

केन्द्रीय मुहर विभाग-2

संदर्भ -: केमूवी-2/16:5405

02 03 2022

विषय: IS 5405:2019 के amendment no. 1 के अनुपालन के दिशानिर्देश

यह उपरोक्त विषय के संदर्भ में है।

सक्षम अधिकारी द्वारा अनुमोदित दिशानिर्देश अनुपालन हेतु संलग्न है।

सभी क्षेत्रीय/शाखा कार्यालयों से अनुरोध है की दिशानिर्देशों का तत्काल प्रभाव से अनुपालन सुनिश्चित करें।

आदित्य दास
वैज्ञानिक D

प्रमुख (केमूवी 2)

सभी क्षेत्रीय/शाखा कार्यालय/प्रयोगशालाएँ/TXD/LRMD

CENTRAL MARKS DEPARTMENT-2

OurRef:CMD-2/16:5405

02 03 2022

Subject: Guidelines for implementation of amendment no. 1 to IS 5405:2019

This has reference to the subject mentioned above.

The Competent Authority has approved the enclosed Guidelines for implementation.

All ROs/BOs are requested to ensure the implementation of the above Guidelines with immediate effect.

(Aditya Das)
Scientist D

Head (CMD-2)

All ROs/BOs/Labs/TXD/LRMD

CENTRAL MARKS DEPARTMENT-2

OurRef:CMD-2/16:5405

Date: 25 02 2022

Subject: Guidelines for implementation of Amendment no. 1 to IS 5405:2019 – (Sanitary Napkins- Specification)

1. Amendment no.1 to IS 5405:2019 has been published. The amendment shall be implemented with effect from **20 April 2022**.
2. All BOs shall inform the Applicants and Licensees under their jurisdiction about implementation of the above amendment within a week of issuance of these guidelines.
3. The significant changes in the standard through this amendment 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 amendment.

Clause No.	Change
5	“Size class” has been substituted for “size” in the table
7.1	Method for determination of pH value has been changed to IS 1390 from IS 1390 (cold method) i.e. “cold method” has been removed
7.4	Requirement for Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization has been made optional
7.5, 8.2.6	Requirement for Biodegradability and Compostability (Optional) has been changed to Compostability and Biodegradability during composting (Optional) and sampling clause has been modified accordingly
9.1	Marking clause has been modified (pad length and size class has to be marked additionally along with information on whether the product is compostable or biodegradable during composting if applicable)

4. The product manual has been modified in accordance with the amendment and is being circulated separately.
5. The guidelines for implementation of the amendment is given below:
 - a) **LICENSEES:**
 - i) All Licensees shall implement the amendment by **20 April 2022**. Any difficulty in implementation shall be brought to the notice of CMD 2 at the earliest but in any case at least 30 days before the last date of implementation. BOs shall ensure that

no Licences are under operation as per IS 5405:2015 without the amendment after **20 April 2022**.

- ii) Apart from the editorial changes, only biocompatibility evaluation has been made optional and marking requirements have been changed through the amendment. **Accordingly, no evidence of conformity of product to the standard with the amendment needs to be submitted by licensees.** However, verification of implementation of the amendment, may be done during the next visit.

a) **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 amendment. However, if the Applicant is desirous of considering the amendment, 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 amendment, 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 amendment. Processing of Applications without consideration of the amendment shall be permitted only upto 19 April 2022 and for such cases Applicant shall give a declaration that they will implement the amendment by **20 April 2022**.
- iii) Beyond **20 April 2022** no Licence shall be granted without consideration of the amendment.

b) **CHANGE IN SCOPE OF LICENCE:**

- i) For change in scope of licence, the relevant provisions as given above for Applicants shall apply.
- ii) However, processing of such applications for change in scope of licence without consideration of the amendment shall be permitted only upto the date of implementation of the amendment by the licensee or upto **20 April 2022** whichever is earlier.

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

Aditya Das
Sc. D

Head (CMD-2)
DDG (Certification)

AMENDMENT NO. 1 DECEMBER 2021**TO****IS 5405 : 2019 SANITARY NAPKINS — SPECIFICATION****(*Second Revision*)**

[*Foreword, third para, d*] — Substitute the following for the existing:

‘The optional requirement of disposability has been modified as the optional requirement of compostability or biodegradability during composting.’

[*Foreword, third para, h*] — Delete.

[*Foreword, third para, k*] — Substitute ‘clauses have’ for ‘clause has’.

(*Page 1, clause 5, informal table*) — Substitute ‘*Size class*’ for ‘*Size*’.

(*Page 2, clause 7.1, second line*) — Delete ‘(cold method)’.

(*Page 3, clause 7.4, subtitle*) — Substitute the following for the existing:

‘7.4 Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization (Optional)’

(*Page 3, clause 7.4, first line*) — Substitute the following for the existing:

‘If required by the buyer, the manufacturer shall ensure that raw material used for manufacturing the final product are safe for user based on its known toxicological characteristics at intended use.’

(*Page 3, clause 7.5*) — Substitute the following for the existing:

‘7.5 Compostability or Biodegradability during Composting (Optional)’

The manufacturer who are claiming their product as compostable or biodegradable during composting shall pass the test on the final product as per IS/ISO 17088.’

(Page 4, clause 8.2.6) — Substitute the following for the existing:

‘8.2.6 The testing for compostability or biodegradability during composting shall be carried out once for existing products and whenever there is a change in the raw material for manufacturing the product.’

(Page 4, clause 9.1, first sentence) — Substitute the following for the existing:

‘Each pack shall be legibly and indelibly marked with the manufacturer’s name or trade mark, size class and pad length, and number of napkins contained in the pack in addition to the following:’

(Page 4, clause 9.1) — Insert the following at the end:

‘e) The information whether the product is compostable or biodegradable during composting (if applicable).’

[Page 6, Annex C, d)] — Substitute ‘positioned’ for ‘provisioned’

(TXD 36)

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