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भारतीय मानक मसौदा

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Draft Indian Standard

Non-chlorinated Plastic Biomedical Waste Bag

ICS 13.030.30

Hospital Biomedical Waste Management and Infection control Sectional Committee, MHD 21	Last date for comments: **07 November 2024**

NATIONAL FOREWORD

(Formal clauses will be added later)

This standard specifies the requirements for Non-Chlorinated Plastic Bags meant for storing and transporting Bio-Medical Waste (as defined in Bio-Medical Waste Management Rules, 2016 as amended from time to time). This standard applies to single use bags that are Non-autoclavable and Autoclavable (for the purpose of deactivating pathogens before disposal and not for reuse).

While formulating this Indian Standard, the following critical parameters (including those listed in the Bio-Medical Waste Management Rules 2016) have been considered:

a) Material requirements specifies the Non-Chlorinated Polymer materials
b) Requirements of thickness, tear strength, impact strength, leakage test and drop test to ensure safe handling of hazardous bio-medical waste.

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: 2022 'Rules for Rounding Off Numerical Values (*Second Revision*)'. 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 for Non-Chlorinated Plastic Bags meant for storing and transporting Bio-Medical Waste (as defined in Bio-Medical Waste Management Rules, 2016 as amended from time to time).

1.2 This standard does not cover the requirements of Biodegradable or Compostable bags for handling Biomedical wastes.

2 REFERENCES

2.1 The following standard contains provision 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 revision 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:

2.2 The Indian Standards given below are necessary adjuncts to this standard.

Indian Standard	***Title***
IS 2500 (Part 1): 2000 ISO 2859-1:1999	Sampling procedures for inspection by attributes: Part 1 sampling schemes indexed by acceptance quality limit (AQL) for lot - by - lot inspection (*Third Revision*)
IS 7019: 1998	Glossary of terms in plastics and flexible packaging, excluding paper (*Second revision*)
IS 12395: 1988	Specification for disposable trash bags of plastics
IS 13360 (Part 5/Sec 3): 2022 ISO 527-3: 2018	Plastics - Method of Testing Part 5 mechanical properties Section 3 Determination of tensile properties test conditions for films and sheets
IS 13360 (Part 5/Sec 10): 2018 ISO 6383-1: 2015	Plastics - Methods of testing: Part 5 Mechanical properties Section 10 Determination of tear resistance of plastics films and sheeting - Trouser tear method (*First Revision*)
IS 14534: 2016	Plastics - Guidelines for the Recovery and Recycling of Plastics Waste (*First Revision*)
IS 16459: 2016 ISO 17557: 2003	Plastics - Film and sheeting - Cast polypropylene (PP) films
IS 17216: 2019	Polyethylene mulch films for agriculture and horticulture – Specification

3 TERMINOLOGY

3.1 For the purpose of this standard, the definitions given in IS 7019 shall apply.

4 MATERIAL REQUIREMENTS

4.1 Raw material

The raw material used for manufacturing natural film/ sheet shall consist of only polyethylene/ Polypropylene resins. Master batch shall be filler free. Any additives/ master batches added to resins shall be as agreed to between the supplier and the purchaser.

4.2 Non-chlorinated autoclavable bags shall be made of polypropylene.

4.3 Non-chlorinated non-autoclavable bag shall be made of polyethylene or polypropylene.

5 SHAPE AND DIMENSION REQUIREMENTS

5.1 The thickness of the bag shall be more than 50 microns.

5.2 The length and width of the bag shall be measured at the central part of the bag spread out flat and should lie within ± 5% of the values declared by the manufacturer.

6 GENERAL REQUIREMENTS

6.1 Bags shall be homogeneous and free from defects such as foam, unevenness, crease, fish eye, mixture of foreign matter, pinhole, etc.

6.2 The shape of the bags shall be uniform and the finish of cut portions shall be of good workmanship.

6.3 The printing on the bags shall be uniform and free from printing defects.

7 FUNCTIONAL REQUIREMENTS

7.1 Drop impact resistance test

A set of 10 bags when tested in accordance with Appendix A of IS 12395, there shall be no occurrence of split or tear in more than one of the bags tested.

