IS 14971 (2001): Polycorbonate Resins for its Safe use in Contact with Foodstuffs, Pharmaceuticals and Drinking Water [PCD 12: Plastics]

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भारतीय मानक

खाद्य सामग्री, औषधियों और पेय जल के संपर्क में इसके सुरक्षित उपयोग के लिए पॉलीकार्बोनेट रेज़िन — विशिष्टि

Indian Standard

POLYCARBONATE RESINS FOR ITS SAFE USE IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER — SPECIFICATION

ICS 67.250; 83.080.20

BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

August 2001

Price Group 4

FOREWORD

This Indian Standard 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.

Polycarbonate finds wide use in food contact and health care applications. Some of the most important and known applications of polycarbonate in this area are infant feeding bottles, drinking water containers, micro-ovenable food containers, blood oxygenator, dialyser tubes, intravenous stopcocks, etc. High molecular weight polycarbonate is inert and essentially insoluble in the components of food, water or body fluid with which it comes in contact in the above applications and in itself does not pose any toxic hazard. It is, however, possible that some transfer will occur of polymer additives, adventitious impurities such as monomers, residual catalysts and solvents and low molecular weight polymer fractions from bulk of polycarbonate into the food, water or body fluid with consequent toxic hazard to the user. The occurrence of acute toxicity due to polycarbonate in contact with food, water or body fluid is most unlikely, since only trace quantities of potentially toxic materials are likely to migrate. However, the accumulation of these potentially toxic materials with time may lead to hazards which may be serious.

Polycarbonate resins 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 US.FDA Regulation 21 CFR 177.1580 and of the Regulations of several other countries like Germany.

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

It is emphasized that these Standards need to be used in combination to provide a system of control to the manufacturers and suppliers as well as the processors and users of Polycarbonate materials to derive maximum benefits. Besides, it may also serve as basis for official agencies to frame suitable legislation to ensure effective safeguard for the safety and health of consumers where polycarbonate in food contact and related applications are concerned.

The composition of the committee responsible for formulation of this standard is given in Annex C.

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

POLYCARBONATE RESINS FOR ITS SAFE USE IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER — SPECIFICATION

1 SCOPE

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

1.2 This standard does not purport to establish suitability of polycarbonate in contact with particular foodstuff, pharmaceutical or drinking water, from other than toxicological considerations.

2 REFERENCES

The following standards 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 standards indicated below:

IS No.	*Title*
4905 : 1968	Methods of random sampling
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 — Methods of analysis (*second revision*)
14972 : 2001	Positive list of constituents of polycarbonate resins in contact with foodstuffs, pharmaceuticals and drinking water

3 TERMINOLOGY

3.1 Polycarbonate

A basic resin produced by condensation polymerization of bis-phenol-A either along or in combination with other bis-phenols with phosgene and co-condensation polymerization products of the above combination with phthalic acid dichlorides.

4 REQUIREMENTS

4.1 Basic Resin

Shall be polycarbonate materials as defined in **3.1** and their blends in any mixing proportions.

4.2 Material

The material shall also comply with the threshold limits of the manufacturing residues, polymerization ingredients and auxiliary items as prescribed in IS 14972.

4.3 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.

4.4 Overall Migration

The material shall also comply with the overall migration limits to 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.

4.5 Storage and Control

4.5.1 *Storage*

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

4.5.2 *Control*

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

4.5.3 Adequate standards of hygiene shall be maintained at all times and plant operators and store men shall be trained in proper hygiene practices.

5 PACKING AND MARKING

5.1 Packing

The material shall be packed in suitable plastic or paper bags, 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 packages shall be clearly marked with the following:

a) Name and type of the material;
b) Indication of the source of manufacture and recognized trade-mark, if any;
c) Date of manufacture;
d) Batch No. or Code No.; and
e) "Food-grade" material.

5.2.2 The packages shall also carry the symbol (*see* 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):

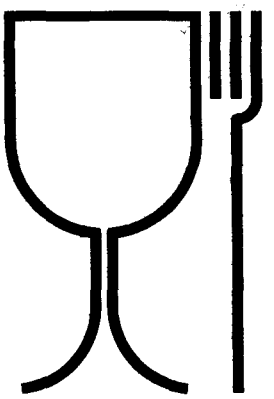

FIG. 1 SYMBOL

5.2.3 BIS Certification Marking

The package may also be marked with the Standard Mark.

5.2.3.1 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. Details of conditions under which a 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

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

ANNEX A

(*Foreword*)

LIST OF INDIAN STANDARDS ON PLASTICS SUITABLE FOR USE IN CONTACT 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 into contact with foodstuffs — Methods of analysis (*second revision*)
10141 : 1982	Positive list of constituents of polyethylene in contact with foodstuffs, pharmaceuticals and drinking water (*first revision*)
10142 : 1982	Polystyrene (crystal and high impact) for its safe use in contact with foodstuffs, pharmaceuticals and drinking water (*first revision*)
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 (Amendment No. 1)
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

IS No.	*Title*
	contact with foodstuffs, pharmaceuticals and drinking water (*first revision*)
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
14972 : 2001	Positive list of constituents of polycarbonate resins in contact with foodstuffs, pharmaceuticals and drinking water

ANNEX B

(*Clause* 6)

SAMPLING OF POLYCARBONATE

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, 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.

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 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 or different forms, the packages belonging to the same batch or manufacture and same form shall be grouped together and each such group shall constitute a lot.

B-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.

B-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 may be followed.

B-3 PREPARATION OF TEST SAMPLES

B-3.1 From each of the packages of the 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 requirement given in **4**.

Table 1 Scale of Sampling

(*Clause* B-2.2)

Number 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.

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 **4**, shall be one.

B-4 NUMBER OF TESTS

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

B-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.

ANNEX C

(Foreword)

COMMITTEE COMPOSITION

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