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Whereas the Parliament of India has set out to provide a practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, and whereas the attached publication of the Bureau of Indian Standards is of particular interest to the public, particularly disadvantaged communities and those engaged in the pursuit of education and knowledge, the attached public safety standard is made available to promote the timely dissemination of this information in an accurate manner to the public.

IS 5339 (2004): Skin Powder for Infants [PCD 19: Cosmetics]
Indian Standard

SKIN POWDER FOR INFANTS — SPECIFICATION
(Second Revision)

ICS 71.100.70

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

December 2004
FOREWORD

This Indian Standard (Second 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.

This standard was originally issued in 1969 and first revised in 1978. The Sectional Committee decided to revise it in the light of experience gained since its publication. Skin powders for infants should not be the cause of bacteriological and fungal contamination. This possibility may be obviated by, for instance, a process of sterilization. In this revision a requirement limit for microbial content has been specified. Important marking requirements for best use before, list of key ingredients on containers and ECO Mark certification have also been incorporated in this revision.

This standard covers the material commonly known in trade as baby powders. These powders are intended to make the infant feel more comfortable and to help prevent skin rashes that arise from or are aggravated by excess moisture. In composition, skin powders for infants do not differ greatly from those intended for adults. One obvious difference is that the infant powders are usually only lightly perfumed or not perfumed at all. The principle followed by many manufacturers is to keep the formula as simple as possible. This reduces the risk of sensitization and irritation. For this reason there are often as few as three or four ingredients in these powders. Stearates, colloidal clay, starch and talc are the common ingredients. Another significant difference is that these powders are free from boric acid.

No stipulations have been made in this standard regarding the composition of skin powders. However, it is necessary that the raw materials used are such that in the concentrations in which they would be present in the finished skin powder, after interaction with other raw materials used in the formulation, they are free from any harmful effects. For determining the dermatological safety of a new formulation, or of a new raw material used in an old formulation, reference may be made to IS 4011 : 1997 'Methods of test for safety evaluation of cosmetics (second revision)'. It shall be the responsibility of the manufacturers of skin powder for infants to satisfy themselves of the dermatological safety of their formulation before releasing the product for sale.

A scheme for labelling environment friendly products known as ECO Mark (optional) 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 and the ECO logo. Requirements for the ECO friendliness will be additional, manufacturing units will be free to opt for Standard Mark alone also.

Composition of the Committee responsible for formulation of this standard is given in Annex H

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
SKIN POWDER FOR INFANTS — SPECIFICATION
(Second Revision)

1 SCOPE
This standard prescribes the requirements and the methods of sampling and test for skin powder for infants.

This standard does not cover skin powder for general use, for which a separate Indian Standard (IS 3959) has been published.

2 REFERENCES
The following standards are necessary adjuncts to this standard. The standards 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:

<table>
<thead>
<tr>
<th>IS No.</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>265 : 1993</td>
<td>Hydrochloric acid (fourth revision)</td>
</tr>
<tr>
<td>266 : 1993</td>
<td>Sulphuric acid (third revision)</td>
</tr>
<tr>
<td>323 : 1959</td>
<td>Specification for rectified spirit</td>
</tr>
<tr>
<td>460 (Part 1) : 1985</td>
<td>Test sieves: Part 1 Wire cloth test sieves (third revision)</td>
</tr>
<tr>
<td>1070 : 1992</td>
<td>Water reagent grade (third revision)</td>
</tr>
<tr>
<td>2088 : 1983</td>
<td>Methods for determination of arsenic (second revision)</td>
</tr>
<tr>
<td>3958 : 1984</td>
<td>Methods of sampling cosmetics (first revision)</td>
</tr>
<tr>
<td>4707</td>
<td>Classification of cosmetic raw materials and adjuncts: (Part 1) : 2001 Dyes colours and pigments (second revision)</td>
</tr>
<tr>
<td></td>
<td>(Part 2) : 2001 List of raw materials generally not recognized as safe for use in cosmetics (second revision)</td>
</tr>
<tr>
<td>3959 : 2004</td>
<td>Skin powder (second revision)</td>
</tr>
<tr>
<td>14648 : 1999</td>
<td>Methods of test for microbiological examinations of cosmetics</td>
</tr>
</tbody>
</table>

3 REQUIREMENTS
3.1 Skin powder for infants shall consist principally of a finely-powdered free flowing absorbent innocuous material such as natural talc and may contain mild perfume, as well as other ingredients consistent with the accepted practice in the cosmetic industry.

