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Packaging Materials: 3. Polypropylene as a Packaging Material for Foods and Beverages

Report

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

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ILSI Europe Report on Packaging Materials: 3. Polypropylene as a Packaging Material for Foods and Beverages

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ILSI

International Life Sciences INSTITUTE

PACKAGING MATERIALS: 3. POLYPROPYLENE AS A PACKAGING MATERIAL FOR FOODS AND BEVERAGES

by Philip Tice

REPORT

PREPARED UNDER THE RESPONSIBILITY OF THE ILSI EUROPE PACKAGING MATERIAL TASK FORCE

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INTRODUCTION

During the second half of the last century plastics played an increasing role as materials for packaging all types of foods and beverages. In addition to replacing more traditional materials such as glass, paperboard and metal, plastics extended the range of foodstuffs sold pre-packaged, providing added convenience for the consumer and increased safety standards. Competitive costs, range of properties and new developments will ensure that plastics remain major food and beverage packaging materials in this new century.

The specific properties of some plastics types have made them suitable for specific forms of food and beverage packaging. Examples include polyethylene terephthalate (PET), which is now extensively used to produce blown bottles for beverages, and foamed polystyrene, widely employed thermoformed into trays for meat, poultry and fish products.

The range of useful properties of polypropylene plastics has resulted in the manufacture of a wide variety of food and beverage packaging types, which extend from films (both cast and oriented) to pots, tubs, bottles and containers, through to bottle caps, container closures and labels. With both the variety of packaging types and competitive costs in manufacturing and processing, polypropylene is now a principal packaging material for many of the individual items of consumers' daily diets.

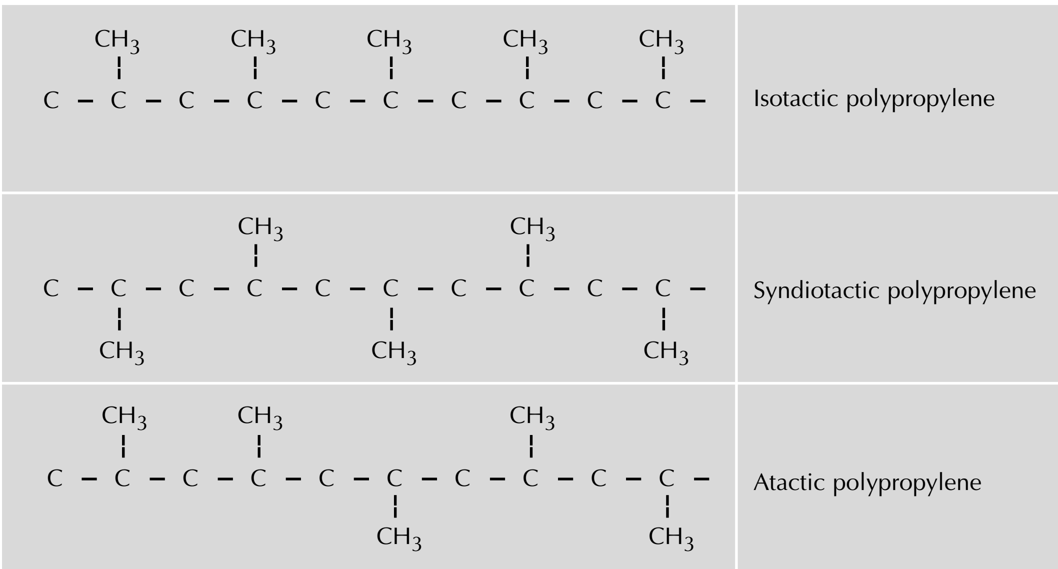
WHAT IS POLYPROPYLENE?

Polypropylene (PP) is a member of the polyolefin class of polymers. These polymers are derived from olefin monomers (unsaturated hydrocarbons); ethylene is the monomer for polyethylene. Polypropylene plastics began to find commercial applications in the 1950s. Thermoplastics based on polypropylene are now second in commercial importance only to those based on polyethylenes. World production of polypropylene reached 30 million tonnes in 2000 and is likely to increase with new production capacity (Robinson, 2001).

Unlike polyethylene, polypropylene has three basic polymeric forms: isotactic, syndiotactic and atactic. These different polymeric forms arise because, compared to the starting substance for polyethylene $CH_2{=}CH_2$ (ethene), the starting substance propylene $CH_3{\bullet}CH{=}CH_2$ (propene), has a methyl (CH_3) group in place of a hydrogen. In the isotactic form of polypropylene the methyl group has the same configuration at each tertiary carbon atom along the polymer chain. In the syndiotactic form, the methyl group alters position on alternative tertiary carbon atoms. In the atactic form, the methyl group takes up random positions on the tertiary carbon atoms.

Schematic illustrations of the three polymer forms are given in Figure 1. The polymer chains are actually helical and with the isotactic form the methyl groups all point outwards.

