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मानक

IS 9636 (1988): Depilatories, Chemical [PCD 19: Cosmetics]



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Indian Standard

SPECIFICATION FOR DEPILATORIES, CHEMICAL

(First Revision)

UDC 665.585.8

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BUREAU OF INDIAN STANDARDS MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG NEW DELHI 110002

February 1989

Indian Standard

SPECIFICATION FOR DEPILATORIES, CHEMICAL

(First Revision)

 $\mathbf{0}. \mathbf{FOREWORD}$

0.1 This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards on 30 June 1988, after the draft finalized by the Cosmetics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

0.2 This Indian Standard was first published in 1980. The Sectional Committee responsible for the formulation of this standard felt that the standard should be revised in order to update and align it with the other international standards. Accordingly in this revision, limits of pH requirement and calcium thioglycollate have been modified.

0.3 Depilatories arc preparations applied to the body to remove the unwanted hair. Such preparations may involve epilatoin or chemical depilation. Epilatories are waxy mixtures in which hair can be removed by wiping or rinsing. Chemical depilatories may have organo mercapto compounds (the most common being thioglycollic acid and its salts), metal sulphides or stannites based composition.

0.4 It is necessary that the raw materials used are such that in the concentrations in which

1. SCOPE

1.1 This standard prescribes the requirements and methods of sampling and test for chemicai depilatories having alkaline-thioglycollic acid composition.

1.1.1 This standard does not cover depilatories of epilatory type and those having metallic sulphides or stannite composition.

2. REQUIREMENTS

2.1 Description — The depilatory shall be in the form of cream or lotion. It shall be colourless or uniformly coloured and shall not emit foul smell.

2.2 An acceptable chemical depilatory formulation should possess the following attributes:

a) It should convert human hair completely

they would be present in the depilatory, after interaction with the other raw materials used in the formulation are free from any harmful effect. For determining the dermatological safety, methods prescribed in IS : 4011-1982* shall be followed. It shall be the responsibility of the manufacturer of the depilatories to satisfy himself of the dermatological safety of his formulation according to this standard before releasing the product for sale.

0.5 Since some individuals are allergic to chemical depilatories, the instructions regarding 'put on test' have been included in the standard as described in 3.3(b).

0.6 For the purpose of deciding whether a particular requirement of this standard is compiled with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960⁺. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

*Methods for dermatological tests for cosmetics (*first revision*).

†Rules for rounding off numerical values (revised).

in about 10 minutes to a soft plastic mass which may be easily removed from the skin by wiping or rinsing;

- b) It should be non-toxic systemically and non-irritant to skin even on long contact;
- c) It should be easily applied, cosmetically elegant, or pleasantly perfumed; and
- d) It should be stain-free to clothing.

2.3 Ingredients — All the raw materials used shall conform to the respective Indian Standard specifications wherever they exist.

2.3.1 The dyes used in the manufacture of depilatories shall comply with the provision of IS : 4707 (Part 1)-1968* subject to the

^{*}Classification of cosmetic raw materials and adjuncts, Part 1.

provisions of Schedule Q of the Drugs and Cosmetic Act as amended from time to time.

2.3.2 Ingredients other than dyes shall comply with the provisions of IS : 4707 (Part 2)-1973*.

2.4 The depilatories in the form of cream or lotion containing thioglycollic acid composition shall comply with the requirements given in Table I when tested by the method prescribed in Appendix A. Reference to the relevant clauses of Appendix A is given in col 4 of the table.

TABLE	1	REQUIREMENTS	FOR	CHEMICAL
		DEPILATORIES		

Sl No.	CHARACTERISTIC	REQUIREMENT	Method of Test
			(Ref to Cl No. in Appen- dix A)
(1)	(2)	(3)	(4)
i)	pН	11.0 to 12.7	A2
ii) Calcium thioglycol- late, calculated as thioglycollic acid, percent by mass		2 · 5 to 5 · 0	A3
iii)	Thermal stability	To pass the test	A4

3. PACKING AND MARKING

3.1 Packing — The material shall be packed in suitable well-closed containers or in lacquered aluminium collapsible tubes (see IS: 3101-1979⁺).

