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मानक

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“पुराने को छोड़ नये के तरफ”

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“Step Out From the Old to the New”

IS 10909 (2001): Positive List of Constituents of Polypropylene and its Copolymers in Contact with Foodstuffs, Pharmaceuticals and Drinking Water [PCD 12: Plastics]



“ज्ञान से एक नये भारत का निर्माण”

Satyanarayan Gangaram Pitroda

“Invent a New India Using Knowledge”



“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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भारतीय मानक

खाद्य सामग्री, औषधियों और पेय जल के सम्पर्क में
पोलीपरोपाइलीन और इसके कोपॉलिमर के संघटकों की
निश्चित सूची

(पहला पुनरीक्षण)

Indian Standard

POSITIVE LIST OF CONSTITUENTS OF
POLYPROPYLENE AND ITS COPOLYMERS IN
CONTACT WITH FOODSTUFFS,
PHARMACEUTICALS AND DRINKING WATER

(*First Revision*)

ICS 67.250;83.080.20

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

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by 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, pharmaceuticals and drinking water. 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 migration of polymer additives, adventitious impurities, such as monomers, catalyst remnants and residual polymerization solvents and of low molecular mass polymer fraction will occur from the plastics into the packaged material with consequent toxic hazard to the consumers of products packed in plastics. 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 health hazards.

This standard was first published in 1984. With the availability of newer, efficient and cost effective additives which can be safely used in contact with foodstuffs, pharmaceuticals and drinking water, the concerned Technical Committee has decided to revise this standard to incorporate more additives. In this revision, the following changes have been made:

- a) Two amendments issued to this standard have been incorporated;
- b) The permitted list of additives has been enlarged; and
- c) The additives have been brought under the heading of auxiliary items for working instead of prescribing under various heads like lubricants, antioxidants, ultra-violet absorbers, anti-blocking agent, etc, which is the practice being following until now.

The additives prescribed in this standard are based on information available from British Plastics Federation (BPF), British Industrial Biological Research Association (BIBRA), FDA Regulations (USA), and EEC Directives.

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

The composition of the Committee responsible for formulation of this standard is given in Annex B.

Indian Standard

POSITIVE LIST OF CONSTITUENTS OF POLYPROPYLENE AND ITS COPOLYMERS IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER

(First Revision)

1 SCOPE

1.1 This standard covers positive list of constituents of polypropylene, namely the homopolymers, and copolymers manufacturing residues and necessary additives, which may be regarded as safe for use, when properly processed, in contact with foodstuffs, pharmaceuticals and drinking water and when present only in the prescribed limits of concentration.

1.2 It does not purport to establish the suitability of the ingredient singly in a particular foodstuff, pharmaceutical or drinking water from other than toxicological considerations.

2 REFERENCE

The following standard contains provisions which, through reference in this text, constitute provisions of the standard. At the time of publication, the edition indicated was 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 edition of the standard indicated below:

<i>IS No.</i>	<i>Title</i>
9833 : 1981	List of pigments and colourants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water

3 TERMINOLOGY

3.1 **Polypropylene** — shall mean:

- a) homopolymers of propylene;
- b) copolymers of propylene with ethylene and/or one or more alkene-1-olefines containing C₄ to C₈. The propylene content must constitute not less than 50 percent by mass and monomers with C₄ to C₈ shall constitute not more than 15 percent by mass;
- c) blends of homopolymers listed in 3.1 (a) with one or more of the copolymers listed under 3.1 (b);
- d) blends of several copolymers listed in 3.1 (b); and
- e) blends of polymers listed in 3.1 (a) to (d) with polyisobutylene, butyl rubber, and/or polyethylene such that the propylene content, of the blend is not less than 50 percent by mass and each of the component complies with laid down specification relating to that component.

4 REQUIREMENTS

4.1 Basic Resin

The homopolymer and copolymers defined in 3 shall be made in such a way that they contain no ingredients or residues of ingredients used in their manufacture other than those listed in 4.2.

4.2 Process Residue

Polypropylene shall contain not more than a total of 0.2 percent by mass of the following when measured by agreed assay technique:

- a) Titanium;
- b) Aluminium;
- c) Sodium carbonate;
- d) Potassium carbonate;
- e) Sodium chloride;
- f) Potassium chloride;
- g) Other chlorides;
- h) Petroleum hydrocarbon fractions; and
- j) Magnesium, zirconium, vanadium, benzoates, ethoxides/alkoxides, and C₁ to C₅ alcohols.

