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Draft Sri Lanka Standard
SPECIFICATION FOR SKIN POWDER FOR CHILDREN
(Third Revision) (DSLS 187 :)

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இவ்வரைவு இலங்கைக் கட்டளையெனக் கருதப்படவோ அன்றிப் பிரயோகிக்கப்படவோ கூடாது
This draft should not be regarded or used as a Sri Lanka Standard.

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Comments to be sent to: SRI LANKA STANDARDS INSTITUTION, 17, VICTORIA PLACE,
ELVITIGALA MAWATHA, COLOMBO 08.

භාඳුන්වීම

මෙම ශ්‍රී ලංකා ප්‍රමිති කෙටුම්පත , ශ්‍රී ලංකා ප්‍රමිති ආයතනය විසින් සකසන ලදුව, සියලුම උදෙසාගේ අංශ වලට තාක්ෂණික විවේචනය සඳහා යවනු ලැබේ.

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XX

Introduction

This Draft Sri Lanka Standard has been prepared by the Sri Lanka Standards Institution and is now being circulated for technical comments to all interested parties.

All comments received will be considered by the SLSI and the draft if necessary, before submission to the Council of the Institution through the relevant Divisional Committee for final approval.

The Institution would appreciate any views on this draft which should be sent before the specified date. It would also be helpful if those who find the draft generally acceptable could kindly notify us accordingly.

All Communications should be addressed to:

The Director General
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Draft Sri Lanka Standard
SPECIFICATION FOR SKIN POWDER FOR CHILDREN
(Third Revision)

DSL 187:

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SRI LANKA

Draft Sri Lanka Standard
SPECIFICATION FOR SKIN POWDER FOR CHILDREN
(Third 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

This Standard was first published in 1973 and subsequently revised in 1982 and 2013. In this third revision, amendment to the second revision has been incorporated. Since starch can also be used as a base ingredient for skin powder for children, two different types depending upon the base ingredient namely, talc and starch were introduced. Requirement of loss on ignition, reference test method for determination of Arsenic, Lead, Cadmium and Mercury and additional marking requirements have been incorporated. More microbial parameters have been introduced.

This product is widely used by children. 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 Standard is subject to the restrictions imposed under the applicable State Legislative requirements.

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 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 publications is gratefully acknowledged:

- | | |
|-------------------|--|
| IS 5339 : 2023 | Skin powder for infants – Specification (Third Revision) |
| IS 14648 : 2005 | Methods of test for microbiological examination of cosmetics and cosmetic raw materials |
| KS EAS 425-2:2023 | Skin powders- Specification- Part 2: Baby powder |
| US 488-2: 2003 | Skin powders- Specification- Part 2: Baby powders |
| (EC) No 1223/2009 | Annex iii List of substances which cosmetic products must not contain except subject to the restrictions laid down |
| (EC) No 1881/2006 | Maximum levels for certain contaminants in foodstuffs, Article 12
Section 2: Mycotoxins |
- 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 for children.

1.2 This Specification does not cover body and face powders for adult use that are covered in **SLS 389** and medicated powders.

1.3 This Standard does not cover products which do not qualify under the criteria for "cosmetics" on evaluation by the local regulatory authority. (See **5.2.12** of **SLS 1587**.)

2 REFERENCES

SLS	102	Rules for rounding off numerical values
SLS	124	Test sieves
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	495	Sampling of cosmetics and toilet preparations
SLS	962: Part 1	Method of test for aflatoxin in foods - Determination of aflatoxin B1, and the total content of aflatoxins B1, B2, G1, and G2 in cereals, nuts and derived products – High performance liquid chromatographic method
SLS	1349	Method for the enumeration and detection of aerobic mesophilic bacteria in cosmetics
SLS	1350	Method for the detection of <i>Pseudomonas aeruginosa</i> in cosmetics
SLS	1351	Method for the detection of <i>Staphylococcus aureus</i> in cosmetics
SLS	1445	Method for the enumeration of yeast and mould in cosmetics
SLS	1488	Method of test for the detection of <i>Candida albicans</i> in cosmetics
SLS	1489	Method of test for the detection of <i>Escherichia coli</i>
SLS	1587	Cosmetics- Packaging and labelling
SLS ISO /TR	17276	Cosmetics- Analytical approach for screening and quantification methods for heavy metals in cosmetics.
ISO /TR	18811	Cosmetics - Guidelines on the stability testing of cosmetic products
SLS ISO	22716	Guidelines on good manufacturing practices for cosmetics
SLS ISO	23674	Cosmetics - analytical methods - direct determination of traces of mercury in cosmetics by thermal decomposition and atomic absorption spectrometry (mercury analyser)

