

File No: PLC/56

Date: August 1997

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

PEN/PET Copolymer

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**PEN/PET Copolymer****1. APPLICANT**

Shell Chemicals (Australasia) Pty Ltd of 1 Spring St MELBOURNE VIC 3000 has submitted a notification statement accompanying their application for assessment of a synthetic polymer of low concern, PEN/PET Copolymer.

2. IDENTITY OF THE CHEMICAL

Name: PEN/PET Copolymer

Trade Name: Hipertuf 85032, 86017 and 89010

Number-Average Molecular Weight (NAMW): > 1 000

Maximum Percentage of Low Molecular Weight Species (Polymers and Oligomers)

(Molecular Weight < 1 000): 0.250

(Molecular Weight < 500): 0.077

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: yellow to white grey, transparent to opaque pellets

Melting Point: 240°C

Density: 1 400 kg/m³

Water Solubility: insoluble (see comments below)

Hydrolysis as a Function of pH: see comments below

Polymer Stability: resistant to thermal degradation

Comments on Physico-Chemical Properties

No data was provided for the water solubility of the polymers. The notifier has provided arguments for the insolubility of the polymer based on; (i) the low solubility of the monomers (< 1 ppm) and consequential lower solubility of the polymer, and (ii) the use of the polymer in containers used to hold aqueous liquids which require low water solubility and water vapour permeability.

The ester linkages of the polymer have the potential to hydrolyse. However, it is anticipated that the insolubility of the polymer will prevent hydrolysis under environmental conditions. The polymer contains no charged groups and will not be cationic or anionic in the typical pH range of use.

4. PURITY OF THE CHEMICAL

Maximum Weight-Percentage of Residual Monomers: 0.021%

5. USE, VOLUME AND FORMULATION

The notified polymer is a polyester for use in high performance packaging (jars and bottles) for food, beverages, pharmaceuticals and cosmetics. Projected import volumes are 3 000 tonnes per year for the first five years.

6. OCCUPATIONAL EXPOSURE

The notified polymer, as pellets, will be imported in fibreglass reinforced polyolefin “supersacks” of 454 kg in weight. Typically the content of the sacks is automatically transferred to a hopper. The resin is dried in the hopper and automatically conveyed to the extrusion machine where it is melted and injected into a preform mould. The mould is cooled and automatically discharged from the machine. The preforms are warehoused and subsequently transferred to a bottle blowing machine as required. Limited exposure to the notified polymer is possible by dermal during the above processes. The machines are fitted with local exhaust ventilation to prevent overheating of the workplace. Fumes are stated not to be generated.

7. PUBLIC EXPOSURE

No public exposure to the notified polymer is expected during distribution and conversion of pellets into solid plastic articles. Disposal of any waste polymer by incineration or landfill is not expected to result in significant public exposure.

The public is expected to have extensive contact with some plastic products containing the notified polymer such as food and beverage containers, and the packing material used for pharmaceuticals and cosmetics.

8. ENVIRONMENTAL EXPOSURE

. Release

Release to the environment of the notified polymer as a result of manufacturing into jars and bottles is expected to be minimal. Manufacturing takes place in a closed system. The polymer will be fed automatically into extrusion and moulding machinery from a hopper. Scrap will be reground and reused. Contaminated polymer scraps will be deposited into municipal landfills or incinerated. Overall, such waste streams would account for at most 0.5% of the annual import of the polymer (i.e. a maximum of 15 tonnes of waste polymer may be deposited in landfill at the maximum rate of import).

Residues remaining in the "super sacks" will be disposed of with sacks to landfill. The notifier has estimated that the residue remaining in each sack will be <907 g (<0.2%). At the maximum rate of import, this corresponds to a maximum of 6 tonnes per annum of polymer, which will be disposed of to landfill with packaging. Used articles containing the polymer will also eventually be deposited in landfills or recycled.

. Fate

In the case of accidental spillage, pellets of the polymer are expected to remain where they are deposited. Should a spill occur to water, the pellets should settle onto the bottom sediments, where they could be collected. Due to the negligible solubility of the polymer, leaching from landfill is highly unlikely, and no movement from the landfill site is expected.

Any incineration of the notified polymer will result in its destruction producing water and oxides of carbon.

The majority of the polymer is not expected to be released to the environment until it has been moulded into films, sheeting or containers. The end use products will either be deposited in landfill or recycled at the end of their useful life.