3.1.1 The powder shall essentially be free from colouring matter. It may be buffered to control pH. It shall be free from boric acid when tested by the method prescribed in Annex A.

3.1.2 Unless specified otherwise, all the raw materials used in the manufacture of skin powder for infants shall conform to the requirements prescribed in the relevant Indian Standards where these exist. Other ingredients shall comply with the provisions of latest version of IS 4707 (Part 2).

3.2 The material shall also comply with the requirements given in Table 1 when tested as prescribed in cols 4 and 5 of the Table 1.

4 ADDITIONAL REQUIREMENTS FOR ECO MARK (OPTIONAL)
4.1 Requirements for quality, safety and performance prescribed under 4.4.1 to 4.1.4.

4.1.1 All the ingredients that go into formulation of cosmetics shall comply with the provisions of IS 4707 (Part 1) and IS 4707 (Part 2). The product shall also meet specific requirements as given in the standard.

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

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

4.1.4 The manufacturer shall produce to BIS 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 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.

4.2 Specific Requirements
4.2.1 Product shall be dermatologically safe when tested as per IS 4011.

4.2.2 Heavy metals calculated as lead (Pb) and arsenic (as As$_2$O$_3$) shall not exceed 20 and 2 ppm, respectively
### Table 1 Requirements for Skin Powder for Infants

*(Clauses 3.2 and 6.2)*

<table>
<thead>
<tr>
<th>Sl No.</th>
<th>Characteristics</th>
<th>Requirement</th>
<th>Method of Test, Ref to IS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>i)</td>
<td>Matter insoluble in boiling water, percent by mass, Min</td>
<td>90.0</td>
<td>B</td>
</tr>
<tr>
<td>ii)</td>
<td>Fineness:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a)</td>
<td>Residue on 75-micron IS Sieve, percent by mass, Max</td>
<td>2.0</td>
<td>C</td>
</tr>
<tr>
<td>b)</td>
<td>Residue on 150-micron IS Sieve, percent by mass, Max</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>iii)</td>
<td>Moisture and volatile matter, percent by mass, Max</td>
<td>2.0</td>
<td>D</td>
</tr>
<tr>
<td>iv)</td>
<td>pH of aqueous suspension</td>
<td>5.5 to 8.0</td>
<td>E</td>
</tr>
<tr>
<td>v)</td>
<td>Heavy metals (as Pb), parts per million, Max</td>
<td>20</td>
<td>F</td>
</tr>
<tr>
<td>vi)</td>
<td>Arsenic (as As$_2$O$_3$), parts per million, Max</td>
<td>2</td>
<td>G</td>
</tr>
<tr>
<td>vii)</td>
<td>Microbial content/limit</td>
<td>Not more than 100</td>
<td>14648</td>
</tr>
<tr>
<td>a)</td>
<td>Total viable count cfu/g</td>
<td>Absent</td>
<td>14648</td>
</tr>
<tr>
<td>b)</td>
<td>Gram Negative pathogens</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1) If all the raw materials requiring test for heavy metals and arsenic have been so tested and comply with the requirements, then the manufacturer may not test the finished cosmetic for heavy metals and arsenic.

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 details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

5 PACKING AND MARKING

5.1 Packing

The material shall be packed in suitable well-closed containers.

