

केन्द्रीय मुहर विभाग-2

हमारा संदर्भ : के.मु.वि.-2/16: 7123

27 03 2018

विषय: आई एस 7123 के संशोधन संख्या 7 के अनुपालन के लिए दिशानिर्देश ।

इसे उपरोक्त विषय का संदर्भ प्राप्त है ।

सक्षम प्राधिकारी ने आई एस 7123:1993 के संशोधन संख्या 7 के अनुपालन हेतु दिशानिर्देश एवं पुनरीक्षित एसटीआई Doc: STI /7123/5 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: 7123

27 03 2018

Subject: Guidelines for implementation of Amendment No. 7 to IS 7123:1993 “Hair Oils”

This has reference to the subject mentioned above.

The Competent Authority has approved guidelines for implementation of Amendment No. 7 to IS 7123:1993 and revised STI Doc: STI /7123/5 March 2018.

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

(Adane Khrasi)
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: 7123

12 03 2018

Subject: Guidelines for implementation of Amendment No. 7 November 2017 to IS 7123 : 1993 ‘Hair Oils – Specification (Second Revision)’.

1. Amendment No.7 to IS 7123:1993 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. 7 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
4.2.4	New clause 4.2.4 has been added for safety evaluation of novel ingredients used in formulation of Hair Oils, the hair oil shall comply to IS 4011.

4. Consequent upon issuance of the amendment, existing STI has been revised as Doc: STI/7123/5 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 7123 : 1993 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 of dyes and colours and other additives used in hair oils 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. 7 to IS 7123 : 1993.

- (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 AND INSPECTION
FOR CERTIFICATION OF
HAIR OILS
ACCORDING TO IS 7123 : 1993
(SECOND REVISION)
(INCORPORATING AMENDMENT NO. 7)**

1. LABORATORY

1.1 A laboratory shall be maintained which shall be suitably equipped and staffed, where the different tests given in the specification shall be carried out in accordance with the methods given in the Indian Standards.

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, effort 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 (I), of the First Schedule of the licence shall be Marked on each container or on the label applied to the container as the case may be, provided that the material in each container to which this mark is thus applied, conforms to every requirement of the specification

5. MARKING

5.1 The containers shall be legibly marked with the following information:

- a. Manufacturer name and recognized trade-mark if any;
- b. Indication of the source of manufacture and type of the Material;
- c. Net quantity in ml or g;
- d. Best used before..... (month and year to be declared by the manufacturer)
- e. Control unit number in code or otherwise to enable the lot of material to be traced back from the records;
- f. List of all ingredients greater than 1percent, in descending order of mass followed by those in concentration less than or equal to 1 percent in any order. Colouring agents may be listed in any order after the other ingredients;
- g. STORE IN COOL PLACE PROTECTED FROM SUN-LIGHT;
- h. BIS Licence No. CM/L.....
- j. BIS website details : www.bis.gov.in

6. PACKING

6.1 The hair oil shall be packed in a suitably well closed container which do not have deleterious effect on the product.

7. LEVELS OF CONTROL

7.1 The tests as indicated in Table 1 of **Annex A** and at 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 shall be maintained in accordance with Clause 2 above.

7.2 All the production conforming to IS 7123 : 1993 shall be marked with the Standard Mark of Bureau of Indian Standards'

8. CONTROL UNIT

8.1 For the purpose of this scheme, the hair oils of one type produced in a day in a batch mixer with the same raw materials and mixed in the same ratio shall constitute a control unit.

8.2 A composite sample shall be drawn from all the mixtures which constitute the control unit.

8.3 On the basis of test results, the decision regarding conformity or otherwise of a control unit to a given requirement shall be made as follows:

8.3.1 A composite sample drawn from each control unit shall be tested for the requirements of description, acid value, peroxide value, lead (Pb) and Arsenic (as As₂O₃). If the sample fails to conform to any of these requirements, the entire quantity of the material in the control unit from which the sample is drawn shall be considered unfit for the purpose of marking.

8.3.2 For the requirement of microbiological examination one composite sample from every third control unit shall be tested. If it fails to conform to the requirement of the specification the material in the control unit shall be considered unfit for marking. Subsequently samples from each consecutive control units shall be tested till three consecutive control units are found conforming to the requirement, whereupon the original frequency of sampling and testing from every third control unit shall be restored.

9. REQUIREMENTS

9.1 Description:

The manufactured hair oil shall be as per Clause 4.1 of IS 7123:1993 and records shall be maintained as per Table 5 of **Annex B**.

9.2 Ingredients

9.2.1 Base oil The oil or oils used as the base shall be of the quality specified in the relevant specification of mineral oil and /or vegetable oil, given under clause 4.2.1 of IS 7123:1993 except for the requirement of colour when used in the formulation of coloured hair oil. Each consignment of the oil received in the factory shall be tested for conformity to the relevant Indian standard before use. In case the consignment is accompanied by a test certificate or if it is BIS certified material, further testing is not required. Licensee to ensure conformity through in-house or outside lab testing or combination thereof, for each type of base oil. Records shall be maintained as per Table 2 of **Annex B**.

