File No PLC/493

31 August 2004

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Topas

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.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
National Occupational Health and Safety Commission
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1161 or + 61 2 6279 1163.

This Full 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:

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
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

Topas

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Amtrade International Pty Ltd
Level 2, 570 St Kilda Road
Melbourne, Vic. 3004

NOTIFICATION CATEGORY
Synthetic Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
2.1 Chemical Name
2.4 CAS Number
2.5 Molecular Formula
2.6 Structural Formula
2.7 Molecular Weight
3.5 Polymer Constituents
4.1 Maximum Introduction 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)
None

NOTIFICATION IN OTHER COUNTRIES
USA: PMN Submission Case Number Y-95-106, Case Number TS95C0C1
Canada: Added to the Domestic Substances List (DSL) (C. Gaz. Pt II, Vol 137:24, 2721 November 19, 2003)
Korea, CAS + ENCS entry added in Handbook of Existing and New Chemical Substances, 9th Edition (Chemical Daily Co., Ltd)
China: On original China inventory

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Cyclic olefin copolymer

MARKETING NAME(S)
Topas

3. COMPOSITION

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

No Substantial Degradability	Yes
Not Water Absorbing	Yes
Low Concentrations of Residual Monomers	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Manufactured Topas will be imported into Australia. The product contains 99.8 to 100% Topas with additives present, if any, being lubricants listed on AICS.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	20 – 80	40 – 160	50 – 200	80 – 300	100 - 400

USE
The notified polymer will be used for production of moulded articles and films, including food contact materials.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description
Manufactured Topas will be imported into Australia in the form of pellets packaged in 25kg bags. The pellets are melt processed by injection moulding to make a wide range of articles including optical lenses, vials, syringes and packaging film for food and pharmaceuticals. The injection moulding process injects molten polymer into the mould to form the intended article. In the case of films, pellets are melted and extruded as a sheet or film which is cooled and stored in rolls for shipment and use as packaging material.

6. EXPOSURE INFORMATION

6.1. Summary of Environmental Exposure
6.1.1. Environmental Release
Topas is to be produced into finished articles. Small quantities of material may remain in empty packaging in which Topas was supplied. Unintentional release may occur in case of transport accident or in handling (e.g. packaging punctured or torn during handling). Being a dry, inert material, any spilt material, which has not been contaminated by other substances, can be swept up for use. Contaminated material would require disposal as for any similar material.

6.1.2. Environmental Fate
Topas is a relatively stable substance which will be released into the environment in the form of finished products, including optical lenses, vials, syringes and packaging films to be used for food and pharmaceuticals. The polymers offer a high heat deflection temperature making them suitable for applications involving steam autoclaving. This indicates Topas is not likely to quickly degrade.

The predominant use will be production of food-contact materials resulting in material being disposed of in municipal waste disposal facilities in the same way as most food-contact materials.

6.2. Summary of Occupational Exposure
Occupational exposure to Topas can be by transport and warehousing workers and machine press operators/loaders.

The material is packaged in 25kg bags from which material might be spilled accidentally. Transport

and warehousing workers may come into contact with spilt material.

Machine press operators or those responsible for loading injection moulding or film manufacturing presses will be required to open bags and fill machine feed hoppers (depending on machine and feed type).

Machine operators and others nearby could be exposed to vapours if the material is overheated.

In the above cases, contact can be dermal and/or inhalation of dust or vapours. Ingestion is unlikely.

Pellet form minimises risk of dust, ocular contact and potential persistent dermal contact. To further minimise risks to operators, safety eyewear is likely to be worn when handling Topas plus an approved respirator if dust generation is likely to exceed exposure limits (10 mg/m^3 total particulates; 3 mg/m^3 respirable particulates) or if decomposition vapours are generated.

Molten material can cause burns if skin contact occurs. Those who may come in direct contact with molten material will wear long pants, shirts with long sleeves plus insulated gloves and face shield.

