

File No PLC/681

January 2007

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

FULL PUBLIC REPORT

Diacron ER-535

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 and Heritage.

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**Director
NICNAS**

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Diacron ER-535**1. APPLICANT AND NOTIFICATION DETAILS****APPLICANT(S)**

Kyocera Mita Australia Pty Ltd (ABN: 77 003 852 444)
Level 3, 6-10 Talavera Rd, North Ryde, NSW, 2113

NOTIFICATION CATEGORY

Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL**CHEMICAL NAME**

1,4-Benzenedicarboxylic acid, polymer with 1,2-ethanediol, 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxy)]bis[ethanol] and 1,1'-[(1-methylethylidene)bis(4,1-phenyleneoxy)]bis[2-propanol]

OTHER NAME(S)

None

MARKETING NAME(S)

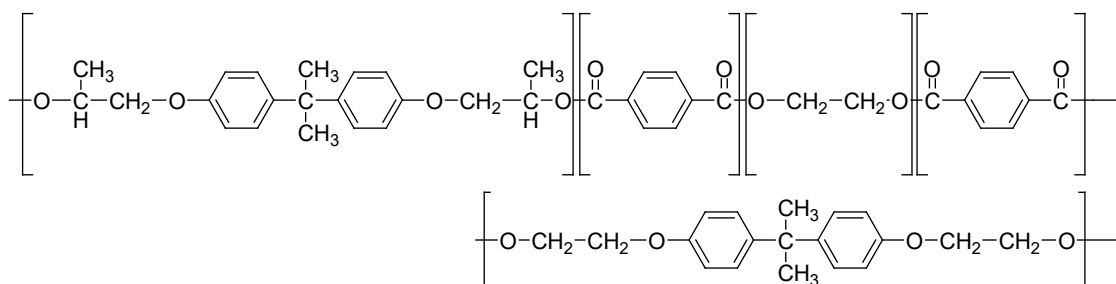
Diacron ER-535

CAS NUMBER

148556-68-7

MOLECULAR FORMULA

$(C_{21}H_{28}O_4.C_{19}H_{24}O_4.C_8H_6O_4.C_2H_6O_2)_x$

STRUCTURAL FORMULA**MOLECULAR WEIGHT**

Number Average Molecular Weight (Mn)	3207
Weight Average Molecular Weight (Mw)	9095
Polydispersity Index (Mw/Mn)	2.84

% of Low MW Species < 1000	6.24
% of Low MW Species < 500	3.26

POLYMER CONSTITUENTS

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % starting</i>	<i>Weight % residual</i>
1,4-Benzendicarboxylic acid	100-21-0	34	<0.01
2-Propanol, 1,1'-[(1-methylethylidene)bis(4,1-phenyleneoxy)]bis-	116-37-0	36	<0.01
Ethanol, 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxy)]bis-	901-44-0	27	<0.01
1,2-Ethanediol	107-21-1	3	<0.01
*Antimony oxide	1309-64-4	0.06	<0.06
*Stannane, dibutyl-oxo-	818-08-6	0.03	<0.03

*Catalysts used in the manufacture of the polymer.

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met (yes/no/not applicable)</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	Solid slightly yellow pellet.
Glass Transition Temp	60°C
Density	1250 kg/m ³ (temperature unspecified)
Water Solubility	<10 mg/L at 20°C (Limit of Detection) based on limited laboratory testing. Test report unseen.
Dissociation Constant	Not determined. The notified polymer does not contain dissociable functionality.
Particle Size	Average particle size 830 µm 99.82% > 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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	0.05	0.29	0.29	0.29	0.29

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will be imported as a component of printer/copier toner at a concentration of 5-90% in purpose built sealed toner cartridges.

Reformulation/manufacture processes

The notified chemical will not be manufactured, repackaged or reformulated in Australia. The toner will be imported and supplied in purpose built, sealed cartridges which would be inserted inside the printing equipment. The sealed cartridges will be handled by service technicians or office workers replacing the spent cartridges in the printer.

Use

The notified polymer is an additive in printer/copier toner.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Transport & Warehousing

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

Service Technicians

Service technicians will come into contact with the sealed cartridges during printer maintenance. Any empty or defective cartridges will be replaced with new ones. No attempt will be made to repair or refill the cartridges. The most likely route of exposure to the notified polymer is dermal although inhalation exposure can also occur however this is unlikely due to the sealed nature of the cartridge. Similarly, accidental oral exposure is not expected to be significant. Exposure is expected to be controlled through the design of the cartridges and the printing machines. Printer maintenance personnel often wear cotton disposable gloves. Pre-packed toner cartridges are sealed and worker exposure to the toner is minimised by the use of the replacement procedures recommended by the manufacturer.

Office Workers

Office workers will replace used, empty cartridges as per the manufacture's instructions. The main route of exposure will be dermal. However, since the cartridges are sealed, there is low risk of such exposure.

Retail Workers

These workers will be involved in opening cardboard cartons, removing the cartridges, which will be contained within an outer cardboard box and stacking the individual boxes onto shelves. These workers will not have any contact with the cartridge and thus minimal exposure to the notified polymer is expected.

PUBLIC EXPOSURE

The scenarios by which the public may be exposed to the notified chemical would involve home use of printers, and are similar to those for office workers. However, it is expected that the public will be using the printer less often than workers.

6.2. Toxicological Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on a toner product containing the notified polymer at a concentration of 20%.

The following toxicological data were for a product containing the notified polymer at a concentration of 20%.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
1. Rat, acute oral	LD50 >2000 mg/kg bw	no	yes	OECD TG 401 OECD TG 423
2. Rabbit, skin irritation	non-irritating	no	no	OECD TG 404
3. Rabbit, eye irritation	slightly irritating	no	yes	OECD TG 405
4. Genotoxicity - bacterial reverse mutation	non mutagenic	no	no	OECD TG 471

All results were indicative of low hazard.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

The OHS risk presented by the notified polymer is expected to be low, based on the minimal exposure to workers and the low intrinsic hazard of the polymer.

PUBLIC HEALTH

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

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Environmental release of the toner 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 toner will be collected and sent to landfill for disposal.

Used cartridges containing up to 5% of toner 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 be removed and disposed of to landfill as solid waste. Residues contained in the disposed cartridges are 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 strongly bound to the paper. In addition to landfill, some printed paper will enter the paper recycling process.

ENVIRONMENTAL FATE

The notified polymer contains polyester functionality that might hydrolyse under severe conditions, but is expected to be stable under normal environmental conditions. Due to its low water solubility, notified polymer disposed of to landfill is expected to remain bound within the soils and sediments and eventually degrade through biotic and abiotic processes. It is not expected to be readily biodegradable but due to its high molecular weight, it is not expected to bioaccumulate. Incineration of the notified polymer will result in the formation of water vapour and oxides of carbon.

7.2. Environmental Hazard Characterisation

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

7.3. 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 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, once dry, 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

8.1. Level of Concern for Occupational Health and Safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

8.2. Level of Concern for Public Health

There is No Significant Concern to public health when used in the proposed manner.

8.3. Level of Concern for the Environment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

9. MATERIAL SAFETY DATA SHEET

9.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

10. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- 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.

- 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

10.1. Secondary Notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under subsection 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 subsection 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.