3.2 Marking — The containers shall be legibly marked with the following information:

- a) Name of the material;
- b) Manufacturer's name and recognized trademark, if any:
- c) Net mass of the material;
- d) Batch number, in code or otherwise, to

*Classification of cosmetic raw materials and adjcunts, Part 2.

†Specification for aluminium collapsible tubes (first revision).

enable the lot of manufacture to be traced back from the records;

- e) Instructions for use; and
- f) Any other requirement as required by the Statutory Authorities.

3.2.1 The containers may also be marked with the Standard Mark.

Note — The use of the Standard Mark is governed by the provisions of the Bureau of Indian Standards Act 1986 and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

3.3 Caution — The following instructions shall appear on the container or on the leaflet which shall be supplied with the pack:

- a) Never use the material on inflamed or broken skin or near cycs. Should this occur, wash with luke warm water and rinse with boric acid solution (approximately 3 percent)
- b) If used for the first time, carry out the following 'put-on' test:

Put-On Test — Use a little hair remover over 5 cm² of skin on inner elbow. If 24 hours later, the skin is normal, the material may be safely used.

4. SAMPLING

4.1 Representative samples of the material shall be drawn as prescribed in IS : 3958-1984*.

4.2 Test for all characteristics shall be carried out on composite sample.

4.3 The material shall be taken to have conformed to the specification if the composite sample passes all the tests.

^{*}Methods of sampling cosmetics.

APPENDIX A

(Clause 2.4 and Table 1)

METHODS OF TEST FOR DEPILATORIES

A-1. QUALITY OF REAGENTS

A-1.1 Unless otherwise specified, pure chemicals and distilled water (*see* IS : 1070-1977*), shall be employed in tests.

Note — 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

A-2. DETERMINATION OF *p*H

A-2.1 Apparatus

A-2.1.1 *p***H Meter** — equipped with a glass electrode.

A-2.2 Procedure—Determine the pH directly in case of lotion or cream using pH meter with glass electrodes.

A-3. DETERMINATION OF CALCIUM THIOGLYCOLLATE

A-3.1 Reagents

A-3.1.1 Concentrated Hydrochloric Acid

*Specification for water for general laboratory use (second revision).

A-3.1.2 Standard Iodine Solution - 0.1 N.

A-3.1.3 Starch Indicator Solution — 0.5 percent (m/v).

A-3.2 Procedure — Accurately weigh about 5 g of the sample in 250-ml conical flask. Add about 75 ml of water and 15 ml of concentrated hydrochloric acid and heat on water bath for 10 minutes. Cool and titrate with iodine solution using starch solution as the indicator.

A-3.3 Calculation — Calculate on the basis that each ml of 0.1 N iodine solution is equivalent to 0.009 21 g of thioglycollic acid.

A-4. THERMAL STABILITY

A-4.1 Procedure — Fill a clear glass round bottle of about 45-ml overflow capacity with the material and close tightly. Keep the bottle at $37\pm1^{\circ}$ C for 16 hours. The material shall be considered to have passed the test if no separation is observed.

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^{*}Sales Office in Calcutta is at 5 Chowringhee Approach, P.O. Princep Street, Calcutta 700072 †Sales Office in Bombay is at Novelty Chambers, Grant Road, Bombay 400097

AMENDMENT NO. 1 DECEMBER 1995 TO IS 9636 : 1988 SPECIFICATION FOR DEPILATORIES, CHEMICAL

(First Revision)

[Page 1, clause 2.2(b)] — Substitute the following for the existing:

'It should be non-toxic and non-irritant when tested in accordance with IS 4011 : 1982'.

[Page 2, clause 2.4, Table 1, Sl No.(ii), col 2] — Substitute the following for the existing:

'Thioglycolic acid salts calculated as thioglycolic acid, percent by mass'.

(PCD 19)

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Reprography Unit, BIS, New Delhi, India

AMENDMENT NO. 2 AUGUST 1998 TO IS 9636 : 1988 SPECIFICATION FOR DEPILATORIES, CHEMICAL

(First Revision)

(*Page* 2, *clause* 3.2) — Insert '(g)' after '(f)' :

'g) Best use before (Month and year to be declared by the manufacturer)'.

