भारतीय मानक
Indian Standard

IS 15608 : 2018

क्रीम ब्लीच — विशिष्टि

(पहला पुनरीक्षण)

Cream Bleach — Specification

(First Revision)

ICS 71.100.70

भारतीय मानक ब्यूरो
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Cosmetics Sectional Committee, PCD 19

FOREWORD

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

Cream bleach is a two component product one containing hydrogen peroxide in a cosmetically acceptable from such as cream, lotion etc. The second component contains activator essentially in a powder or cream from which when mixed with a cream reacts and liberates the necessary quantity of nascent oxygen for action. Additionally, it may contain soothing anti-inflammatory, cooling applications and optionally it may contain spatula, tray etc. to facilitate application of product.

Cream bleach and activator are extemporaneously mixed in the proportion advised by the manufacturer and applied. Such application is held on the skin/hair for a period as specified and rinsed off, adequate precautions in respect of product suitability on customer is to be taken.

This standard was first published in 2005. The first revision was taken up to keep pace with the latest technological developments and international practices. In this revision following major changes have been made:

a) The words '*for skin*' included at the end of **1.1**,
b) Compliance with IS 4011, for safety evaluation of novel ingredients,
c) 'Non-ammonia based activator cream', its requirements and corresponding test methods incorporated in Table 2,
d) The marking clause has been harmonized with Rule 148 of *the Drugs and Cosmetics Rules*, 1945, and
e) Amendments 1 and 2 issued to its previous version (2005) have been incorporated.

No stipulation has been made in this standard regarding composition of cream bleaches. The manufacturer has a choice of using variety of raw materials and combination thereof. However, it is necessary that the raw materials used are such that in the concentration in which they would be present in the finished cosmetic formulation after interaction with other raw materials, are free from any harmful effects.

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 'Rules for rounding off numerical values (*revised*).' The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

CREAM BLEACH — SPECIFICATION

(First Revision)

1 SCOPE

1.1 This standard prescribes the requirement and the methods of sampling and tests for cream bleach for skin.

1.2 Cosmetic preparations which are fluid at ambient temperature, classified generally as lotions, milks, etc., and skin creams generally vanishing cream, cold cream, cleansing cream, moisturizing cream, sports cream, foundation cream, hand cream, emollient cream and general purpose cream are excluded from the scope of this standard.

2 REFERENCES

The standards given below contain provisions which, through reference, in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS No.	*Title*
2088 : 1983	Methods for determination of arsenic (*second revision*)
3958 : 1984	Methods of sampling cosmetics (*first revision*)
4011 : 2018	Methods of test for safety evaluation of cosmetics (*third revision*)
4707	Classification of cosmetics raw materials and adjuncts:
(Part 1) : 2017	Colourants (*third revision*)
(Part 2) : 2017	List of raw materials generally not recognized as safe for use in cosmetics (*fourth revision*)
14648 : 2011	Microbiological examination of cosmetics and cosmetic raw materials — Methods of test (*second revision*)

3 REQUIREMENTS

3.1 Description

Cream bleach is normally supplied in two packs, one containing cream and the other containing cream or powder activator in duo pack form. Cream bleach shall be white or coloured, smooth, having uniform consistency and may be perfumed.

3.2 Ingredients

3.2.1 If dyes, colours (pigments, lakes etc.) are to be added, these shall be as specified in IS 4707 (Part 1), or *Schedule 'Q' of the Drugs and Cosmetics Rules*.

3.2.2 Ingredients other than colourants used in formulation of cream bleach shall comply with the provisions of IS 4707 (Part 2).

3.2.3 Unless specified otherwise, all the raw materials used in the manufacture of cream bleach shall conform to the requirements prescribed in the relevant Indian Standards, where such standards exist.

3.2.4 For safety evaluation of novel ingredients used in formulation of cream bleach, the hair shampoo shall comply to IS 4011.

3.3 The cream shall comply with the requirements given in Table 1, when tested as prescribed in col 4 of Table 1 and activator (powder/cream) shall comply with the requirements given in Table 2.