5 AUXILIARY ITEMS FOR WORKING

5.2 Pigments and Colourants

5.1 The auxiliary items prescribed in Table 1 may be used to maximum level, percentage weight/weight, of the final product in polypropylene polymers given in 3.1.

The pigments and colourants used shall comply with list and limits prescribed in IS 9833.

Table 1 Auxiliary Items
(Clause 5.1)

Chemical Name (1)	Maximum Level of Use Percentage Weight/Weight of Final Product (2)
Aluminium silicate	50
Aluminium stearate	3
Behenic acid	1
Benzene propanoic acid 3-(1, 1-dimethyl ethyl)- β (3,1-dimethylethyl)-4 - hydroxyphenyl-4-hydroxy- β methyl-1, 2-ethanediyl ester	0.5
1, 4-Benzenedicarboxylic acid, bis [2-(1, 1-dimethyl ethyl)-6- {[3-(1,1-dimethylethyl)-2-hydroxy-5-methyl phenyl [methyl]]-4-methyl phenyl] ester	0.075
β ,3(or4)-Bis(octadecylthio)cyclohexylethane	0.3
2, 6 Bis (1-methyl heptadacyl)-p-cresol	0.3
3,9-Bis[2-{3-(3- <i>tert</i> -butyl-4-hydroxy-5-methylphenyl) propionyloxy }-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5,5] undecan	0.3
5,7-Bis1,1-dimethylethyl-3-hydroxi-2(3H)-benzofuranone, eaction products with o-xylene	0.02
Bis(p-ethylbenzylidene)sorbitol	0.3
4,4-Bis (a, a dimethyl benzyl) diphenylamine	0.3 ¹⁾
2, 5 Bis 5'- <i>tert</i> -butylbenzoxaly (2) thiophene	0.02 ¹⁾
Bis (2, 4-di- <i>tert</i> -butyl phenyl) pentaerythritol diphosphite with upto 1% tri-isopropanolamine	0.01
2-(3'- <i>Tert</i> -butyl-2'-hydroxy-5'-methyl-phenyl)-5-chloro-benzotriazole having melting range of 137-141°C	0.5
N,N-Bis (2-hydroxyethyl) alkyl (12-C18) amine	0.1
Bis [2,2' methylene bis 4 methyl G- <i>tert</i> butyl phenol] terephthalate	0.1
Butylated hydroxyanisole	0.05
Butylated hydroxytoluene	0.2
Butyl lactate	5
<i>n</i> -Butyl stearate	5
Butyric acid, 3,3-bis (3- <i>tert</i> -butyl-4-hydroxyphenyl) ethylene ester	0.5
Calcium benzoate	2
Calcium carbonate	25
Calcium bis [monoethyl 3,5-di- <i>tert</i> -butyl-4-hydroxybenzyl phosphonate]	0.2
Calcium hydroxide	0.1
Calcium perlargonate	—
Calcium octoate	1.5
Calcium oxide	10
Calcium oxide dispersion	20
Calcium palmitate	5
Calcium stearate	5
Carbon black	5
Cyclic neopentanetetrayl bis (octadecyl phosphite)	0.25
4,4' Cyclohexylidenebis (2-cyclohexyl phenol)	0.1
Citric acid monohydrate	0.01
Dibenzylidene sorbitol	0.25
2,6 Di- <i>tert</i> -butyl-4-ethyl phenol	0.01 ²⁾
2,6-di(α -methyl benzyl)-4-methyl phenol	0.2
3,5-Di- <i>tert</i> -butyl-4-hydroxyhydrocinnamic acid triester with	0.5
1,3,5-tris(2-hydroxyethyl)-5-triazine-2,4,6-(1H, 3H, 5H) trione	
<i>Di-tert</i> -butylphenyl phosphonite condensation with biphenyl	0.1
2,4-Di- <i>tert</i> -butylphenyl-3,5-di- <i>tert</i> -butyl-4-hydroxy-benzoate	0.5 ¹⁾
3,5-Di- <i>tert</i> -butyl-4-hydroxy hydrocinnamic acid triester with 1,3,5-tris (2-hydroxy ethyl)-5-triazine-2,4,6-(1H, 3H, 5H) trione	0.5
Dilauryl thiodipropionate	1.0

