

केन्द्रीय मुहर विभाग-2

हमारा संदर्भ : के.मु.वि.-2/16: 10350

27 03 2018

विषय: आई एस 10350 के संशोधन संख्या 4 के अनुपालन के लिए दिशानिर्देश ।

इसे उपरोक्त विषय का संदर्भ प्राप्त है ।

सक्षम प्राधिकारी ने आई एस 10350:1999 के संशोधन संख्या 4 के अनुपालन हेतु दिशानिर्देश एवं पुनरीक्षित एसटीआई Doc: STI/10350/5 मार्च 2018 को अनुमोदित कर दिया है ।

सभी क्षेत्रीय और शाखा कार्यालयों से अनुरोध है कि उपरोक्त दिशा-निर्देश का अनुपालन तत्काल प्रभाव से सुनिश्चित करें ।

(अदाने ख्रासी)
वैज्ञानिक सी

प्रमुख (सीएमडी-2) (हस्ता/-)

सभी क्षेत्रीय/शाखा/पीसीडी/प्रयोगशालाओं को परिचालित

प्रतिलिपि : आई टी एस विभाग - बी आई एस इंटरनेट पर डालने हेतु

CENTRAL MARKS DEPARTMENT-2

Our ref: CMD-2/16: 10350

27 03 2018

Subject: Guidelines for implementation of Amendment No. 4 to IS 10350:1999 “Powder Hair Dyes”

This has reference to the subject mentioned above.

The Competent Authority has approved guidelines for implementation of Amendment No. 4 to IS **10350:1999** and revised STI Doc: STI/10350/5 March 2018.

All BOs are requested to ensure the implementation of the above guidelines with immediate effect.

(Adane Khraasi)
Scientist-C

Head (CMD-2)-Sd/-

Circulated to: All ROs/BOs/PCD/Labs.

Copy to: ITS for hosting on BIS Intranet

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16: 10350

14 03 2018

Subject: Guidelines for implementation of Amendment No. 4, November 2017 to IS 10350 : 1999 ‘Powder Hair Dyes – Specification (Second Revision)’.

1. Amendment No.4 to IS 10350:1999 has been published and notified vide Gazette Notification S.O. 515(E) dated 05 02 2018. The date till which the standard without Amendment No. 4 shall remain in force is **24 07 2018**.
2. All BOs shall inform the Applicants/Licensees under their jurisdiction about implementation of the above amendment.
3. The significant changes in the amendment as listed in the Table below is 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	Requirement
4.3	Following addition has been made at the end of clause 4.3: ‘For safety evaluation of novel ingredients used in formulation of powder hair dyes, the powder hair dye shall comply with IS 4011.’

4. Consequent upon issuance of the amendment, existing STI has been revised as Doc: STI/10350/5 March 2018.
5. The guidelines for implementation of the amendment is given below:

A. For Licensees:

- (i) All Licensees shall implement the amendment by 24 07 2018. BOs shall ensure that no Licences are under operation as per IS 10350 : 1999 without the amendment after 24 07 2018.
- (ii) As and when any novel ingredient is added in the formulation, licensee shall declare the novel ingredient and carry out the test as per IS 4011.
- (iii) BO may issue endorsement for the revised STI after receipt of STI Acceptance and the confirmation from the Licensee on implementation of the amendment. If the Licensee fails to complete all actions by 24 07 2018 it shall be dealt with as per OMPC.

B. For Applicants:

- (i) All Applicants shall ensure that the ingredients other than dyes shall comply with the provisions of IS 4707 (Part 1) and IS 4707 (Part 2) subject to the provisions of the Drugs and Cosmetics Act, 1940 and rules framed thereunder. If any novel ingredient is added in the formulation applicant shall declare the novel ingredient and submit a test report as per IS 4011, complying to Amendment No. 4 to IS 10350 : 1999.
- (ii) Beyond 24 07 2018 no Licence shall be granted without consideration of the amendment.

C. For Inclusions:

- (i) For Inclusion of New Varieties, the relevant provisions as given above for Applicants shall apply.
 - (ii) However, processing of Inclusions without consideration of the amendment shall be permitted only upto the date of implementation of the amendment by the licensee or upto 24 07 2018 whichever is earlier.
6. The above guidelines come into force with immediate effect.

