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

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भारतीय मानक

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(दूसरा पुनरीक्षण)

Indian Standard

SKIN POWDER FOR INFANTS — SPECIFICATION

(Second Revision)

ICS 71.100.70

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

December 2004

Price Group 4

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 ISI 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:

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

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 *p*H. 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 col 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 there under, 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_2O_3) shall not exceed 20 and 2 ppm, respectively

Table 1 Requirements for Skin Powder for Infants

(*Clauses* 3.2 *and* 6.2)

Sl No.	Characteristics	Requirement	Method of Test, Ref to	
			Annex	IS No.
(1)	(2)	(3)	(4)	(5)
i)	Matter insoluble in boiling water, percent by mass, *Min*	90.0	B	—
ii)	Fineness:		C	—
	a) Residue on 75-micron IS Sieve, percent by mass, *Max*	2.0		
	b) Residue on 150-micron IS Sieve, percent by mass, *Max*	0.5		
iii)	Moisture and volatile matter, percent by mass, *Max*	2.0	D	—
iv)	*p*H of aqueous suspension	5.5 to 8.0	E	—
v)	[1] Heavy metals (as Pb), parts per million, *Max*	20	F	—
vi)	[1] Arsenic (as As_2O_3), parts per million, *Max*	2	G	—
vii)	Microbial content/limit			
	a) Total viable count cfu/g	Not more than 100		14648
	b) Gram Negative pathogens	Absent		14648

[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.

when tested by the respective method prescribed in Indian Standards.

4.2.3 For ECO Mark the product package shall be packed in such packages which shall be recyclable or biodegradable.

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.

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.

5.2.2 If the product is covered under ECO Mark (optional), it shall be suitably marked with ECO Mark logo besides Standard Mark. The label may clearly specify that ECO Mark is applicable to the contents or the package or both, as case may be. If the product package is not separately covered under ECO Mark scheme, it shall be clearly mentioned on the product that ECO Mark label is applicable to contents only.

6 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.

6.3 The material shall be taken to have conformed to the standard if the composite samples passes all the tests.

7 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

$$\text{Matter insoluble in boiling water, percent by mass} = \frac{100 \times M_1}{M}$$

where

M_1 = mass in g of the residue, and

M = 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

$$\text{Material retained on the specified sieve, percent by mass} = \frac{100 \times M_1}{M}$$

where

M_1 = mass in g of the residue retained on the specified sieve, and

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

ANNEX D

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

DETERMINATION OF MOISTURE AND VOLATILE MATTER

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, 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

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

DETERMINATION OF *p*H OF AQUEOUS SUSPENSION

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 *p*H of the suspension using a *p*H meter within 5 min of making the suspension. In case of a material which does not wet, the *p*H shall be determined on the filtrate.

ANNEX F

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

TEST FOR HEAVY METALS

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 millilitre 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 ($SnCl_2$, $2H_2O$) 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

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Organization	*Representative(s)*
Directorate General of Health Services, New Delhi	SHRI ASHWINI KUMAR (***Chairman***)
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Member Secretary
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Director (PCD), BIS

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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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