Table 1 Requirements for Cream

(*Clause* 3.3 *and* 5.3)

Sl No.	Characteristics	Requirements	Method of Test, Ref to Annex
(1)	(2)	(3)	(4)
i)	*p*H	2.5 to 4.5	A
ii)	Assay (as hydrogen peroxide), percent by mass	3.5 to 5.5	B

Table 2 Requirements for Activator Powder/ Cream

(*Clause* 3.3 *and* 5.3)

Sl No.	Characteristics	Requirements				Method of Test, Ref to Annex	
		Powder		Cream		Annex	IS
		Ammonia Based	Oxygen Generating	Ammonia Based	Non-Ammonia Based		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
i)	*p*H of 10 percent aqueous solution	7-11	10-13	8-11	8-13	A	—
ii)	Assay						
	a) As ammonium bicarbonate, percent by mass, *Min*	15	—	4	—	C	—
	b) As oxygen content, percent by mass, *Max*	—	3.5	—	—	D	—
	c) Total alkalinity (as NaOH), percent by mass, *Min*	—	—	—	4	E	—
iii)	Total fatty substances, percent by mass, *Min*	—	—	5	5	F	—
iv)	Heavy metals (as Pb), parts per million, *Max*	20	20	20	20	G	—
v)	Arsenic (As As_2O_3), parts per million, *Max*	2	2	2	2	H	—
vi)	Total plate count, cfu/g, *Max*	1 000	1 000	1 000	1 000	—	14 648

NOTES

1 When the cream bleach and activator are mixed, total hydrogen peroxide percent by mass in the mixture shall not be more than 4.

2 *p*H of the mixed product shall be in the range 6.0 to 9.5.

3 When both the bleach and activator are in cream form, proper labelling of bleach cream and activator cream shall be ensured by the manufacturer.

4 PACKING AND MARKING

4.1 Packing

The cream bleach (cream and activator) shall be packed in suitable well closed, air-tight containers and both shall be given with instruction sheet, spatula in suitable cartons.

4.2 Marking

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

a) Name of the product;

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

c) Net content of the material;

d) Active content of the product (percent content of hydrogen peroxide);

e) Month and year of manufacture;

f) Batch or lot number, in code or otherwise;

g) List the ingredients (at the time of manufacture) under the title 'Ingredients' as follows:

1) For ingredients more than 1 percent (by mass or volume) — List the ingredients in decreasing order of percentage.

2) For ingredients less than 1 percent (by mass or volume) — List the ingredients in any order.

NOTE — This is exempted in case of pack sizes less than 30 g of solid/semi-solid and 60 ml of liquid.

h) 'Use before ……' (Month and year to be declared by the manufacturer);

j) Warning 'FOR EXTERNAL USE ONLY';

k) Cautions:

1) The product should not be used for bleaching around the eyes.

2) Hydrogen peroxide may cause skin irritation in certain cases, so a preliminary test according to the accompanying direction should first be made.

m) Instructions for use; and

n) Any other information required by statutory authorities.

4.2.2 In addition to the above, each package shall contain instructions in English and local language on the following lines for carrying out the test:

'Hydrogen peroxide 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 cream bleach as prepared for use to the area and allow it to dry. After 10 to 15 min or as directed by the manufacturer, wash the area gently with soap and water. If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the cream bleach exists. The test should, however, be carried out before each and every application.'

4.3 BIS Certification Marking

The cream bleach may also be marked with the Standard Mark.

4.3.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations made thereunder. The details of the conditions under which the licence for use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

5 SAMPLING

5.1 Representative samples of the material shall be drawn as prescribed in IS 3958.

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

5.3 The material shall be taken to have conformed to the specifications if the composite sample passes all the tests, as per Table 1 and Table 2.

6 QUALITY OF REAGENTS

Unless specified otherwise, pure chemicals and distilled water (*see* IS 1070) shall be employed in the tests.

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

ANNEX A

[*Table* 1, *S1 No.* (i) and *Table* 2, *Sl No.* (i)]

DETERMINATION OF *p*H

A-1 APPARATUS

A calibrated *p*H meter, equipped with a combined glass electrode.

A-2 PROCEDURE

Weigh accurately about 40 ± 1.0 g of the cream in 50 ml beaker. Determine the *p*H of cream bleach at 27 ± 2°C using the *p*H meter. Weigh accurately about 10 ± 1.0 g of activator powder in 250 ml beaker. Add 100 ml water, stir for 5 min. Determine the *p*H of suspension at 27 ± 2°C using the *p*H meter.

ANNEX B

[*Table* 1, *Sl No.* (ii)]

DETERMINATION OF HYDROGEN PEROXIDE (ASSAY)

B-1 REAGENTS

B-1.1 Potassium Permanganate (0. 1 N)

Dissolve 3.3 g of potassium permanganate in 1 000 ml distilled water, heat it on water bath for 1 h, allow to stand for 2 days, filter through glass wool or filter paper No. 1 and standardize the solution.

