File No PLC/714

October 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Benzoic acid, 4-(4-phenoxyphenoxy)-, homopolymer

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 Water Resources.

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:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Polymers International Australia Pty Ltd (ABN 92 069 883 825)
17-19 Endeavour Way, BRAESIDE VIC 3195

NOTIFICATION CATEGORY
Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Molecular Weight, Residual Monomers/Impurities, Import Volume

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)
No

NOTIFICATION IN OTHER COUNTRIES
Korea (2007), China and USA

2. IDENTITY OF CHEMICAL

MARKETING NAME
Gatone PEEK

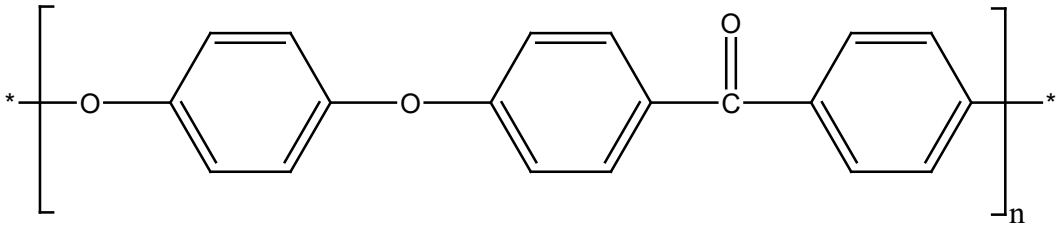
CHEMICAL NAME
Benzoic acid, 4-(4-phenoxyphenoxy)-, homopolymer

CAS NUMBER
88049-74-5

OTHER NAME
Polyetheretherketone

MOLECULAR FORMULA
$(C_{19}H_{14}O_4)_x$

STRUCTURAL FORMULA



% of Low MW Species < 1000 Da < 5%
% of Low MW Species < 500 Da < 5%

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) > 10000 Da

POLYMER CONSTITUENTS

Chemical Name	*CAS No.*	*Weight % starting*
Benzoic acid, 4-(4-phenoxyphenoxy)-	88049-73-4	100

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	Criterion met (yes/no/not applicable)
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: Odourless pellets, or a white, grey or beige powder.

Melting Point/Glass Transition Temp	343°C
Density	1350 kg/m^3 (temperature unspecified)
Water Solubility	Estimated <0.1%, consistent with its hydrophobic structure.
Dissociation Constant	The notified polymer does not contain any acidic or basic groups.
Particle Size	Pellets: 2.81 mm diameter
(delete if liquid or solution)	Powders: < 250 µm % respirable (<10 µm) = 18.5% % inhalable (<100 µm) = 90.3%
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	0-1	1-3	3-10	3-10	3-10

Use
As a component of plastic injection moulded articles, such as parts for use in the electrical/electronic industry.

Mode of Introduction and Disposal

The notified polymer will be imported in the form of pellets and powder (50-99% notified polymer) in 3.8, 7.6, 11.3 L plastic pails and 25 kg bags. These formulations of the notified polymer will be blended with additives and/or colourants, such as glass fibre, carbon fibre, titanium dioxide, carbon black, or other polymers.

The products containing the notified polymer will be imported through Sydney or Melbourne, and transported within Australia by road.

Reformulation/manufacture processes

The notified polymer will be imported as a component of solid pellets or powder ready for moulding and injection into end use products. There will be no reformulation or repackaging of the notified polymer before use.

During the manufacturing of injection-moulded articles, the content of imported bags or pails will be transferred to a hopper equipped with dust extractors. The resin will be dried into the hopper and automatically conveyed to the injection machine where it will be melted and injection-moulded into shapes. The moulded articles will be cooled and automatically discharged from the machine. They will then be warehoused and subsequently assembled into finished consumer products. Rejected parts will be collected, grounded into pieces, and re-used for the manufacture of articles.

6. HUMAN HEALTH IMPLICATIONS

Exposure Assessment

OCCUPATIONAL EXPOSURE

Dermal and ocular exposure may potentially occur during certain processes involving the notified polymer, such as weighing and addition of the notified polymer to the hopper for injection moulding, or during the grinding of rejected articles. However, exposure to significant amounts of the notified polymer will be limited because of the largely automated processes, and the engineering controls and personal protective equipment worn by workers (gloves and safety goggles). Workers will make dermal contact with the notified polymer (up to 99%) in finished articles. However, the notified polymer is unavailable for exposure as it is incorporated into the articles.