3 TYPES

Based on the basic ingredient, skin powder shall be of following two types;

- i) Type 1- talc as base ingredient (90 per cent, minimum); and

- ii) Type 2- starch as base ingredient (90 per cent, minimum).

4 REQUIREMENTS

4.1 General requirements

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

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

Weigh to the nearest gram, about 20 g of the material into a beaker, and allow a carefully controlled stream of water to overflow. Grit is heavier and will remain in the beaker with some powder. Check the residue in the beaker for the presence of grit by rubbing the residue between the finger and thumb.

4.1.3 The material shall be free from colouring matter when examined visually.

4.1.4 Skin powder for children shall be manufactured by a process adhering to Good Manufacturing Practices (GMP) complying with **SLS ISO 22716**.

4.1.5 It shall be the responsibility of the manufacturers of skin powder for children, to ensure the safety of their formulation before releasing the product for sale. Results of safety assessment/such studies shall be available and shall be produced, whenever required.

4.1.6 The shelf life of skin powders for children shall meet the performance and stability requirements given by the manufacturer based on the in-vitro accelerated test / full test period including shelf life after opening for starch based skin powder. The date of expiry/ best before/ shelf life of the finished product shall be determined using appropriate stability tests as per **ISO/ TR 18811**.

4.1.7 The Corn (maize) starch shall be used for skin powders for children. Supplier shall provide documentary evidence of compliance with the international Standards to the effect that Corn (maize) starch is of food or cosmetic grade. Modified Corn starch shall not be used as raw material.

4.1.8 Evidence shall be provided from a recognized certification body to ensure talc materials are free from asbestos.

4.2 Raw materials

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

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

4.3 Other requirements

4.3.1 Boric acid

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

4.3.2 The product shall also comply with the requirements given in Table 1, when tested in accordance with the relevant methods given in Column 5 of the table.

TABLE 1 – Requirements for skin powder for children

SI No. (1)	Characteristic (2)	Requirement		Method of test (5)
		Type 1 (3)	Type 2 (4)	
i)	Matter insoluble in boiling water, per cent by mass, min.	90.0	-	Appendix C
ii)	Fineness: a) Residue on 75- μ m sieve, per cent by mass, max.	2.0	2.0	} Appendix D
	b) Residue on 150- μ m sieve, per cent by mass, max.	0.1	0.5	
iii)	Moisture and volatile matter, per cent by mass, max.	1.0	15.0	Appendix E
iv)	pH of aqueous suspension	5.5 to 8.0	5.5 to 8.0	Appendix F
v)	Loss on ignition, per cent by mass	9 (max.)	90 (min.)	Appendix G
vi)	Lead (as Pb), mg/kg, max.	10	10	Appendix H
vii)	Arsenic (as As), mg/kg, max.	1.5	1.5	Appendix H
viii)	Cadmium (as Cd), mg/kg, max.	3	3	Appendix H
ix)	Mercury (as Hg), mg/kg, max.	1	1	Appendix J
x)	Aflatoxins			
	a) Aflatoxin B ₁ , μ g/ kg, max.	-	2.0	} SLS 962: Part 1
	b) Total aflatoxin, μ g/ kg, max.	-	4.0	

4.4 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 2 - Microbiological limits

Sl. No. (1)	Organism (2)	Limit (3)	Method of test (4)
i)	Total aerobic mesophilic microorganisms (bacteria, yeast and mould), per g, max.	100 CFU	SLS 1349 and SLS 1445
ii)	<i>Pseudomonas aeruginosa</i> , per g	Absent	SLS 1350
iii)	<i>Staphylococcus aureus</i> , per g	Absent	SLS 1351
iv)	<i>E coli</i> , per g	Absent	SLS 1489
v)	<i>Candida albicans</i> , per g	Absent	SLS 1488

5 PACKAGING

The product shall be packed in suitable, well closed containers to protect the contents during transportation, handling and storage and shall not cause any contamination or react with the contents. Glass shall not be used for containers.