B-1.1.1 *Procedure for Standardization*

Weigh accurately about 200 mg of sodium oxalate, previously dried at 110°C to constant weight and dissolve it in 250 ml of water. Add 7 ml of concentrated sulphuric acid, heat to about 70°C and titrate with 0.1 N potassium permanganate solution, with constant stirring until a pale pink colour, which persist for 15 s is produced. The temperature at any stage of the titration should not be less than 60°C. Calculate the normality.

NOTE — Each 6.7 mg of sodium oxalate is equivalent to 1 ml of 0.1 N potassium permanganate.

B-1.2 Sulphuric Acid (20 Percent)

Take 700 ml of ice cold distilled water in 1 000 ml volumetric flask, add slowly along walls 200 ml of concentrated sulphuric acid, cool and make the volume up to 1 000 ml mark with distilled water.

B-1.3 Concentrated Sulphuric Acid

B-1.4 Sodium Oxalate

Analytical reagent grade.

B-2 PROCEDURE (ASSAY)

Weigh accurately about 1.0 g cream in 100 ml beaker. Add distilled water slowly and disperse the cream. Transfer the contents of the beaker quantitatively to a 250 ml conical flask with the aid of water. Add 20 ml of 20 percent sulphuric acid solution and shake vigorously. Titrate the contents of the flask with 0.1 N potassium permanganate solution. The end point is reached when faint pink colour persists for 15 s.

B-3 CALCULATION

Hydrogen peroxide content, percent by mass

$$= \frac{V \times N \times 1.701}{W}$$

where,

V = volume, in ml, of $KMnO_4$ required for titration;

N = normality of potassium permanganate ($KMnO_4$); and

W = mass in g, of the cream taken for titration.

ANNEX C

[*Table 2, Sl No.* (ii) (a)]

DETERMINATION OF AMMONIUM BICARBONATE

C-1 REAGENTS

C-1.1 Sodium Hydroxide (1 N)

Dissolve 42 g of sodium hydroxide in 1 000 ml volumetric flask using 500 ml distilled water, cool to room temperature and make the volume with distilled water to 1 000 ml.

C-1.2 Sulphuric Acid (1 N)

Take ice cold 700 ml distilled water in 1 000 ml volumetric flask, add slowly along walls 26.7 ml of concentrated sulphuric acid, cool and make up volume up to 1 000 ml mark with distilled water.

C-1.3 Methyl Red Solution

Dissolve 0.1 g of methyl red in 100 ml of 60 percent rectified spirit.

C-2 STANDARDIZATION

Weigh accurately about 5.0 g of potassium hydrogen phthalate, previously powdered and dried at 120°C for 2 h and dissolve in 75 ml of water. Add 0.1 ml of phenolphthalein solution and titrate with the 1 N sodium hydroxide solution until pink colour is produced.

NOTE — Each ml of 1 N sodium hydroxide is equivalent to 0.2042 g of potassium hydrogen phthalate.

C-3 PROCEDURE

Weigh accurately about 1.0 g activator (previously dried at 60°C for 15 min) in 250 ml conical flask and dissolve in 23 ml distilled water, add 25 ml of 1 N sulphuric acid and boil for 10 min replacing any loss of volume with distilled water. Cool the solution. Titrate the contents of the flask with 1 N sodium hydroxide by using methyl red as indicator. End point reaches when colour changes from red to yellow. Carry out blank in similar manner with 25 ml of 1 N sulphuric acid without substance.

C-4 CALCULATION

Calculate ammonium bicarbonate content percent by mass by following formula. Each ml of 1 N sodium hydroxide is equivalent to 0.07906 g of ammonium bicarbonate.

Consumed reading = (Blank reading – Sample reading)

Volume of 1 N sodium hydroxide = (1 N Sodium hydroxide consumed in blank – 1N Sodium hydroxide consumed in test)

Content of ammonium bicarbonate by mass

$$= \frac{V \times N \times 7.906}{M}$$

where,

V = volume in ml, of 1N sodium hydroxide consumed;

N = normality of 1N sodium hydroxide; and

M = mass in g, of activator.

ANNEX D

[*Table 2, Sl No.* (ii) (b)]

DETERMINATION OF OXYGEN CONTENT

D-1 REAGENTS

D-1.1 Sodium Thiosulphate (0.1 N)

Dissolve 25 g of sodium thiosulphate and 200 mg of sodium carbonate in 1 000 ml volumetric flask and make the volume with distilled water.

D-1.2 Hydrochloric Acid (2 N)

Take 700 ml of ice Cold distilled water in 1 000 ml volumetric flask, add slowly along walls 170 ml of concentrated hydrochloric acid, cool and volume up to 1 000 ml mark with distilled water.

