SRI LANKA STANDARD 1191: 2021

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SPECIFICATION FOR
BABY OIL
(*First Revision*)

SRI LANKA STANDARDS INSTITUTION

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SLS 1191: 2021

Gr. 6

SRI LANKA STANDARDS INSTITUTION
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Colombo 8
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 BABY OIL
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FOREWORD

This Standard was approved by the Sectoral Committee on Chemical 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 2021-07-29

This Standard was first published in 1999. In this First Revision, three types of baby oil categorized with respect to the base oil(s) used as main ingredient have been introduced. The maximum limits specified for acid value and peroxide value have been changed considering three types of baby oils. The requirements for relative density and saponification value were removed as those parameters are related to the characteristics of the oil used. The microbiological limits and heavy metal limits have been updated. A new requirement for stability has been included.

This Standard is subjected to the restrictions imposed under the applicable State Legislative requirements.

For the purpose of deciding whether a particular requirement of this Standard is complied with, the final value, observed or calculated, expressing the results of a test or an analysis, shall be rounded off in accordance with **SLS 102.** The number of significant figures to be retained in the rounded off value shall be the same as that of the specified value in this Standard.

In the preparation of this Standard, the assistance derived from the following publications is gratefully acknowledged:

ISO 17516 Cosmetics – Microbiology – Microbiological limits
IS 7123: 2019 Hair oils- Specification
IS 7299: 2017 Mineral oil for cosmetic industry – Specification
Standards for fragrances published by the International Fragrance Association (IFRA)

1 SCOPE

1.1 This Standard prescribes the requirements, methods of sampling and test for baby oil.

1.2 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

ISO 660	Animal and vegetable fats and oils — Determination of acid value and acidity
ISO 3960	Animal and vegetable fats and oils — Determination of peroxide value — Iodometric (visual) endpoint determination
ISO 15305	Animal and vegetable fats and oils — Determination of Lovibond colour
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 102	Rules for rounding off numerical values
SLS 428	Random sampling methods
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 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	Method for the enumeration of yeast and mould in cosmetics
SLS 1489	Cosmetics - Microbiology - Detection of *Escherichia coli* in cosmetics
SLS 1587	Cosmetics – Packaging and labeling

3 DEFINITION

3.1 cosmetic: Any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth and includes deodorants and perfumes

4 TYPES

Baby oil shall be of the following three types:

4.1 Type **1** based on vegetable oil or blends of vegetable oils;
4.2 Type **2** based on mineral oil; and
4.3 Type **3** based on mixture of vegetable oils (raw/ refined) and mineral oil.

5 REQUIREMENTS

5.1 General requirements

5.1.1 It shall be free from any sedimentation and suspended matter other than intentionally added at 27 ± 2 °C and unpleasant rancid odour.

5.1.2 Baby oil shall be manufactured by a process adhering to Good Manufacturing Practices (GMP) complying with **SLS ISO 22716**.

5.1.3 Baby oil shall not segregate or physically deteriorate during normal conditions of storage and use.

5.1.4 Baby oil shall meet performance and requirements of this specifications for the complete duration of the declared shelf life. The date of expiry / best before / shelf life of the finished product shall be determined using appropriate stability tests as per **ISO/TR 18811**.

5.1.5 It shall be the responsibility of the manufacturers of finished baby oil, to ensure the safety of their formulation before releasing the product for sale. Results of safety assessments/such studies shall be available and shall be produced, whenever required.

5.2 Raw materials

5.2.1 All raw materials used in the manufacture of baby oil shall comply with the provisions of Part **1** and Part **2** of **SLS 457**.

5.2.2 It shall be the responsibility of the manufacturer to provide evidence for compliance of any fragrances used with the standards published by International Fragrance Association.

5.3 Other requirements

Baby oil 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.

TABLE 1 - Requirements for baby oil

Sl. No. (1)	**Characteristic** (2)	**Requirement** (3)	**Method of Test** (4)
i)	Acid value, max. a) Type **1** baby oil and Type **3** baby oil b) Type **2** baby oil	1.0 Pass the test	**ISO 660** Appendix **B**
ii)	Peroxide value, milliequivalents/kg, max.	10.0	**ISO 3960**
iii)	Sulphur and Sulphides (for Type **2** and Type **3**)	Pass the test	Appendix **C**
iv)	Stability	Pass the test	Appendix **D**

5.4 Microbiological limits

Baby oil shall also comply with the microbiological limits given in Table **2** when tested in accordance with the relevant method given in Column (**4)** of the table.

TABLE 2 - Microbiological limits

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

5.5 Limits for heavy metals

Baby oil 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

6 PACKAGING

The baby oil shall be packed in a well sealed container which does not have deleterious effect on the product.

7 LABELING

7.1 The following information shall be legibly and indelibly marked on each container.

a) Name of the product as "Baby oil";
b) Name of oil(s) used, according to the Type given in **4** (see **7.1.1**);
c) Name and address of the manufacturer including country of origin; (Name and address of the manufacturer and the distributor shall be marked on imported baby oils).
d) Registered trade mark or brand name, if any;
e) Batch or lot number;
f) Net content in ml;
g) Date of manufacture;
h) Expiry date/ best before;
j) List of ingredients;
k) Instruction, for use where necessary;
m) Special precautions to be observed in use, if required; and
n) Specific warning statement necessary or appropriate, if any.