A significant proportion (approximately 19%) of the polymer dust that may potentially be generated during injection moulding will be respirable (mean particle size < 10 μm). In addition, respirable dust may be generated during grinding of rejected articles or during cleaning operations. Inhalation exposure to the fine powder during injection moulding is expected to be largely controlled by the use of Local Exhaust Ventilation (LEV) and respirators as necessary. Because injection moulding is expected to be mostly automated, enclosed and/or contained with respect to dust, the concentration of dust in the workplace should be minimised by the use of LEV. There may be some potential for exposure while cleaning up dust residues but as this should be conducted using an industrial vacuum cleaner the majority of the dust should be collected into the vacuum cleaner itself and there should be little atmospheric dust generated. There is a possibility of dust generation during emptying and cleaning of the industrial vacuum cleaner where the use of a respirator will be required.

PUBLIC EXPOSURE

Members of the public may make dermal contact with articles containing the notified polymer.

Toxicological Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of no significant health impact. This assumption of low concern is supported by toxicological endpoints observed in studies conducted on the notified polymer using non-standard testing methods. The notified polymer was administered by systemic injection into mice, intracutaneous injection into rabbits and intramuscularly (implantation test) using rabbits. No mortality, toxic signs or irritation were observed.

However the polymer contains approximately 19% respirable particle and is of high molecular weight (> 10000 Da). Water insoluble high molecular weigh polymers used in respirable size range (< 10 μm) have the potential to cause lung overloading. There is no information on the inhalation toxicity of the polymer.

Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

The OHS risk presented by the notified polymer is expected to be low, based on the expected minimal exposure to workers provided that they have adequate respiratory protection against inhalation of the polymer when handling the notified polymer. Automated processes and/or respirators are required when handling the powder.

The Australian recommended exposure standard for nuisance dust is 10 mg/m^3 [NOHSC 3008:(1995)], but a recommended exposure limit of 3 mg/m^3 has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for "respirable (insoluble) particulates (not otherwise regulated)".

PUBLIC HEALTH

The risk to public health will be negligible because the notified polymer would not be bioavailable.

7. ENVIRONMENTAL IMPLICATIONS

Exposure Assessment

ENVIRONMENTAL RELEASE

Environmental release of the notified polymer is summarised in the following table.

Source of release	% Annual Volume	Released to
Residual notified polymer within import containers	< 1%	Landfill
Non-recyclable spills	< 1%	Landfill
Reformulation equipment cleaning	< 1%	Landfill
End-of-Life of formulated products containing the notified polymer.	> 97%	Landfill

ENVIRONMENTAL FATE

Notified polymer that is disposed to landfill is expected to be immobile, due to its low solubility in water. Eventually, the notified polymer is expected to degrade via biotic and abiotic mechanisms to simple organic compounds and water. Due to the large molecular weight and low water solubility, the notified polymer is not expected to bioaccumulate.

Environmental Hazard Characterisation

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

Environmental Risk Assessment

Based on the proposed use pattern, the release of the notified polymer to the environment is expected to be very low. The use pattern of the notified polymer in injection moulded parts will result in limited if any exposure to the aquatic environment. While no ecotoxicity data are available, due to limited release to water it is unlikely that the polymer would exist at levels which could pose a risk to aquatic organisms. The high molecular weight indicates a low potential for bioaccumulation.

Based on the reported exposure levels and use pattern, the polymer is not considered to pose a risk to the environment when it is stored, transported and used in the proposed manner.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment
Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable. However due to the presence of particles in the respirable range workers will need to have respiratory protection when handling the imported material.

When used in the proposed manner the risk to the public is considered to be acceptable.

Environmental risk assessment

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

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer in powder form:
  - Use of Local Exhaust Ventilation when handing the notified polymer in powder form
  - Avoid the formation of airborne dusts
  - Where engineering controls are not adequate, use polymer pellets instead of powder

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during certain processes where dust may be generated:
  - Use of respirator when handling notified polymer in powder form and during cleanup operations
  - Use of gloves, safety goggles and overalls

- In the interest of occupational health and safety, the following guidelines and precautions should be observed for use of the notified polymer as introduced in powder form
  - The level of atmospheric nuisance dust should be maintained as low as possible. The ASCC exposure standard for atmospheric dust is 10 mg/m^3 but a recommended exposure limit of 3 mg/m^3 has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for "respirable (insoluble) particulates (not otherwise regulated)".

  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.

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.

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 chemical 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.
- changes in the operations such as significant exposure to the imported polymer are expected.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from use as a component of plastic injection moulded articles, or is likely to change significantly;
- the amount of chemical being introduced has increased from 10 tonne per annum, or is likely to increase, significantly;
- if the chemical 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 of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.