the PLC criteria and can therefore be assumed to be of low hazard.

Occupational Health and Safety Risk Assessment

Dermal and ocular exposure to the notified polymer may occur during formulation of toner products and refilling/replacing spent ink cartridges in offices. However, given the assumed low hazard of the notified polymer, the risk via these routes is not expected to be unacceptable.

The notified polymer is insoluble, contains a proportion of high molecular weight particles (Weight Average Molecular Weight >10,000 Da.) in the inhalable and respirable ranges (2.1% ≤100 µm). Therefore, it may have the potential to cause irreversible lung damage (US EPA, 2007: <http://www.epa.gov/oppt/newchems/pubs/hmwtpoly.htm>). Workers may experience inhalation exposure to airborne particles of the notified polymer during reformulation processes. While the particle size is large (97.9% ≥100 µm), a proportion of particles fall within the breathing zone and have the potential to accumulate and cause lung overloading in workers during handling. The use of local exhaust ventilation (LEV) and suitable personal protective equipment, such as respirators suitable for particulates, would minimise the exposure to airborne particles and therefore the risk would not be expected to be unacceptable.

Public Health Risk Assessment

Members of the public may be exposed to the notified polymer during public use of photocopiers. These exposures are expected to be similar to those for office workers. However, it is expected that the public will be using the photocopier less often than office workers.

The risk to public health presented by the notified polymer is expected to be low due to its assumed low hazard and low potential for exposure.

7. ENVIRONMENTAL IMPLICATIONS

Environmental Release

Environmental release of the notified polymer is not expected during importation, storage and transportation. Spillage during a transport accident is the most likely reason for environmental release. In such an event, individual container capacity and container specifications would limit the extent of release since each toner

cartridge is designed to prevent leakage. If leakage does occur, the notified polymer will be collected and sent to landfill for disposal.

Used cartridges containing up to 5% of the notified polymer will either be returned to the distributor for recycling or reuse, or sent to landfill for disposal. Residual notified polymer within recycled cartridges is expected to remain within these containers, although release could occur from deterioration of the cartridge while in the landfill waste.

Toner containing the notified polymer will be applied to paper products. Some waste paper could be disposed of directly to landfill with the notified polymer bound to the paper. In addition to landfill, some printed paper will enter the paper recycling process.

Environmental Fate

The notified polymer contains groups that might hydrolyse under severe conditions, but is expected to be stable under normal environmental conditions. Due to its low water solubility, the notified polymer in solid wastes is expected to remain bound within the soils and sediments of landfills and eventually degrade through biotic and abiotic processes. If spilt on land, the notified polymer is expected to bind to soil and become immobilised in the soil layer. If spilt to water, it is not expected to dissolve but rather disperse or settle to sediment. It is not expected to be readily biodegradable and due to its high molecular weight, it is not expected to bioaccumulate.

Hazard Characterisation

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

Environmental Risk Assessment

While environmental exposure is limited during toner use, the total import volume of the notified polymer will ultimately be disposed of in either landfill or be incinerated. The widespread use pattern indicates that landfills throughout Australia would receive the notified polymer bound into the toner matrix within cartridges and on paper products. The used toner containing the notified polymer would be expected to remain within the container unless breached. On paper the notified polymer will interact with other components to form a stable polymer matrix and, is expected to be immobile and pose little risk to the environment.

During recycling processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, toner detachment from the fibres, pulp brightness and the whiteness of paper. These aqueous wastes are expected to go to sewer. Very little of the notified polymer is expected to partition to the supernatant water which is released to the sewer. Sludge generated during the washing process is dried and incinerated or sent to landfill for disposal.

The notified polymer is not likely to present a risk to the environment when it is stored, transported, used, recycled and disposed of in the proposed manner.

8. CONCLUSIONS AND RECOMMENDATIONS

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

Based on the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- In the interest of occupational health and safety, the following precautions should be observed for use of the notified polymer as introduced in powder form:

- Avoid the generation of airborne dusts.
 - The American Conference of Governmental Industrial Hygienists (ACGIH) exposure level of 3 mg/m³ should be used for “respirable (insoluble) particulates (not otherwise regulated)”.
- If necessary, employers should ensure that a suitable respirator for particulates in the breathing zone is used by workers to minimise occupational exposure to the notified polymer during certain processes where dust may be generated.

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

- 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.

Storage

- Store in a cool, well-ventilated place away from flame and spark-producing equipment.

Emergency procedures

- Dust generation should be avoided during clean up of spilled toner containing the notified polymer should and carefully transfer into sealed waste container.

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 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 component of photocopier toner or is likely to change significantly;
 - the amount of notified polymer being introduced has increased from 10 tonnes, or is likely to increase, significantly;
 - if 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 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.

Material Safety Data Sheet

The MSDS for products 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.