Biodegradation is unlikely. Biological membranes are not permeable to polymers of very large molecular size and therefore bioaccumulation of the notified polymer is not expected (1, 2).

The polymer is an analogue of PET and is expected to replace PET in some applications. As such, it is anticipated that it will become part of the PET waste stream which accounts for approximately 0.6% of the domestic waste stream (3). The notifier has estimated that the current rate of recycling of PET is 30% Australia wide reaching 50% in capital cities. This is in accord with figures published by Planet Ark. In 1995 30% of the PET waste stream was recycled Australia wide (~15 000 tonnes of PET). The figure was higher in Sydney where it reached 53% (4). It is anticipated that the recycling rates of the notified polymer will be similar to that of PET.

9. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided which is acceptable for polymers of low concern with a NAMW greater than 1 000 according to the Act.

10. ASSESSMENT OF ENVIRONMENTAL HAZARD

Disposal of the notified polymer to landfill is unlikely to present a hazard to the environment as it will be in a pellet form or as finished products. Bioconcentration and leaching are both considered to be unlikely to occur, due to the high molecular weight of the polymer and its insoluble nature. Biodegradation of the product is also considered unlikely. Incineration of the notified polymer will result in its destruction, producing water and oxides of carbon.

The low environmental exposure of the polymer as a result of the proposed use, together with its expected negligible environmental toxicity, indicate that the overall environmental hazard should be negligible.

11. ASSESSMENT OF OCCUPATIONAL AND PUBLIC HEALTH AND SAFETY EFFECTS

PEN/PET Copolymer has been notified as a synthetic polymer of low concern under section 23 for the purposes of section 24A of the Act. The polymer meets the criteria for a synthetic polymer of low concern specified in regulation 4A of the Act and can, therefore, be considered to be of low hazard to human health.

The occupational risk posed to transport and storage workers is negligible, given the expected negligible exposure to the notified chemical under normal circumstances, and the anticipated low health hazard.

The occupational health risk to workers involved in the melting and extruding of the notified polymer is low. Dermal contact is expected to be the main form of exposure and the level of polymer dust is stated to be low. Melting and extrusion of the notified polymer is expected to take place in closed systems, which will limit contact with the polymer in molten form, and local exhaust ventilation will be employed.

There is negligible potential for public exposure to the polymer arising from importation, storage, transportation and melt extrusion or injection moulding. Similarly, the potential for public exposure to the chemical during transport and disposal of process waste and clean-up waste after a spill is very minor.

While there may be significant public contact with the notified polymer in the form of plastic film and plastic articles such as containers, there seems no likely route of exposure and absorption.

Some of the film or articles may be used for food contact applications so that migration of residual monomers and low molecular weight species into food is possible. To assess the risk of adverse health effects to consumers, both toxicological and migration studies were conducted, the latter being conducted using

PEN homopolymer (see PLC/52). PEN/PET Copolymer can be formed from two common monomers and one of two alternate monomers and the toxicological and migration studies were conducted on each of these alternate monomers. Each of the latter two monomers were stated to be present at 0.021% in the polymer. Migration of one residual monomer to four food simulating solvents has been shown to occur. Water, olive oil, and 15% w/v and 3% w/v aqueous solutions of ethanol and acetic acid, respectively, were used as solvents under test conditions of 10 days at 40°C (all simulants) and 2 hours at 70°C (aqueous simulants only). Only low levels of the monomer were detected in each of the food simulants tested (less than 0.05 mg/L of each simulant). In other studies (not submitted by the notifier) conducted with the notified polymer, it has been shown that a mixture of PEN oligomers may be extracted with food simulating solvents (water, 3% w/v aqueous solution of acetic acid, 50% v/v aqueous solution of ethanol, heptane). The NAMW of extracted oligomers ranged from 299 to 580, and on an 'in food' basis, levels ranged from 2 to 77 ppb. These levels can be considered negligible in terms of health effects.