Figure 1. Schematic illustrations of the three polymeric forms of polypropylene



Commercial propylene homo-polymers are primarily isotactic with ≤5% of the atactic form and are high-molecular-weight semi-crystalline solids. Impact strength (toughness) is moderate, but tensile strength and stiffness are excellent. It is the semi-crystalline nature as well as the other properties that make the isotactic form the most suitable as a commercial plastic for food packaging and other applications.

Improvements in impact strength of isotactic polypropylene are obtained by co-polymerising with ethylene and/or 1-butene (typically 1%–7%), which produces random co-polymers. These co-polymers are relatively transparent but have lowered melting points, with reduced stiffness and tensile strengths. Commercial propylene homo-polymer can become rather brittle at sub-zero temperatures. The propylene-ethylene co-polymers are less brittle at low temperatures.

Blending of commercial propylene homo-polymer with propylene-ethylene co-polymers also is used to modify and improve the physical properties of tensile strength and toughness.

Syndiotactic propylene polymers are less crystalline. They have found only limited use, mainly as elastomers.

The atactic form of polypropylene, which is amorphous and tacky, is used as a hot-melt adhesive but has few other applications.

Other properties of commercial propylene homo-polymer include low water vapour transmissions, medium gas permeability, good resistance to solvents, good resistance to grease/oils and chemicals, good abrasion resistance, good gloss and high clarity in oriented (stretched) film form. In recent years clarity of polypropylene plastics in non-oriented (un-stretched) thicker forms, such as those used for pots and containers, has been improved with developments in manufacturing processes.

Propylene homo-polymers and the co-polymers are prone to oxidative degradation, particularly at the elevated temperatures used for processing. The formulations of all commercial polypropylene plastics therefore, contain effective antioxidants (*see Basic Chemistry section*). Oxidation causes polypropylene to break down to lower-molecular-weight products.

Plastics formulated from propylene homo-polymer and the co-polymers can be processed by all the common plastic manufacturing processes: blow moulding, injection moulding, thermo-forming and film formation, both cast and oriented. Co-polymers with ethylene are usually preferred for injection moulding and blow moulding. Melt-viscosity, which correlates with the weight-average molecular weight of the polymer, is used to select the grade appropriate for the specific process. Standardised melt-flow rate (MFR) tests are normally used to provide the information. Polymer grades with low MFR values (high molecular weight) are used in sheet extrusion, for subsequent thermoforming processing and also for blow moulding. Films are manufactured from intermediate grades, and grades with the higher MFR values are used for injection moulding (Brady and Marsh, 1997; Parker, 1997; Robertson, 1992).

BASIC CHEMISTRY

Monomers/starting substances of polypropylene and the co-polymers

The chemical substances used to manufacture propylene homo-polymer, the co-polymers and blends are the monomers: propylene (propene), ethylene (ethene) and 1-butene (but-1-ene). All three are gases with boiling points of –47.7°C, –102.4°C and –6.5°C, respectively.

The chemical formulas for these monomers are:

propylene: $CH_2{=}CHCH_3$

ethylene: $CH_2{=}CH_2$

1-butene: $CH_2{=}CHCH_2CH_3$

Propylene, ethylene and 1-butene are obtained at low cost by cracking oil and other hydrocarbon feedstocks (Parker, 1997; Ashford, 1994).

Manufacture of polypropylene and the co-polymers

Polypropylene is manufactured by the polymerisation of propylene monomer. Polymerisation of propylene can yield any of the three polymer forms, isotactic, syndiotactic or atactic, described in the previous section. The catalyst and polymerisation conditions primarily determine which of the polymer forms is produced predominately.

To produce commercial polypropylene, which consists largely of the isotactic form, stereospecific catalysts are used. The simplest stereospecific catalysts are those based on titanium trichloride with alkyl aluminium co-catalysts, but they can produce significant amounts of the atactic form of the polymer. The amounts of the atactic form can be reduced and the stereoregularity of the isotactic form increased with catalyst modifiers based on organic compounds containing oxygen, sulphur and nitrogen.

Some of the most advanced catalyst systems contain titanium tetrachloride, an organic diester supported on magnesium chloride with the addition of a silane-ether modifier and trialkyl aluminium co-catalyst. With these catalyst systems isotactic polymer can be manufactured in high yields with virtually no atactic by-product (Parker, 1997).

Recent developments with metallocene catalysts, which are based on transition metals such as zirconium and hafnium, have produced isotactic polymers in high yields, with narrow molecular weight distributions and high stereoregularity. High-purity propylene, however, is required and these catalysts have yet to be brought into mainstream polypropylene manufacture (Kroschwitz, 1998; Moore, 1996).

Manufacture of oriented polypropylene (OPP) films

Both propylene homo-polymers and the co-polymers are used to produce OPP films.

