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IS 10284 (1982): Lipsalve [PCD 19: Cosmetics]

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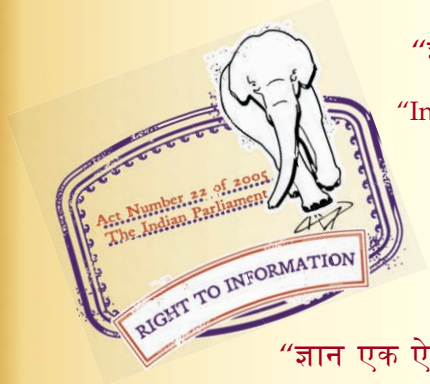

"ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है"
Bhartṛhari—Nītiśatakam
"Knowledge is such a treasure which cannot be stolen"

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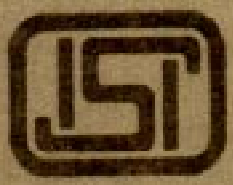
IS : 10284 - 1982
(Reaffirmed 2005)

Indian Standard

SPECIFICATION FOR LIPSALVE

UDC 665·584·264



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

Gr 3

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SPECIFICATION FOR LIPSALVE

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(*Continued on page* 2)

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Indian Standard

SPECIFICATION FOR LIPSALVE

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 24 September 1982, after the draft finalized by the Cosmetics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

0.2 Lipsalve consists of a homogeneous suspension of ingredients which are petroleum or vegetable oil based. It is useful in protecting the lips against chapping and cracking in extremes of temperature by forming a thin protective layer.

0.3 For the purpose of deciding whether a particular requirement of this standard is complied 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.

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1. SCOPE

1.1 This standard prescribes the requirements for lipsalves (lip balm) which are petroleum or vegetable oil based.

1.2 Emulsion types, either oil-in-water or water-in-oil are not included. This standard also does not cover, lipsalves which contain ingredients that have an effect on the physiological functions of the body or lips for which specific therapeutic claims are made and also lipsticks or lipgloss.

2. TYPES

2.1 The material shall be of the following three types in the stick or unctuous form:

Type 1 — The material shall be based on petrolem products, such as white petroleum jelly, microcrystalline wax, liquid paraffin, etc.

*Rules for rounding off numerical values (*revised*).

Type 2 — The material shall be based on vegetable oils and waxes such as castor oil, coconut oil, groundnut oil*, etc, and beeswax (*see* IS : 4028-1982†).

Type 3 — The material shall be based on a mixture of petroleum products, vegetable oils and waxes.

3. REQUIREMENTS

3.1 Description — The lipsalves shall be in the form of solid sticks or soft unctuous mass.

3.2 Ingredients — Unless specified otherwise, all the raw materials used in the manufacture of lipsalves shall conform to the requirements prescribed in the relevant Indian Standards, where such standards exist subject to the provisions of schedule Q of The Drugs and Cosmetics Act as amended from time to time.

3.2.1 Dyes used in the manufacture of lipsalves shall comply with the provisions of IS : 4707 (Part I)-1968‡.

3.2.2 Ingredients other than dyes shall comply with the provisions of IS : 4707 (Part II)-1973§.

3.2.2.1 *For type 1* — Petroleum products used shall be of the quality specified below:

a) *Mineral oil — see* IS : 7229-1974‖.
b) *Paraffin wax-type 1 — see* IS : 4654-1974¶.
c) *Soft petroleum jelly — see* IS : 4887-1980**.
d) *Microcrystalline wax*

3.2.2.2 *For type 2* — Vegetable oils and waxes used shall be of quality specified below :

a) *Coconut oil for cosmetic industry*
b) *Sesame oil for cosmetic industry*
c) *Castor oil for cosmetic industry*
d) *Groundnut oil for cosmetic industry*

} (*see* IS*)

*Specifications of these materials for cosmetic grade are under preparation.
†Specification for beeswax, bleached for cosmetic industry (*first revision*).
‡Classification of cosmetic raw materials and adjuncts, Part I.
§Classification of cosmetic raw materials and adjuncts, Part II.
‖Specification for mineral oil for cosmetic industry.
¶Specification for paraffin wax (*first revision*).
**Specification for petroleum jelly for cosmetic industry.

e) *Olive oil*

f) *Hydrogenated vegetable oils*

g) *Beeswax* — IS : 4028-1982*.