D-1.3 Buffer (*p*H 6.85)

Dissolve 14.4 g disodium hydrogen orthophosphate and 5.726 g potassium dihydrogen orthophosphate in 500 ml distilled water.

D-2 PROCEDURE

Weigh accurately about 0.25 g powder and transfer it into an iodine flask containing 20 ml buffer *p*H 6.85 and 5 ml of 2 N hydrochloric acid. Then add 5 g of potassium iodide into it. Shake the solution well and keep it in dark place for 20 min. Add 20 ml

of distilled water in it and titrate it with 0.1 N sodium thiosulphate.

NOTE — End point reaches when yellowish brown colour disappears.

D-3 CALCULATION

$$\text{Oxygen content, percent by mass} = \frac{(\text{Burette Reading} \times 0.0008 \times \text{Exact normality of 0.1 N } Na_2S_2O_3 \times 100)}{(\text{Weight of powder taken, in g} \times 0.1)}$$

NOTE — Each ml of 0.1 N sodium thiosulphate is equivalent to 0.0008 g of oxygen.

ANNEX E

[*Table* 2, *Sl No*. (ii) (c)]

DETERMINATION OF TOTAL ALKALINITY

E-1 GENERAL

The cream is dispersed in water and titrated with standard acid using methyl orange as indicator. Total alkalinity of the cream is expressed as NaOH.

E-2 REAGENTS

E-2.1 Standard Sulphuric Acid or Hydrochloric Acid

Approximately 0.5 N.

E-2.2 Methyl Orange Indicator

Dissolve 0.1 g in 100 ml of water.

E-3 PROCEDURE

Take 2 g of sample (cream) in a conical flask, add 50 ml water, sonicate for 5 to 10 min to disperse, heat the flask over a water bath to make a uniform dispersion and titrate the solution with standard sulphuric or hydrochloric acid, using methyl orange indicator. Appearance of pink colour from yellow is the end point.

E-4 CALCULATION

Unless otherwise specified or agreed to between the purchaser or the supplier, calculate the total alkalinity (as NaOH) percent by mass as given below.

Total alkalinity (as NaOH) percent by mass

$$= \frac{4V \times N}{M}$$

where,

V = volume in ml, of standard sulphuric or hydrochloric acid;

N = normality of standard sulphuric or hydrochloric acid; and

M = mass in, g of the substance taken for test.

ANNEX F

[*Table* 2, *Sl No*. (iii)]

DETERMINATION OF TOTAL FATTY SUBSTANCE CONTENT

F-1 PRINCIPLE OF THE METHOD

The emulsion is broken with dilute mineral acid and the fatty matter is extracted with petroleum ether. It is weighed after removal of the solvent.

F-2 REAGENTS

F-2.1 Dilute Hydrochloric Acid — 1:1 (*v/v*).

F-2.2 Petroleum Ether (60°C - 80°C)

F-2.3 Methyl Orange Indicator Solution — Dissolve 0.1 g of methyl orange in 100 ml of water.

F-2.4 Sodium Sulphate (Anhydrous) — Desiccated.

F-3 PROCEDURE

Weigh accurately about 2 g of the material into a conical flask, add 25 ml of dilute hydrochloric acid, fit a reflux condenser into the flask, and boil the contents until the solution is perfectly clear. Pour the contents

of the flask into a 300 ml separating funnel and allow it to cool to room temperature, Rinse the conical flask with 50 ml of petroleum ether in portions of 10 ml. Pour the petroleum ether rinsings into the separating funnel, shake the separating funnel well and leave until the layers separate. Separate out the aqueous phase and shake it out with 50 ml portions of petroleum ether twice. Combine all the ether extracts and wash them with water until free of acid (when tested with methyl orange indicator solution). Filter the petroleum ether extracts through a filter paper containing sodium sulphate (anhydrous) into a conical flask which has been previously dried at a temperature of 90 ± 2°C and then weigh. Wash the sodium sulphate on the filter with petroleum ether and combine the washings with filtrate. Distil off the petroleum ether and dry the material remaining in the flask at a temperature of 90 ± 2°C to constant mass.

F-4 CALCULATION

$$\text{Total fatty substance, percent by mass} = \frac{100\ M_1}{M_2}$$

where,

M_1 = mass of the residue, in g; and

M_2 = mass of the material taken for-the test, in g.

ANNEX G

[*Table 2, S1 No.* (iv)]

DETERMINATION OF HEAVY METALS

G-1 OUTLINE OF THE METHOD

The colour produced with thioacetamide reagent in test solution is matched against that obtained with standard lead solution.

G-2 APPARATUS

G-2.1 Nessler Cylinders — 50 ml capacity.

