

## केन्द्रीय मुहर विभाग-2

हमारा संदर्भ : के.मु.वी.-2/16: 8481

09 02 2018

**विषय:** आई एस 8481:2005 खिजाब, तरल जैल और क्रीम - विशिष्टि के प्रारूप संशोधित एसटीआई

1. भारतीय मानक 8481:2005 पर संशोधन संख्या 2, नवम्बर 2017 को प्रकाशित किया गया है। संशोधन संख्या 2 के प्रकाशित किए जाने पर मौजूदा एसटीआई को पुनरीक्षित किया गया है
2. कृपया संलग्न प्रारूप एसटीआई/8481/2 XXXX 2018 की प्रति का अवलोकन करें।
3. सभी संबंधित से अनुरोध है कि प्रारूप दस्तावेज़ की जांच करें और 20 फरवरी 2018 तक या उससे पहले केन्द्रीय मुहर विभाग-2 को टिप्पणी भेजें।
4. सभी शाखा कार्यालयों से अनुरोध किया जाता है कि संबंधित प्रारूप दस्तावेजों को सभी आवेदकों/ लाईसेंसधारियों/ को जो उनके अधिकार क्षेत्र में हैं, टिप्पणियों के लिए उनकी जानकारी में लाएं और साथ ही टिप्पणियों को, यदि कोई हो, निर्धारित समय के भीतर मुहर विभाग-2 को भेजें।

(अदाने ख्रासी)  
वैज्ञानिक सी

**प्रमुख (सीएमडी-2)** (हस्ता/-)

सभी क्षेत्रीय/शाखा/पीसीडी/एमएसडी कार्यालयों को परिचालित

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

## CENTRAL MARKS DEPARTMENT-2

Our ref: CMD-2/16: 8481

09 02 2018

**Subject: Draft Revised STI for IS 8481:2005, Specification for Oxidation Hair Dyes, Liquid, Gel and Cream.**

1. Amendment No. 2 November 2017 to IS 8481:2005 has been published. Consequent upon issuance of Amendment No. 2 the existing STI has been revised.
2. Copy of draft STI /8481/2 XXXX 2018 for the above product is enclosed for kind perusal.
3. All concerned are requested to examine the draft document and provide comments to CMD-2 on or before 20 February 2018.
4. All BOs are also requested to bring the draft document to the notice of applicants/licensees under their jurisdiction for their comments as well and forward such comments, if any to CMD-2 within the stipulated time as above.

(Adane Khraasi)  
Scientist-C

**Head (CMD-2)(sd/-)**

All ROs/BOs/PCD/MSD

Copy to: ITS for hosting on BIS Intranet.

***DRAFT***  
**SCHEME OF TESTING AND INSPECTION  
FOR CERTIFICATION OF  
OXIDATION HAIR DYES, LIQUID, GEL AND CREAM  
ACCORDING TO IS 8481 : 2005  
(Incorporating Amendment No. 2)  
(Third Revision)**

**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 equipments 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, as given in Column (1), of the First Schedule of the licence shall be Marked on each container of Oxidation Hair Dyes, Liquid, Gel and Creams on the label applied to it, as the case may be provided always that the material in each container to which this mark is thus applied, conform 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’; ‘keep away from children’;
- d) Declaration ‘Maximum arylamine (PPD) after dilution as per manufacturer’s instructions 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), and
- h) Batch/No;
- i) Licence No.(CM/L.....)
- j) BIS website details: [www.bis.gov.in](http://www.bis.gov.in)
- k) Each container shall be labelled conspicuously with the following warnings

**“Warning – The material shall not be used for dyeing the eyelashes or eyebrows as its use may cause blindness; Keep away from children”**

- l) Each container shall be labelled conspicuously with the following caution:

**“Caution – para-phenylenediamine may cause skin irritation in certain cases, so a preliminary test according to the accompanying direction should first be made (see leaflet provided inside).”**

- m) For details of BIS certification scheme, visit website [www.bis.org.in](http://www.bis.org.in)
- n) Any other information required by statutory authorities.

5.2 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); Each package shall contain instructions in English and local language on the following lines for carrying out the test:

“Para-phenylenediamine containing preparations may cause serious inflammation of the skin in some cases and so a preliminary test should always be carried out to determine whether or not special sensitivity exists. For carrying out the test, cleanse a small area of skin behind the ear or upon the inner surface of the forearm, using either soap and water or alcohol. Apply a small quantity of the hair dye as prepared for use to the area and allow it to dry. After 24 hours, wash the area gently with soap and water. If no irritation or

inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should, however, be

carried out before each and every application. This preparation should on no account be used for dyeing eyebrows or eyelashes as severe inflammation of the eye or even blindness may result.”