The two main processes employed to manufacture OPP films, including coextrusion products, are the tenter-frame process and the bubble process. In both these processes extruded polymer is mechanically stretched, which orientates and aligns the polymer molecules in the machine direction (MD) and transverse direction (TD). This treatment results in marked improvements in transparency, strength, moisture barrier properties and low temperature durability, compared to cast film. The improved strength of oriented films allows useful film products to be produced with reduced thickness. The physical properties of films produced by the two processes are quite similar (Brady and Marsh, 1997; Kroschwitz, 1998). Cast films have the "softer" feel characteristic of polyethylene films.

Additives used in polypropylene plastics

Additives must be incorporated into the basic polypropylene polymers and the co-polymers to maintain and provide the required physical properties and to ensure efficient processing and handling of the finished products. All additives used in food-contact polypropylene plastics must be approved for use under relevant safety regulations, be of good technical quality to meet purity criteria and comply with any migration or other restrictions (see Regulatory Aspects section). It is also necessary to ensure that additives do not impart taints or off-odours to packaged foodstuffs.

Polymerisation processing conditions and catalysts largely determine the characteristics of the polypropylene polymer produced. The stereoregularity of the polymer can be further increased by addition of nucleating agents which, in turn, increase crystallisation and improve the clarity and stiffness of the plastic. Nucleating agents particularly effective in polypropylene plastics are benzoate salts (sodium-, potassium-, aluminium-) and sorbitols, such as bis-benzylidene sorbitol. These are added at concentrations up to 0.5% (Gächter and Müller, 1993; Moore, 1996).

Polypropylene and the co-polymers are prone to oxidation, and antioxidants are necessary to prevent degradation of the polymer. Two main antioxidant types, the phenolic and phosphite types, are used at concentrations of 0.01%–0.5% wt. Thio-ethers are also used and provide synergistic effects when combined with one of the phenolics (Moore, 1996; Gächter and Müller, 1993).

For films, it is necessary to improve the properties of slip (friction) and blocking (film layers sticking together). Improvements in these properties are achieved by adding slip agents and suitable fine particulate fillers to the polymer. Typical slip agents are the fatty acid amides oleamide and erucamide, which "bloom" to the film surface after manufacture. Clays with a particle size of a few microns are typically used as particulate fillers at concentrations of around 0.1% wt (Moore, 1996; Gächter and Müller, 1993).

Pots and containers are often white or coloured. Titanium dioxide and calcium carbonate are added to the polymer to produce white plastics. Some substances added as fillers, such as calcium carbonate, improve the properties of impact strength and thermal stability but reduce stiffness and tensile strength (Brydson, 1996). “Pearlised” opaque OPP films, widely used for packaging foods such as biscuits and confectionery, are produced by incorporating small quantities of a particulate material, such as calcium carbonate, that generates surrounding air-filled voids during the stretching process. The opacity and whiteness of the finished film is primarily a result of the voids (Gächter and Müller, 1993; Brady and Marsh, 1997).

Polypropylene, like most plastics, has a tendency to accumulate surface static charges. This can result in handling problems and “pick-up” of dirt on the finished packaging, affecting the external appearance of the film, pot or container. Anti-static agents are incorporated to minimise this problem. Typical anti-static agents are the glycerol monoesters and the ethoxylated secondary amines added to the polymer at concentrations of 0.1%–1.0% wt. These agents have hydrophilic character and limited solubility in the polymer, which result in migration to the plastic surface, where they become active (Moore, 1996; Gächter and Müller, 1993).

Anti-mist agents, required for some uses of OPP films, usually are applied to finished films and are hydrophilic substances similar in physical character to anti-static agents.

Additives, such as colourants, whitening agents, slip additives and anti-static agents, often are incorporated conveniently into the basic polymer before processing by means of master batches. Master batches are concentrates of the additive(s) dispersed in the same or similar polymer type.

Although not strictly additives, mould-release agents are used in injection moulding operations. Quick-acting slip agents, mentioned earlier, can act as mould-release agents. Silicones are also used.

MIGRATION OF SUBSTANCES FROM POLYPROPYLENE PLASTICS UNDER CONDITIONS OF USE

Substances that may migrate from polypropylene plastics to foodstuffs include residual monomers, low-molecular-weight polymer (oligomers) and any additives or other substances used in the formulations. The quantities of substances that migrate from polypropylene plastics into the foods and beverages with which they come into contact depend largely on the food or beverage type, the contact temperature and the contact time. With all plastic types, migrations increase with temperature and time in contact. The food contact uses of polypropylene plastics are described in the next section of this report. Hydrophobic substances, such as oligomers and the antioxidants, have a tendency to migrate into fatty foods, whereas hydrophilic substances, such as anti-static agents, have a tendency to migrate into high-moisture foods. The exposure temperatures range from cold storage to microwave heating and cooking, with contact periods ranging from minutes to weeks or months.