G-2.2 Weighing Scale — 0.0001 g accuracy.

G-2.3 Volumetric Flasks — 100 ml capacity.

G-2.4 Platinum Crucible

G-2.5 Pipette (2, 10 ml)

G-3 REAGENTS

G-3.1 Concentrated Hydrochloric Acid

G-3.2 Concentrated Nitric Acid

G-3.3 Hydrofluoric Acid

G-3.4 Dilute Acetic Acid — 6 M (342 ml of glacial acetic acid diluted to 1000 ml with water).

G-3.5 Glycerol Mixture — Take 15 ml of 1M sodium hydroxide and add 5 ml water and 20 ml of 85 percent glycerol. Mix well.

G-3.6 Thioacetamide Reagent — Weigh 80 mg of thioacetamide and add 2 ml water to it. Shake to dissolve. Add 10 ml glycerol mixture, heat on water bath for 20 s, cool and use immediately.

G-3.7 Lead Nitrate Stock Solution (100 ppm as Pb) — Dissolve 0.1599 g of lead nitrate in water containing 1 ml of nitric acid and makeup the solution to 1 000 ml.

G-3.8 Standard Lead Solution (10 ppm as Pb) — Dilute 10 ml of lead nitrate stock solution with water to 100 ml. Each ml is equivalent to 0.01 mg of lead (Pb).

G-3.9 Acetate Buffer (3.5 *p*H) — Dissolve 25 g of ammonium acetate in 25 ml water and add 38 ml of 7 M hydrochloric acid. Adjust the *p*H to 3.5 either with 2 M hydrochloric acid or 6M ammonia and dilute to 100 ml with water.

G-4 PROCEDURE

G-4.1 Place 2 g of cream bleach sample accurately weighed in a platinum dish and incinerate for about 2 h at 525°C to 550°C. Cool and add 1 to 2 ml of hydrochloric acid and 0.5 ml nitric acid and evaporate to dryness on the steam bath. Dissolve the residue in 5 ml hot water, evaporate to dryness and treat it with hydrofluoric acid. Evaporate again to dryness. Dilute it with water (about 50 ml). Filter the solution, if necessaxy, with suction through a fine fritted glass filter and dilute the filtrate and wash it to 100 ml in a graduated flask. This solution shall be used for tests given in **G-4.2** and **H-3** as test solution.

G-4.2 Transfer 25 ml of test solution prepared in **G-4.1** in a 50 ml Nessler cylinder, add further 2 ml of test solution and 2 ml acetate buffer (*p*H = 3.5) and mix well. Add 1.2 ml of thioacetamide reagent, mix and immediately dilute with water to 50 ml and allow to stand for 2 min.

G-4.3 In the second Nessler cylinder, place 1 ml standard lead solution (*see* **G-3.8**) and add 2 ml of test solution. Dilute with water to 25 ml, and add 2 ml acetate buffer (*p*H 3.5). Mix, add 1.2 ml of thioacetamide reagent, and immediately dilute with water to 50 ml. Allow to stand for 2 min. Compare the colour produced in the two Nessler cylinders.

G-5 RESULT

The limit prescribed in Table 1 shall be taken as not having been exceeded, if the intensity of colour produced in the test solution is not greater than that produced in the second Nessler cylinder which is a control test.

ANNEX H

[*Table* 2, *Sl No.* (v)]

DETERMINATION OF ARSENIC

H-1 PRINCIPLE

Arsenic present in a solution of the material is reduced to arsine, which is made to react with mercuric bromide paper. The stain produced is compared with a standard stain.

H-2 REAGENT

H-2.1 Mixed Acid

Dilute one volume of concentrated sulphuric acid with four volumes of water. Add 10 g of sodium chloride for each 100 ml of the solution.

H-2.2 Ferric Ammonium Sulphate Solution

Dissolve 64 g of ferric ammonium sulphate in water containing 10 ml of mixed acid and makeup to one litre.

H-2.3 Concentrated Hydrochloric Acid [*see* IS 265 : 1993 'Hydrochloric acid — Specification (*fourth revision*)']

H-2.4 Stannous Chloride Solution — Dissolve 80 g of stannous chloride ($SnCl_2 2H_2O$) in 100 ml of water containing 5 ml of concentrated hydrochloric acid.

H-3 PROCEDURE

Carry out the test as prescribed in IS 2088, adding into the Gutzeit bottle, 2 ml of ferric ammonium sulphate solution, 0.5 ml of stannous chloride solution and 25 ml of sample solution as prepared in **G-4.1**.

For comparison, prepare a stain using 0.001 mg of arsenic trioxide.

Bureau of Indian Standards

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

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