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मानक

IS 13576 (1992): Ethylene menthacrylic acid (EMAA) copolymers and terpolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water [PCD 12: Plastics]

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## Indian Standard

ETHYLENE METHACRYLIC ACID (EMAA) COPOLYMERS AND TERPOLYMERS FOR THEIR SAFE USE IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER — SPECIFICATION

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**Price Group 3** 

#### 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.

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, advertitious 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 materials with time may lead to hazards which may be serious.

Ethylene-Methacrylic Acid (EMAA) copolymers and terpolymers which are at present not being manufactured in the country are of particular usefulness in packaging industry particularly in contact with foodstuffs, pharmaceuticals and drinking water. At ambient temperature they are generally as inert toxicologically as any man-made product. They are, resistant to attack by most acids, bases and organic solvents at ambient temperatures, but can be attacked by strong oxidizing acids at elevated temperatures.

These resins have narrow-to-broad molecular weight distribution and depending on resin type can be used in either blown or cast extrusion, moulding and extrusion coating operations. When processed as mono-films or coextrusions, these resins impart qualities such as good impact strength, hot tack, optical properties, formability, solvent resistance, low temperature heat sealing, and adhesion to other materials along with a good balance of processing characteristics. When coated on a substance like unprimed foil these resins offer superior bond strength and heat seal properties. During normal processing, storage and use, these resins do not present a significant flammability hazard, but like nearly all organic materials, they burn under suitable conditions. Products of complete combustion are carbon dioxide, metal oxides and water. Products of incomplete combustion include carbon monoxide and organic acids, aldehydes and alcohols.

Disposal of scrap EMAA copolymers and terpolymers presents no special problems. Because they are inert materials, the preferred methods is burial in a properly operated land fill. Incineration is an alternative disposal procedure. Under good combustion conditions, such as found in forced draft incinerators, these resins are converted to carbon dioxide, metal oxides, water and trace components. Incineration creates energy which can be used as heat or to generate electricity.

EMAA copolymers and terpolymers are considered as safe for use as articles or components of articles intended for use in contact with foodstuffs, in accordance with the code of Federal Regulation FDA, USA (21 CFR 177.1330). These resins are not considered as hazardous substances under the definitions of the Occupational Safety and Health Administration (OSHA) "Hazard Communication Standard" (29 CFR 1910.1200), the Federal Hazardous Substance ACT, USA (16 CFR 1500.3) and the Hazardous Materials Transportation Act, USA (49 CFR 172.101) respectively.

This standard is intended to be used with the series of Indian Standards on plastics for food contact application which is 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 of plastics as well as the fabricators 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.

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

## ETHYLENE METHACRYLIC ACID (EMAA) COPOLYMERS AND TERPOLYMERS FOR THEIR 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 EMMA copolymers (resins) for the manufacture of plastics 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, pharmeceuticals and drinking water, from other than toxicological considerations.

#### **2 NORMATIVE 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 revisions, 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 for random sampling
- 9833 : 1981 List of pigments and colourants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water
- 9845: 1986 Methods of analysis for the determination of specific and/ or overall migration of articles intended to come into contact with foodstuffs, pharmaceuticals and drinking water
- 11434 : 1985 Ionomer resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water

*IS No*. 11435 : 1985 Title

Positive list of constituents of ionomers resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water

13577: 1992 Positive list of constituents of ethylene methacrylic acid (EMAA) copolymers and terpolymers in contact with foodstuffs, pharmaceuticals and drinking water

#### **3 TERMINOLOGY**

For the purpose of this standard, the definitions given in 13577 : 1992 F shall apply.

#### **4 REQUIREMENTS**

#### 4.1 Basic Resins

**4.1.1** The ethylene-methacrylic acid (EMAA) copolymer shall consist of basic copolymers produced by the copolymerization of ethylene and methacrylic acid such that the copolymers contain no more than 20 percent by mass of polymer units derived from methacrylic acids. The residual methacrylic acid shall be determined in accordance with **3.2.1** of IS 11434 : 1985.

**4.1.2** The ethylene-methacrylic acid-vinyl acetate terpolymers shall consist of basic copolymers produced by the copolymerization of ethylene, methacrylic acid and vinyl acetate such that the copolymers contain no more than 15 percent by mass of polymer units derived from methacrylic acid.

The ethylene-methacrylic acid-isobutyl acrylate terpolymers shall consist of basic copolymers produced by the copolymerization of mathacrylic acid, ethylene and isobutyl acrylate such that the copolymers contain no less than 70 percent by mass of polymer units derived from ethylene, no more than fifteen percent by mass of polymer units derived from methacrylic acid and no more than 20 percent by mass of polymer units derived from isobutyl acrylate.

#### 4.1.3 Blends

There shall be no limits on the proportions of any of the acid copolymers and EMAA terpolymers that may be blended with each other or EMAA based ionomers as specified in IS 11434 : 1985 and IS 11435 : 1985 respectively.

#### 4.1.4 Additive Concentrates

The total level of slip agent and/or anti-block agent added to the acid copolymer shall not exceed 25 percent by mass prior to let-down.

#### 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 13577 : 1992.

#### 4.3 Pigments and Colourants

In case coloured material is used for food packaging applications, it shall comply with the list and limits of the pigments and colourants prescribed in 1S 9833 : 1981.

#### 4.4 Overall Migration

The material shall comply with the overall migration limits of 60 mg/1, Max of simulants and  $10 \text{ mg/dm}^2$ , Max of the surface of the material or article when tested by the method prescribed in IS 9845 : 1986.

#### 4.5 Storage, Control and Safety

#### 4.5.1 Storage

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

#### 4.5.2 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. **4.5.3** Adequate standards of hygiene shall be maintained at all sites and plant operators and storemen shall be trained in proper hygiene practices.