Any migration of substances from polypropylene plastics must comply with migration restrictions specified in safety laws and regulations. These are discussed in the Regulatory Aspects section with test methods used to ensure compliance with the regulations. The legislative overall migration limit controls the total quantity of migrating substances, helps prevent undue adulteration of the foodstuff by plastics components, and acts as an overall control on foodstuff safety. Specific migration limits (SML) on individual substances, based on toxicological data (*see Safety/Toxicology section*), are specified when migration of the substance to foodstuffs, below the overall migration limit, could present a risk to the health of the consumer.

Surveys are carried out by national authorities to assess levels of migration of substances from plastics to foodstuffs, but most migration testing is performed on plastics before use by manufacturers and users, to confirm compliance with legislative migration limits. Such pre-use migration testing usually is performed with food simulants, as permitted in the relevant legislation (European Commission, 1997). With the extension of the list of additives with restrictions in the recent amendments (6th and 7th) to European Commission Directive 90/128/EEC (European Commission, 2001; European Commission, 2002), the requirements for migration testing will increase. In recent years European laboratories experienced in the field have been involved in collaborative research to establish mathematical models that can predict levels of migration of individual plastics substances under specified conditions of use. Initial work has concentrated on polyethylene and polypropylene plastics with a variety of typically used additives, such as antioxidants (O'Brien and Cooper, 2001). The results of this research, which has been co-ordinated under a European Commission Project (European Commission, 2000), has enabled the European Commission to incorporate in the 6th amendment to Directive 90/128/EEC (European Commission, 2001) the use of "generally recognised diffusion models based on scientific evidence". The use of validated mathematical predictive diffusion models will enable practical migration testing to be reduced significantly.

Reported migration values for polypropylene plastics in all forms – films, pots, tubs and containers – and with all four food simulants are typically well below the regulatory overall migration limit of 10 mg/dm^2 and any relevant SMLs for additives. As the high temperature stability of polypropylene plastics allows them to be used for microwave cooking and heating of foodstuffs, migrations at the relevant elevated temperatures have been investigated (Cooper *et al.*, 1998; Alnafouri and Franz, 1999; European Commission, 1994; de Kruijf and Rijk, 1997; Czerniawski and Pogorzelska, 1997). Data on migration of additives from polypropylene and other polymers, and the factors influencing migration have been reviewed comprehensively (Figge, 1996).

POLYPROPYLENE AND FOOD PACKAGING APPLICATIONS

The competitive costs of polypropylene plastics combined with their versatile properties have made these plastics the preferred type of packaging for a wide range of foodstuffs in all the common forms of food packaging: pots, containers, tubs, bottles, pouches and wrapping films. It is the most widely used plastics material for rigid-type food packaging, with the exception of beverage bottles, where PET (polyethylene terephthalate) is the leader, and milk bottles, where the plastic type is usually HDPE (high-density polyethylene) (Brown, 1992).

Films are produced as either cast or biaxially oriented OPP films. The gas barrier properties (oxygen and carbon dioxide) of OPP films are improved with coatings and multilayer structures. Sealability is obtained either with coatings or lamination with polyethylene or propylene-ethylene co-polymers. OPP films have good barrier properties against loss of food aromas, but the coatings and the multilayer structures with barrier resins provide improvements where necessary. Polyvinylidene co-polymers (PVdC), acrylics and ethylene vinyl alcohol (EVOH) are the main gas barrier resins used (Giles, 1999). Gas barrier properties and barriers to ultraviolet (UV) light are also obtained with metallised (aluminium) surface treatments or by lamination with aluminium foils. Coated and laminated films are used in the form of bags or pouches, as sealed wrapping, as overwraps with the food product on plastic trays, in cartonboard containers or as lidding on containers. Films are pigmented or pearlised to provide opacity or colours. For some uses in which the food product gives off moisture, such as chilled fresh salads, the film surfaces are treated with anti-mist agents to prevent condensing moisture obscuring the food products. OPP films also are used as bottle labels, because unlike paper, they eliminate mould growth, do not easily rip, have good abrasion resistance and do not come off bottles when chilled in iced water.

