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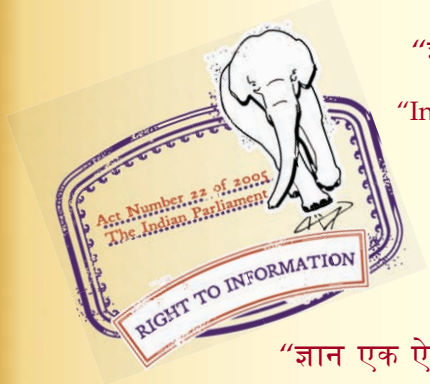
IS 10142 (1999): Polystyrene (Crystal and High Impact) for its Safe Use in Contact with Foodstuffs, Pharmaceuticals and Drinking Water Specification [PCD 12: Plastics]



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IS 10142 : 1999
(Reaffirmed 2003)

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(पहला पुनरीक्षण)

Indian Standard

POLYSTYRENE (CRYSTAL AND HIGH IMPACT) FOR ITS SAFE USE IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER — SPECIFICATION

(First Revision)

ICS 83.080.01; 67.250

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

November 1999 **Price Group 3**

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Plastics Sectional Committee, had been approved by the Petroleum, Coal and Related Products Division Council.

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 of polymer additives, adventitious impurities, such as monomers, catalyst remnants and residual polymerisation solvents and of low molecular mass polymer fractions may occur from the plastics into the packaged material with consequent toxic hazard to 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.

This standard was first published in 1982 covering the requirements for styrene polymers. In this revision the following modifications have been effected:

i) Title has been changed to cover Polystyrene (Crystal and high impact) as given in FDA Regulations, USA instead of 'styrene' as existig now since this standard pertains only to polystyrene and not to other styrene based polymers like ABS, SAN, etc, and correspondingly the requirements for polystyrene (crystal and high impact) only have been included;

ii) The limit of residual styrene monomer content has been revised;

iii) Test method for determination of total residual styrene monomer content has been revised inline with FDA Regulations, USA;

iv) Weight/weight criteria for migration into food and weight/area criteria for containers have been modified in line with EEC Directives; and

v) The requirements of residual styrene monomer and overall migration have been modified.

This standard is intended to be used with the series of Indian Standards published so far on Plastics for food contact application which is given in Annex A. The standard on 'Positive list of Constituents of styrne polymers in contact with foodstuffs, pharmaceuticals and drinking water' has already been published as IS 10149:1982 'Positive list of constituents of polystyrene (crystal and high impact) incontact with foodstuffs, pharmaceuticals and drinking water'. It is hoped that with these two standards, the statutory bodies will be able to effectively monitor the quality of polystyrene (crystal and high impact) material for the end-uses under consideration.

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 fabrications of thermoplastics 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.

Polystyrene (crystal and high impact) material are considered as safe for use as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food in accordance with USFDA Regulation 21 CFR 177.1640, Btitish Plastics Federation and EEC Directives.

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 'Rules for rounding off numerical values *(revised)* '. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

POLYSTYRENE (CRYSTAL AND HIGH IMPACT) FOR ITS SAFE USE IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER — SPECIFICATION

(First Revision)

1 SCOPE

1.1 This standard specifies the requirements and methods of sampling and test for polystyrene (crystal and high impact) 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 foodstuff, pharmaceutical or drinking water, from other than toxicological considerations.

2 NORMATIVE REFERENCES

The following standard contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standard indicated below :

IS No.	*Title*
4905 : 1968	Methods for random sampling
9833 : 1981	List of pigments and colorants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water
9845 : 1998	Determination of overall migration of constituents of plastics materials and articles intended to come in contact with foodstuffs — Method of analysis (*second revision*)
10149 : 1982	Positive list of constituents of polystyrne (crystal and high impact) in contact with foodstuffs, pharmaceuticals and drinking water

3 TERMINOLOGY

For the purpose of this standard, the definitions of polystyrene materials shall mean:

a) homo polymers of styrene produced by the polymerisation of styrene, and

b) rubber modified polystyrene consisting of basic polymers produced by combining styrene butadiene copolymers and/or polybutadiene with polystyrene either during or after polymerisation of the polystyrene such that the finished basic polymers contain not less than 75 percent by mass of total polymer units derived from styrene monomer.