#### 4.5.4 Safety

#### 4.5.4.1 Spills

Spills of any process material are a safety hazard. Spilled EMAA resins pellets can be very slippery under foot and should be swept up immediately and disposed of properly.

#### 4.5.4.2 Dust (Fines)

The dust or fines of the EMAA resins generated in processing operations (such as grinding of reworked material) is classified as inert or nuisance dust. The OSHA-regulated maximum permissible concentration of nuisance dust is 15 mg per cubic metre and the respirable fraction of the dust may not exceed 5 mg per cubic metre (29 CFR 1910.1000 of US, FDA).

#### 4.5.4.3 Fire

In the event of a fire, personnel entering the area should use a fresh air supply. All types of extinguishers including water, dry chemical, carbon dioxide, and foam can be used to fight fires involving these resins.

#### **5 PACKING AND MARKING**

#### 5.1 Packing

The material shall be suitably packed with suitable liner in gunny/paper bags or boxes or cartons, 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 following:

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

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

5.2.3 The package may also be marked with the Standard Mark.

#### 6 SAMPLING

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



FIG. 1

#### ANNEX A

#### (Foreword)

#### LIST OF INDIAN STANDARDS ON PLASTICS SUITABLE FOR USE WITH FOODSTUFF

IS No.	Title	IS No.	Title		
9833 : 1981	List of pigments and colourant for use in plastics in contact with foodstuffs, pharmaceuti- cals and drinking water	10149 : 1982	Positive list of constituents of styrene polymers in contact with foodstuffs, pharmaceuti- cals and drinking water		
9845 : 1986	Methods of analysis for the determination of specific and/ or overall migration of consti- tuents of plastics materials and articls intended to come into contact with foodstuffs (first	10151 : 1982	Polyvinylchloride (PVC) and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water		
10141 : 1982	revision) Positive list of constituents of polyethylene in contact with foodstuffs	10171 : 1987	Guide on suitability of plastics		
		•	revision)		
		10909 : 1984	Positive list of constituents of		
10142 : 1 <b>9</b> 82	Styrene polymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water		polypropylene and its copoly- mers in contact with foodstuffs, pharmaceuticals and drinking water		
10146 : 1982	Polyethylene for its safe use in contact with foodstuffs, phar- maceuticals and drinking water	10910:1984	Polypropylene and its copoly- mers for its safe use in contact with foodstuffs, pharmaceuti-		
10148 : 1982	Positive list of constituents of polyvinyl chloride (PVC) and its copolymers in contact with foodstuffs, pharmaceuticals and drinking water	11434 : 1985	Specification for ionomer resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water		

IS No.	Title	IS No.	Title
11435 : 1985	Positive list of constituents of ionomer resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking		Nylonn-6 polymer for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
11704 : 1986	water Specification for ethylene/ acrylic acid (EAA) copolymers for its safe use in contact with foodstuffs, pharmaceuticals and	12252 : 1987	Specification for polyalkylene terephthalates (PET and PBT) for their safe use in contact with foodstuffs, pharmaceuti- cals and drinking water
11705 : 1986	drinking water Positive list of constituents for ethylene/acrylic acid (EAA) copolymers for its safe use in contact with foodstuffs, phar- maceuticals and drinking water	13449 : 1992	Positive list of constituents of ethylene vinyl acetate (EVA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
12229 : 1987	Positive list of polyalkylene terephthalates (PET and PBT) for their safe use in contact with foodstuffs, pharmaceuti- cals and drinking water	13577 : 1992	Positive list of constituents of ethylene methacrylic and (EMAA) copolymers and tex- polymer in contact with food- stuffs, pharmaceuticals and drinking water
12247 : 1988	Specification for Nylon-6 poly- mer for its safe use in contact with foodstuffs, pharmaceutical and drinking water	13601 : 1992	Specification for ethylene vinyl acelate (EVA) copolymers for its safe use in contact with food-stuffs pharmaceuticals and
12248 : 1988	Positive list of constituents of		drinking water

#### ANNEX B

#### (Clause 6)

#### SAMPLING OF EMAA COPOLYMERS AND TERPOLYMERS

#### **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 a suitable, clean, dry airtight 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 airtight 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

No. of

In a single consignment all the packages of the same class, 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 type/class, the packages belonging to the same batch of manufacture and same class/type shall be grouped together and each group shall constitute a lot.

B-2.1.1 The packages may consist of container of EMAA resins and its terpolymers 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.

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 : 1968 may be followed.

#### **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

co	llect	ed f	from	each	package	e shall	be	sufficient
to	test	all	the r	equir	ements g	iven in	4.	

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**

**B-4.1** Tests for determining all the requirements in 4 shall be carried out on individual test samples.

#### **B-5 CRITERIA FOR CONFORMITY**

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

$$(\overline{X}) = \frac{\text{Sum of test results}}{\text{Number of tests}}$$

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

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

 $(\overline{X}) + KR \leq$  the maximum value specified; and

where the value of K shall be chosen from table as given below:

#### Value of K for Various Sample Size and AQL

Table 1 Scale of Sampling		Sample Size	AQL				
of Packages in the Lot	Sample Size	-	0.65	1.00	1.50	2.50	4.00
(1)	(2)	3	_	—		0.587	0.502
Up to 50	3	4		0.651	0·598	0.525	0.450
51 to 150	4	5	0·66 <b>3</b>	0.614	0.565	0 <b>·49</b> 8	0.431
51 to 300 01 to 500	5 7	7	0·61 <b>3</b>	0·596	0.525	0.465	0.405
01 and above	10	10	0.755	0.703	0.650	0·57 <b>9</b>	0.570

#### Standard Mark

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 Standard 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.

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