SRI LANKA STANDARD 187 : 2013
UDC 668.584.46

SPECIFICATION FOR
SKIN POWDER FOR BABIES
(Second Revision)

SRI LANKA STANDARDS INSTITUTION

Sri Lanka Standard

SPECIFICATION FOR SKIN POWDER FOR BABIES

(*Second Revision*)

SLS 187 : 2013

(Attached AMD 546)

Gr.5

SRI LANKA STANDARDS INSTITUTION
17, Victoria Place
Elvitigala Mawatha
Colombo 08
SRI LANKA

Sri Lanka Standards are subject to periodical revision in order to accommodate the progress made by industry. Suggestions for improvement will be recorded and brought to the notice of the Committees to which the revisions are entrusted.

This standard does not purport to include all the necessary provisions of a contract.

Sri Lanka Standard
SPECIFICATION FOR SKIN POWDER FOR BABIES
(*Second Revision*)

FOREWORD

This standard was approved by the Sectoral Committee on Chemicals and Polymer Technology and was authorized for adoption and publication as a Sri Lanka Standard by the Council of the Sri Lanka Standards Institution on 2013-04-30.

This specification was first published in 1973 and the First Revision was issued in 1982. In this Second Revision, the quality parameters applicable to skin powder with or without herbs/ herbal extracts and medicated skin powder for babies considered, limits for pH and Lead have been revised and the methods of test for the microbiological requirements have been included. Additional marking requirements have been included.

This product is commonly known in the trade as baby powder or baby talc. This powder is different from that meant for adults, in that it lacks or has the minimum of extra ingredients which could be tolerated by adults, but which have undesirable effects on babies including infants. The powder is intended to make the babies feel more comfortable and to help prevent skin rashes that arise from or are aggravated by excess moisture. In order to reduce the risk of sensitization and irritation, the manufacturers are advised to maintain a simple formula. A properly designed device at the mouth of the container for deliberate opening is essential to control the emission of powder to avoid inadvertent inhalation of the powder by the users.

This specification is subject to the restrictions imposed under the Cosmetics, Devices and Drugs Act No. 27 of 1980 and the regulations framed thereunder.

For the purpose of deciding whether a particular requirement of this specification is complied with, the final value, measured or computed, expressing the result of a test or an analysis, shall be rounded off in accordance with **SLS 102**. The number of decimal places retained in the rounded off value shall be the same as that of the specified value in this specification.

In the formulation of this specification, the assistance derived from the following publication is gratefully acknowledged :

IS 5339 : 2004 Indian Standard Skin powder for infants - Specification
IS 14648 : 2005 Indian Standard Methods of test for microbiological examination of cosmetics and cosmetic raw materials
Standards for fragrances published by the International Fragrance Association (IFRA)

1 SCOPE

1.1 This specification prescribes the quality and safety requirements and methods of sampling and test for skin powder with or without herbs/ herbal extracts and medicated skin powder for babies including infants.

1.2 This specification does not prescribe methods of test for therapeutic/ medicinal claims of skin powders for babies.

2 REFERENCES

SLS 102 Rules for rounding off numerical values
SLS 124 Test sieves
SLS 311 Methods for the determination of Lead
SLS 312 Methods for the determination of Arsenic
SLS 457 Classification of cosmetic raw materials and adjuncts
Part 2 Raw materials and adjuncts other than dyes, colours and pigments not recognized as safe
SLS 495 Sampling of cosmetics and toilet preparations
SLS 1316 Code of good manufacturing practices for cosmetics industry
SLS 1349 Method for the enumeration and detection of aerobic mesophilic bacteria in cosmetics
SLS 1350 Method for the detection of *Pseudomonas aeruginosa* in cosmetics
SLS 1351 Method for the detection of *Staphylococcus aureus* in cosmetics
SLS 1445 Sri Lanka Standard Method for the enumeration of yeast and mould in cosmetics

3 REQUIREMENTS

3.1 General requirements

3.1.1 Skin powder for babies shall consist principally of a finely powdered, free flowing, absorbent, innocuous material.

3.1.2 It shall be completely free from grit. To test for freedom from grit, the following method shall be used.

Take about 20 g of the material, weigh to the nearest g, in a beaker, and remove, by overflow under a carefully controlled stream of water, the bulk of the material. The grit being heavier will remain in the beaker along with some powder. Test the residue in the beaker for the presence of grit, by rubbing the residue between the finger and the thumb.

3.1.3 The material shall be free from colouring matter.

3.1.4 Skin powder for babies shall be manufactured by a process adhering to Good Manufacturing Practices (GMP) complying with **SLS 1316**.