9.2.2 Dyes and colours

Dyes and colours shall be those included in Schedule Q of Drugs and Cosmetics rules and shall be as per IS 4707(Part 1) and records maintained as per Table 3 of **Annex B**

9.2.3 Other additives

Other additives shall conform to the requirements **prescribed** in IS 4707 (Part 2) for which the licensees shall be required to give an undertaking that the **additives** (names to be given) used by them in the preparation of hair oil **conform to IS 4707 (Part 2)** and records maintained as per Table 4 of **Annex B**.

9.3 Microbiological examination:

Microbiological requirements shall be as per Clause 4.4 of IS 7123:1993 and records maintained as per table 6 of **Annex B**

9.4 Other requirements

In respect of all other clauses of the specification, the factory shall maintain appropriate controls and checks to ensure that their product conforms to the various requirements of the specification as per clauses 4.1, 4.2.4, 4.3, 4.5 and 4.6 of IS 7123:1993 and records maintained as per table 5 of **Annex B**.

9.5 For safety evaluation of novel ingredients used in formulation of Hair Oils, the hair oil shall comply to IS 4011.

10. REJECTIONS

10.1 A separate record shall be maintained giving information relating to the rejections of hair oil not conforming to the requirements of the specification and the method of their disposal. Such material shall in no circumstances be stored together with that conforming to the specification.

11. SAMPLES

11.1 The licensee shall supply, free of charge, the samples required in accordance with the Bureau of Indian Standards (Certification) Regulations from his factory or godown. The Bureau 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 consumers against BIS Standard Mark and not "conforming to" their 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 intimation to BIS.

The marking of the product shall be stopped immediately if directed to do so by BIS for any reason. The marking then may be resumed only after permission by BIS. The information regarding resumption of marking shall also be sent to the 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, at **Annex C** which has to be authenticated by a Chartered Accountant.

Annex-A
TABLE 1
LEVELS OF CONTROL (Clause 7 of STI)
IS 7123:1993 HAIR OILS

IS Clause no	Requirements	Test method Reference	No of samples to be tested	Frequency	Remarks	
4.1	Description	IS 7123	One	Each control unit		Records to be maintained as per table 5 of Annex B
4.2.1	Base Oil	As per Indian Standard referred in 4.2.1 of IS 7123	One	Each consignment	Testing need not be done if the consignment of oil is accompanied by a test certificate from the supplier or if it is BIS certified material. Licensee ensure conformity through in-house	Records to be maintained as per table 2 of Annex B
4.2.2	Dyes and colours	Schedule Q of Drugs and Cosmetic Rules and IS 4707 (Part 1)	One	Each consignment	or outside lab testing or combination thereof, for each type	Records to be maintained as per table 3 of Annex B
4.2.3	Other additives	IS 4707 (Pt 2)	One	Each consignment		Records to be maintained as per table 4 of Annex B
4.2.4	For safety evaluation of novel ingredients used in formulation of Hair Oils, the hair oil 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.

4.3	Acid value	IS 7123 A-2.1(for type 1 & 3) and or A2.2 (for type 2)	One	Each control unit		Records to be maintained as per table 5 of Annex B
4.4	Microbiological examination	IS 7123 A-3	One	Every this control unit	See 7.3 of STI	Records to be maintained as per table 6 of Annex B
4.5	Peroxide value	IS 7123 A-4	One	Each control unit		Records to be maintained as per table 5 of Annex B
4.6	Lead	IS 7123 A-5	One	Each control unit		Records to be maintained as per table 5 of Annex B
4.6	Arsenic	IS 7123 A-6	One	Each control unit		Records to be maintained as per table 5 of Annex B

Table 5 -Record of testing of Hair Oil as per Clause 4.1, 4.2.4, 4.3, 4.5, 4.6 of IS 7123:1993

(Clause 9.4 & 9.5 of STI)

Sl.No	Date of Manufacture	Batch no.	Test results						Remarks
			Description	Novel Ingredients	Acid value	Peroxide value	Heavy Metals		
							Lead	Arsenic	
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)

Table 6- Records of Microbial examination as per clause 4.4 of IS 7123:1993
(Clause 9.3 of STI)

SL.NO	Date of Manufacture	Batch no.	Microbial examination			Remarks
			Avg. Number of colonies per gm of sample on Nutrient agar	Avg. Number of colonies per gm of sample on Sabouraud Agar Medium	Mean of the two average numbers	
(1)	(2)	(3)	(4)	(5)	(6)	(7)

ANNEX C
PROFORMA FOR OBTAINING PRODUCTION DETAILS
(Clause 14 of STI)
(Period to be covered by the Report beingto.....)*

Name of Licensee:

CM/L No. :

Name of Articles(s) IS No. :

Grade/type/Size/Variety/Class/ Rating:

1. Brand/Trade/Name(s) of BIS Certification Marked Products
2. Total production of the article(s) licensed for certification marking
3. Total production of the article(s) conforming to Indian Standard
4. Production covered with BIS Certification Mark and its approximate value a.) Quantity
b.) Value Rs.
5. Brand Name used on production covered under BIS Certification Mark
6. 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)

7. Quantity not covered with BIS Certification Mark. If any, and the reasons for such noncoverage
8. Brand Name under which non certified goods were sold
9. Quantity Exported with BIS Standard Mark and its value
10. Brand Name under which BIS Certified goods are exported

11. Authentication by Chartered Accountant