

PACKAGING MATERIALS

1. POLYETHYLENE TEREPHTHALATE (PET) FOR FOOD PACKAGING APPLICATIONS

ILSI



International
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INSTITUTE

REPORT

Prepared under the responsibility of the
ILSI Europe Packaging Material Task Force

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Report on Packaging Materials: 1. Polyethylene Terephthalate (PET) for Food Packaging Applications

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INTRODUCTION

Polyethylene terephthalate (PET) is a plastic material which has found increasing applications within the packaging field. It is a simple long-chain polymer. Its chemical inertness, together with other physical properties, has made it particularly suitable for food packaging applications.

This monograph is intended to give the salient facts about PET as a food packaging material. It describes the properties of PET with respect to its effects on the safety and health of consumers. It should be seen as a first introduction to the more detailed information available, much of which is referenced.



WHAT IS PET?

PET is an acronym for polyethylene terephthalate, which is a long-chain polymer belonging to the generic family of polyesters [1]. PET is formed from the intermediates, terephthalic acid (TPA) and ethylene glycol (EG), which are both derived from oil feedstock. There are other polyesters based on different intermediates but all are formed by a polymerisation reaction between an acid and an alcohol.

PET, in its purest form, is an amorphous glass-like material. Under the influence of direct modifying additives it develops crystallinity. Also, crystallinity can be developed by heat treatment of the polymer melt.

Originally patented and exploited by DuPont during the search for new fibre-forming polymers [2,3], polyester fibre applications have developed to such an extent that PET represents over 50% of world synthetic fibre manufacture [4]. PET is used alone or blended with cotton or wool to impart better wash/wear and crease resistant properties to textiles.

In the late 1950s PET was developed as a film. It was first used for video, photographic and X-ray films in addition to uses in flexible packaging. Later PET was modified for use in injection moulded and extruded articles, primarily reinforced with glass fibre. In the early 1970s PET was stretched by blow moulding techniques which produced the first oriented three dimensional structures initiating the rapid exploitation of PET as lightweight, tough, unbreakable bottles [5].

THE MANUFACTURE OF PET

Polyesters are made by the reaction of bifunctional acids and alcohols, in the presence of a metal catalyst. The key polymerisation step is known as a condensation reaction in which molecules react and release water. This is followed by a second polymerisation reaction, which occurs in the solid phase.

For manufacture of PET the intermediates, pure terephthalic acid (TPA) and ethylene glycol (ethanediol), are derived from crude oil. When heated together the first product is a monomer (BHET - bis-hydroxyethyl-terephthalate) mixed with low molecular weight polymers (oligomers). The mixture then reacts further, distils out excess ethylene glycol and forms the PET (Figure 1). At this stage the PET is a viscous molten liquid. It is extruded, and water quenched to form a glass-like amorphous material. Some PET is also manufactured using technology based on the dimethyl ester of terephthalic acid (DMT).

The required high molecular weight PET is manufactured by a second polymerisation stage carried out in the solid state at lower temperatures. This effectively removes all volatile impurities, like acetaldehyde, free glycols and water. The high molecular weight is essential for good mechanical properties providing stiffness, toughness and creep resistance while, at the same time, giving sufficient flexibility to resist bursting and breaking under pressure.

The PET described so far is the simplest typical product. However, many modifications are introduced to develop specific properties for the various packaging applications and to suit particular manufacturing equipment. Usually the modifications are of a chemical nature to make manipulation of the PET between different crystalline forms easier.

For example, small concentrations of an appropriate co-monomer (isophthalic acid – IPA or 1,4-cyclohexanedimethanol) slow down the rate of crystallisation and allow the manufacture of thicker bottle walls, sheets and films. A typical example would be in the heavier, thicker bottles used for refillable container systems. There is also a requirement to extend the rate of crystallisation to restrict movement and deformation at elevated temperatures, for example in ovenable food trays. In this case a nucleating agent or crystallisation promoter is employed and the molecular weight is increased.

PET is becoming the package of choice for many food products, particularly beverages and mineral waters. The main reasons for its popularity are the properties of glass-like transparency coupled with adequate gas barrier properties for retention of carbonation. Also it exhibits a high toughness/weight property ratio which allows lightweight, large capacity safe unbreakable containers (<1.5L).

FOOD PACKAGING APPLICATIONS

In general it can be seen that the desired properties for packaging applications are attained from the intrinsic properties of PET polymer. Therefore additives such as antioxidants, plasticisers, heat or UV stabilisers are not required. Colourants in low concentrations (usually less than 500 ppm) are used for some PET commercial grades and, like catalysts, become encapsulated or incorporated as part of the polymer chain. They are added at either the resin or pack manufacturing stage and possess extremely low extractability.