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

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

6 MARKING AND / OR LABELLING

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

- a) Name of the product;
- b) Type of skin powder as “talc based/ starch based”;
- c) Name and address of the manufacturer including country of origin (**NOTE:** Name and address of the manufacturer and the distributor need to be marked on imported products);
- d) Registered trade mark, if any;
- e) Brand name, if any;

- f) Net content of the material, in grams,;
- g) Batch or code or lot identification number;
- h) Date of manufacture;
- j) Best before / shelf life (Including shelf life after opening for starch based skin powder);
- k) List of ingredients;
- l) Instructions for use where necessary;
- m) Special precautions to be observed in use, if required;
- n) Specific warning statement necessary or appropriate to prevent health hazard; and
- o) Warning statement as 'Not recommended for infants (below 1 year).

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

7 SAMPLING

Representative samples of the product for ascertaining conformity to the requirements of this Specification shall be drawn as prescribed in Appendix A.

8 METHODS OF TEST

8.1 Tests shall be carried out as prescribed in Appendices **B** to **J** of this Specification and **SLS 962 Part 1, SLS 1349, SLS 1350, SLS 1351, SLS 1445, SLS 1488 and SLS 1489 and SLS ISO/ TR 17276, SLS ISO 23674**.

8.2 Unless otherwise stated, only reagents of analytical grade and only distilled water shall be used during the analysis.

APPENDIX A COMPLIANCE OF A LOT

The sampling scheme given in Appendix A should be applied where compliance of a lot to the requirements of this Standard is to be assessed based on statistical sampling and inspection.

Where compliance with this Standard is to be assured, appropriate schemes of sampling and inspection shall be adopted based on manufacturer's control systems coupled with type tests and testing procedures.

A.1 LOT

A.1.1 In any consignment, all packages/ containers of the same type and capacity belonging to one batch of manufacture or supply shall constitute a lot.

A.2 GENERAL REQUIREMENTS OF SAMPLING

A.2.1 In drawing, preparing, storing and handling samples, precautions and directions as in Clause 4 of SLS 495 shall be followed.

A.3 SCALE OF SAMPLING

A.3.1 The samples shall be inspected and tested from each lot for ascertaining conformity of the lot to the requirements of this Specification. Representative number of units shall be drawn according to the relevant clauses of SLS 495.

A.3.2 The number of packages/ containers to be selected as the gross sample shall be in accordance with Clause 6.3.1 of SLS 495.

A.3.3 The number of containers to be selected as the composite and individual samples shall be in accordance with Clause 6.4 of SLS 495.

A.4 NUMBER OF TESTS

A.4.1 Each package/ container selected as in A.3.2 shall be inspected for packaging and marking requirements specified in Clause 5 and 6.

A.4.2 Each individual sample selected as in A.3.3 shall be tested for colouring matter and determination of boric acid specified in Clause 4.1.3 and 4.3.1.

A.4.3 Composite sample selected as in A.3.3 shall be tested for freedom from grit and determination of other requirements specified in Clause 4.1.2 and 4.3.2.

A.4.4 Each individual sample selected as in A.3.3 shall be tested for determination of microbiological limits specified in Clause 4.4.

A.5 CRITERIA FOR CONFORMITY

A lot shall be declared as conforming to the requirements of this Specification if the following conditions are satisfied.

A.5.1 Each package/container examined as in A.4.1 shall satisfies the relevant requirements.

A.5.2 Each individual sample examined as in A.4.2 and A.4.4 shall satisfy the relevant requirements.

A.5.3 Composite sample examined as in A.4.3 shall 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. 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 vapors that come off the other bent tube (outlet tube). A green flame is obtained if Boric acid is present.