Table 1 (Continued)

Chemical Name (1)	Maximum Level of Use Percentage Weight/Weight of Final Product (2)
2,4, dimethoxy-6-(1-pyrenyl)-8-triazine dimethylidibenzylidene sorbitol	0.02
Disteryl thiodipropionate	1.0
2,4-Dimethoxy-6-(1-pyrenyl)-S-triazine	0.01
Dimethyl succinate 2-(4-hydroxy 2,2,6,6-tetramethyl 1-piperidyl) ethanol polycondensate	0.3
Distearyl pentaerythritol diphosphite	0.3
2,4 Di- <i>tert</i> -pentyl-6 1-(3,5-di- <i>tert</i> -pentyl-2-hydroxy phenyl) ethyl phenyl acrylate	0.2
N, N' Distearoyl ethylenediamine	5
<i>n</i> -Dodecanol	2
Dolomite	2 ³⁾
<i>Di-tert</i> -butylphenyl phosphonite condensation product with bisphenol/M.P.85 to 110 °C.	0.1
Erucamide	0.2
2-Ethoxy-5- <i>ter</i> thutyl-2'-ethyl-oxalic acid bisanilid (85-90%) and 2-ethoxy-5- <i>tert</i> butyl-2'-ethyl-4- <i>tert</i> butyl-oxalic acid-bisanilid	0.2
2,2'-Ethylidenebis (4, 6-di- <i>tert</i> -butylphenol)	0.05
Fumaric acid	2.5
Glycerine	3.5
Glyceryl oleate	3
Glyceryl stearate	3
Glyceryl ricinoleate	3
Glyceryl triacetate	30
Heavy liquid paraffin	10
Hexadecyl 3,5-di- <i>tert</i> butyl-4-hydroxy benzoate	0.5
<i>a</i> -hydroxy- <i>q</i> -hydroxy poly (oxyethylene) polyonypropylene	0.2
Hydrotalcite (basic magnesium aluminium carbonate hydrate)	0.3
2-Hydroxy-4-isooctoxy-benzophenone	0.5
2 2'-Hydroxy -3'- <i>tert</i> -butyl-5'-methylphenyl-5-chloro- benzotriazol M.P.126-132	0.5
2-Hydroxy-4-n-octoxy-benzophenone	3.5
Lauric diethanolamide	0.5
Lithium benzoate	0.4
N-Lauroylsarcosine	0.4 ⁴⁾
Magnesium benzoate	2
Magnesium oxide	0.05
Magnesium stearate	1
Maleic anhydride grafted polyethylene	10
Mannitol	2.5
2,2'-Methylene bis (4-methyl-6- <i>tert</i> -butyl phenol)	0.01
2,2'-Methylene bis 6-(1-methylcyclo-hexyl)- <i>p</i> -cresol	0.2
N,N-Bis (2-hydroxyethyl) alkyl (C12-C18) amine	0.1
7, [2 h Naphtho (1,2-d)triazol-2-yl] 3-phenylcoumarin	0.1
2:1 Nickel Complex of 3,5-di- <i>tert</i> -butyl-4-hydroxy-benzyl monoethylphosphate	0.3
<i>n</i> -Octadecyl-B (4'-hydroxy-3'-5' di <i>tert</i> butyl phenyl) Propionate	0.5
Oleamide	0.2
Octadecyl hydroxyhydrocinnamate	0.25
Oxidised bis(hydrogenated tallow alkyl) amine	0.05
O,O-di- <i>n</i> -Octadecyl 3,5-di- <i>tert</i> -butyl-4-hydroxybenzyl Phosphonate	0.5
2,2'-Oxamidobis[ethyl-3-(3,5-di- <i>tert</i> -butyl-4-hydroxyphenyl) propionate]	0.5
Phosphoric acid, cyclic butylethyl propanediol, 2,4,6- <i>tri-tert</i> -butylphenyl ester	0.2
Phosphoric acid, cyclic neopentane tetrayl bis(2,4-di- <i>tert</i> -butylphenyl) ester	0.1
Phosphorous acid cyclic butyl ethyl propanediol, 2,4,6- <i>tri-tert</i> -butylphenyl ester	0.2
Pentaerythritol	3
Polyvinyl cyclohexane	0.1
Poly[6-morpholino-s-triazine-2,4-cyl{2,2,6,6-tetramethyl-4-piperidyl}imino]hexamethylene [(2,2,0,6-tetramethyl-4-piperidyl)imino] Polyisobutylene	5
Polydimethyl Siloxane	5
Polyoxyethylene (20) Sorbitan monolaurate	3