(Adane Khrasi)
Scientist C, CMD-2

Head (CMD-2)-Sd/-

DDG (Certification)

**SCHEME OF TESTING & INSPECTION
FOR CERTIFICATION OF
POWDER HAIR DYES
ACCORDING TO IS 10350:1999
(Second Revision)
(Incorporating Amendment No. 4)**

1. LABORATORY

- 1.1 A laboratory shall be maintained, which shall be suitably equipped and staffed, where different tests given in the specification shall be carried out in accordance with the method given in the Indian Standard.
- 1.2 All testing equipment shall be periodically checked, verified and calibrated and records of such checks/verification/calibration shall be maintained.

2. TEST RECORDS

- 2.1 All records of the tests as per this Scheme of Testing and Inspection shall be kept in suitable forms.
- 2.2 Copies of any such records that may be required by BIS shall be made available at any time on request.

3. QUALITY CONTROL

- 3.1 It is recommended that, as far as possible, Statistical Quality Control (SQC) methods may be used for controlling the quality of the product during production as envisaged in this Scheme [See IS 397 (Various parts)].
- 3.2 In addition, efforts should be made to gradually introduce a Quality Management System in accordance with IS/ISO 9001.

4. STANDARD MARK

- 4.1 The Standard Mark(s) as given in Column (1) of the First Schedule of the licence shall be stenciled/ printed on each container and the box in which it is packed as the case may be, provided that the powder hair dye in each container and the box to which this Mark is thus applied, conforms to every requirement of the specification

5. MARKING

- 5.1 Each container (pouch/glass bottles, etc.) and the package (carton/box) containing the same shall be marked with the following information:
 - a) Name of the material;
 - b) Indication of the source of manufacture;
 - c) Warning “ shall not be used for dyeing eyelashes or eyebrows;”#
 - d) Declaration “ maximum arylamine (p-phenylenediamine) after dilution as per manufacturer’s instruction for use (to be declared by manufacturer);”
 - e) Net content;

- f) Shade of dye
- g) Best use before -----(Month and year to be declared by the manufacturer)*
- h) Any other information required by statutory authorities;
- i) Minimum PPD content for dyes in powder form;
- j) Batch number; and
- k) Month and year of manufacture
- l) BIS Licence No. CM/L.....
- m) BIS website details : www.bis.gov.in

Note: This is exempted in case of pack size of 30 g/60 ml or less.

* Note: This is examined in case of pack size of 10 g/25 ml or less and if the shelf life of the product is more than 24 months.

In addition to the above, the following information shall also be given in the attached leaflet:

- a) Procedure for conducting preliminary test for sensitivity (patch test);
- b) Instruction for use; and
- c) List of key ingredients

6. PACKING

- 6.1 The material shall be packed in suitable airtight containers since it is essential to keep it away from light and moisture.

7. LEVELS OF CONTROL

- 7.1 The analysis and tests as indicated in Table 1 and at the levels of control specified therein, shall be carried out on the whole production of the factory which is covered by this scheme and appropriate records and charts maintained in accordance with paragraph 2 above. All the production which conforms to the Indian Standard and covered under this licence shall be marked with the Standard Mark.

8. CONTROL UNIT

- 8.1 For the purpose of this scheme, powder hair dyes of one type blended at a time shall be constitute one control unit.
- 8.2 For the purpose of this Scheme, the control unit shall be as follows:

9. RAW MATERIALS

- 9.1 Raw materials used in the manufacture of powder hair dye shall conform to the requirements prescribed in the relevant Indian Standard where such standards exist, subject to the provisions of the Drugs and Cosmetics Act, as amended from time to time and updated.
- 9.2 The dyes used, if any, in the manufacture of powder hair dyes shall comply with the provisions of IS 4707(Part 1) subject to the provision of the Drugs and cosmetics Act, as amended from time to time and updated.

9.3 Ingredients other than dyes shall comply with the provisions of IS 4707(Part-2).

9.4 For safety evaluation of novel ingredients used in formulation of powder hair dyes shall comply to IS 4011.

10. REJECTION

10.1 A separate record providing the detailed information regarding the rejected control unit and mode of their disposal shall be maintained. Such material shall in no case be stored together with that conforming to the specification.

11. SAMPLES

11.1 The licensee shall supply, free of charge, the sample(s) required in accordance with the Bureau of Indian Standards (Certification) Regulations from the factory or godown. The BIS shall pay for the samples taken by it from the open market.