The three major packaging applications of PET are as containers (bottles, jars and tubs), semi-rigid sheet for thermoforming (trays and blisters) and thin oriented films (bags and snack food wrappers) (Table 1).

PET bottles and jars are manufactured by the process of *injection stretch blow moulding*, a process developed specifically to maximise the beneficial properties of PET (Figure 2). Selection of the optimum 'blowing temperature' is vital to achieve the best balance of properties. Impact resistance, transparency, stiffness, gas barrier properties and creep are all optimised during this part of the operation.

Table 1. PET in Food Applications

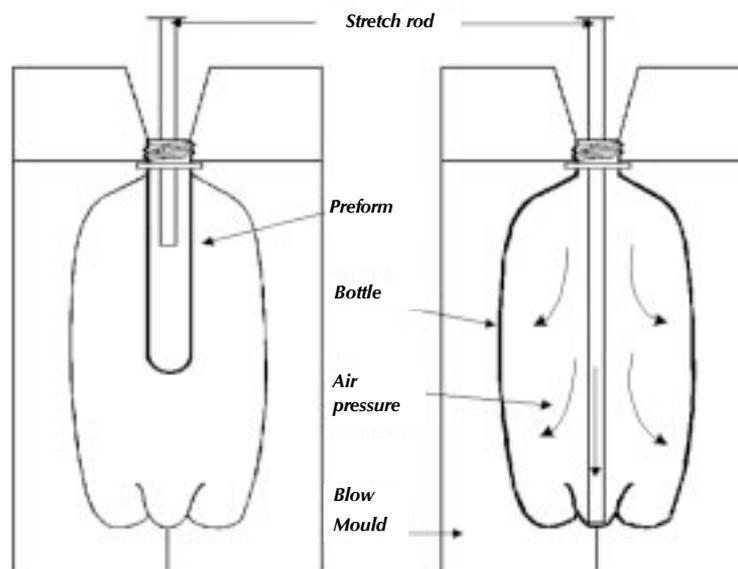
PET Product	Applications
Bottles	Beverages, soft drinks, fruit juices, and mineral waters. Especially suitable for carbonated drinks. Cooking and salad oils, sauces and dressings.
Wide mouth jars and tubs	Jams, preserves, fruits and dried foods
Trays	Pre-cooked meals for re-heating in either microwave or conventional ovens, pasta dishes, meats and vegetables
Films and metallised foils	'Boil in bag' pre-cooked meals, snack foods, nuts, sweets, long life confectionery, ice creams, and spreads
Coatings	Microwave susceptors
PET products with added oxygen barrier	Beer, vacuum packed dairy products e.g. cheese, processed meats, 'Bag in Box' wines, condiments, coffee, cakes, syrups,

Semi-rigid transparent PET sheet, the precursor for thermoforming PET articles, is made by extruding a ribbon of molten PET polymer onto a series of cooling and compressing rolls. The cooled sheet is then stored before feeding through a thermoforming line, which heats the sheet, stamps, forms, and cuts out the article all in one process.

Manufacture of thin, biaxially oriented PET film is a much more demanding operation, which develops fully the properties of the PET [6]. The excellent thermal properties of PET film allow it to be processed and used over a wider temperature range (-70 to +150°C) than most common packaging films. It is ideal for retort packaging, dual ovenable lidding and 'boil in the bag' applications. PET films have the chemical inertness and good gas barrier properties that are important for many medical, pharmaceutical and food products. They can be used in the demanding sterilisation processes based on steam, ethylene oxide and radiation. The key to achieving these properties is again manipulation between the different crystallisation states.

Using co-injection, co-extrusion, laminating or coating technologies PET can be combined with other plastics to extend its applications, for example to achieve additional protection against oxygen and moisture, thereby preventing rancidity and similar 'off-flavours'.

Figure 2. Stretch blow moulding of a PET bottle.



HEALTH AND SAFETY CONSIDERATIONS

In today's markets almost all prepared food reaches the consumer in a packaged form. Once a packaging is selected as appropriate, it is essential to know the extent of any interactions between the food and its packaging material. Any interactions should preferably be absent or extremely small. Transfer of substances (migration) between the food and its packaging – or the reverse – does sometimes occur in trace quantities and such migration needs to be assessed to assure it is minimal.

Substances which migrate readily are usually low molecular weight and volatile. Food-grade PET essentially contains only very high molecular weight species with little or no migration propensity, so actual migration is minuscule. However, the slightest interactions are now detectable by sophisticated analytical techniques, and monitoring of migration is relatively easy. Many studies have been made on PET and have always given a reassuring picture [7].