3.2.2.3 *For type 3* — The petroleum products, vegetable oils and waxes used shall be of quality specified in **3.2.2.1** and **3.2.2.2.**

3.3 The raw materials used should not have any harmful effect on the mucous membrance of the skin around lips, and also the interaction of such raw materials in the finished products shall not have any toxic or sensitizing effect (*see* IS : 4011-1982†).

3.4 The lipsalve shall also comply with the requirements given in Table 1, when tested as given in col 5 of the table.

TABLE 1 REQUIREMENTS FOR LIPSALVE

Sl No.	Characteristic	Requirement		Method of Test (Ref to Cl No. in Appendix A)
		Stick Form	Unctuous Form	
(1)	(2)	(3)	(4)	(5)
i)	Melting range, °C	48 to 64	35 to 53	A-1
ii)	Consistency, millimetre per 10	50 to 100	100 to 275	A-2
iii)	Rancidity	To pass the test	To pass the test	A-3
iv)	Stability	To pass the test	To pass the test	A-4
v)	Arsenic (as As_2O_3), parts per million, *Max*	2	2	A-5
vi)	Heavy metals (as Pb), parts per million, *Max*	20	20	A-6

4. PACKING AND MARKING

4.1 Packing — The lipsalve shall be packed in metallic, plastic or any other container.

*Specification for beeswax, bleached for cosmetic industry (*first revision*).

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

4.2 Each container shall be legibly marked with the following information:

a) Name and type of the material;

b) Manufacturer's name and recognised trade-mark, if any;

c) Net mass of material;

d) ' For external use only ' and batch number in code or otherwise to enable the lot of the manufacture to be traced back from records; and

e) Any other information as required by the statutory authorities.

4.2.1 The containers may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI 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 ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

5. SAMPLING

5.1 Representative samples of the material shall be drawn as prescribed in IS : 3958-1966*.

5.2 Tests for all characteristics shall be carried out on the composite sample.

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

6. TEST METHODS

6.1 Tests shall be carried out according to the methods prescribed in Appendix A. Reference to relevant clauses of Appendix A is given in col 5 of Table 1.

6.2 Quality of Reagents — Unless specified otherwise, pure chemicals and distilled water (*see* IS : 1070-1977†) shall be used in tests.

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

*Methods of sampling cosmetics and toilet goods.

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

APPENDIX A

(*Clause* 3.4)

METHODS OF TEST FOR LIPSALVE

A-1. DETERMINATION OF MELTING RANGE (POINT)

A-1.1 Procedure

A-1.1.1 Melt a quantity of the sample slowly while stirring until it reaches a temperature of 90 to 92°C. Remove the source of heat and allow the molten sample to cool to a temperature of 8 to 10°C above the expected melting point. Chill the bulb of a thermometer (range 1 to 100°C) to 5°C, wipe it dry and while it is still cold, dip it into the molten sample so that approximately half of the bulb is submerged. Withdraw it immediately and hold it vertically away from heat until the wax surface dulls, then dip it for five minutes into a water-bath having a temperature not higher than 16°C.

A-1.1.2 Fix the thermometer prepared in **A-1.1.1** securely in a test-tube so that its lowest tip is about 15 mm above the bottom of the test-tube. Suspend the test-tube in a water-bath adjusted to 16°C and raise the temperature of the bath at a rate of 2°C per minute; up to 30°C. After the temperature of the bath has reached 30°C adjust the rate of rise to 1°C per minute and note the temperature at which the first drop of the melted sample leaves the thermometer. Repeat the determination twice on a freshly melted portion of the sample. If the variation in three determinations is less than 1°C take the average of the three as the melting point. If the variation in the three determinations is more than 1°C make two additional determinations and take the average of the five. Report whether the average of the five determinations is within the range specified or not.

A-2. DETERMINATION OF CONSISTENCY

A-2.0 Outline of the Method — Determination of consistency of the material is made by measuring the penetration of a standard cone at $25{\cdot}0 \pm 0{\cdot}5$°C.

