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उत्पाद मैनुअल
Ethylene Vinyl Acetate (EVA) Copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water

IS 13601:1993 के अनसार

PRODUCT MANUAL
FOR Ethylene Vinyl Acetate (EVA) Copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water ACCORDING TO IS 13601:1993

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना- I के तहत प्रमाणन के संचालन में अभ्यास और पारदर्शिता के संचालन में पारदर्शिता सुनिश्चित करने के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन लाइसेंस/प्रमाणपत्र प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता है।

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment)Regulations,2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate.

1.	**उत्पाद** **Product**	:	IS 13601:1993
	शीर्षक **Title**	:	Ethylene Vinyl Acetate (EVA) Copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water - Specification
	संशोधनों की संख्या **No. of amendments**	:	01
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	No specific requirements
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	In case coloured material is to be covered in the scope of licence, sample shall be tested for conformity to requirement for pigments and colourants as per Cl. 4.3 of IS 13601:1993
c)	**नमूने का आकार** **Sample Size**	:	3 packages

3.	**परीक्षण उपकरणों की सूची** **List of Test Equipment**	:	Please refer Annex-A
4.	**निरीक्षण और परीक्षण की स्कीम** **Scheme of Inspection and Testing**	:	Please refer Annex-B
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**		
	Vinyl Acetate Content, Cl 4.1.1 Additive Concentrates, Cl 4.1.2		
6.	**लाइसेंस का दायरा /Scope of the Licence:**		
	"Licence is granted to use Standard Mark as per IS 13601:1993 with the following scope:		
	Name of the product	Ethylene Vinyl Acetate (EVA) Copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water	
	Optional requirements	Coloured material/Uncoloured material	

BUREAU OF INDIAN STANDARDS
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ANNEX – A

LIST OF TEST EQUIPMENTS

Major test equipment required to test as per the Indian Standard

Sl. No.	Tests Used In With Clause Reference	Test Equipment/Chemical
1	Vinyl Acetate Content, Cl. 4.1.1	**Pyrolysis method** Combustion Furnaces capable of maintaining temperature of 400 deg. C, Combustion tube with B 29 ground glass joints, Prefabricated ground glass joint to fit the pyrolysis tube (gas disperser), Quartz boat to fit inside combustion tube, tall form bubbler 500 ml capacity, regulated nitrogen gas supply, pipette, burette and other laboratory glassware. Hydrochloric Acid, Sodium Hydroxide, Phenolpthalein, rectified spirit, distilled water and other laboratory reagents IR spectrophotometry IR Spectrophotometer (350 to 7000 cm^{-1}, hydraulic press of 10 tonne capacity, press plates and spacer, dial gauge micrometer (0.002 mm LC), Melinex film or other equivalent PET films of thickness 100 micron
2	Limits of pigments and colourants, Cl. 4.3	**For determination of Lead, Arsenic, Mercury, Cadmium, Zinc, Barium, Chromium, Antimony as per Cl. 15 of IS 1699:1995** Kjeldahl Flasks, Atomic Absorption Spectrophotometer, hydride generation vessel accessory, Standard solution of copper, zinc, antimony, lead, barium, arsenic, cadmium and other reagents **For determination of primary aromatic amines and sulphonated aromatic amine (as per Annex B of IS 9833:2014)** Weighing balance, ultrasonic bath, Centrifuge capable of 3000 rpm, HPLC system (equipped with gradient elution, DAD detector and pump), Column: (Nucleodur 100-5 C18 ec (Machery Nagel); 250 mm × 4 mm, 5 µm or Equivalent) pH strips, Hydrochloric Acid, Sodium Hydroxide, Methanol HPLC grade, Analytical Reference Standards, phosphoric acid, Diammonium Hydrogen Phosphate **For determination of Polychlorinated biphenyl as per Annex C of IS 9833:2014** LRGC HRMS with EI Mode, Rotary Evaporator, and Weighing Balance nearest to 0.000 1 g, Micropipette with Disposable Pipette Tip, Surgical Hand Gloves, Glass Column, Magnetic Stirrer and Magnetic Bar, Ground Joint Conical Flask— 500 ml, Conditioning/Test chamber for maintaining temperature condition 22 ± 2°C.

		Dust free environment with positive pressure inside the laboratory by air handling unit and laboratory reagents.
3	Overall migration, Cl. 4.4	Simulating solvents as per Cl. 4 of IS 9845:1998 Electric oven/water bath/, pressure cooker electric hot plate with temperature control regulator, analytical balance sensitive upto 0.1 mg, heat resistant glass beakers of 1000 ml capacity, stainless steel evaporating dish of 100 ml capacity, stainless steel tongs, glass rod, plate glass, cylindrical glass jar, glass/stainless steel pins as per IS 9845:1998

The list above is indicative only and may not be considered as exhaustive

ANNEX B

SCHEME OF INSPECTION AND TESTING

1. **LABORATORY-** A laboratory shall be maintained, which shall be suitably equipped (as given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the method given in the specification.

1.1 The manufacturer shall prepare and implement a calibration plan for the test equipment.

2. **TEST RECORD**- The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. **PACKING AND MARKING** - The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each package containing the material provided always that the material so marked conforms to each requirement of the specification.

3.2 The material shall be packed in paper/plastics bags with suitable liner, as agreed between the purchaser and the supplier, in a manner so as to ensure that the items do not become contaminated during storage. Each package shall be marked with the following:

a) Indication of source of manufacturer i.e. Manufacturer's Name and/or Trade Mark
b) Name and Type material
c) Month and Year of manufacture
d) Net Mass of material
e) Lot and batch number
f) BIS licence number and "For BIS certification details please visit www.bis.gov.in"

3.3 The package shall also carry the symbol as per Cl. 5.2.2 of IS 13601:1993 clearly embossed/printed on it in accordance with the EEC directive 80/590/EEC

5. **CONTROL UNIT**- For the purpose of this scheme, the entire quantity of material manufactured under similar conditions in a day shall be taken as one control unit.

6. **LEVELS OF CONTROL** :- The tests as indicate in Table 1 and at the levels of controls in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and records maintained in accordance with paragraph 2 above.

6.1 All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark.

7. **STORAGE, AND HYGIENIC CONDITIONS**: Plastics materials intended for food contact use shall be stored separately from other materials in closed, properly identified containers. Adequate standards of hygiene shall be maintained at all times and plant operators and storemen shall be trained in proper hygienic practices.

8. **REJECTION -** Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act,2016.

TABLE1

LEVELS OF CONTROL

(1)				(2)	(3)		
Test Details				**Test equipment requirement** R: required (or)S: Sub-contracting permitted	**Levels of Control**		
Cl.	Requirement	Test Methods Clause Reference			No. of Sample	Frequency	Remarks
4.1.1	Vinyl Acetate Content	Annex B	IS 13601	R	03	Each control unit	
4.1.2	Additive concentrates	4.1.2	-do-	R	03	-do-	
4.3	Pigments and colourants		IS 9833	S	03	Every month	For coloured materials only
4.4	Overall migration		IS 9845	S	03	Every 3 months	

Note-1: Whether test equipment is required or sub-contracting is permitted in column 2 shall be decided by the Bureau and shall be mandatory. Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note–2: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by BO Head.