IS : 10146 - 1982
(Reaffirmed 1997)

Indian Standard

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

(Third Reprint MARCH 1999)

UDC 678.742.2 : 621.798 : 663/664+615.1/.4 :614.8

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

Gr 3 *June* 1982

Indian Standard

SPECIFICATION FOR POLYETHYLENE FOR ITS SAFE USE IN CONTACT WITHFOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER

Plastics Sectional Committee, PCDC 12

Chairman

DR K. J. BALAKRISHNA
A-10, Shantinagar, Cantonment, Kanpur

Members	*Representing*
DR P. C. ANTONY	Indian Plastics Ltd, Bombay
SHRI N. L. BIRLA (*Alternate*)	
SHRI A. S. ATHALYE	All India Plastics Manufacturers' Association, Bombay
SECRETARY (AIPMA) (*Alternate*)	
DR P. K. BANERJEE	Polyolefins Industries Ltd, Bombay
SHRI A. T. BASAK	Directorate General of Supplies and Disposals, New Delhi
SHRI B. B. RAI (*Alternate*)	
SHRI K. J. BHATT	State Trading Corporation of India Ltd, New Delhi
SHRI BHAGWAN DASWANI (*Alternate*)	
SHRI S. T. BHOJWANI	Bright Brothers Ltd, Bombay
SHRI A. H. KHAN (*Alternate*)	
SHRI T. S. BIDDAPA	National Organic Chemical Industries Ltd, Bombay
SHRI J. K. VADODARIA (*Alternate*)	
DR R. P. DAMBAL	Indian Telephone Industries Ltd, Bangalore
SHRI G. V. RAO (*Alternate*)	
DR S. P. SINGH DHAKAREY	Ministry of Defence (DGI)
SHRI N. C. BOSE (*Alternate*)	
SHRI O. P. DHAMIJA	Export Inspection Council of India, Calcutta
SHRI M. K. UNNIKRISHNAN (*Alternate*)	
SHRI DION FERNANDES	Plastics & Linoleum Export Promotion Council, Bombay
SHRI K. RAMANI (*Alternate*)	

(*Continued on page 2*)

(*Continued from page* 1)

Members	*Representing*
SHRI M. S. FRANCIS	Central Institute of Plastics Engineering and Tools, Madras
SHRI CHANDRAKANT B. GARWARE SHRI H. S. SURI (*Alternate*)	Garware Synthetics Pvt Ltd, Bombay
SHRI A. GHOSH SHRI S. M. LAHIRI (*Alternate*)	National Test House, Calcutta
SHRI S. K. JAIN SHRI K. A. T. VARGHESE (*Alternate*)	Hoechst Dyes & Chemicals Ltd, Bombay
DR S. P. MANIK SHRI N. KRISHNANPPA (*Alternate*)	Railway Board (Ministry of Railways)
SHRI P. R. MAHALINGAM SHRI S. S. GATTANI (*Alternate*)	Chemicals & Plastics (India) Ltd, Madras
SHRI P. R. MALHAN SHRI S. R. SINGH (*Alternate*)	Development Commissioner, Small Scale Industries, New Delhi
SHRI R. C. MISHRA SHRI G. L. ANAND (*Alternate*) SHRI A. K. BASU (*Alternate*)	Bharat Heavy Electricals Ltd, Bhopal
SHRI S. MITRA DR B. R. C. ANAND (*Alternate*)	Calico Chemicals (Plastics and Fibres Division), Bombay
SHRI K. R. NARASIMHAN DR S. LAKSHMANAN (*Alternate*)	Metal Box Ltd, Calcutta
SHRI V. NIJHAWAN SHRI A. K. GUPTA (*Alternate*)	Union Carbide India Ltd, Calcutta
SHRI M. S. RAMAMURTHI SHRI C. U. KHANDHERIA (*Alternate*)	Polychem Limited, Bombay
SHRI O. P. RATRA	National Buildings Organization, New Delhi
SHRI D. A. REES SHRI O. P. BANERJEE (*Alternate*)	Kosmek Plastics Manufacturing Ltd, Bombay
SHRI R. SANTHANAM SHRI D. JAIN (*Alternate*)	The Alkali & Chemical Corporation of India Limited, Calcutta
DR P. R. SESHAN SHRI A. K. RAY (*Alternate*)	Indian Petrochemicals Corporation Ltd, Vadodara
SHRI P. P. SHARMA SHRI N. K. AGARWAL (*Alternate*)	Directorate General of Technical Development, New Delhi
DR J. VAID DR S. P. BHIDE (*Alternate*)	Peico Electronics & Electricals Ltd, Pune
DR S. P. VOHRA SHRI Y. V. CHITTAL (*Alternate*)	Bakelite Hylam Ltd, Hyderabad
SHRI M. S. SAXENA, Director (P&C) (*Secretary*)	Director General, BIS (*Ex-officio Member*)

(*Continued on page* 10)

Indian Standard

SPECIFICATION FOR POLYETHYLENE 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 13 May 1982, 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 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 will occur of polymer additives, adventitious impurities, such as monomers, catalyst remnants and residual polymerisation 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 Initially the Sectional Committee responsible for the preparation of this standard had prepared three codes of practice for safe use of polyvinyl chloride (IS : 7288-1974*), polyethylene (IS : 7277-1974†), and styrene polymers (IS : 7961-1976‡) in contact with foodstuffs, pharmaceuticals and drinking water. Taking cognizance of the pressing need to monitor the quality of plastics intended to come in contact with foodstuffs, pharmaceuticals and drinking water which could not be done on the basis of standard codes of practice, the Committee decided to prepare

*Code of practice for safe use of polyvinyl chloride (PVC) and its copolymers in contact with foodstuffs, pharmaceuticals and drinking water.