5.2 Marking

The containers shall be legibly marked with the following information:

- a) Name of the material;
- b) Manufacturer’s name and/or his recognized trade-mark, if any;
- c) Net mass of the material;
- d) Month and year of manufacturing/packing;
- e) Batch or lot number, in code or otherwise;
- f) Expiry date or "Best use before . . . " (month and year to be declared by the manufacturer);

**NOTE** — This requirement is exempted:
1) In case of pack sizes of 10 g or less.
2) If the shelf life of the product is more than 24 months.

- g) List of key ingredients; and

**NOTE** — This is exempted in case of pack sizes of 30 g or less.

- h) Any other information required by statutory authorities.

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

### Sampling

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

6.2 Tests for all the characteristics shall be carried out on the composite sample as per methods referred under col 4 of Table 1.

### Quality of Reagents

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

**NOTE** — ’Pure chemicals’ shall mean chemicals that do not contain impurities which affect the results of analysis.
ANNEX A
(Clause 3.1.1)
TEST FOR FREEDOM FROM BORIC ACID

A-1 REAGENTS
A-1.1 Concentrated Sulphuric Acid — See IS 266.
A-1.2 Rectified Spirit — See IS 323.

A-2 PROCEDURE
Weigh about 1 g of the material in a porcelain or china dish. Add about 2 ml of concentrated sulphuric acid and stir thoroughly with a glass rod. Then add about 5 ml of rectified spirit and again stir thoroughly. Ignite and observe the appearance of the flame.

A-2.1 The material shall be considered to be free from boric acid if the flame does not have a green outer edge.

ANNEX B
[Table 1, Sl No. (i)]
DETERMINATION OF MATTER INSOLUBLE IN BOILING WATER

B-1 REAGENT
B-1.1 Rectified Spirit — See IS 323.

B-2 PROCEDURE
Weigh accurately about 1 g of the material and transfer to a 500 ml beaker. If necessary, wet the material with a little rectified spirit. Add to the beaker about 200 ml of water and boil. Allow to settle and filter the supernatant liquid through a Gooch crucible. Wash the residue in the beaker with water and transfer completely to the filter. Dry the residue in the crucible at 105 ± 2°C to constant mass.

B-3 CALCULATION
Matter insoluble in boiling water, \[
\text{percent by mass} = \frac{100 \times M_i}{M}
\]
where
\[M_i = \text{mass in g of the residue, and}
M = \text{mass in g of the material taken for the test.}
\]

ANNEX C
[Table 1, Sl No. (ii)]
DETERMINATION OF FINENESS

C-1 REAGENT
C-1.1 Denatured Spirit — Filtered.

C-2 PROCEDURE
Place about 10 g of the material, accurately weighed, in the specified IS Sieve and wash by means of a slow stream of running tap water and finally with fine stream from a wash bottle until as much material as would pass through the sieve has passed. In case the material is not easily wetted by water, the washing could be started with a slow stream of filtered denatured spirit. Let the water drain from the sieve and then dry the sieve containing the residue on a stream bath. Transfer the residue on to a tared watch glass carefully and dry it to constant mass at 105 ± 2°C.

C-3 CALCULATION
Material retained on the specified sieve, percent by mass \[
= \frac{100 \times M_i}{M}
\]
where
\[M_i = \text{mass in g of the residue retained on the specified sieve, and}
M = \text{mass in g of the material taken for the test.}
\]
ANNEX D

D-1 PROCEDURE
Weigh accurately about 5g of the material in a porcelain or glass dish, about 6 to 8 cm in diameter and about 2 to 4 cm in depth. Dry in an air oven at a temperature of 105 ± 2 °C to constant mass (within ±5 mg).

D-2 CALCULATION
Moisture and volatile matter, \( \text{percent by mass} = \frac{100 \times M_1}{M} \)
where
\( M_1 = \) loss in mass in g on drying, and
\( M = \) mass in g of the material taken for the test.

ANNEX E

E-1 PROCEDURE
Take 10 g of the material in a 150 ml beaker and add 90 ml of freshly boiled and cooled water. Stir well to make a thorough suspension. Determine the pH of the suspension using a pH meter within 5 min of making the suspension. In case of a material which does not wet, the pH shall be determined on the filtrate.

