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IS 10910 (1984): Polypropylene and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water [PCD 12: Plastics]



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Indian Standard

**SPECIFICATION FOR POLYPROPYLENE
AND ITS COPOLYMERS FOR ITS SAFE USE
IN CONTACT WITH FOODSTUFFS,
PHARMACEUTICALS AND DRINKING WATER**

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**BUREAU OF INDIAN STANDARDS
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Indian Standard

SPECIFICATION FOR POLYPROPYLENE AND ITS COPOLYMERS FOR ITS SAFE USE IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER

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Indian Standard

SPECIFICATION FOR POLYPROPYLENE AND ITS COPOLYMERS FOR ITS SAFE USE IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 15 March 1984, after the draft finalized by the Plastics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

0.2 Plastics are now being used on a large scale for packaging of foodstuffs, and pharmaceuticals. Where direct contact occurs between the packed commodity and the plastics, the high-molecular-mass polymer itself does not pose a toxic hazard being inert and essentially insoluble in food. There is, however, a likelihood that some transfer will occur of polymer additives, adventitious impurities, such as monomers, catalyst remnants and residual polymerisation solvents and of low molecular mass polymer fractions, from the plastics into the packaged material with consequent toxic hazard to the consumers. The occurrence of acute toxicity due to plastics materials in contact with food is most unlikely, since only trace quantities of potentially toxic materials are likely to migrate. However, the accumulation of these toxic materials with time may lead to hazards which may be serious.

0.3 This standard is intended to be used with the following series of standards on food contact plastics, being one among this series:

IS : 9833-1981 Classification of pigments and colourants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water;

IS : 9845-1981 Method of analysis for determination of specific and/or overall migration of constituents of plastics materials and articles intended to come into contact with foodstuffs;

IS : 10141-1982 Positive list of constituents of polyethylene in contact with foodstuffs, pharmaceuticals and drinking water;

IS : 10142-1982 Specification for styrene polymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water;

IS : 10146-1982 Specification for polyethylene for its safe use in contact with foodstuffs, pharmaceuticals and drinking water;

IS : 10148-1982 Positive list of constituents of polyvinyl chloride (PVC) and its copolymers in contact with foodstuffs, pharmaceuticals and drinking water;

IS : 10149-1982 Positive list of constituents of styrene polymers in contact with foodstuffs, pharmaceuticals and drinking water;

IS : 10151-1982 Specification for polyvinyl chloride (PVC) and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water;

IS : 10171-1982 Guide on suitability of plastics for food packaging; and

IS : 10909-1984 Positive list of constituents of polypropylene and its copolymers in contact with foodstuffs, pharmaceuticals and drinking water.

0.4 It is emphasized that these standards need to be used in combination to provide a system of control to the manufacturers of plastics as well as to the fabricators of the thermoplastic packaging materials to derive maximum benefits. Besides, it may also serve as basis for official agencies to frame suitable legislation to ensure effective safeguards for the safety and health of consumers where thermoplastics for food contact applications are concerned.

0.5 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard specifies requirements and methods of sampling and test for polypropylene for the manufacture of plastic items used in contact with foodstuffs, pharmaceuticals and drinking water.

*Rules for rounding off numerical values (revised).

1.2 The standard does not purport to establish the suitability of the packaging media with particular foodstuff, pharmaceutical or drinking water from other than toxicological considerations.

2. TERMINOLOGY

2.1 For the purpose of this standard, the definitions of polypropylene as given in 2 of IS : 10909-1984* shall apply.

3. REQUIREMENTS

3.1 **Basic Resin** — Homopolymers of propylene, copolymers of propylene with other 1-alkenes containing up to 8 carbon atoms in which the comonomer content is not exceeding 15 percent by mass, blends of homopolymers of propylene with one or more of the copolymers and blends of several copolymers of propylene as prescribed in IS : 10909-1984*.

3.2 **Material** — The material shall also comply with the threshold limits of the manufacturing residues, polymerization ingredients and auxiliary items as prescribed in IS : 10909-1984*.

3.3 **Pigments and Colourants** — In case the coloured material is used for food-packaging applications it shall comply with the list and limits of the pigments and colourants prescribed in IS : 9833-1981†.

3.4 **Overall Migration** — The material shall also comply with the overall migration limits as detailed below when tested by the method prescribed in IS : 9845-1981‡:

- a) 60 mg/kg (*Max*) of the foodstuff; in the case of liquid foodstuffs or of stimulants, the limit shall be 60 mg/l (*Max*). However, the value of the overall migration limit shall be equal to 10 mg/dm² of the surface of the material or article in the following cases:
 - i) Containers or articles which are similar to containers or which in any case may be filled to a capacity less than 250 ml provided it is possible to calculate the surface area of contact with the foodstuff.