A-2.1 Apparatus

A-2.1.1 *Penetrometer* — Any suitable penetrometer which permits the specified cone to drop vertically without appreciable friction for at least 40 mm and which indicates accurately the depth of penetration to the nearest 0·1 mm. The instrument shall have a table to carry the test

sample, which may be adjusted to the horizontal before making the test. A mechanism for releasing and clamping the loaded cone shall be provided.

A-2.1.2 *Cone* — Consisting of a conical body of brass or corrosion resistant steel with detachable hardened steel tip, constructed to conform to the dimensions and tolerances shown in Fig. 1. The total moving mass, namely, that of the cone and its movable attachments, shall be 150·0 ± 0·1 g. The attachments consist of a rigid shaft having a suitable device at its lower end for engaging the cone. The outer surface should be polished to a very smooth finish.

A-2.1.3 *Constant Temperature Bath* — A water-bath capable of regulation at 25°C ± 0·5°C and of suitable design for conveniently bringing the sample container to the test temperature. The bath should be provided with a cover to maintain the temperature of the air above the sample at 25°C.

A-2.1.4 *Timing Device* — A stop-watch or other suitable instrument capable of measuring an interval of 5 seconds to within 0·2 second.

A-2.1.5 *Sample Container* — Flat-bottomed, metal or glass cylinders that are 100 ± 6 mm in diameter and not less than 60 mm in height.

A-2.2 Procedure — Melt a quantity of the sample at 82·0 ± 2·5°C, pour into one or more of the sample containers, filling to within 6 mm of the brim. Cool at 25·0 ± 2·5°C over a period of not less than 16 hours protecting from draughts. Two hours before the test, place the containers in a water-bath at 25·0 ± 0·5°C. If the room temperature is below 23·5°C or above 26·5°C, adjust the temperature of the cone to 25·0 ± 0 5°C by placing it in the water-bath.

A-2.2.1 Without disturbing the surface of the sample, place the container on the penetrometer table, and lower the cone until the tip just touches the top surface of the sample at a spot 25 to 38 mm from the edge of the container. Adjust the zero setting and quickly release the plunger, then hold it free for 5 seconds. Secure the plunger, and read the total penetration from the scale. Make 3 or more trials each so spaced that there is no overlapping of the areas of penetration. Where the penetration exceeds 20 mm use a separate container of the sample for each trial. Read the penetration to the nearest 0·1 mm. Calculate the average of the three or more readings, and conduct further trials to a total of 10 if the individual results differ from the average by more than ± 3 percent.

A-2.3 Calculation

$$\text{Consistency} = \frac{A}{10}$$

where

A = mean of all the values of penetration in mm.

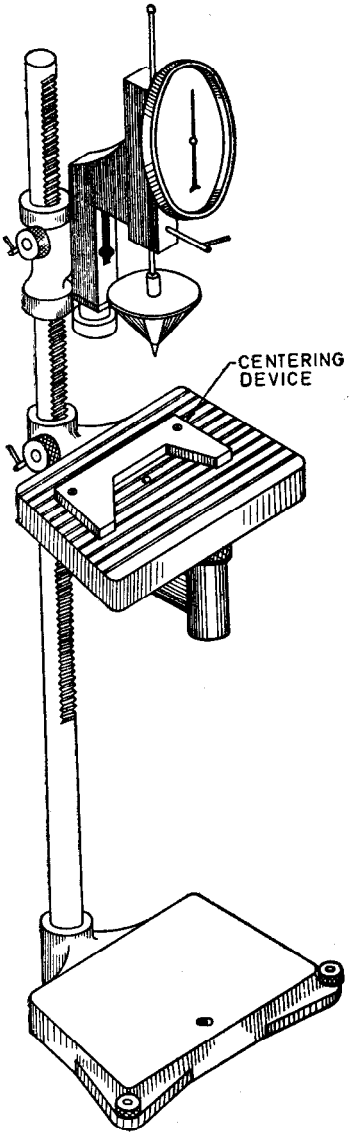

FIG. 1 PENETROMETER

A-3. TEST FOR RANCIDITY

A-3.1 Reagents

A-3.1.1 *Concentrated Hydrochloric Acid — See* IS : 265-1976*.

A-3.1.2 *Phloroglucinol Solution* — Dissolve 0·1 g of phloroglucinol in 100 ml of diethyl ether.