4 REQUIREMENTS

4.1 Basic Resin

To comply with this standard, the styrene polymers defined in **3** shall be made in such a way that they contain no ingredients or residuals of ingredients other than those listed in **4.1.1**, **4.1.2** and **4.1.3**.

4.1.1 *Residual Monomer*

The total residual styrene monomer, when present, shall not exceed 0.1 percent by mass of the polymer when tested according to the method prescribed in Annex B.

4.1.2 *Material*

The material shall comply with the threshold limits of the catalyst, emulsifying agents, suspension agents, miscellaneous polymerisation additives and other additives as prescribed in IS 10149.

4.1.3 *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.

4.2 Overall Migration

The material shall also comply with the overall migration limits of 60 mg/l, *Max* of the simulant and 10 mg/dm^2, *Max* of the surface of the material or article, when tested by the method prescribed in IS 9845.

4.3 The requirements of this standard is considered fully met when the two requirements mentioned in **4** are met, that is, basic resin characteristics at **4.1** and overall migration at **4.2.**

4.4 Storage and Control

4.4.1 *Storage*

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

4.4.2 *Control*

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

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

5 PACKING AND MARKING

5.1 Packing

The material shall be suitably packed in Paper/Polythene/Plastic bags (with or without 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.

5.2 Marking

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

5.2.2 The packages shall also carry the symbol (Fig. 1) clearly embossed/printed on it (in accordance with the EEC Directive 80/590/EEC 'Symbol' that shall accompany materials and articles intended to come into contact with foodstuffs).

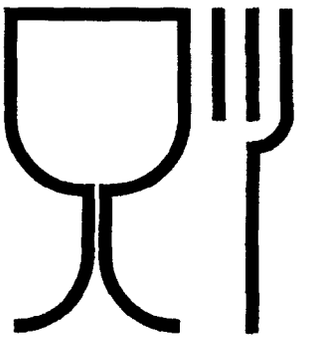

FIG. 1 SYMBOL

5.3 BIS Certification Marking

The package may also be marked with the Standard Mark.

5.3.1 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.

6 SAMPLING

6.1 Preparation of Test Samples

The method of drawing representative samples of the material and the criteria for conformity shall be as prescribed in Annex C.

ANNEX A

(*Foreword*)

LIST OF INDIAN STANDARDS ON PLASTICS SUITABLE FOR USE WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER

IS No.	*Title*
9833 : 1981	List of pigments and colourants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water
9845 : 1998	Determination of overall migration of constituents of plastics materials and articles intended to come in contact with foodstuffs—Method of analysis (*second revision*)
10141 : 1982	Positive list of constituents of polyethylene in contact with foodstuffs,pharmaceuticals and drinking water
10146 : 1982	Polyethylene for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
10148 : 1982	Positive list of constituents of polyvinyl chloride (PVC) and its copolymers in contact with foodstuffs, pharmaceuticals and drinking water
10149 : 1982	Positive list of constituents of polystyrene (crystal and high impact) in contact with foodstuffs, pharmaceuticals and drinking water
10151 : 1982	Polyvinyl chloride (PVC) and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
10171 : 1999	Guide on suitability of plastics for food packaging (*second revision*)
10909 : 1984	Positive list of constituents of polypropylene and its copolymers in contact with foodstuffs, pharmaceuticals and drinking water
10910 : 1984	Polypropylene and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
11434 : 1985	Ionomers resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
11435 : 1985	Positive list of constituents of ionomer resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
11704 : 1986	Ethylene/acrylic acid (EAA) copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
11705 : 1986	Positive list of constituents of Ethylene/acrylic acid (EAA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
12229 : 1987	Positive list of constituents of polyalkylene terephthalates (PET & PBT) for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
12247 : 1988	Nylon-6 polymer for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
12248 : 1988	Positive list of constituents of Nylon-6 polymer for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
12252 : 1987	Polyalkylene terephthalates (PET & PBT) for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
13449 : 1992	Positive list of constituents of ethylene vinyl acetate (EVA) copolymers in contact with foodstuffs, pharmaceuticals and drinking water
13576 : 1992	Ethylene methacrylic and (EMAA) copolymers and terpolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
13577 : 1992	Positive list of constituents of ethylene methacrylic (EMAA) copolymers and terpolymers in contact with foodstuffs, pharmaceuticals and drinking water
13601 : 1993	Ethylene vinyl acetate (EVA) copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water

ANNEX B

(*Clause* 4.1.1)

ANALYTICAL METHOD FOR DETERMINATION OF TOTAL RESIDUAL STYRENE MONOMER CONTENT

B-1 GENERAL

This method is suitable for the determination of residual styrene monomer in all types of styrene polymers.