FOOD PACKAGING LEGISLATION

The basic principle of the European Union food contact materials and articles legislation is expounded in the Framework Directive from 1976, 76/893/EEC, which states that 'food contact materials should not transfer to foodstuffs any of their constituents in quantities that could endanger human health or cause a deterioration in the organoleptic characteristics of the foodstuff'. A second Framework Directive, 89/109/EEC, defines the requirements for all materials intended for food contact applications – not only plastics. Within this Framework Directive there is a specific Directive for all plastics, 90/128/EEC. There have already been five amendments to this Directive concerning monomers, each of which has extended the positive listings. (The last of these was Directive 1999/91/EC of 23 November 1999).

Member states were required to institute the provisions of the original Directive by the end of December 1992. In general, these Directives deal with three major principles underlying the legislation:

- Establishment of positive lists of authorised substances.
- An overall migration limit (OML) of these substances into the foodstuff.
- Where necessary, specific migration limits (SML's) for particular substances.

Directive 82/711/EEC specifies the basic rules for testing for both OML and SMLs, stipulating the liquids (food simulants) to be used for testing and the time and temperature of the migration test. Amendments deal with any new developments, e.g. the use of plastics above 121°C and in microwave ovens. The Directive specifies an overall migration limit of 10 mg/dm² of food-contact surface or 60 mg/kg (60 ppm) in food. In addition, specific migration limits have been established for the monomers commonly used in making PET (Table 2).

Table 2. Monomers commonly used in making PET and copolyesters for food packaging

Monomer	Specific migration limit (SML)
<i>Terephthalic acid</i>	7.5 mg/kg
<i>Terephthalic acid, dimethyl ester</i>	No SML
<i>Isophthalic acid</i> ^a	5mg/kg
<i>Isophthalic acid, dimethyl ester</i>	0.05 mg/kg
<i>Ethylene glycol (EG)</i>	30 mg/kg (Alone or with diethylene glycol or stearic acid esters of ethylene glycol)
<i>Diethylene glycol (DEG)</i>	30 mg/kg (Alone or with ethylene glycol or stearic acid esters of ethylene glycol)
<i>1,4-Bis(hydroxymethyl)cyclohexane</i>	No SML

^a *Terephthalic acid, Terephthalic acid, dimethyl ester, Isophthalic acid, dimethyl ester, ethylene glycol, and 1,4-Bis (hydroxymethyl)cyclohexane have been reviewed by the Scientific Committee on Food and have been placed in Section A, the list of authorised monomers for use in the manufacture of polymers intended to come into contact with foodstuffs. A fifth amendment (6 February 1998) includes isophthalic acid in Section A and introduces the SML of 5mg/kg. This amendment also changes the SML for EG and DEG to include the stearic acid esters of EG*

CEN, the European Committee for Standardisation, as ENV 1186, [8] has published copies of test methods that can be applied under various conditions of use. If a product complies with the compositional requirements of the Directives, i.e. it is produced from authorised monomers and additives, then it may be tested for any desired condition of use. If it meets the migration requirements, then it is acceptable for use in applications covered by that test method. Typical food simulants are used in the tests like hot water, acetic acid, ethyl alcohol and olive oil.

It is important to note that the test must be carried out on the finished product to be used for the purpose. Polymer manufacturers often organise these procedures but the main responsibility to ensure compliance is with the producer and user of the article who knows exactly how the product is manufactured and what it contains.

The principles behind regulatory rules of other countries are similar to the EU in that they seek to provide sound, objective criteria that can be used to assess whether the material to be used is in compliance with the regulations. The procedures and responsibilities are also similar, i.e. the producers and users of materials and articles must ensure compliance under the conditions of intended use. Protocols are similarly defined. All food contact articles, including the base polymers, colourants, or other additives must comply or be the subject of an applicable exemption from regulatory cover.

TOXICOLOGICAL STATUS OF PET MATERIALS

PET itself is biologically inert if ingested, is dermally safe during handling and is not a hazard if inhaled. No evidence of toxicity has been detected in feeding studies using animals. Negative results from Ames tests and studies into unscheduled DNA synthesis indicate that PET is not genotoxic. Similar studies conducted with monomers and typical PET intermediates also indicate that these materials are essentially non toxic and pose no threats to human health [9].

One particular widely used additive, antimony trioxide, has given cause for concern. However, a new and very comprehensive and detailed animal feeding study concludes that there is no risk arising from the use of antimony trioxide in PET products [10]. A diet containing up to 20g/kg of antimony trioxide had no detectable toxic effects. Genotoxicity tests were also negative.

The endocrine glands of the human body generate hormones that control vital processes associated with life such as reproduction, regulation of metabolism, mental processes and many aspects of development before birth. The body also has hundreds of hormone receptors, each one designed to receive a particular chemical signal from a hormone to initiate the biological activity associated with the hormone.