†Code of practice for safe use of polyethylene in contact with foodstuffs, pharmaceutical and drinking water.

‡Code of practice for safe use of styrene polymers in contact with foodstuffs, pharmaceuticals and drinking water.

the following series of Indian Standards dealing with various aspects of 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 migration of constituents of plastics 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; and

IS : 10151-1982 Specification for polyvinyl chloride (PVC) and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water; and

IS : 10171-1982 Guide on suitability of plastics for food packaging.

Eventually the three codes of practice would be withdrawn with the publication of the product specification along with the corresponding positive list for the three plastics. Standards for other plastics for food contact applications like polypropylene and unsaturated polyester resins which are under preparation are expected to follow the same pattern, namely, a product specification with a corresponding positive list. It is hoped that this set of Indian Standards for plastics considered safe for food contact applications would help the statutory bodies to effectively monitor the quality of plastics for this end use.

0.4 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.

0.5 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 polyethylene plastic 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 this suitability of the packaging media with particular foodstuff, pharmaceutical or drinking water, from other than toxicological considerations.

2. TERMINOLOGY

2.1 For the purpose of this standard the definitions of polyethylene given in 2 of IS : 10141-1982† shall apply.

3. REQUIREMENTS

3.1 Basic Resin — Homopolymers of ethylene; copolymers of ethylene with other 1-alkenes containing up to 8 carbon atoms in which the co-monomer content is not exceeding 15 percent by mass, blends of homopolymers of ethylene with one or more of the copolymers and blends of several copolymers of ethylene as prescribed in IS : 10141-1982†.

3.2 Material — The material shall also comply with the threshold limits of the manufacturing residues polymerization ingredients auxiliary items as prescribed in IS : 10141-1982†.

---

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

†Positive list of constituents of polyethylene in contact with foodstuffs, pharmaceuticals and drinking water.

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 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†.

a) 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 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:

1) 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.

2) 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 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.

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 liner in gunny/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.

---

*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 plastics materials, and articles intended to come into contact with foodstuffs.

4.2 Marking — Each package shall be clearly marked with the name and types 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 Standard Mark.

4.2.2 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.

5. SAMPLING

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

APPENDIX A

(*Clause* 5.1)

SAMPLING OF POLYETHYLENE AND ITS COPOLYMERS

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, 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.

A-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.

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 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.

A-2.1.1 The packages may consist of containers of PVC and its copolymers, rolls, films or vials.

A-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

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.

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 : 4905-1968* 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.

A-5. CRITERIA FOR CONFORMITY

A-5.1 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.

*Methods for random sampling.

(*Continued from page* 2)

Plastics in Food Packaging and Allied Industries Subcommittee, PCDC 12 : 12

Convener	*Representing*
SHRI D. S. CHADHA	Central Committee for Food Standards (Directorate General of Health Services), New Delhi
Members	
SHRI B. ANANDASWAMY	Central Food Technological Research Institute (CSIR), Mysore
DR P. K. BANERJEE	Polyolefins Industries Ltd, Bombay
SHRI V. DORAIRAJ (*Alternate*)	
SHRI S. T. BHOJWANI	Bright Brothers Ltd, Bombay
SHRI A. H. KHAN (*Alternate*)	
SHRI T. S. BIDDAPA	National Organic Chemicals Industries Ltd, Bombay
SHRI J. K. VADODARIA (*Alternate*)	
SHRI P. V. DATAR	Polychem Ltd, Bombay
SHRI C. U. KHANDHERIA (*Alternate*)	
DR S. S. GOTHOSKAR	Drugs Controller (India), New Delhi
SHRI D. S. CHADHA (*Alternate*)	
SHRI D. JAIN	The Alkali & Chemicals Corporation of India Ltd, Calcutta
SHRI S. K. JAIN	Hoechst Dyes & Chemicals Ltd, Bombay
SHRI K. A. T. VARGHESE (*Alternate*)	
SHRI R. KALIDAS	Chemicals & Plastics (India) Ltd, Madras
SHRI S. S. GATTANI (*Alternate*)	
SHRI K. R. NARASIMHAN	Metal Box India Ltd, Calcutta
DR S. LAKSHMANAN (*Alternate*)	
SHRI P. V. NARAYANAN	Indian Institute of Packaging, Bombay
SHRI G. S. PURUSHOTHAMAN (*Alternate*)	
DR N. P. RAO	Defence Institute of Food Preservation & Storage, New Delhi
SHRI V. K. MATHUR (*Alternate*)	
REPRESENTATIVE	Bhabha Atomic Research Centre, Bombay
DR B. R. ROY	Central Food Laboratory, Calcutta
SHRI K. C. SAH	Union Carbide India Ltd, Calcutta
SHRI V. NIJHAWAN (*Alternate*)	
DR N. SEN	Hindustan Lever Ltd, Bombay
DR P. R. SESHAN	Indian Petrochemicals Corporation Ltd, Vadodara
SHRI A. K. RAY (*Alternate*)	
SHRI P. P. SHARMA	Directorate General of Technical Development, New Delhi
SHRI N. K. AGARWAL (*Alternate*)	
SHRI L. SHETH	Bakelite Hylam Ltd, Hyderabad
SHRI G. K. SRINIVASAN (*Alternate*)	
SHRI O. P. SRIVASTAVA	Defence Food Research Laboratory, Mysore
SHRI A. N. SRIVASTAVA (*Alternate*)	