B-2 PRINCIPLE

The sample is dissolved in methylene chloride. An aliquot of the solution is injected into a gas chromatograph. The amount of styrene monomer present is determined from the area of the resulting peak.

B-3 APPARATUS

B-3.1 Gas Chromatograph

Beckman GC-2A gas chromatograph with hydrogen flame detector or apparatus of equivalent sensitivity.

B-3.2 Chromatograph Column

6.35 mm outside diameter, stainless steel tubing (0.71 mm wall thickness), 1.2 m in length, packed with 20 percent polyethylene glycol (20 000 molecular weight) on alkaline treated 60-80 mesh firebrick.

B-3.3 Recorder

Millivolt range of 0-1, chart speed of 12.7 mm per minute.

B-4 REAGENTS

Compressed air, purified; helium gas; hydrogen gas; methylene chloride, redistilled; and styrene monomer, redistilled.

B-5 OPERATING CONDITIONS FOR THE GAS CHROMATOGRAPH

B-5.1 The column is operated at a temperature of 100°C with a helium flow rate of 82 mm per minute.

B-5.2 The hydrogen burner is operated with 1.1 kg/cm^2 of air pressure and 0.5 kg/cm^2 of hydrogen pressure.

B-5.3 The attenuation of the hydrogen flame detector is set at 2×10^2.

B-6 STANDARDIZATION

B-6.1 Prepare a standard solution by weighing accurately 15 to 20 mg of styrene monomer into a 2-ounce bottle containing 25.0 mm of methylene chloride. Cap the bottle tightly and shake to thoroughly mix the solution.

B-6.2 By means of a microlitre syringe, inject 1 microlitre of the standard solution into the gas chromatograph. Measure the area of the styrene monomer peak which emerges after approximately 12 minutes.

B-7 PROCEDURE

B-7.1 Transfer 1 g of sample (accurately weighed to the nearest 0.001 g) to a 2-ounce bottle and add several glass beads. Pipette 25.0 ml of methylene chloride into the bottle. Cap the bottle tightly and place on a mechanical shaker. Shake until the polymer is completely dissolved. If any insoluble residue remains, allow the bottle to stand (or centrifuge at a low speed) until a clear supernatant layer appears.

B-7.2 By means of a microlitre syringe, inject 3 microlitres of the clear supernatant liquid into the gas chromatograph.

B-7.3 Measure the area of the resulting styrene monomer peak. Compare the sample peak area with the area produced by the standard styrene monomer solution. Calculation:

B-8 CALCULATION

$$\text{Percentage residual styrene monomer} = \frac{\text{mg monomer in standard} \times \text{peak area of sample}}{\text{Peak area of monomer standard} \times \text{sample weight in g}} \times 30$$

ANNEX C

(*Clause* 6.1)

SAMPLING OF POLYSTYRENE

C-1 GENERAL

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

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

C-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.

C-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.

C-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.

C-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.

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

C-2 SCALE OF SAMPLING

C-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.

C-2.1.1 The packages may consist of containers of polystyrene materials, rolls, films, vials, etc.

C-2.2 For ascertaining the conformity of the material to the requirements of this specification, samples 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 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

NOTE — When the number of packages in the lot is less than three, all the packages shall be sampled.

C-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 may be followed.

C-3 PREPARATION OF TEST SAMPLES

C-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 **4**.

C-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 **4**, shall be one.

C-4 NUMBER OF TESTS

Tests for determining all the requirements given in **4** shall be carried out on the individual test samples.

C-5 CRITERIA FOR CONFORMITY

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.

Bureau of Indian Standards

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

This Indian Standard has been developed from Doc : No. PCD 12 (1632).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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Printed at Printograph, New Delh, Ph.: 5726847