There has been increasing public concern that certain man-made chemicals, if absorbed into the body, can act like the female hormone oestrogen disrupting the normal endocrine cycles and causing genetic disorders or adverse reproduction effects like reduced male sperm counts. It is important to stress that the chemistry of compounds that are used to manufacture PET shows no evidence of oestrogenic activity. There is a significant body of evidence that demonstrates that the use of PET is not a concern and is perfectly safe in this respect. PET and its components have no links with any reported endocrine disruptors [9,15,16].

MIGRATION OF PET COMPONENTS

The official EU test methods stipulate the use of food simulants typical of all food types. These are water, 3% acetic acid, 15% ethanol (higher levels for specific alcoholic products) or rectified olive oil at times and temperatures to relate to conditions of use, (e.g. olive oil 10 days at 40°C). The US FDA stipulates n-heptane as the oil simulant but the intention is the same. PET manufacturers and container producers have been applying these tests over many years – repeatedly checking new processes, materials, additives and developing applications as they arise – and a large database of information is available. The extensive tests all show results that comply well with the standards required.

Similar studies designed to detect metal additive migration (e.g., antimony catalysts) show only trace levels of antimony (less than 5 ppb). Oral toxicity studies using the extracted species have been completed, and in all cases no adverse effects have been observed at exposures expected to occur from the use of PET packaging systems.

Acetaldehyde (CH_3CHO) is the dominant, volatile product that is formed during thermal degradation of PET (Figure 3). It is only formed when the polymer is molten and results primarily from thermochemical reactions. However, it is very important to control the level of acetaldehyde because of its ability to add to or to change the taste of foods packaged in PET.

Figure 3. Acetaldehyde formation



Acetaldehyde is a simple, naturally occurring organic chemical found in many ripe fruits e.g. apples, grapes and citrus fruits (up to 230 ppm). It is produced during the fermentation of sugar to alcohol and is a natural constituent of butter, olives, frozen vegetables and cheese. It forms in wine and other alcoholic beverages after exposure to air (up to 140 ppm). It even occurs as an intermediate in the decomposition of sugars in the body and hence can be found as traces in blood. Acetaldehyde is listed as an approved additive and is used to enhance citrus flavours helping to create natural, fruity tastes and fragrances [11]. As a flavour ingredient it can be found in ice creams, sweets, baked goods, chocolates, rum and wine [12,13]. Acetaldehyde is, therefore, a harmless chemical in these circumstances, but it does have a flavour and, in its pure state, a sharp, penetrating fruity aroma.

Typical concentrations of acetaldehyde in PET used for beverage packaging would certainly be less than 10 ppm and probably closer to 4-5 ppm. Toxicological data on acetaldehyde are readily available and exposure and ingestion in concentrations derived from PET packaging are of no concern other than that of taint [14].

USE OF RECOVERED PET IN FOOD CONTACT END USES

Recovered and recycled PET has to comply with all the rules and regulations that apply to virgin materials. The health and safety of the consumer is of prime importance when considering reuse and recycling of plastics, or any materials in food contact uses.

One particular physical property of PET makes it much more suitable than other plastic materials for use as a recovered, recycled material. This is its low diffusion coefficient. Since this is about a factor of 100 lower than some other materials, this means that it is correspondingly more difficult for contaminants to diffuse into or out of PET [17].

There is no EU legislation in current operation that deal specifically with this topic. Most plastic regulations neither preclude nor allow the use of recycled plastics in food contact applications. However, there are exceptions and some national regulations forbid the use of recycled plastics in food contact applications. Any plans to use recycled plastics should be congruent with the regulations currently in force nationally and may require consultation with the relevant authorities.

The first results of detailed research work to define the safe boundaries and limitations of such use were available in December 1997 [18], and the findings are likely to form the basis of any EU legislation seen as necessary. The reader can consult another ILSI Europe report, "Recycling of Plastics for Food Contact Use" [19], that deals specifically with this issue and contains guidelines for recycling of plastics for food contact applications.

In relation to re-use of bottles, detailed studies have been completed investigating all the health, safety and environmental aspects of using PET in refillable systems. The reader is referred to two references in particular which define, describe and review all the procedures involved [7,9]. A Code of Practice has been developed for application to refillable bottles, which will ensure maximum product safety, and encourage complete acceptance by the consumer [26].

A healthy recycling industry has been formed around PET [20–25]. Since it can be recycled by a variety of processes, it can be used as a disposable, recoverable packaging or as a refillable packaging.

GENERAL CONCLUSIONS

The chemistry of PET is simple and its intrinsic properties do not rely on the presence of additives. It can be recycled, and this is being done on an increasing scale.

General toxicity and genotoxicity studies, on PET, its monomers and typical intermediates indicate that this material does not pose a threat to human health. There is a significant body of evidence demonstrating that PET shows no oestrogenic activity.

As PET can be used in many packaging forms ranging from wrapping films to bottles, it constitutes a valuable basic packaging material for a variety of foodstuffs.



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