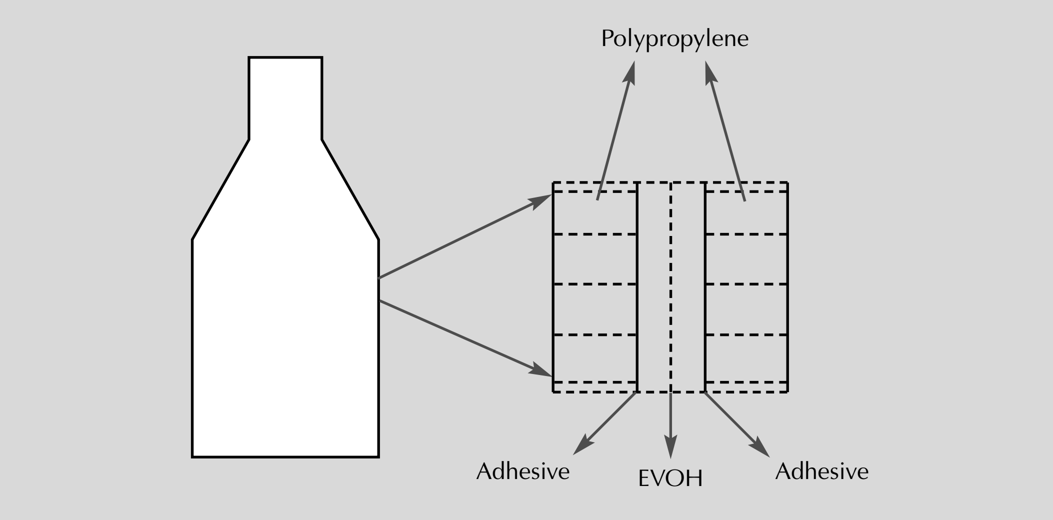
Polypropylene is coated or laminated onto paperboard for containers and disposable items for direct consumption of foods and beverages.

Polypropylene pots and containers are either produced by injection moulding or by thermoforming processes. Bottles are produced by the blow moulding process. When bottles, containers and trays require improved gas barrier properties, for example those used for sauces and ready-meals, they are made as a multilayer structure with a barrier resin, typically EVOH, as a core layer sandwiched between polypropylene layers. Because adhesives are necessary to bind the EVOH to the polypropylene, such multilayer structures will consist of five individual layers. Typical adhesives are the ethylene-vinyl acetate-vinyl alcohol terpolymers with 82%–90% ethylene contents. The structure of a five-layer bottle with an EVOH barrier layer is shown in Figure 2.

In recent years polypropylene has replaced other plastics in a number of applications. A typical replacement is for regenerated cellulose films (cellophane) for wrapping confectionery. Both the "crinkle" and dead-twist properties of cellophane can now be reproduced with polypropylene films. Polypropylene, with its good resistance to oils and fats, is also now the principal plastic type used for margarine tubs.

The exterior surfaces of much food packaging are printed to provide product identification and use information for the consumer. Surface treatments, such as corona discharge or acrylic coatings, are necessary to ensure good print adhesion (Brady and Marsh, 1997). For some packaging types, the polypropylene plastic surfaces also require anti-static agents to prevent attraction of dirt and maintain good product appearance.

Figure 2. Multi-layer polypropylene bottle with EVOH barrier layer



Polypropylene plastics are available in thicker forms for pots and containers with significantly improved clarity, although still not equalling that of crystal polystyrene. Other applications include jars that can be sterilised or pasteurised for hot filling.

Further extended uses of food-contact polypropylene plastics include kitchenware such as reusable domestic and commercial food-storage containers and disposable beverage glasses.

Polypropylene and the co-polymer plastics also find extensive use for caps and closures for bottles, pots and containers (Brady and Marsh, 1997).

The relatively high melting point of polypropylene means that the plastic, either in the form of containers or as coated board, can be used for microwave heating/cooking of foods such as ready meals.

Polypropylene plastics are used for re-usable trays and crates for retail bulk delivery of foodstuffs, including bread products, fruit and vegetables.

The major forms of polypropylene packaging and examples of food types for which they are used are:

Pots/containers: yoghurt, desserts, margarine, cottage cheese, soups, sauces, chilled salads, pot noodles (microwave heating)

Cast film bags: bread, filled baguettes

OPP film bags/wraps: crisps, wide range of snacks, muesli, peanuts and other nuts, biscuits, confectionery, spices, pasta, rice, sugar, porridge, bakery products

OPP film overwraps with food on trays/in cartons: fresh and chilled fruit and vegetables, cooked meats, pasties, bakery products, tea

Multilayer lidding films: controlled atmosphere packs for food products such as meat and fish

Film pouches: sauces, dried and liquid soups, cooked meats

Bottles with barrier resins: sauces

Bottle caps and closures: soft drinks, cider, mineral waters, oils

Paperboard/polypropylene (PP) laminates: dairy products, ready meals (microwave heating)

REGULATORY ASPECTS

Regulations that apply to polypropylene: Directives on food contact materials and articles, and on plastics for food contact

In the early 1970s work started in Europe to harmonise the then current disparate safety laws and regulations within the European Union Member States "on materials and articles intended to come into contact with foodstuffs". The principal aims were to ensure that the health of the consumer was protected and to remove barriers to trade.

The subsequent activities of the European Commission, in collaboration with the plastics industry, have resulted in framework directives that lay down the basic safety requirements for all food contact materials and articles and directives dealing specifically with food-contact plastics.