ANNEX F

F-1 OUTLINE OF THE METHOD
The colour produced with hydrogen sulphide solution is matched against that obtained with standard lead solution.

F-2 APPARATUS
F-2.1 Nessler Cylinders — 50-ml capacity.

F-3 REAGENTS
F-3.1 Dilute Hydrochloric Acid — Approximately 5 N.
F-3.2 Dilute Acetic Acid — Approximately 1 N.
F-3.3 Dilute Ammonium Hydroxide — Approximately 5 N.
F-3.4 Hydrogen Sulphide Solution — Standard.
F-3.5 Standard Lead Solution — Dissolve 1.600 g of lead nitrate in water and make up the solution to 1 000 ml. Pipette out 10 ml of the solution and dilute again to 1 000 ml with water. One milliliter of this solution contain 0.01 mg of lead (as Pb).

F-4 PROCEDURE
Weigh about 2.000 g of material in a crucible and heat on a hot plate and then in a muffle furnace to ignite it at 600°C to constant mass. Add 3 ml of dilute hydrochloric acid, warm (wait till no more dissolution occurs) and make up the volume to 100 ml. Filter the solution. Transfer 25 ml of the filtrate into a Nessler’s cylinder. In the second Nessler’s cylinder, add 2 ml of dilute acetic acid, 1.0 ml of standard lead solution and make up the volume with water to 25 ml. Add 10 ml of hydrogen sulphide solution to each Nessler cylinder and make up the volume with water to 50 ml. Mix and allow to stand for 10 min. Compare the colour produced in the two Nessler’s cylinders. Blank determination without samples are recommended to avoid errors arising out of reagents.

F-5 RESULTS
The sample may be taken to have passed the test, if the colour developed in the sample solution is less than that of standard solution.
ANNEX G

[Table 1, Sl No. (vi)]

DETERMINATION OF ARSENIC

G-1 OUTLINE OF THE METHOD
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.

G-2 REAGENTS

G-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.

G-2.2 Ferric Ammonium Sulphate Solution — Dissolve 64 g of ferric ammonium sulphate in water containing 10 ml of mixed acid and make up to one litre.

G-2.3 Concentrated Hydrochloric Acid — See IS 265.

G-2.4 Stannous Chloride Solution — Dissolve 80 g of stannous chloride (SnCl₂, 2H₂O) in 100 ml of water containing 5 ml of concentrated hydrochloric acid.

G-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 F-4.