12. REPLACEMENT

12.1 Whenever a complaint is received soon after the goods with Standard Mark have been purchased and used, and if there is adequate evidence that the goods have not been misused, defective goods or their components are replaced or repaired free of cost by the licensee in case the complaint is proved to be genuine and the warranty period (where applicable) has not expired. The final authority to judge the conformity of the product to the Indian Standard shall be with the Bureau.

12.2 In the event of any damages caused by the goods bearing the standard mark, or any claim being filed by the consumer against BIS Standard Mark and not “conforming to” the relevant Indian Standard, entire liability arising out of such non-conforming product shall be of the licensee and BIS shall not in any way be responsible in such cases.

13. STOP MARKING

13.1 The marking of the product shall be stopped under intimation to the Bureau if, at any time, there is some difficulty in maintaining the conformity of the product to the specification, or the testing equipment goes out of order or due to any other reason. The marking may be resumed as soon as the defects are removed under intimation to BIS.

13.2 The marking of the product shall be stopped immediately if directed to do so by BIS for any reason. The marking may then be resumed only after permission by BIS. The information regarding resumption of markings shall also be sent to BIS.

14. PRODUCTION DATA

14.1 The licensee shall send to BIS a statement of quantity produced, marked and exported by him and the value thereof at the end of each operative year of the licence as per the enclosed proforma (Annex 1) which has to be authenticated by a Chartered Accountant.

TABEL 1
IS 10350:1999
TABLE 1 LEVELS OF CONTROL
(Para 6 of the Scheme of Testing and Inspection)

Test Details			Levels of Control		
Clause/Table (1)	Requirements (2)	Test Method (3)	Reference (4)	No. of Samples (5)	Frequency (6)
4.1	Description	Visual	IS 10350:99	One	Each control unit
4.3	For safety evaluation of novel ingredients used in formulation of powder hair dyes, the powder hair dye shall comply to IS 4011.	4.2.4	IS 4011	One	As and when any novel ingredient is added in the formulation, licensee shall declare the novel ingredient and carry out the test as per IS 4011.
Table 1	pH of 5% (m/m) solution in water	Annex A	-do-	One	-do-
-do-	Active matter (as PPD Content) Percent by mass	Annex B	-do-	One	-do-
-do-	Heavy metals as lead (Pb), parts per million	Annex C	-do-	One	Once in every six months
-do-	Arsenic (as As ₂ O ₃), parts per million	Annex D	-do-	One	-do-
Table 2	Calculated active matter (as PPD content) in the solution after recommended dilution with water, percent by mass	Note under table 2	-do-	One	-Each control unit-

FORM 1
(Clause 2 of Scheme of Testing and Inspection)

TEST RECORDS FOR POWDER HAIR DYES

Date of manufacture	Control Unit No.	Shade	Quantity of powder hair dyes produced in the control unit	Test Result							
				Description	Novel ingredients	pH of 5% solution in water	Active matter as PPD Content percent by mass	Heavy metals as lead (Pb), parts per million,	Arsenic as (As ₂ O ₃), parts per million,	Calculated active matter (as PPD in the solution after recommended dilution with water)	Remarks
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)

PROFORMA-I

PROFORMA FOR OBTAINING PRODUCTION DETAILS

(Period to be covered by the Report:)

Name of Licensee

CM/L No.

Name of Articles(s)

IS No.

Grade/type/Size/Variety/Class/ Rating

1.1 Brand/Trade/Name(s) of BIS Certification Marked Products :

2. Total production of the article(s) licensed for certification marking :

2.1 Total production of the article(s) conforming to Indian Standard :

3. Production covered with BIS Certification Mark and its approximate value

a) Quantity :

b) Value Rs. :

3.1 Brand Name used on production covered under BIS Certification Mark :

3.2 Calculation of marking fee on Unit-rate basis: Marking Fee per unit

a) Unit :

b) Quantity covered with BIS Certification Mark – :

*Information to be filled up by BO before forwarding to the licensee.

Note: In case a clause is not applicable, suitable remarks may be given against it.

c) Marking fee rounded off in whole rupees as obtained by applying unit rates given in (a) on quantity given in (b)

4. Quantity not covered with BIS Certification Mark. If any, and the reasons for such non-coverage

4.1 Brand Name under which non certified goods were sold

5. Quantity Exported with BIS Standard Mark and its value

5.1 Brand Name under which BIS Certified goods are exported

6. Authentication by Chartered Accountant