3.1.5 The Skin powder for babies shall meet performance and stability specifications given by the manufacturer based on in-vitro studies for the complete duration of the declared shelf life. The date of expiry / best before / shelf life of the finished product shall be determined based on the results of the stability.

3.2 Raw materials

3.2.1 The raw materials shall comply with the provisions of **SLS 457 : Part 2**.

3.2.2 The fragrances used shall be in accordance with the Standards for fragrances published by the International Fragrance Association (IFRA).

3.2.3 *Free from boric acid*

The product shall be free from boric acid when tested by the method prescribed in Appendix **B**.

3.3 Other requirements

The product shall also comply with the requirements given in Table **1**, when tested in accordance with the relevant methods given in Column **4** of the table.

3.4 Microbiological limits

The skin powder shall also comply with the microbiological limits given in Table **2** when tested in accordance with the relevant methods given in Column **4** of the table.

TABLE 1 – Requirements for skin powder for babies

Sl No. (1)	Characteristic (2)	Requirement (3)	Method of test reference (4)
i)	Matter insoluble in boiling water, per cent by mass, min.	90.0	Appendix C
ii)	Fineness :		
	a) Residue on 75-µm sieve, per cent by mass, max.	2.0	Appendix D
	b) Residue on 150- µm sieve, per cent by mass, max.	0.1	
iii)	Moisture and volatile matter, per cent by mass, max.	1.0	Appendix E
iv)	pH of aqueous suspension	5.5 to 8.0	Appendix F
v)	Lead (as Pb), mg/kg, max.	10	SLS 311
vi)	Arsenic (as As), mg/kg, max.	1.5	SLS 312

TABLE 2 - Microbiological limits

Sl. No. (1)	Test (2)	Limit (3)	Method of test (4)
i)	Total microbial count, per g, max. (see Note) a) Aerobic plate count b) Yeast and mould count	100	 SLS 1349 SLS 1445
ii)	*Pseudomonas aeruginosa*	Absent*	SLS 1350
iii)	*Staphylococcus aureus*	Absent*	SLS 1351

* in 10 g

NOTE *: Total microbial count refers to the combination of total aerobic plate count and yeasts and mould count.*

4 PACKAGING

The product shall be packed in suitable, well closed containers. Glass shall not be used for containers.

The containers shall be so designed that they cannot be opened by a baby.

NOTE : *A number of these containers may be enclosed in a package.*

5 MARKING

5.1 The containers shall be marked legibly and indelibly with the following:

a) Name of the product ;
b) Name and address of the manufacturer for products manufactured in Sri Lanka. Name and address of the manufacturer and the distributor in Sri Lanka/ Importer for imported products including country of origin;
c) Registered trade mark, if any ;
d) Brand name, if any ;
e) Net content, in grams, of the material ; ;
f) Batch or code or lot identification number ;
g) Date of manufacture ;
h) Best before / shelf life ;
j) List of ingredients;
k) Instructions for use where necessary ;
m) Special precautions to be observed in use , if required ; and
n) Specific warning statement necessary or appropriate to prevent health hazard.

6 METHODS OF TEST

6.1 Tests shall be carried out as prescribed in Appendix **A** and the relevant Appendices indicated in Column **4** of Table **1** and Table **2**.

6.2 Unless otherwise specified all reagents used shall be of recognized analytical grade and wherever water is mentioned distilled water or de-ionized water shall be used.

APPENDIX A
COMPLIANCE OF A LOT

The sampling scheme given in this Appendix should apply where compliance of a lot to the requirements of this standard has to be assessed based on statistical sampling and inspection.

Where compliance with this standard is to be assessed based on manufacturer's control systems, appropriate schemes of sampling and inspection coupled with type, testing and check tests or any other procedure, an appropriate scheme of sampling and inspection should be adopted.

A.1 LOT

In any consignment packages / containers of the same type and capacity belonging to one batch of manufacture or supply shall constitute as a lot.

A.2 SCALE OF SAMPLING

A.2.1 Representative samples of the material shall be drawn according to the relevant clauses of **SLS 495**.

A.3 NUMBER OF TESTS

A.3.1 Each container selected as in **6.2** and **6.3.1** of **SLS 495** shall be examined for packaging and marking requirements (see **4** and **5**).

A.3.2 Test for detection of boric acid (see **3.2.2**) shall be carried out on each individual sample obtained as in **6.4.2** of **SLS 495**.

A.3.3 Tests for determination of other requirements of the specification (see **3.3** and **3.4**) shall be conducted on the composite sample obtained as in **6.4.1** of **SLS 495**.

A.4 CRITERIA FOR CONFORMITY

A lot shall be declared as conforming to the requirements of this specification, if the following conditions are satisfied :

A.4.1 Each container examined as in **A.3.1** satisfies the relevant requirements.