A-3.2 Procedure — Shake 10 g of the material, melted if necessary, with 10 ml of concentrated hydrochloric acid and 10 ml of phloroglucinol solution. Shake for 1 minute.

A-3.2.1 The material shall be taken to have passed the test if no pink colour develops.

A-4. TEST FOR STABILITY

A-4.1 Procedure — Place 50 g of the material in the beaker under the ultra violet lamp and expose it for 6 hours. If the product does not deteriorate after the exposure period, the product shall be taken to have passed the test.

A-5. TEST FOR ARSENIC

A-5.1 Reagents

A-5.1.1 *Concentrated Sulphuric Acid — See* IS : 266-1977†.

A-5.1.2 *Concentrated Nitric Acid — See* IS : 264-1976‡.

A-5.2 Procedure

A-5.2.1 *Preparation of Sample* — Weigh 2·000 g of the sample in a Kjeldahl flask of 500-ml capacity. Add 15 ml of concentrated sulphuric acid followed by 4 ml of concentrated nitric acid. Heat cautiously. Add drop by drop more nitric acid, if required, from a pipette to speed up the oxidation of the sample. The total amount of nitric acid shall be noted for use in the control test. When oxidation is complete, the solution is clear and faint yellow; at that stage, add 20 ml of water and again boil to fuming. Ensure removal of all nitric acid.

A-5.2.2 Carry out the test for arsenic with the solution prepared in **A-5.2.1** as given in IS : 2088-1971§. Compare the stain obtained with that produced with 0·004 mg of arsenic trioxide.

*Specification for hydrochloric acid (*second revision*).

†Specification for sulphuric acid (*second revision*).

‡Specification for nitric acid (*second revision*).

§Methods for determination of arsenic (*first revision*).

A-6. TEST FOR HEAVY METALS

A-6.1 Apparatus

A-6.1.1 *Nessler Tubes* — 50-ml capacity, matched.

A-6.2 Reagents

A-6.2.1 *Ammonium Acetate Solution* — 10 percent.

A-6.2.2 *Ammonium Citrate Solution* — Dissolve 8·75 g of citric acid in water, neutralise with ammonia and dilute with water to 100 ml.

A-6.2.3 *Ammonium Hydroxide* — 10 percent (*m/m*).

A-6.2.4 *Potassium Cyanide Solution* — 10 percent (*m/m*).

A-6.2.5 *Sodium Sulphide Solution* — 10 percent (*m/m*).

A-6.2.6 *Standard Lead Solution* — Dissolve 1·600 g of lead nitrate in water and 10 ml of concentrated nitric acid and dilute to 1 000 ml. Pipette out 10 ml of the solution and dilute it again to 1 000 ml with water. One millilitre of the final solution contains 0·01 mg of lead (as Pb). The solution shall be freshly prepared before use.

A-6.3 Procedure

A-6.3.1 *Preparation of Sample* — Treat 2·000 g of the sample as prescribed in **A-5.2.1**.

A-6.3.2 Take the solution prepared in **A-6.3.1** in a Nessler tube, add 10 ml of ammonium acetate solution, 5 ml of ammonium citrate solution, 5 ml of ammonium hydroxide and 1 ml of potassium cyanide solution and dilute to 50 ml with water; then add two drops of sodium sulphide solution and mix well. In another Nessler tube, carry out a control test using 4 ml of standard lead solution and the same quantities of other reagents as used in the test with the material.

A-6.3.3 The material shall be taken as not having exceeded the limit prescribed in Table 1, if intensity of colour produced with the material not greater than that produced in the control test.

AMENDMENT NO. 1 AUGUST 1998
TO
IS 10284 : 1982 SPECIFICATION FOR LIPSALVE

(*Page* 3, *clause* **0.2**) — Insert the following new clause after **0.2** and renumber the subsequent clause:

'**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 ISI 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 lipsalve 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 lipsalve.'

(*Page* 5, *clause* **3.4**) — Insert the following clauses after **3.4**:

3.5 Additional Requirements for ECO Mark

3.5.1 *General Requirements*

3.5.1.1 The product shall conform to the requirements for quality, safety and performance prescribed under clauses **3.1** to **3.4**.

