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IS 12252 (1987): Polyalkylene terephthalates (PET, PBT) for their safe use in contact with foodstuffs, pharmaceuticals and drinking water [PCD 12: Plastics]



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Indian Standard

**SPECIFICATION FOR POLYALKYLENE
TEREPHTHALATES (PET AND PBT) FOR THEIR
SAFE USE IN CONTACT WITH FOODSTUFFS,
PHARMACEUTICALS AND DRINKING WATER**

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Indian Standard

SPECIFICATION FOR POLYALKYLENE TEREPHTHALATES (PET AND PBT) FOR THEIR SAFE USE IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER

0. FOREWORD

0.1 This Indian Standard was adopted by the Bureau of Indian Standards on 10 December 1987, 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 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 of polymer additives, adventitious impurities, such as monomers, catalyst remnants and residual polymerization solvents and of low molecular mass polymer fractions will occur 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 Polyalkylene terephthalates (saturated polyesters) are amongst the thermoplastic materials used extensively in other countries and now in India for packaging of foodstuffs and pharmaceuticals. These are included in the FDA Regulation 21 CFR 177 : 1630, USA and the Regulations of several other countries like Japan, West Germany, France, Holland, Italy, Belgium and Korea.

0.4 Acetaldehyde is generated in small amount as

a by-product during condensation and subsequent processing of the polymer. However, no limits of acetaldehyde content are prescribed for such polymers in USFDA and other overseas standards. For mineral water and cola-based drinks, it is reported to be affecting their taste mildly after long storage. For such uses, if required, the limit of acetaldehyde content and test method shall be mutually agreed to between the purchaser and the supplier.

0.5 This standard is intended to be used with the series of Indian Standards on plastics for food contact application which is given in Appendix A.

0.6 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 the fabricators of 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.

0.7 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.

*Rules for rounding off numerical values (revised).

1. SCOPE

1.1 This standard specifies the requirements and methods of sampling and test for polyalkylene terephthalates (PET and PBT) also known as thermoplastic saturated polyesters polymer materials for the manufacture of plastic items used in contact with foodstuffs, pharmaceuticals and drinking water.

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

2. TERMINOLOGY

2.1 For the purpose of this standard the definitions of thermoplastics (saturated) polyesters given in IS : 12229-1987* shall apply.

3. REQUIREMENTS

3.1 Basic Material — Thermoplastic (saturated)

*Positive list of constituents of polyalkylene terephthalates (PET and PBT) for their safe use in contact with foodstuffs, pharmaceuticals and drinking water.

polyesters are condensation products of dimethyl-terephthalate (DMT)/terephthalic acid (PTA) and diols such as monoethylene glycol/1,4-butanediol as prescribed in the positive list. They shall not contain any other ingredients or residues than described in the clauses below and in IS : 12229-1987*.

3.2 Other Ingredients — The material shall comply with the threshold limits of the manufacturing residues, polymerization ingredients and auxiliary items as prescribed in IS : 12229-1987*.

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 pigments and colourants prescribed in IS : 9833-1981†.

3.4 Overall Migration — The material shall comply with the overall migration limits of 60 mg/l, *Max* of simulant and 10 mg/dm², *Max* of the surface of the material or article when tested by the method prescribed in IS : 9845-1986‡.

3.5 Storage and Control

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

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

*Positive list of constituents of polyalkylene terephthalates (PET and PBT) for their safe use in contact with foodstuffs, pharmaceuticals and drinking water.

†List 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 plastic materials and articles intended to come into contact with foodstuffs (*first revision*).

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 packed in gunny/paper bags with suitable liner, as agreed between the purchaser and the supplier, in a manner so as to ensure that the items do not become contaminated during storage. It shall be securely sealed to prevent any ingress of moisture.

4.2 Marking — Each package shall be clearly marked with the following information :

- Manufacturer's name and/or trade-mark, if any;
- Name and type of material;
- Month and year of manufacture;
- Net mass of the material; and
- Lot and batch number.

4.2.1 The packages may also be marked with the Standard Mark.

NOTE — 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 Standards Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

5. SAMPLING

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

APPENDIX A

(Clause 0.5)

LIST OF INDIAN STANDARDS ON PLASTICS SUITABLE FOR USE WITH FOODSTUFF

IS : 9833-1981	List of pigments and colourant for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water (with Amendment No. 1)
IS : 9845-1986	Methods 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 (*first revision*)

IS : 10141-1982	Positive list of constituents of polyethylene in contact with foodstuffs (with Amendment No. 1)	IS : 10910-1984	Polypropylene and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS : 10142-1982	Styrene polymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water	IS : 11434-1985	Specification for ionomer resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS : 10146-1982	Polyethylene for its safe use in contact with foodstuffs, pharmaceuticals and drinking water	IS : 11435-1985	Positive list of constituents of ionomer resins for its 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 : 11704-1986	Specification for ethylene/ acrylic acid (EAA) copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS : 10149-1982	Positive list of constituent of styrene polymers in contact with foodstuffs, pharmaceuticals and drinking water	IS : 11705-1986	Positive list of constituents of ethylene/ acrylic acid (EAA) copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS : 10151-1982	Polyvinyl chloride (PVC) and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water	IS : 12229-1987	Positive list of constituents of polyalkylene terephthalates (PET and PBT) for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS : 10171-1982	Guide on suitability of plastics for food packaging		
IS : 10909-1984	Positive list of constituents of polypropylene and its copolymers in contact with foodstuffs, pharmaceuticals and drinking water		

APPENDIX B

(Clause 5.1)

SAMPLING OF POLYALKYLENE TEREPHTHALATES (PET AND PBT)

B-1. GENERAL

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

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

B-1.3 The sampling instrument, where 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.

B-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.

B-1.5 The samples shall be placed in a suitable, clean, dry, 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.

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

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

B-2. SCALE OF SAMPLING

B-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 of 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.

B-2.1.1 The packages may consist of container of polyalkylene terephthalate (PET/PBT) chips and its rolls, films or vials.

B-2.2 For ascertaining the conformity of the material to the requirements of this specification, sample shall be tested from each lot separately. The number 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

NO. OF PACKAGES IN THE LOT	SAMPLE SIZE
(1)	(2)
Up to 50	3
51 to 150	4
151 to 300	5
301 to 500	7
501 and above	10

B-2.2.1 These packages shall be selected at random from the lot and in order to ensure the randomness of selection, procedures given in IS : 4905-1969* may be followed.

*Methods for random sampling.

B-3. PREPARATION OF TEST SAMPLES

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

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

B-4. NUMBER OF TESTS

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

B-5. CRITERIA FOR CONFORMITY

B-5.1 From the individual test results, the average \bar{x} and the range (R) shall be calculated as follows :

where

$$\bar{x} = \frac{\text{Sum of the test results}}{\text{Number of tests}}$$

R = difference between the maximum and the minimum values of the test results.

The lot shall be declared as conforming to the requirement of various characteristics if:

$x + KR \leq$ the maximum value specified; and where the value of K shall be chosen from as given below:

Value of K for Various Sample Size and AQL

AQL Sample Size					
	0.65	1.00	1.50	2.50	4.00
3	—	—	—	.587	.502
4	—	.651	.598	.525	.450
5	.663	.614	.565	.498	.431
7	.613	.596	.525	.465	.405
10	.755	.703	.650	.579	.507

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