7.2 Printing ink adhesion test

When tested in accordance with the method given in Annex A, the printed matter shall be readable.

7.3 Drop test

The strength of the bag shall be determined by filling it with round shaped gravels (< 20 mm Dia) up to 1/5th of the height of the bag and subjecting to a flat drop from a height of 1.2 m on a flat hard surface. Subsequently the bag shall conform to test as per clause 7.1.

7.4 Tensile Strength and Elongation

For polyethylene material, the specimen shall have minimum tensile strength and elongation (machine direction and transverse direction) as specified in IS 17216 when tested as per IS 13360 (Part 5/Sec 3). For polypropylene material, the specimen shall meet the requirements as specified in IS 16459 when tested as per IS 13360 (Part 5/Sec 3).

7.5 Tear Strength

The specimen shall have minimum tear strength of 5.90 N when determined in accordance with IS 13360 (Part 5/ Sec 10).

7.6 Ability to withstand autoclaving (for autoclavable bags only)

The bag shall be filled with round shaped gravels (< 20 mm Dia) up to 1/5th of the height of the bag and shall be autoclaved as per the following given conditions:

i) A temperature of not less than 121° C and pressure of 103.4 kPa for an autoclave residence time of not less than 60 minutes; or

ii) A temperature of not less than 135° C and pressure of 213.7 kPa for an autoclave residence time of not less than 45 minutes; or

iii) A temperature of not less than 149° C and pressure of 358.5 kPa for an autoclave residence time of not less than 30 minutes.

Subsequently the bag should be allowed to attain room temperature and when tested as per clause 7.4, shall achieve minimum 80 % of the tensile strength and elongation requirements.

8 SAMPLING REQUIREMENTS

8.1 Lot

In a consignment all the bags of the same class and size manufactured from the same material under similar conditions of production shall be grouped together to constitute a lot.

8.2 For ascertaining the conformity of the lot, the procedure for sampling and inspection as given in IS 2500 (Part 1) shall be followed.

8.3 For ascertaining the conformity for dimensional requirements and appearance, a single sampling plan with general inspection level 11 and Acceptable Quality Limit (AQL) of 1.5 percent as given in Tables I and II-A of IS 2500 (Part 1) shall be followed.

8.4 For all other requirements a single sampling plan with special inspection level S-4 and Acceptable Quality Limit (AQL) of 1.5 percent as given in Tables 1 and II-A of IS 2500 (Part 1) shall be followed.

9 MARKING AND LABELLING REQUIREMENTS

9.1 Each Biomedical waste handling bag shall be marked with the following information:

a) Labelling as per Annexure C (cytotoxic symbol to be marked for cytotoxic wastes only)

b) Dimensions of the bag

c) Volumetric capacity (Approximate)

d) Name of the manufacturer

e) Made from non-chlorinated polymers

f) Recycling mark as per IS 14534;

g) Label print as “non-autoclavable” or “autoclavable,” as applicable, and

h) Any other marking and labelling requirements as stipulated in Bio-Medical Waste Management Rules, 2016 as amended from time to time.

9.2 BIS Certification Marking

The product (s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the BIS Act, 2016 and the Rules and Regulations framed there under, and the product(s) may be marked with the Standard Mark.

9.3 Certificate to be provided by supplier

The product shall be chlorine-free and a certificate to this effect shall be obtained from NABL accredited/ BIS-recognized laboratory.

ANNEX A
(Clause 7.2)
TEST FOR PRINTING INK ADHESION

A-1 Rub the printed matter with cotton dipped in EDTA solution with normal thumb pressure and thereafter apply two strips of 25 mm wide transparent pressure-sensitive tape or cello-tape to the printed area of the bag, one piece down the length of the bag and the other along the width.

A-2 Press the tape firmly on to the bag and leave for 15 s.

A-3 Remove the tape by pulling slowly at about 1 cm from one end at about 90° to the pouch surface.

A-4 After the test, the printed material shall be readable.

ANNEX B
(Clause 9.1)
LABEL FOR BIO-MEDICAL WASTE BAGS

FIG 1 BIOHAZARD SYMBOL

FIG 2 CYTOTOXIC HAZARD SYMBOL