- b) Instruction for use; and
- c) List of key ingredients.

## **6. PACKING**

6.1 The dye and the developer shall be filled separately in amber colored glass bottles and properly capped. Other suitable containers may also be used. The developer may also be filled in suitable plastic containers. The two are packed in the same carton. The bottles and the carton shall be suitably labelled.

## **7. LEVELS OF CONTROL**

7.1 The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

7.2 All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

## **8. CONTROL UNIT**

8.1 For the purpose of this scheme, Oxidation hair dyes, liquid, gel and creams of one type blended at a time shall constitute one Control Unit.

## **9. RAW MATERIALS**

9.1 Raw materials used in the manufacturing of Oxidation hair dyes, liquid, gel and creams shall conform to the requirements prescribed in the relevant Indian Standard where such standards exist.

9.2 The dyes used, if any, in the manufacturing of Oxidation hair dyes, liquid, gel and cream shall comply with the provision of IS 4707(Part 1 and IS 4707(Part 2) subject to provisions of the Drugs and *Cosmetics Act*, 1940 & rules frame thereunder.

**9.3 For safety evaluation of novel ingredients used in formulation of oxidation hair dyes, liquid, gel and cream; the oxidation 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 or samples required in accordance with the Bureau of Indian Standards (Certification) Regulations from his factory or godown. 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 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 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. The marking may be resumed as soon as the defects are removed under to intimation to BIS.

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.



**TABLE 1**  
**LEVELS OF CONTROL**  
**IS 8481 : 2005 OXIDATION HAIR DYES, LIQUID, GEL AND CREAM**  
 (Clause 7 of Scheme of Testing and Inspection)

(1)				(3)		
Testing details				Level of Control		
Clause	Requirements	Test Methods Clause Reference		No. of samples	Frequency	Remarks
4.1	Description	Visual	IS 8481	One	Each Control Unit	
4.2 & 4.3	Ingredients					Ingredients of dye 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.
4.4	Safety evaluation of novel ingredients used in formulation of oxidation hair dyes	4.3.1	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.
4.5 Table 1	pH of Dye	Annex A	-do-	One	Each Control Unit	
-do-	Active matter (as PPD Content) percentage by mass	Annex B or D	-do-	One	-do-	
-do-	Dye Ingredients	Annex D or E	-do-	One	-do-	
4.6 Table 2	pH of Developer	Annex A	-do-	One	-do-	
-do-	Assay (as H <sub>2</sub> O <sub>2</sub> ) percentage by mass	Annex C	-do-	One	-do-	
4.7	Additional requirements for ECO MARK					

4.7.1.1 to 4.7.1.9	General Requirements	-	-do-	One	-do-	Additional requirements to be tested for ECO Mark
4.7.2.1	Dermatological Requirement	-	IS 4011	One	Once in three months	As and When any novel ingredient is added in the formulation
4.7.2.2	Heavy Metals Lead (Pb)	Annex C	IS 10350	One	Once in six months	-do-
4.7.2.2	Heavy Metals Arsenic (as AS <sub>2</sub> O <sub>3</sub> )	Annex D	-do-	One	-do-	-do-



**ANNEX 1**  
**PROFORMA FOR OBTAINING PRODUCTION DETAILS**  
(Clause 14 of Scheme of Testing and Inspection)

Period covered	
Name of Licensee CM/L No.	
Name of Articles (s)	IS No.
Grade/Type/Size/Variety/Class/Rating	
Brand/Trade/Name(s) of Product covered under BIS Certification Mark	
Total production of the articles(s) licensed for certification marking	
Total production of the article(s) conforming to Indian Standard	
Production covered with BIS Certification Mark and its Value : a) Quantity b) Value (Rs.)	
Brand Name used on production covered under BIS Certification Mark	
Calculation of marking fee on unit-rate basis; Marking Fee per unit a) Unit b) Quantity covered with BIS Certification Mark  c) Marking fee rounded off in whole rupees as obtained by applying unit rates given in (a) on quantity given in (b) <b>NOTE:</b> In case a clause is not applicable, suitable remarks may be given against it	
Quantity not covered with BIS Certification Mark, if any.	
Reasons for such non-coverage	
Brand Name under which non-ISI goods were sold	
Quantity exported with BIS Standard Mark and its value	
Brand Name under which BIS Certified goods are exported	
Authentication by Chartered Accountant	