(PCD 19)

Reprography Unit, BIS, New Delhi, India

AMENDMENT NO. 3 DECEMBER 1998 TO IS 9636 : 1988 SPECIFICATION FOR DEPILATORIES, CHEMICAL

(First Revision)

(Page 1, Foreword, clause 0.3) - Insert the following para after 0.3:

'A scheme for labelling environment friendly products known as ECO Mark has been introduced at the instance of the Ministry of Environment and Forests (MEF), Government of India. The ECO Mark is being administered by the *Bureau of Indian Standards Act*, 1986 as per the Resolution No. 71 dated 21 February 1991 and No. 768 dated 24 August 1992 published in the Gazette of the Government of India. For a product to be eligible for marking with ECO logo, it shall also carry the Standard Mark of BIS besides meeting additional environment friendly requirements. For this purpose, the Standard Mark of BIS would be a single mark being a combination of the BIS monogram [S] and the ECO logo. Requirements for ECO friendliness will be additional, manufacturing units will be free to opt for Standard Mark alone also.

This amendment is based on the Gazette Notification No. 170 dated 18 May 1996 for depilatories, chemical as environment friendly products published in the Gazette of the Government of India. This amendment is, therefore, being issued to this standard to include environment friendly requirements for depilatories, chemical.'

(Page 2, clause 2.4) — Insert the following clauses after 2.4 and renumber the subsequent clauses:

2.5 Additional Requirement for ECO Mark

2.5.1 General Requirements

2.5.1.1 The product shall conform to the requirements for quality, safety and performance prescribed under clauses 2.1 to 2.4.

2.5.1.2 All the ingredients that go into formulation of cosmetics shall comply with the provisions of IS 4707 (Part 1) 'Classification for cosmetic raw materials and adjuncts : Part 1 Dyes, colours and pigments (*first revision*)' and IS 4707 (Part 2) 'Classification for cosmetic raw materials and adjuncts : Part 2 List of raw materials generally not recognized as safe for use in cosmetics (*first revision*)'.

Amend No. 1 to IS 9636 : 1988

The product shall also meet specific requirements as given in the standard.

2.5.1.3 The product package shall display a list of ingredients in descending order of quantity present.

2.5.1.4 The product shall not be manufactured from any carcinogenic ingredients.

2.5.1.5 The manufacturer shall produce to BIS the environmental consent clearance from the concerned State Pollution Control Board as per the provisions of the Water (Prevention and Control of Pollution) Cess Act, 1977 and the Air (Prevention and Control of Pollution) Act, 1981 along with the authorization, if required under the Environment (Protection) Act, 1986 and the Rules made thereunder, while applying for ECO Mark. Additionally, provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder shall also be complied with.

2.5.2 Specific Requirements

2.5.2.1 Product shall be dermatologically safe when tested as prescribed in IS 4011.

25.2.2 Heavy metals calculated as lead (Pb) and arsenic (As₂O₃) shall not exceed 20 and 2 ppm, respectively when tested by the respective method prescribed in Indian Standards.

(Page 2, clause 3.1) --- Insert the following clause after 3.1 and renumber the subsequent clauses:

'3.2 The material for product packaging shall meet the parameters envolved under the scheme of labelling environment friendly packaging/packaging materials.'

[Page 2, clause 3.3 (renumbered 3.4)] — Insert the following clause after 3.4 and renumber the subsequent clause:

'3.5 The product package shall be suitably marked that ECO Mark label is applicable only to the contents, if the product package is not separately covered under the ECO Mark scheme.'

AMENDMENT NO. 4 APRIL 2001 TO IS 9636 : 1988 SPECIFICATION FOR DEPILATORIES, CHEMICAL

(First Revision)

[Page 2, clause 3.2(g) and Amendment No. 2] — Substitute the following for the existing:

'g) Best use before......(Month & year to be declared by the manufacturer).

NOTE — This is exempted in case of pack sizes of 10 g/25 ml or less and if the shelf life of the product is more than 24 months.'

(*Page 2, clause 3.2*) — Insert (h) after (g):

h) List of key ingredients.

NOTE --- This is exempted in case of pack sizes of 30 g/60 ml or less.'

(PCD 19)