6.3. Summary of Public Exposure

Topas is for use in manufacture of finished articles and film, including optical lenses, vials, syringes and packaging film for food and pharmaceuticals. The public will not be exposed to the notified polymer in its raw form. The public will only be exposed to finished articles and film manufactured from the notified polymer.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa	Solid
Melting Point/Glass Transition Temp	Does not melt. Softening point varies with grade.
Density	1.02 kg/m^3 at 25ºC
Water Solubility	Negligible <0.1%
Particle Size	Pellets 3.2mm diameter
Reactivity	Stable.
Degradation Products	Carbon monoxide, carbon dioxide and hydrocarbons

7.1. Comments

Topas consists of a hydrophobic hydrocarbon backbone with no polar functional groups. As such, water solubility is expected to be low. The low water solubility has been confirmed experimentally (<0.1%).

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

The following toxicological end-points were submitted:

Endpoint	*Result*	*Classified?*	*Effects Observed?*
1. Rat, acute oral	LD50 >2000 mg/kg bw	no	no

The result was indicative of low acute toxicity.

8.2. Human Health Hazard Assessment

Topas has low potential for presenting health hazards resulting from its solid, pelletised form, lack of functional groups of concern and low solubility. The most significant potential health effects are physical ocular damage or irritation if a pellet or pellet fragment contacts the eye and possible burns resulting from skin contact with molten material. In addition, spilled pellets may pose a slip hazard. Acute toxicity studies confirm the product is of low acute toxicity. In summary, the notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No toxicological data were submitted. Polynonionic polymers which have NAMW>1000 are generally of low concern.

9.2. Environmental Hazard Assessment

Topas poses minimal environmental hazard. Effects of resin pellets on wildlife that may ingest them is not well understood but it is believed that certain birds may not be able to pass plastic pellets through their digestive tracts. This risk associated with this hazard is minimised by the pellets being used to manufacture finished articles which do not pose the same threat to birds.

In the manufacture of finished articles, faulty articles produced will be disposed of in commercial waste as applicable for finished food contact materials and as done for other polymer products.

At the end of its useful life, articles containing the notified polymer will generally be disposed of to landfill, where the notified polymer will not hydrolyse and is expected to degrade slowly and associate with soils and sediments due to its low water solubility and mobility.

10. RISK ASSESSMENT

10.1. Environment

Topas is not considered to be a risk to the environment based on its form and use pattern.

10.2. Occupational Health and Safety

Topas poses low risk to workers. Risks posed are easily mitigated by wearing of protective clothing, including wearing long trousers and long sleeve shirts with insulated gloves if likely to contact molten material and eye protection where pellets or pellet fragments may come in contact with eyes.

10.3. Public Health

Topas will not be supplied to the public. Topas is relatively inert and has been approved for use in food contact materials in the USA and EU indicating there is little risk to people who consume foods which have been in contact with articles produced using Topas or from handling such articles. The acceptability of Topas for use in food contact materials is largely due to the material not leaching into foodstuffs, pharmaceuticals, etc. It is not bioavailable when incorporated into finished articles. Consequently, risk to the public is low.

11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

11.1. Environmental Risk Assessment

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

11.2. Human Health Risk Assessment

11.2.1. Occupational health and safety

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

11.2.2. Public health

There is Negligible Concern to public health when used for production of finished articles and films including food-contact materials.

12. MATERIAL SAFETY DATA SHEET

12.1. 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.

13. 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 unless operator is likely to come in contact with molten material or pellets may enter eye. Eye protection should be worn if there is a risk of material entering eye. If handling or likely to contact molten material, operators should wear long trousers, shirt with long sleeves and insulated gloves.
- A copy of the MSDS should be easily accessible to employees.

Disposal

- The notified polymer should be disposed of in routine commercial waste.

Storage

- The following precautions should be taken by warehousing/storage facilities regarding storage of the notified polymer:
  - Avoid storage with strong oxidising agents.

Emergency procedures

- Spills/release of the notified polymer should be handled by sweeping and recovery. Material which has not been contaminated can be used. Contaminated material should be disposed of in commercial waste.

13.1. 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.

No additional secondary notification conditions are stipulated.