Article 2 in the current Framework Directive 89/109/EEC states the fundamental requirements:

> Materials and articles must be manufactured in compliance with good manufacturing practice so that under their normal and foreseeable conditions of use, they do not transfer their constituents to foodstuffs which could:
>
> - endanger human health
> - bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof

The first plastics directive was published only in 1990 as European Commission Directive 90/128/EEC "relating to plastics materials and articles intended to come into contact with foodstuffs", although earlier directives published in the 1980s provided the rules for migration testing. Directive 90/128/EEC contains the overall migration limit and a list of authorised plastic monomers, some with restrictions either as specific migration limits (SMLs) or residue limits in the plastic (maximum quantity or QM). Seven amendments have been made to Directive 90/128/EEC adding further monomers to the list and/or changing their restrictions. The most fundamental change has been the introduction of an "Incomplete List of Additives". As with the monomers, some additives have been assigned restrictions that are mainly SMLs. It should be noted that the list of additives is not complete and currently excludes, for example, polymeric additives, solvents and colourants. It is permissible to use additives that are not in the "Incomplete List of Additives", providing they are currently accepted and approved for use in one or more European Union Member States. Information on plastics additives that have been evaluated by the Scientific Committee on Food (SCF), the advisory body to the European Commission, but which have not yet been inserted in an amendment to Directive 90/128/EEC, can be found in the Commission's Synoptic Document. It should be noted however, that the Synoptic Document is to date only a working document of the European Commission without official legal status.

At the present time the plastics Directive 90/128/EEC and amendments do not cover substances classed as adhesives or surface coatings, but such substances must comply with the fundamental requirements of the Framework Directive 89/109/EEC, detailed previously.

Colourants used in food contact plastics are also not covered currently by any European Commission directive. There is, however, a Council of Europe Resolution AP(89)1 "on the use of colourants in plastics coming into contact with food". This resolution is currently under review. It requires that colourants should not pose a risk to health or affect food quality and that they should be sufficiently integrated within the finished material so that there is no visible migration under normal conditions of use. Purity criteria and specifications cover contaminants such as toxic heavy metals, aromatic amines and PCBs.

Colourants and pigments often are incorporated into polypropylene plastics using master batches which typically consist of a base polymer (polypropylene) and the colourant/pigment at a high concentration. Master batches also are used to incorporate additional additives, such as anti-static and slip agents, sometimes with additional substances acting as carriers.

As with adhesives and coatings, colourants and any carriers must fully meet the fundamental requirements of Article 2 in European Directive 89/109/EEC.

Full details on all the directives relating to food-contact materials and articles and the Commission's Synoptic Document can be found at http://cpf.jrc.it/webpack/, which is organised on behalf of the European Commission by the Food Products & Consumer Goods Group of the Institute of Health & Consumer Protection at the Joint Research Centre, Ispra, Italy.

The provisions of the European directives are brought into use by individual European Union Member States implementing them into their national laws and legislative systems. The laws of some European Member States contain additional legislative specifications and restrictions for food-contact plastics, particularly on components not yet covered by the directives. Some countries not within the European Union, for example Switzerland, have adopted some of the provisions of the European Directives into their national laws.

Migration: overall migration limits, specific migration limits (SMLs)

The overall migration limit contained in Directive 90/128/EEC is specified as 10 milligrams of plastics substances released per square decimetre of plastic surface area (mg/dm^2) or, alternatively, 60 milligrams of plastics substances transferring to 1 kilogram of foodstuff (mg/kg).

Propylene, the monomer used to manufacture polypropylene, and the two monomers ethylene and 1-butene, used in the manufacture of the principal co-polymers, are in the *List of Authorized Monomers and Other Starting Substance* in Directive 90/128/EEC, with no restrictions. No changes have been made to the status of these three monomers in the succeeding seven amendments to this directive.

All these monomers are very volatile gases and, consequently, residues in processed polypropylene plastics are typically not detectable.

Many of the plastics additives used in polypropylene plastics are now listed in the recent amendments to Directive 90/128/EEC, and some have restrictions assigned.

Table 1 lists typical additives used in polypropylene plastics with the current restriction status.

Table 1. Typical additives in polypropylene plastics and restrictions

ADDITIVE	RESTRICTION
Pentaerythritol tetrakis [3-(3,5-di-tert-butyl-4-hydroxphenyl)propionate] – antioxidant	None
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate – antioxidant	SML = 6 mg/kg (6th amendment, Directive 90/128/EEC)
Phosphorous acid, tri(2,4-di-tert-butylphenyl) ester – antioxidant	None
Erucamide, oleamide, stearamide – slip agents	None
N,N-bis(2-hydroxyethyl)alkyl(C8-C18) amine and amine hydrochlorides – anti-static agents	SML (T) = 1.2 mg/kg expressed as N,N-bis (2-hydroxyethyl) alkyl(C8-C18) amine

Standard overall migration test methods for testing polypropylene plastics to establish compliance with the overall migration limit have been prepared as standard ENV 1186 by Technical Committee 194/Sub-Committee 1 of the European Committee for Standardization (CEN). This standard has recently been up-dated and revised, and will be converted to an EN standard in 2002 (European Committee for Standardization, 2002). At the present time there are no standard migration test methods for legislation-restricted plastics additives.