A.4.2 Each container examined as in **A.3.2** satisfies the relevant requirement.

A.4.3 The composite samples tested as in **A.3.3** satisfies the relevant requirements.

APPENDIX B
DETERMINATION OF BORIC ACID

B.1 PROCEDURE

Weigh to the nearest milligram, about 1 g of the material and place it in a boiling tube (20 mm x 3 mm). Add about 2 ml of concentrated sulphuric acid and about 5 ml of methyl alcohol. Stopper the tube with a cork carrying two bent tubes as shown in Figure 1. Boil the contents in the test tube. Blow in air through one tube and light the vapours that come off the other bent tube (outlet tube). A green flame is obtained if boric acid is present.

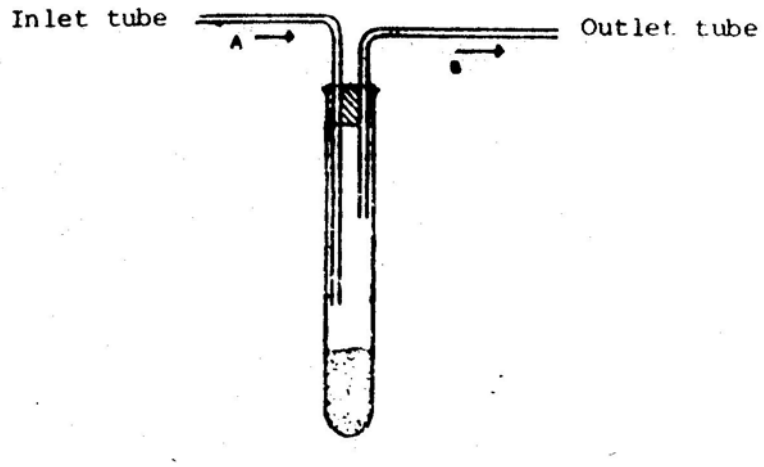

FIGURE 1 – Boiling tube arrangement for Detection of boric acid

APPENDIX C
DETERMINATION OF MATTER INSOLUBLE IN BOILING WATER

C.2 REAGENT

Rectified spirit

C.3 PROCEDURE

Weigh, to the nearest milligram, about 1 g of the material and transfer to a 500-ml beaker. If necessary, wet the material with a few drops of 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 crucible. Dry the residue in the crucible at 105 ± 2 °C, cool in a desiccator and weigh. Repeat the heating, cooling and weighing operations until the difference in mass between two successive weighings does not exceed 5 mg.

C.4 CALCULATION

$$Matter\ insoluble\ in\ boiling\ water,\ per\ cent\ by\ mass = \frac{100\ m_1}{m}$$

where,

m_1 is the mass, in g, of the residue; and

m is the mass, in g, of the material taken for the test.

APPENDIX D
DETERMINATION OF FINENESS

D.1 REAGENT

Denatured spirit, filtered

D.2 PROCEDURE

Weigh to the nearest milligram, about 10 g of the material, in a a) 75-µm sieve, b) 150-µm sieve, both sieves conforming to **SLS 124** and wash by means of a slow stream of running tap water and finally with a fine stream, from a wash bottle until all the material that can 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 steam bath. Carefully transfer the residue into a tared watch glass and dry it at 105 ± 2°C. Cool in a desiccator and weigh. Repeat the heating, cooling and weighing operations until the difference in mass between two successive weighings does not exceed 10 mg.

D.3 CALCULATION

$$\textit{Material retained on the specified sieve per cent by mass} = \frac{100\ m_1}{m}$$

where,

m_1 is the mass, in g, of the residue retained on the specific sieve ; and
m is the mass, in g, of the material taken for the test.

APPENDIX E
DETERMINATION OF MOISTURE AND VOLATILE MATTER

E.1 PROCEDURE

Weigh to the nearest mg, about 5g of the material into a porcelain or glass dish, about 60-mm to 80-mm in diameter and about 20-mm to 40-mm in depth. Dry in an air oven at a temperature of 105 ± 2°C. Cool in a desiccator and weigh. Repeat the heating, cooling and weighing operations until the difference in mass between two successive weighings does not exceed 5 mg.

E.2 CALCULATION

$$\textit{Moisture and volatile matter, per cent by mass} = \frac{100\ m_1}{m}$$

where,

m_1 is the loss in mass, in g, on drying ; and

m is the mass, in g, of the material taken for the test.

APPENDIX F
DETERMINATION OF pH OF AQUEOUS SUSPENSION

F.1 PROCEDURE

Take 10.0 ± 0.1g 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. Using a pH meter, determine the pH of the suspension after 60 ± 5 s of making the suspension at 27 ± 2°C.

