

केंद्रीय मुहर विभाग-2

संदर्भ : कें.मु.वि-2/जी-73/16: 17397 (पार्ट 1)

दिनांक 29/09/2022

विषय: संशोधित आई एस 17397 (पार्ट 1) : 2022 के अनुपालन के दिशा निर्देश ।

- 1) यह उपरोक्त के संदर्भ में है।
- 2) सक्षम अधिकारी द्वारा अनुमोदित दिशा निर्देश अनुपालन हेतु संलग्न है।
- 3) सभी शाखा कार्यालयों से अनुरोध है कि वे अपने अधिकार क्षेत्र में आने वाले आवेदकों और लाइसेंसधारियों को संशोधित मानक के कार्यान्वयन के बारे में सूचित करें।

(शौविक चंदा)
वैज्ञानिक-डी

प्रमुख, (कें.मु.वि.-2)

सभी क्षेत्रीय/शाखा कार्यालयों /प्रयोगशालाओं/PCD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16: 17397 (Part 1)

Dated: 29/09/2022

Subject: Guidelines for Implementation of IS 17397 (Part 1) : 2022

1. This has reference to the subject mentioned above.
2. The Competent Authority has approved the enclosed Guidelines for implementation.
3. All BOs are requested to inform the Applicants and Licensees under their jurisdiction about implementation of the revised Standard.

(Shouvik Chanda)
Scientist-D

Head (CMD 2)

All ROs/BOs/Labs/PCD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:17397(P-1)

29-09-2022

Subject: Guidelines for implementation of revised IS 17397(Part-1):2022 to IS 17397(Part-1):2020/ISO 16365-1:2014 for Plastics – Thermoplastic Polyurethanes for Moulding and Extrusion Materials Part 1 Designation System and Specifications

1. IS 17397(Part-1):2020/ISO 16365-1:2014 has been revised as IS 17397(Part-1):2022 for Plastics – Thermoplastic Polyurethanes for Moulding and Extrusion Materials Part 1 Designation System and Specifications. IS 17397(Part-1):2020/ISO 16365-1:2014 shall be withdrawn w.e.f. 13 March 2023.
2. All BOs shall inform the Applicants and Licensees under their jurisdiction about implementation of the above amendment
3. The significant changes in the standard through this revision as listed in the Table are given for the purpose of general guidance. BOs shall ensure that the product conforms to all the requirements, as applicable, as per the revised Indian Standard.

Clause no. of IS 17397(P-1):2022	Changes
Title of the Indian Standard	The title of the Indian Standard has been changed from: Plastics – Thermoplastic Polyurethanes for Moulding and Extrusion Part 1 Designation System and Basis for Specifications To Plastics – Thermoplastic Polyurethanes for Moulding and Extrusion Part 1 Designation System and Specifications
Scope	a) Reference to ISO 16365-2 in the scope has been deleted b) Additional properties are to be determined as per test methods specified in IS 17397(P-2), instead of ISO 16365-2
Cl. 4.1.1, Designation System	Designation code for Thermoplastics material is to be done based on 6 Data Blocks instead of 5 Data blocks, with the addition of Data Block 1 for Indian Standard. Accordingly, the subsequent Data Blocks have been renumbered.
Cl. 4.2.5; Data Block 5	Test for Hardness shall be determined as per test methods specified in IS 13360(Part 5/Sec 11), instead of ISO 868. Test for Tensile modulus of elasticity shall be determined as per test methods specified in IS 13360 (Part 5/Sec 1)/IS 13360 (Part 5/Sec 2)/IS 13360 (Part

	5/Sec 3)/IS 13360 (Part 5/Sec 25)/ISO 527-5, instead of ISO 527 (all parts). (These test methods were part of earlier product manual i.e. PM/IS 17397(Part-1)/1, March 2022 also)
Cl. 4.3; Coding Example	It has been mentioned that there will be no space/hyphen between two alphabets/number within a block except data block 1. But each data block will be mentioned and separated by a space/hyphen. Also, the maximum number of letter/numbers for each data block has been specified.
Cl. 6.3; Special Requirements of Polymer Used for Molding or Extrusion Articles in Contact with Food Stuffs, Pharmaceutical and Drinking Water	New clause has been introduced; if the product is used in contact with foodstuffs, pharmaceuticals and drinking water, the material is required to be tested for Pigments and Colorants and Overall Migration
Cl. 6.3.1.3; Storage and Control	New clause has been introduced incorporating directions for Storage and Control including hygienic requirements to be maintained for Articles in Contact with Food Stuffs, Pharmaceutical and Drinking Water
Cl. 7.1 and 7.2; Packing and Marking	New clause has been incorporated w.r.t. packing and marking as these were not part of the earlier version of the standard
Cl. 8; Sampling	New clause has been incorporated w.r.t. sampling as this was not part of the earlier version of the standard

4. The existing Product manual has been revised to incorporate the changes due to the revised IS and it is being circulated separately through BIS website, as Product Manual Doc: PM/ IS 17397(Part-1)/ 2, September 2022.

5. The guidelines for implementation of the revised IS is given below:

A. LICENSEES:

- (i) All Licensees shall implement the revised Indian Standard by 13 March 2023. Any difficulty in implementation shall be brought to the notice of CMD-2 at the earliest. BOs shall ensure that no Licences are under operation as per IS 17397(Part-1):2020/ISO 16365-1:2014 after 13 March 2023. The status of implementation of IS 17397(Part-1):2022 shall be confirmed by Head (BO) to CMD-II within two weeks of the last date of implementation of concurrent running.
- (ii) Verification of implementation of the revised Standard, shall be done during next visit.
- (iii) If the Licensee fails to complete all actions by 13 March 2023 it shall be dealt with as per the prevailing guidelines.

B. APPLICATIONS FOR GRANT OF LICENCE:

- (i) Existing Applications where Sample has been submitted in the Laboratory/Test Report has been issued by the Laboratory may be processed without consideration of the revised IS. However, if the Applicant is desirous of considering the revised IS, a declaration may be obtained from the Applicant to that effect and the Application may be processed accordingly. An undertaking shall also be obtained from such Applicants that if the sample fails while considering the provisions of the revised IS, Licence will not be granted as per the old version.
- (ii) Applications which are recorded henceforth may be processed with or without consideration of the revised IS. Processing of Applications without consideration of the revised IS shall be permitted only upto 13 March 2023 and for such cases Applicant shall give a declaration that they will implement the amendment by 13 March 2023.
- (iii) Beyond 13 March 2023 no Licence shall be granted as per the old version.

C. CHANGE IN SCOPE OF LICENCE:

- (i) For change in scope of licence, the relevant provisions as given above for Applicants shall apply.
- (ii) If any licensee wishes to claim in their scope of licence that their material is complying with Clause 6.3(Special Requirements of Polymer Used for Molding or Extrusion Articles in Contact with Food Stuffs, Pharmaceutical and Drinking Water), the same shall be treated as a request for extension in scope of licence and the sample shall conform to the requirements of Cl. 6.3 also.
- (iii) However, processing of such applications for change in scope of licence without consideration of the revised IS shall be permitted only upto the date of implementation of the revised IS by the licensee or upto 13 March 2023 whichever is earlier.

6. The above guidelines come into force with immediate effect.

(Shouvik Chanda)
Scientist D

Head (CMD-2)
DDG(Certification)

Circulated to:

- i) **All RO/BOs**
- ii) **All other concerned - through BIS intranet**