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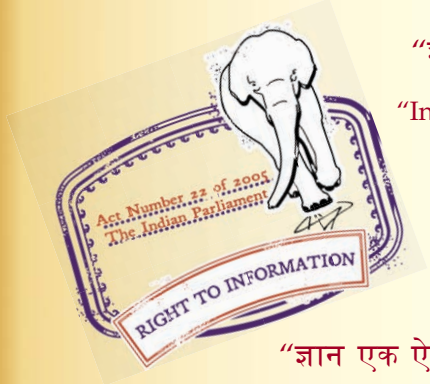
IS 11434 (1985): ionomer resins for its safe use in contact with foodstuffs, pharmaceutical and drinking water [PCD 12: Plastics]



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IS : 11434 - 1985

(Reaffirmed 2003)

Indian Standard

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

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Indian Standard

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

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Indian Standard

SPECIFICATION FOR IONOMER RESINS 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 2 December 1985, 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 in 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 may occur of polymer additives, adventitious impurities, such as monomers, catalyst remnants and residual polymerization 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 Ionomer resins which at present are not being manufactured in the country, are a new breed of third generation polymers. These resins are of particular usefulness in the packaging industry. Ionomer resins may be converted into films by conventional processing methods such as blown, coextrusion, cast, lamination. The distinctiveness of ionomer resins lies in the following areas:

a) Sealing through product (particularly oils and dusty powders) residue,

b) Resistance to oil penetration,

c) Very high hot seal (hot tack) strength, and

d) Low sealing temperature.

These properties would reduce seal failures. Ionomer resins may also be combined with a variety of other polymers to give film structures, such as nylon/ionomer, HDPE/ionomer, polyester/LDPE/ionomer, BOPP/ ionomer, polyester/aluminium/ionomer.

0.4 This standard is intended to be used with the following series of Indian Standards on plastics for food contact applications:

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

IS : 9845-1981 Method of analysis for the determination of specific and/or overall migrations of constituents of plastic 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,

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

IS : 10910-1984 Specification for polypropylene and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water, and

IS : 11435-1985 Positive list of ionomer resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water.

0.4.1 Standards for other plastics for food contact applications like ethylene/acrylic acid (EAA) copolymer which are under preparation are

expected to follow the same pattern, namely, a product specification with a corresponding positive list.

0.5 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.

0.6 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 the requirements and methods of sampling and test for ionomer resins 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 and drinking water, from other than toxicological considerations.

2. TERMINOLOGY

2.1 For the purpose of this standard, the definitions given in IS : 11435-1985† shall apply.

3. REQUIREMENTS

3.1 Basic Resins

3.1.1 In the ethylene-methacrylic acid copolymers, the methacrylic acid content shall not exceed 20 percent by mass.

3.1.2 In the ethylene-methacrylic acid-vinyl acetate terpolymers, the methacrylic acid content shall not exceed 15 percent by mass, in the

*Rules for rounding off numerical values (*revised*).

†Positive list of constituents of ionomer resins for its safe use in contact with foodstuff, pharmaceuticals and drinking water.

ethylene-methacrylic acid-isobutyl acrylate terpolymers, the resin shall contain not less than 70 percent by mass of ethylene and not more than 15 percent by mass of methacrylic acid and not more than 20 percent by mass of isobutyl acrylate.

3.1.3 *Blends* — There shall be no limits on the proportions of any of the ionomeric copolymers and ionomeric terpolymers that may be blended with each other.

3.1.4 *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.

3.2 Material — The material shall also comply with the threshold limits of the manufacturing residues polymerization ingredients auxiliary items as prescribed in IS : 11435-1985*.

3.2.1 *Method for Determining Residual Methacrylic Acid* — A measured mass of polymer sample is placed in a reflux vessel together with a known amount of distilled water and a known amount of propionic acid internal standard solution. The mixture is refluxed for 2 hours. The residual acids in the ionomer resin are extracted into the water. When the solution is cool, a sample is analysed for methacrylic acid by gas chromatography. Calculations are carried out by measuring the peak height of each component and rationing the height with that of the propionic acid internal standard peak. Calibration is done by running and appropriate number of standard samples covering the analytical range of interest.

NOTE — Full details of the method shall be provided by the manufacturer, if required by any competent authority.

3.3 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 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‡:

60 mg/kg (*Max*) of the foodstuff. In the case of liquid foodstuffs or of simulants, the limit shall be 60 mg/l (*Max*). However, the

*Positive list of constituents of ionomer resins for its safe use in contact with foodstuff, pharmaceuticals and drinking water.

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

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

value of the overall migration limit shall be equal to 10 mg/dm^2 of the surface of the material or article in the following cases:

a) 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; and

b) Sheets, foils and other non-fillable article 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 other 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 written 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 linear 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.

4.2 Marking — 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.

4.2.1 The package may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI 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 ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

5. SAMPLING

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

APPENDIX A

(*Clause* 5.1)

SAMPLING OF IONOMER RESINS

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, 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.

A-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.

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 from 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.

A-2.1.1 The packages may consist of container of ionomer resins and its copolymers rolls, films or vials.

A-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 2.

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

A-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.

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 a suitable sampling instrument. The total quantity of material collected from each package shall be sufficient to test all the requirements given in **3**.

A-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.

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.

*Methods for random sampling.

A-5. CRITERIA FOR CONFORMITY

A-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 requirements of various characteristics if:

$\bar{X} + K\,R \leqslant$ 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

Sample Size	*AQL*				
	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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