Table 1 (Concluded)

Chemical Name (1)	Maximum Level of Use Percentage Weight/Weight of Final Product (2)
Polyoxyethylene (20) Sorbitan mono-oleate	3
Polyoxyethylene (20) Sorbitan monopalmitate	3
Polyoxyethylene (20) Sorbitan monostearate	3
Polyoxyethylene (20) Sorbitan tristearate	3
Poly [6(1,1,3,3-tetramethyl butyl amino) 1,3,5-triazine -2,4-diyl] [4-(2,2,6,6-tetramethyl-piperidyl) imino]-hexamethylene [4-(2,2,6,6-tetramethyl piperidyl) imino]	0.3
Polypropylene glycol	0.5
Silicon dioxide	10
Sodium alkylsulphonate	2.5
Sodium benzoate	—
Sodium calcium alumino silicate hydrate	—
Sorbitan monolaurate	3
Sorbitan monooleate	3
Sorbitan monopalmitate	3
Sorbitan monostearate	3
Sorbitan trioleate	3
Sorbitan tristearate	3
2-stearamido-ethyl stearate	3
Sodium di(<i>p-tert</i> -butylphenyl) phosphate	0.35
Sodium 2,2'-methylenebis(4,6- <i>di-tert</i> -butylphenyl) phosphate	0.3
2-Stearamido-ethyl stearate	3
Stearic/palmitic acid	5
Styrenated <i>p</i> -cresol	0.2 ⁵⁾
Talc	40
Terpolymer of ethylene propylene and 1,4 hexadiene	25
Tetrakis-(2,4-di- <i>tert</i> -butyl-phenyl)-4,4'- biphenylene diphosphonite	0.3
Tetrakis[methylene-3-(3',5'- <i>di-tert</i> -butyl-4'-hydroxyphenyl)propionate] methane	0.5
4,4'-Thio-bis (6- <i>tert</i> -butyl- <i>m</i> -cresol)	0.25
Thiodipropionic acid	0.1
Titanium dioxide	20
α -Tocopherol	—
1,3,5-Trimethyl-2,4,6-tris (3,5- <i>di-tert</i> -butyl-4-hydroxy benzyl) benzene	1
Tri (mixed mono and dinonyl phenyl) phosphite	1
1,3,5-Tris (4- <i>tert</i> -butyl-3-hydroxy-2,6-dimethyl-benzyl)-1,3,5-triazine 2,,4,6 (1h,3h, 5h)- trione	0.25
1,3,5-tris(3,5- <i>di-tert</i> -butyl-4-hydroxyhydrocinnamoyl)hexahydro-s-triazine	0.1
1,3,5-Tris (3,5- <i>di-tert</i> -butyl-4-hydroxy-benzyl)-S triazine-2,4,6 (1h, 3h, 5h) trione	0.1
2-[2,4,8,10-tetrakis(1,1-dimethyl)benzo[d,f][1,3,2]-dioxaphosphepin-6-yl]-N,N-bis[2][2,4, 8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]dioxaphosphepin-6-yl]oxy]ethyl]ethan amine	0.075
Tris (2, 4, di- <i>tert</i> -byutylpheny) phosphite	0.25
Trisodium phosphate	0.1
1,1,3-Tris (2-methyl-4-hydroxy-5- <i>tert</i> -butylphenyl) butane	0.25 ¹⁾
Vinylidene fluoride/hexa fluoropropylene copolymer	0.05
White soft paraffin	25
Zinc acetate	0.2
Zinc benzoate	2
Zinc di-(2-ethylhexanoate)	1.5
Zinc oxide	—
Zinc stearate	3

¹⁾ Non-fatty food only.

²⁾ Maximum thickness of article in contact with foodstuff, pharmaceuticals and drinking water shall be 0.0635 cm.