*Positive list of constituents of polypropylene and its copolymers in contact with foodstuffs, pharmaceuticals and drinking water.

†Classification of pigments and colourants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water.

‡Method of analysis for the determination of specific and/or overall migration of constituents of plastics materials and articles intended to come into contact with foodstuffs.

- ii) Sheets, foils and other non-fillable articles for which ratio between the surface area of the material or article and the quantity of foodstuffs, in contact may not be calculated.

3.5 Storage and Control

3.5.1 Storage — Plastics materials intended for food contact use shall be stored separately from materials in closed, properly identified containers.

3.5.2 Control — An authorized person shall supervise and control the issue of plastics materials to the process or manufacturing area and shall maintain appropriate records of the issue of such materials.

3.5.3 Adequate standards of hygiene shall be maintained at all times and plant operators and storemen shall be trained in proper hygiene practices.

4. PACKING AND MARKING

4.1 Packing — The material shall be suitably packed with suitable liner in gunny/paper bags, as agreed to between the purchaser and the supplier, in a manner so as to ensure that the items do not become contaminated during storage.

4.2 Marking — Each package shall be clearly marked with the name and types of the material, month and year of manufacture of the material, name of the manufacturer and his trade-mark, if any.

4.2.1 The packages may also be marked with **Standard mark**.

4.2.2 The use of the Standard Mark is governed by the provisions of the Bureau of Indian Standards Act, 1986 and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

5. SAMPLING

5.1 Preparation of the Test Samples — The method of drawing representative sample of the material and the criteria for conformity shall be as prescribed in Appendix A.

A P P E N D I X A*(Clause 5.1)***SAMPLING OF POLYPROPYLENE AND ITS COPOLYMERS****A-1. GENERAL**

A-1.1 In drawing, preparing, storing and handling samples, the following precautions and directions shall be observed.

A-1.2 Samples shall not be taken in an exposed place.

A-1.3 The sampling instrument wherever applicable, shall be made of stainless steel or any other suitable material on which the material shall have no action. The instrument shall be clean and dry.

A-1.4 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination.

A-1.5 The samples shall be placed in a suitable, clean, dry, and air-tight metal or glass containers on which the material has no action. The sample containers shall be of such a size that they are almost completely filled by the sample.

A-1.6 Each sample container shall be sealed air-tight with a stopper after filling and marked with full details of sampling, such as date of sampling, and the month and year of manufacture of the material.

A-1.7 Samples shall be stored in such a manner that the temperature of the material does not vary unduly from the normal temperature.

A-2. SCALE OF SAMPLING

A-2.1 Lot — In a single consignment all the packages of the same class, same type, same form and belonging to the same batch of manufacture shall be grouped together to constitute a lot. If a consignment is known to consist of packages belonging to different batches of manufacture or different forms, the packages belonging to the same batch of manufacture and same form shall be grouped together and each such group shall constitute a lot.

A-2.1.1 The packages may consist of containers of polypropylene and its copolymers rolls, films or vials.

A-2.2 For ascertaining the conformity of the material to the requirements of this specification, samples shall be tested from each lot separately. The numbers of packages to be sampled shall depend on the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

TABLE 1 SCALE OF SAMPLING

NUMBER OF PACKAGES IN THE LOT	SAMPLE SIZE
(1)	(2)
1	1
2 to 15	2
16 to 50	3
51 to 100	4
101 to 300	5
301 to 500	6
501 to 1 000	8
1 001 and above	10

A-2.2.1 These packages shall be selected at random from the lot and in order to ensure the randomness of selection, procedure given in IS : 4905-1968* may be followed.

A-3. PREPARATION OF TEST SAMPLES

A-3.1 From each of the packages of material selected, small portions of material shall be drawn with the help of suitable sampling instrument. The total quantity of material collected from each package shall be sufficient to test all the requirements given in 3 of the specification.

A-3.2 In the case of packages consisting of containers, vials, rolls or films, the number of items to be selected from package for testing each of the requirements given in 3 shall be one.

A-4. NUMBER OF TESTS

A-4.1 Tests for determining all the requirements given in 3 shall be carried out on the individual test samples.

A-5. CRITERIA FOR CONFORMITY

A-5.1 The lot shall be declared as conforming to the requirements of this specification if all the test results on individual samples meet the relevant specification requirements.

*Methods for random sampling.

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