BUREAU OF INDIAN STANDARDS

Headquarters:
Manak Bhavan, 9 Bahadur Shah Zafar Marg, NEW DELHI 110002
Telephones: 323 0131, 323 3375, 323 9402
Fax : 91 11 3234062, 91 11 3239399, 91 11 3239382

Telegrams : Manaksanstha
(Common to all Offices)

Central Laboratory:	Telephone
Plot No. 20/9, Site IV, Sahibabad Industrial Area, SAHIBABAD 201010	8-77 00 32
Regional Offices:	
Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg, NEW DELHI 110002	323 76 17
*Eastern : 1/14 CIT Scheme VII M, V.I.P. Road, Maniktola, CALCUTTA 700054	337 86 62
Northern : SCO 335-336, Sector 34-A, CHANDIGARH 160022	60 38 43
Southern : C.I.T. Campus, IV Cross Road, CHENNAI 600113	235 23 15
†Western : Manakalaya, E9 Behind Marol Telephone Exchange, Andheri (East), MUMBAI 400093	832 92 95
Branch Offices:	
'Pushpak', Nurmohamed Shaikh Marg, Khanpur, AHMEDABAD 380001	550 13 48
‡Peenya Industrial Area, 1st Stage, Bangalore - Tumkur Road, BANGALORE 560058	839 49 55
Gangotri Complex, 5th Floor, Bhadbhada Road, T. T. Nagar, BHOPAL 462003	55 40 21
Plot No. 62-63, Unit VI, Ganga Nagar, BHUBANESHWAR 751001	40 36 27
Kalaikathir Buildings, 670 Avinashi Road, COIMBATORE 641037	21 01 41
Plot No. 43, Sector 16 A, Mathura Road, FARIDABAD 121001	8-28 88 01
Savitri Complex, 116 G. T. Road, GHAZIABAD 201001	8-71 19 96
53/5 Ward No. 29, R. G. Barua Road, 5th By-lane, GUWAHATI 781003	54 11 37
5-8-58C, L. N. Gupta Marg, Nampally Station Road, HYDERABAD 500001	20 10 83
E-52, Chitaranjan Marg, C-Scheme, JAIPUR 302001	37 29 25
117/418 B, Sarvodaya Nagar, KANPUR 208005	21 68 76
Seth Bhawan, 2nd Floor, Behind Leela Cinema, Naval Kishore Road, LUCKNOW 226001	23 89 23
Patliputra Industrial Estate, PATNA 800013	26 23 05
T. C. No. 14/1421, University P. O. Palayam, THIRUVANANTHAPURAM 695034	6 21 17
NIT Building, Second Floor, Gokulpat Market, NAGPUR 440010	52 51 71
Institution of Engineers (India) Building, 1332 Shivaji Nagar, PUNE 411005	32 36 35

*Sales Office is at 5 Chowringhee Approach, P. O. Princep Street, CALCUTTA 700072 — 27 10 85

†Sales Office is at Novelty Chambers, Grant Road, MUMBAI 400007 — 309 65 28

‡Sales Office is at 'F' Block, Unity Building, Narashimaraja Square, BANGALORE 560002 — 222 39 71

Printed at New India Printing Press, Khurja, India

AMENDMENT NO. 1 MARCH 2002
TO
IS 10146 : 1982 SPECIFICATION FOR POLYETHYLENE FOR ITS SAFE USE IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER

(*Page* 6, *clause* **3.4**) — Substitute the following for the existing matter:

3.4 Overall Migration — The material shall comply with the overall migration limits of 60 mg/l, *Max* of simulants and 10 mg/dm^2, *Max* of the surface of the material or article when tested by the method prescribed in IS 9845 : 1998†.

[*Page* 6, *footnote with* (†) *mark*] — Substitute the following for the existing footnote:

'†Determination of overall migration of constituents of plastics materials and articles intended to come in contact with foodstuffs — Method of analysis (*second revision*).'

(PCD 12)

Reprography Unit, BIS, New Delhi, India