3.5.1.2 All the ingredients that go into formulation of cosmetics shall comply with the provisions of IS 4707 (Part 1) : 1988 'Classification of cosmetic raw materials and adjuncts: Part 1 Dyes, colours and pigments (*first revision*)' and IS 4707 (Part 2) : 1993 'Classification for cosmetic raw materials and adjuncts: Part 2 List of raw materials generally not recognized as safe (*first revision*)'.

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

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

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

3.5.1.5 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.

3.5.2 *Specific Requirements*

3.5.2.1 Product shall be dermatologically safe when tested as prescribed in IS 4011 : 1997 'Methods of test for safety evaluations of cosmetics (*second revision*)'.

3.5.2.2 Heavy metals calculated as lead (Pb) and arsenic (As_2O_3) shall not exceed 20 and 2 ppm, respectively when tested by the respective method prescribed in Indian Standards.

(*Page* 5, *clause* **4.1**) — Insert the following clause after **4.1** and renumber the subsequent clauses:

'**4.2** For ECO Mark, the product shall be packed in such packages which shall be recyclable/reusable or biodegradable.'

[*Page* 6, *clause* **4.2.1** (*renumbered* **4.3.1**)] — Insert the following clause after **4.2.1**:

'**4.3.2** 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.'

(PCD 19)

Reprography Unit, BIS, New Delhi, India

AMENDMENT NO. 2 AUGUST 1998
TO
IS 10284 : 1982 SPECIFICATION FOR LIPSALVE

[*Page* 6, *clause* 4.2(d)]— Insert '(e)' after '(d)' and renumber the subsequent item:

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

(PCD 19)

Reprography Unit, BIS, New Delhi, India

AMENDMENT NO. 3 MAY 2002
TO
IS 10284 : 1982 SPECIFICATION FOR LIPSALVE

[*Page* 5, *Table* 1, *Sl No.* (iii)] — Substitute the following for the existing:

'iii) Peroxide value meq/1 000 g 10 10 A-3'

[*Page* 6, *clause* 4.2(e) (*see also Amendment No.* 2)] — Substitute the following for the existing:

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

NOTE — This is exempted 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.'

[*Page* 6, *clause* 4.2(e) (*see also Amendment No.* 2)] — Insert (f) after (e) and renumber the subsequent item:

f) List of key ingredients.

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

(*Page* 10, *clause* A-3) — Substitute the following for the existing:

'A-3 TEST FOR PEROXIDE VALUE

A-3.1 Reagents

A-3.1.1 *Glacial Acetic Acid*

A-3.1.2 *Chloroform*

A-3.1.3 *Potassium Iodide Solution* — saturated, freshly prepared.

A-3.1.4 *Standard Sodium Thiosulphate Solution* — 0.01 N, freshly standardized.

A-3.1.5 *Starch Indication Solution*

Triturate 5 g of starch and 0.01 g of mercuric iodide with 30 ml of cold water and slowly pour it with stirring into one litre of boiling water. Boil for 3 minutes. Allow to cool and decant off the supernatant clear liquid.

A-3.2 Procedure

Weigh accurately about 5 g of the material in a 250-ml glass stoppered conical flask and dissolve by shaking in 30 ml of a mixed solvent containing 3 parts by volume of glacial acetic acid and 2 parts by volume of chloroform. Add 0.5 ml of freshly prepared saturated potassium iodide solution. Shake and after 2 minutes with occasional shaking, add 30 ml of water and titrate with standard sodium thiosulphate solution. Add the thiosulphate solution until the colour of the titrated solution becomes light yellow. Then add 1 ml of starch indicator solution and continue the titration till the disappearance of the blue colour. Carry out a blank determination without using the sample.

A-3.3 Calculation

$$\text{Peroxide value milli - equivalents/1 000 g} = \frac{1\,000\,(V_1 - V_2)\,N}{M}$$

where

V_1 = volume of ml of standard sodium thiosulphate solution required with the sample;

V_2 = volume in ml of standard sodium thiosulphate solution required with the blank;

N = normality of standard sodium thiosulphate solution; and

M = mass in g of the sample taken for the test.

(PCD 19)

Reprography Unit, BIS, New Delhi, India