Toxicological studies have been conducted with the above residual monomer and the data assessed as NA/503. The data suggest that the monomer is of low acute toxicity in rats ($LD_{50} > 5\,000$ mg/kg, oral route; $LC_{50} > 1\,230$ mg/m³, inhalational route) and rabbits ($LD_{50} > 2\,000$ mg/kg, dermal route), is a slight skin and eye irritant in rabbits and is not a skin sensitiser in guinea pigs. In a 90-day dietary study in rats, in which animals were exposed to the notified chemical at dietary concentrations of 0, 2 000, 10 000 or 50 000 ppm, diarrhoea, decreased urinary pH and male liver weights, and dilation of the caecum and/or colon were reported at 50 000 ppm, and food consumption was increased from 10 000 ppm. The monomer was not mutagenic in *Salmonella typhimurium* or Chinese Hamster ovary (CHO) cells, but was considered weakly clastogenic in CHO cells.

Although the above residual monomer in PEN/PET Copolymer is considered weakly clastogenic, it will be present at low levels and no significant migration of the monomer occurs as described above. If oligomers were extracted from PEN homopolymer under normal conditions of use, results obtained with food simulating solvents suggest that exposure levels will be extremely low.

An alternate residual monomer, used in place of the one mentioned above to manufacture the polymer, may also be present in the polymer at levels of 0.021%. Similar migration studies to those mentioned above gave levels of less than 0.024 mg/kg of the monomer in the food simulants.

Toxicological studies have also been conducted with this monomer and a separate assessment (NA/504) conducted. The monomer exhibited low acute oral and dermal toxicity in rats ($LD_{50} > 5\,000$ mg/kg for oral and 2 000 mg/kg for dermal). The monomer was not a skin or eye irritant in rabbits. It was not a skin sensitiser in a Buehler type skin sensitisation study using guinea pigs.

An acute inhalation study in rats showed lung pathology at very high doses over 2.15 mg/L. A repeat exposure inhalation study showed that an exposure of 10 mg/m³ (6 h/day, 5 days/week) causes no treatment related effects after 4 weeks in rats.

A repeat dose 90-day oral toxicity study in rats indicated no treatment related toxic effects at dietary levels of up to 5.0%.

The genotoxicity data at first reading appears to show no significant increase in micronuclei, mutations or chromosomal alterations in a range of assays. In all assays, apart from the micronucleus assay, the notified chemical is 'dissolved' in dimethylsulfoxide (DMSO) but in all these studies the insolubility of the notified chemical in DMSO and media was noted.

It can be concluded that the toxicological hazard presented by this monomer is minimal, it will be present at low levels and no significant migration occurs.

The use of the notified polymer in end-use products such as food and beverage containers and as packaging material for pharmaceuticals and cosmetics is, therefore, not expected to result in significant public exposure to the polymer, to low molecular weight species or to residual monomers. The proposed uses of the notified polymer present negligible risk to public safety.

12. RECOMMENDATIONS

To minimise occupational exposure to the notified polymer the following guidelines and precautions should be observed:

- Spillage of the notified polymer should be avoided, spillages should be cleaned up promptly and put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

Given that the notified polymer will be used for food contact applications, the notifier may need to contact the individual Australian State jurisdictions, as State food laws require that manufacturers ensure that materials used in food packaging are fit for that purpose. In addition, given that the notified polymer will also be used to manufacture packaging material for pharmaceuticals, the notifier should submit an appropriate application to the Medical Devices Section of the Conformity Assessment Branch of the Therapeutic Goods Administration.

13. MATERIAL SAFETY DATA SHEET

The MSDS for the notified polymer was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (5).

This MSDS was provided by the notifier as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the notifier.

14. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act secondary notification of the notified polymer shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

15. REFERENCES

1. Anliker, R., Moser, P. & Poppinger, D. 1988, 'Bioaccumulation of dyestuffs and organic pigments in fish. Relationships to hydrophobicity and steric factors', *Chemosphere*, vol. 17, no. 8, pp. 1631-1644.
2. Gobas, F.A.P.C., Opperhuizen, A. & Hutzinger, O. 1986, 'Bioconcentration of hydrophobic chemicals in fish: relationship with membrane permeation', *Environmental Toxicology and Chemistry*, vol. 5, pp. 637-646.
3. Planet Ark 1997, *The Planet Ark Recycling Report*, Internet Address: <http://www.planet.ark.com.au/recycle/recyc21.htm>.
4. Planet Ark 1997, *The Planet Ark Recycling Report*, Internet Address: <http://www.planet.ark.com.au/recycle/recyc25.htm>.
5. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*, Australian Government Publishing Service, Canberra.