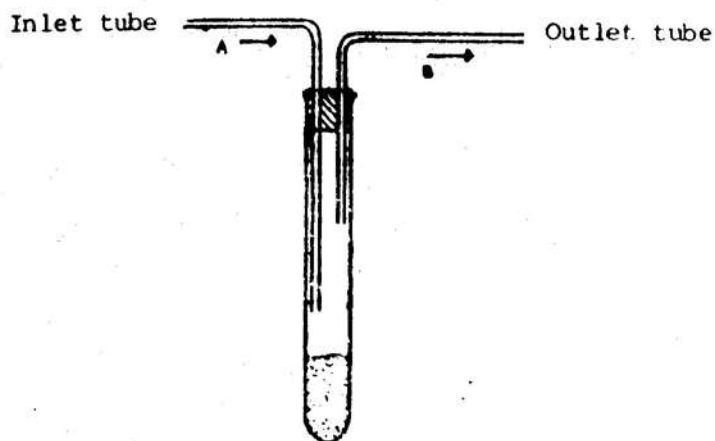


FIGURE 1 – Boiling tube arrangement for detection of Boric acid

APPENDIX C DETERMINATION OF MATTER INSOLUBLE IN BOILING WATER

C.1 REAGENT

Rectified spirit

C.2 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 sintered glass crucible of pore size range between 10 μm to 16 μm . Wash the residue in the beaker with water and transfer completely. Dry the residue in the crucible at $105\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$. 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.3 CALCULATION

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

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 REAGENTS

Denatured spirit, filtered

D.2 PROCEDURE

D.2.1 For type 1

Weigh to the nearest milligram, about 10 g of the material, in a a) 75- μm sieve and 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. 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 carefully transfer the residue into a watch glass and dry it in an oven at $105 \pm 2^\circ\text{C}$. Cool it in a desiccator and weigh. Repeat the heating, cooling and weighing until get the constant weight.

D.2.2 For Type 2

Weigh to the nearest milligram, about 10 g of the material, in a a) 75- μm sieve and b) 150- μm sieve, both sieves conforming to **SLS 124**. After complete transferring of weighed quantity of material on sieve initially gently shake sieve in horizontal direction. Try to pass maximum possible

quantity of the weighed material through sieve by shaking sieve in horizontal direction. Now use clean dry camel hair soft brush or equivalent brush to remove any clogging of sieve or break off lump due to material. With the help of brush try to pass material through sieve by applying gentle pressure on material. After confirming that no more material is passing through the sieve then residue left on the sieve shall be transferred to a tarred oil paper. Note the weight of the residue.

D.3 CALCULATION

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

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 5 g 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 it 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

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

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 ± 0.1 g of the material in a 150-mL beaker and add 90 mL of freshly boiled and cooled distilled water. Stir well to make a thorough suspension. Determine the pH of the suspension at a temperature of $27 \pm 2^\circ\text{C}$, using a pH meter after 5 ± 1 min of making the suspension. In case of a material which does not wet, the pH shall be determined on the filtrate.

APPENDIX G DETERMINATION OF LOSS ON IGNITION

G.1 PROCEDURE

Weigh accurately about 4 g of the material in a crucible. Ignite the material in the dish by keeping in a muffle furnace at 550°C to 600°C for about 1 hour until material becomes grey ash colour. Cool the dish in a desiccator and weigh. Repeat the process of igniting, cooling and weighing at half - hour intervals until get the constant weight.

G.2 CALCULATION

$$\text{Loss on ignition, per cent by mass} = \frac{100 \times (M - m)}{M}$$

where,

m is the mass, in g, of the ignited material; and

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

APPENDIX H DETERMINATION OF LEAD, ARSENIC AND CADMIUM

Two methods have been prescribed for the determination of Lead, Arsenic and Cadmium content. The method prescribed in **H.1** shall be the reference method and shall be carried out in case of any dispute.

H.1 METHOD 1

Lead, Arsenic and Cadmium content shall be determined as prescribed in **SLS ISO 21392**.

H.2 METHOD 2

Lead, Arsenic and Cadmium content shall be determined as prescribed in **SLS ISO/ TR 17276.**'

APPENDIX J DETERMINATION OF MERCURY CONTENT

Two methods have been prescribed for the determination of Mercury content. The method prescribed in **J.1** shall be the reference method and shall be carried out in case of any dispute.

J.1 METHOD 1 – MERCURY ANALYZER METHOD

Mercury content shall be determined as prescribed in **SLS ISO 23674**.

J.2 METHOD 2

Mercury content shall be determined as prescribed in **SLS ISO/ TR 17276**.

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