AMD 546

Amendment No: 01 approved on 2021-04-30 to SLS 187:2013

SRI LANKA STANDARD SPECIFICATION FOR SKIN POWDER FOR BABIES (*Second Revision*)

FOREWORD

Delete the text given in fourth paragraph and substitute the following:

"This Specification is subject to the restrictions imposed under the applicable State Legislative requirements. "

2 REFERENCES

Delete the "SLS 457" and "SLS 1316" in the reference list and substitute the followings:

"ISO/TR 17276	Cosmetics - Analytical approach for screening and quantification methods for heavy metals in cosmetics
SLS 457	Cosmetics- Classification of raw materials Part 1: Substances permitted subject to restrictions and permitted colourants, preservatives and UV filters Part 2: Prohibited substances
SLS ISO 22716	Guidelines on good manufacturing practices for cosmetics"
SLS 1587	Cosmetics - Packaging and labelling"

3.1 General requirements

Delete the "**SLS 1316**" and substitute the "**SLS ISO 22716**" at the end of the text given in Clause **3.1.4**"

Insert the following new Clauses:

3.1.6 "It shall be the responsibility of the manufacturer to provide evidence for assessment of safety on human health in the final product formulation before releasing the product for sale. Results of safety assessments/such studies shall be produced, whenever required."

3.1.7 "Evidence shall be provided from a recognized certification body for the talc materials used for manufacture skin powders shall be free from asbestos."

3.2 Raw materials

Delete the Clause **3.2.1** and substitute with the following:

AMD 546

3.2.1 "The raw materials used shall comply with the provisions of Part **1** and Part **2** of **SLS 457**."

Insert the following new Clause below the text given under Table **2 NOTE**

3.5 Limits for heavy metals

3.5.1 Skin powder for babies shall also comply with the heavy metals limits given in Table **3** when tested in accordance with **ISO /TR 17276.**

TABLE 3 – Heavy metals limits

Sl. No. (1)	**Test** (2)	**Limit** (3)
i)	Lead (as Pb), mg/kg, max.	10
ii)	Arsenic (as As), mg/kg, max.	1.5
iii)	Mercury (as Hg), mg/kg, max.	1
iv)	Cadmium (as Cd), mg/kg, max.	3

5 MARKING

Insert the following new Clause:

"**5.2** The marking and labelling shall also be in accordance with **SLS 1587**."

……

SLS CERTIFICATION MARK

The Sri Lanka Standards Institution is the owner of the registered certification mark shown below. Beneath the mark, the number of the Sri Lanka Standard relevant to the product is indicated. This mark may be used only by those who have obtained permits under the SLS certification marks scheme. The presence of this mark on or in relation to a product conveys the assurance that they have been produced to comply with the requirements of the relevant Sri Lanka Standard under a well designed system of quality control inspection and testing operated by the manufacturer and supervised by the SLSI *which includes surveillance inspection of the factory, testing of both factory and market samples.*

Further particulars of the terms and conditions of the permit may be obtained from the Sri *Lanka Standards Institution, 17, Victoria Place, Elvitigala Mawatha, Colombo 08.*

Printed at SLSI (Printing Unit)

SRI LANKA STANDARDS INSTITUTION

The Sri Lanka Standards Institution (SLSI) is the National Standards Organization of Sri Lanka established under the Sri Lanka Standards Institution Act No. 6 of 1984 which repealed and replaced the Bureau of Ceylon Standards Act No. 38 of 1964.The Institution functions under the Ministry of Technology, Research & Atomic Energy.

The principal objects of the Institution as set out in the Act are to prepare standards and promote their adoption, to provide facilities for examination and testing of products, to operate a Certification Marks Scheme, to certify the quality of products meant for local consumption or exports and to promote standardization and quality control by educational, consultancy and research activity.

The Institution is financed by Government grants, and by the income from the sale of its publications and other services offered for Industry and Business Sector. Financial and Administrative control is vested in a Council appointed in accordance with the provisions of the Act.

The development and formulation of National Standards is carried out by Technical Experts and representatives of other interest groups, assisted by the permanent officers of the Institution. These Technical Committees are appointed under the purview of the sectoral committees which in return are appointed by the Council. The Sectoral committees give the final Technical approval for the Draft National Standards prior to the approval by the Council of the SLSI.

All members of the Technical and Sectoral Committees render their services in an honorary capacity. In this process the Institution endeavours to ensure adequate representation of all view points.

In the International field the Institution represents Sri Lanka in the International Organization for Standardization (ISO), and participates in such fields of Standardization as are of special interest to Sri Lanka.

Printed at the Sri Lanka Standards Institution, 17, Victoria place, Elvitigala Mawatha, Colombo 08.