³⁾ Non-acidic food only.

⁴⁾ Film only.

⁵⁾ Not by food contact above 65°C.

ANNEX A

(Foreword)

LIST OF INDIAN STANDARDS ON PLASTICS SUITABLE FOR USE IN CONTACT WITH
FOODSTUFF, PHARMACEUTICALS AND DRINKING WATER

<i>IS No.</i>	<i>Title</i>	<i>IS No.</i>	<i>Title</i>
9833 : 1981	List of pigments and colourants for use in plastics 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
9845 : 1998	Method of analysis for determination of specific and/or overall migration of constituents of plastics materials and articles intended to come into contact with foodstuffs (<i>second revision</i>)	11705 : 1986	Positive list of constituents of Ethylene/acrylic acid (EAA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
10141 : 2001	Positive list of constituents of polyethylene and its copolymers in contact with foodstuffs, pharmaceuticals and drinking water (<i>first revision</i>)	12229 : 1987	Positive list of constituents of polyalkylene terephthalates (PET & PBT) for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
10142 : 1999	Polystyrene (crystal and high impact) for its safe use in contact with foodstuffs, pharmaceuticals and drinking water (<i>first revision</i>)	12247 : 1988	Nylon-6 polymer for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
10146 : 1982	Polyethylene 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
10148 : 1982	Positive list of constituents of polyvinyl chloride and its copolymers for 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
10149 : 1982	Positive list of constituents of polystyrene (crystal and high impact) 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
10151 : 1982	Polyvinyl chloride (PVC) and its copolymers for 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
10171 : 1999	Guide on suitability of plastics for food packaging (<i>second revision</i>)	13601 : 1993	Ethylene vinyl acetate (EVA) copolymers for its safe use 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	14971 : 2001	Polycarbonate resins 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	14972 : 2001	Positive list of constituents of polycarbonate resins 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	14996 : 2001	Positive list of constituents of modified poly (phenylene oxide)

IS 10909 : 2001

<i>IS No.</i>	<i>Title</i>	<i>IS No.</i>	<i>Title</i>
14997 : 2001	(PPO) in contact with foodstuffs, pharmaceuticals and drinking water Modified poly (phenylene oxide) (PPO) resins for their safe use in contact with foodstuffs, pharmaceuticals and drinking water	14999 : 2001	moulded articles in contact with foodstuffs, pharmaceuticals and drinking water Melamine-formaldehyde moulding materials for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
14998 : 2001	Positive list of constituents of melamine-formaldehyde resins in		

ANNEX B*(Foreword)***COMMITTEE COMPOSITION****Plastics Sectional Committee, PCD 12**

<i>Organization</i>	<i>Representative(s)</i>
Internet ExchangeNext.com Limited, Mumbai Amines and Plasticizers Ltd, Mumbai	SHRI SARUP CHOWDHARY (<i>Chairman</i>) SHRI V. V. KULKARNI DR R. V. UTEKAR (<i>Alternate</i>)
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Ministry of Food Processing Industries, New Delhi National Chemical Laboratory, Pune	SHRI O. P. GERA DR S. S. MAHAJAN DR S. S. KULKARNI (<i>Alternate</i>)
National Dairy Development Board, Anand	DR R. S. LATHANA SHRI S. K. KHANDELWAL (<i>Alternate</i>)
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Shriram Institute for Industrial Research, Delhi	DR R. C. SOOD

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Tata Engg & Locomotive Co Ltd, Jamshedpur	SHRI U. K. NATH SHRIMATI A. D. SATHE (<i>Alternate</i>)
The All India Plastics Manufacturers Association, Mumbai	SHRI R. K. AGGARWAL SHRI K. B. EASWARAN (<i>Alternate</i>)
The Plastics & Linoleums Export Promotion Council, Mumbai VIP Industries, Mumbai	SHRI R. P. KALYANPUR SHRI SIDDHARTHA ROY SHRI A. S. DALVE (<i>Alternate</i>)
XPRO India Ltd, Faridabad	SHRI C. BHASKAR SHRI MANMOHAN KRISHAN (<i>Alternate</i>)
BIS Directorate General	SHRI ANJAN KAR, Director & Head (PCD) [Representing Director General (<i>Ex-officio</i>)]

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