United States of America FDA regulations

The United States have their own regulations for the control of plastics materials used in contact with foodstuffs. These are produced by the U.S. Food and Drug Administration (FDA). Substances that may transfer from plastics to foodstuffs are classified as "indirect food additives".

Regulations for polypropylene plastics and the co-polymers are contained in Code of Federal Regulations (CFR) Title 21 Part 177.1520, Olefin Polymers. Additives that may be used in polypropylene plastics and the co-polymers are contained in CFR Title 21 Part 178, Indirect Food Additives: Adjuvants, Production Aids and Sanitizers. This part contains separate sub-parts dealing with, for example, antioxidants (2010), antistatic and antifogging agents (3130), clarifying agents (3295), colorants (3297) and release agents (3860). These regulations do not contain any specific migration limits for the listed substances, in contrast to the European regulations.

Also included in the FDA regulations is a part entitled Threshold of Regulation for Substances Used in Food-Contact Articles (Part 170.39). The threshold of regulation concept was introduced in 1995 to meet the American *de minimis* requirement to concentrate only on issues of concern and not on those considered to be trivial. From scientific data it has been concluded that substances that migrate from packaging to foodstuffs at concentrations ≤0.5 ppb do not present a significant risk to the health of the consumer and, in turn, do not need to be the subject of regulation. With the assumption that the total human daily diet consists of 1.5 kg of food and 1.5 kg of fluids the maximum daily intake of the substance should not exceed 1.5 microgram, under the regulation. Substances known or suspected to be carcinogens are excluded.

In Europe work is currently ongoing on a similar concept under the title Threshold of Toxicological Concern for Chemical Substances Present in the Diet. Again this is a scientifically based concept that aims to establish a concentration for substances in the diet for which there is no significant risk to the health of the consumer. Developments on this concept by an ILSI Europe Task Force and other experts were discussed in depth at a workshop held in October 1999 (Kroes, *et al*., 2000; Barlow, *et al*., 2001).

The FDA regulations are updated annually. Full details of these regulations applicable to polypropylene, the co-polymers and additives that can be used with these plastics are available at:
http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr177_01.html and
http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr178_01.html.

These American regulations are often used by non-European countries that do not have their own detailed regulations and in areas not yet harmonised in Europe.

SAFETY/TOXICOLOGY

Polypropylene plastics are basically inert materials and do not present a health hazard to the consumer in either handling the plastics or consuming foodstuffs with which they have come into contact. All polypropylene plastics packaging that come into direct contact with foods and beverages comply fully with the safety requirements in the relevant European Directives on food-contact plastics.

As reported in the previous section, the three monomers, propylene, ethylene and 1-butene, used in the manufacture of polypropylene plastics and the principal co-polymers have not been assigned any specific migration limits (SMLs) or any other restrictions in Directive 90/128/EEC. The decisions not to assign any restrictions to these monomers were based primarily on toxicological assessments by the European Commission's Scientific Committee on Food (SCF) and the fact that these monomers are very volatile and easily lost from processed plastics. The three monomers are gases at ambient temperatures with sub-zero boiling points.

The SCF's opinion for all three monomers stated: "Residues of this gas in plastics are very small. The gas has low toxic potential. Migration into food will be toxicologically negligible" (Clayton and Clayton, 1981-1982).

The three monomers have been placed in SCF List 3, "Substances for which an acceptable daily intake (ADI) or tolerable daily intake (TDI) could not be established, but where present use could be accepted. Some of these substances are volatile and therefore unlikely to be present in the finished product".

The fact that these monomers are very volatile gases with residues typically not detectable in processed polypropylene plastics significantly reduces the possibility of oxides of these monomers being present. Both ethylene oxide and propylene oxide have been assigned a QM restriction of 1 mg/kg in Directive 90/128/EEC. (QM = maximum permitted quantity of the "residual" substances in the material or articles)

Plastics additives receive the same SCF assessments as the monomers, and, where necessary, restrictions are assigned to ensure that any migration to foodstuffs does not present a health hazard to the consumer. The SCF assessments are based primarily on toxicological data obtained from the substance, for which there is a core set of tests. However, as any potential safety hazard to the consumer is related to the extent of migration of the substance from the plastic, a reduced dossier of toxicological test results may be acceptable where it has been demonstrated that migration is <5 mg/kg foodstuff. Where the migration is very low, < 0.05 mg/kg foodstuff, it may be necessary to demonstrate only the absence of mutagenic potential by three mutagenicity tests. Once an assessment has been completed and any restriction assigned, such as an SML, the data are published in an amendment to Directive 90/128/EEC. An SML value is arrived at by multiplying the TDI value by 60, which is based on the assumption that an average consumer weighs 60 kg and eats 1 kg each day of a foodstuff which has been in contact with the plastic containing the particular substance.