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

**(Foreword)**

## COMMITTEE COMPOSITION

Cosmetics Sectional Committee, PCD 19

<table>
<thead>
<tr>
<th>Organization</th>
<th>Representative(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directorate General of Health Services, New Delhi</td>
<td>SHRI ASHWINI KUMAR <em>(Chairman)</em></td>
</tr>
<tr>
<td>All India Small Scale Cosmetic Manufacturer's Association, Mumbai</td>
<td>SHRI M. B. DESAI</td>
</tr>
<tr>
<td></td>
<td>SHRI B. M. CHOPRA <em>(Alternate I)</em></td>
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<td></td>
<td>SHRI S. CHATTERJEE <em>(Alternate II)</em></td>
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<td>Bengal Chemicals &amp; Pharmaceuticals Ltd, Kolkata</td>
<td>DR SAJAL K. ROY CHOWDHURY</td>
</tr>
<tr>
<td>Central Drugs Laboratory, Kolkata</td>
<td>DR A. K. MANDAL <em>(Alternate)</em></td>
</tr>
<tr>
<td>Central India Pharmacopoeia Laboratory, Ghaziabad</td>
<td>DR M. K. MAZUMDER</td>
</tr>
<tr>
<td>Consumer Education and Research Centre, Ahmedabad</td>
<td>DR A. C. DAS GUPTA <em>(Alternate)</em></td>
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<tr>
<td>Consumer Guidance Society, Mumbai</td>
<td>DR SANTOSH K. TALWAR</td>
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<tr>
<td>Colgate-Palmolive (India) Ltd, Mumbai</td>
<td>DR S. K. TALWAR <em>(Alternate)</em></td>
</tr>
<tr>
<td>Commissioner, Food &amp; Drugs Administration, Mumbai</td>
<td>DR SUKOMAL DAS <em>(Alternate)</em></td>
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<tr>
<td>Dabur Research Foundation, Sahibabad</td>
<td>DR A. C. DAS GUPTA <em>(Alternate)</em></td>
</tr>
<tr>
<td>Food &amp; Drugs Control Administration, Gujarat State, Gandhinagar</td>
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<td>SHRI Y. S. YELLORE <em>(Alternate)</em></td>
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<td>Hygienic Research Institute, Mumbai</td>
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<tr>
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<td>Johnson &amp; Johnson Ltd, Mumbai</td>
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</tr>
<tr>
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<td>SHRI SUNEIL AGGARWAL <em>(Alternate I)</em></td>
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<td>DR NEENA SHARMA <em>(Alternate II)</em></td>
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<td>Maharishi Ayurved Products, Noida (U.P.)</td>
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<td>Shingar Ltd, Mumbai</td>
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<td>Le' Orcaif India Pvt Ltd, Umbergaon, Gujarat</td>
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<td>DR (SHRIMATI) ROHINI THAKKAR <em>(Alternate)</em></td>
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<td>MRS SHWETA PURANDARE <em>(Alternate)</em></td>
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<td>DR S. ASHOKNARAN</td>
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<td>Procter &amp; Gamble, Mumbai</td>
<td>DR ARCHANA SHERING</td>
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<tr>
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<td>DR K. C. GOUNDEN</td>
</tr>
<tr>
<td>Procter &amp; Gamble, Mumbai</td>
<td>PROF B. K. GUPTA</td>
</tr>
</tbody>
</table>
### IS 5339 : 2004

#### Organization

- Marico India Ltd, Mumbai
- Cavinkare Ltd, Chennai
- BIS Directorate General

#### Representative(s)

- Shri R. Mohile
  - Shri Benedict M. (Alternate)
- Dr. M. P. Prasad
  - Dr. G. V. Rao (Alternate)
- Shri Anjan Kar, Director and Head (PCD)
  - [Representing Director General (Ex-officio)]

#### Member Secretary

- Dr (Shrimati) Viday Malik
  - Director (PCD), BIS

---

#### Skin Care Products Subcommittee, PCD 19 : 3

- Hindustan Lever Research Centre, Mumbai
- Bengal Chemicals & Pharmaceuticals Ltd, Kolkata
- Cadila Health Care Ltd, Ahmedabad
- Cavin Kare Ltd, Chennai
- Consumer Education and Research Centre, Ahmedabad
- Colgate Palmolive (India) Ltd, Mumbai
- Johnson & Johnson Ltd, Mumbai
- Maharishi Ayurved Products, Noida (U.P.)
- Procter & Gamble, Mumbai
- Shingar Ltd, Mumbai
- Le’Oreal India Pvt Ltd, Umbergaon, Gujarat

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- Dr. Raj Kohli
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  - Dr (Shrimati) N. Sharma (Alternate II)
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  - Dr V. R. Bambulkar (Alternate)
- Dr. S. C. Saxena
  - Shri D. K. Shrivasata (Alternate)
- Shrimati Shweta Purandare
  - Dr. Arun Viswanath (Alternate)
- Shri V. K. Singh
  - Shrimati Swati Singh (Alternate)
- Dr. Archana Shekher
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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Amendments Issued Since Publication

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BUREAU OF INDIAN STANDARDS

Headquarters:
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Telephones : 2323 0131, 2323 33 75, 2323 9402

Telegrams : Manaksanstha
((Common to all offices)

Regional Offices:
Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg
NEW DELHI 110 002
  \[2323 7617\]
  \[2323 3841\]

Eastern : 1/14 C.I.T. Scheme VII M, V. I. P. Road, Kankurgachi
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