As mentioned in the previous section an example of an additive typically used in polypropylene plastics is the antioxidant octadecyl 3-(3.5-di-tert-butyl-4-hydroxyphenyl)-propionate, with an assigned SML of 6 mg/kg in the 6th amendment to the Directive (European Commission, 2001). This additive has been placed in SCF List 2, Substances for which a TDI or a t-TDI has been established by the Committee.

The SCF Opinion was: "TDI: 0.1 mg/kg body weight. Several oral rat studies (3-weeks to 3 months), 2-year oral studies in mice and rats, two -generation and tetratogenicity studies, mutagenicity tests. (RIVM doc.31-03-92)".

The above quoted summary data from the SCF assessments and similar data produced for other plastics monomers and additives can be found in the European Commission's Synoptic Document *Draft of Provisional List of Monomers and Additives Used in the Manufacture of Plastics and Coatings Intended to come into Contact with Foodstuffs*. The latest version of the document is available at http://cpf.jrc.it/webpack/.

ENVIRONMENTAL ASPECTS

EC Directive on Packaging and Packaging Waste

The principal European Union environmental legislation affecting manufacturers and users of plastic packaging is European Commission Directive 94/62/EC on Packaging and Packaging Waste.

The basic aim of the directive is to:

> Harmonise national measures concerning packaging and packaging waste management in order to provide a high level of environmental protection as well as to ensure the functioning of the internal market thereby avoiding barriers to trade.

The directive specifies packaging waste and re-cycling targets that each individual European Union Member State must achieve. These targets are currently under review with the intention of increasing the target percentage values.

At the present time no European Commission Directives or regulations apply specifically to food-contact materials and articles made from re-cycled plastics. The regulatory situation in individual European countries varies, with some forbidding the use of re-cycled materials and others leaving it up to the user to ensure full compliance with the European Directives, and national regulations on food-contact plastics and the overall safety of the foodstuff.

Recyclability and reuse

During the 1990s laboratories participating in a European Commission funded project (European Commission, DG XII, 1997) carried out in-depth studies to assess possible health risks to consumers from foodstuffs packaged in either re-used plastics packaging or packaging made from recycled plastics.

The principal concern with the use of preused plastic food packaging and the use of packaging made from recycled plastic material is the possibility that the original packaging, after use, was contaminated with hazardous substances. Plastics packaging intended to be reused or re-cycled to make new packaging can be cleaned, but hazardous contaminants may not always be efficiently removed. The propensity for organic contaminants to be absorbed and retained by a plastic and then to diffuse out into food from reused/recycled packaging is dependent on the physical nature of the plastics type. The project identified rigid PVC and PET as plastics with low sorption and diffusion characteristics and the polyethylene plastics at the opposite end of the range. Polypropylene plastics have sorption/diffusion characteristics in the middle of the range.

Guidelines for the use of recycled plastics for food-contact applications are contained in the ILSI Europe Report *Recycling of Plastics for Food Contact Use* (International Life Sciences Institute, 1998).

A possible use of recycled polypropylene plastics for new food-contact plastics has been investigated in three-layer coextruded cups, in which the recycled plastic is the middle layer and the outer layers are virgin plastic. The virgin polypropylene layer on the inside of the cups acts as a functional barrier between the recycled plastic layer and the foodstuff (Franz, *et al*., 1994).

For recycling purposes, polypropylene plastic packaging often contains the following internationally recognised symbol, which identifies the plastic as polypropylene by both the number 5 and the letters PP (Figure 3). This is typically found on the base of bottles, pots and containers.

Figure 3. International labelling symbol for polypropylene.

Incineration

Because polypropylene and the co-polymer plastics are hydrocarbon polymers, incineration produces combustion products similar to those from hydrocarbon fuels. The small quantities of the plastics additives and the coatings or barrier layers will produce only small amounts of other combustion products. Incineration is therefore an effective process for disposal of polypropylene plastics and at the same time produces energy that can be used to generate electricity or for heating.

GENERAL CONCLUSIONS

Polypropylene has been determined to be a safe food-contact plastics material and, with its versatile properties, has become the preferred packaging material for a wide range of foodstuffs, from a variety of dairy products, through confectionery and bread to ready meals that can be prepared quickly for consumption by microwave heating.

Polypropylene and the associated co-polymers can be processed into all the main forms of packaging: both cast and oriented films, pots, tubs, bottles and containers. In addition, polypropylene plastics are extensively used for bottle and container closures and labels. Multilayer structures and coated films with barrier resins ensure that the quality and safety of the packaged foodstuffs are maintained effectively.

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