7.1.1 Composition percentage of mineral oil as well as vegetable oil shall be declared in Type **3** baby oil.

7.2 A number of such containers, as agreed to between the purchaser and the supplier, shall be packed in cartons. Each carton shall be marked with the following:

a) Name of the product as “Baby oil”;
b) Name and address of the manufacturer including country of origin; (Name and address of the manufacturer and the distributor shall be marked on imported baby oils).
c) Registered trade mark or brand name, if any;
d) Batch or lot identification number/code; and
e) Number of containers.

7.3 The packaging and labeling shall also be in accordance with **SLS 1587.**

8 SAMPLING

The method of drawing representative samples of the product for ascertaining conforming to the requirements of this specification shall be prescribed in Appendix **A.**

9 METHOD OF TEST

Tests shall be carried out as per the methods given in Column (**4)** of Table **1** and Table **2** of this standard and **ISO /TR 17276**.

APPENDIX A
COMPLIANCE OF A LOT

The sampling scheme given in this appendix 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 based on manufacturer's control systems coupled with type testing and check tests or any other procedure, appropriate scheme of sampling and inspection should be adopted.

A.1 LOT

In any consignment all containers of baby oil of the same size belonging to one batch of manufacture or supply shall constitute a lot.

A.2 GENERAL REQUIREMENTS OF SAMPLING

In drawing, preparation, storing and handling samples the following precautions shall be observed:

A.2.1 Samples shall be drawn in an environment not exposed to damp air, dust and soot.

A.2.2 A sampling tube may be used for drawing the material from the containers. It shall be clean and dry when used

A.2.3 The samples shall be placed in clean, dry, glass or any other suitable containers. The sample containers shall be sealed air-tight after filling and shall be marked with the necessary details of sampling.

A.2.4 The material being sampled, the samples, the sampling instrument and the sample containers shall be protected from adventitious contamination.

A.2.5 Samples shall be stored, so that conditions of storage do not affect the quality of the material.

A.2.6 When drawing samples for microbiological examination in addition to the requirements specified in **A.2.1** to **A.2.5** the following precautions shall be observed.

A.2.6.1 Samples shall be drawn under aseptic conditions.

A.2.6.2 The sampling instrument and sample containers shall be sterilized using an appropriate method.

A.3 SCALE OF SAMPLING

A.3.1 Samples shall be tested from each lot for ascertaining the conformity of the material to the requirements of this Standard.

A.3.2 The number of containers to be selected from a lot shall be in accordance with Table **4.**

TABLE 4 - Scale of sampling

Number of containers in the lot (1)	**Number of containers to be selected** (2)
Up to 150	3
151 to 500	5
501 to 1 200	6
1 201 to 3 200	8
3 201 and above	10

A.3.3 If the containers are packed in cartons, at least 05 per cent of the cartons shall be selected from the lot and as far as possible equal number of containers shall be drawn from each carton to form the sample size as given in Column **(2)** of Table **4**.

A.3.4 Containers and cartons shall be selected at random. In order to ensure randomness of selection, random number tables as given in **SLS 428** shall be used.

A.4 COMPOSITE SAMPLE

A.4.1 An equal quantity of material shall be drawn from each container selected as in **A.3.2**. The material so obtained shall be mixed thoroughly to form a composite sample which shall be of sufficient size to carry out the tests specified in **A.5.2**.

A.4.2 A separate composite sample of sufficient size shall be prepared under the conditions specified in **A.2.6** for testing microbiological limits before the preparation of the composite sample for testing other requirements.

A.5 NUMBER OF TESTS

A.5.1 Each container and/or carton selected as in **A.3.2** or **A.3.3** shall be inspected for packaging and marking requirements.

A.5.2 The composite sample prepared as in **A.4.1** shall be tested for the requirements given in **5.3** and **5.4**.

A.5.3 The composite sample prepared as in **A.4.2** shall be tested for the requirements given in **5.5**.

A.6 CRITERIA FOR CONFORMITY

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

A.6.1 Each container and/or carton inspected as in **A.5.1** satisfies the marking and packaging requirements.

A.6.2 Each composite sample tested as in **A.5.2** and **A.5.3** satisfies the relevant requirements.

APPENDIX B
DETERMINATION OF ACID VALUE (FOR TYPE 2 OIL)

B.1. PROCEDURE

B.1.1. Shake 20 g of the material with an equal amount of hot distilled water.

B.1.2 Test the aqueous portion with blue litmus paper.

B.1.3 The material shall be taken as pass the test if the litmus does not change its colour.

APPENDIX C
TEST FOR SULPHUR AND SULPHIDES

C.1. MATERIALS

C.1.1 Copper strips, freshly polished, 10 mm wide

C.2 PROCEDURE

Place in a beaker about 100 g of the sample and keep on a water-bath at a temperature of $95 \pm 2\ ^0$C. Partially immerse the Copper strip in the sample and allow to remain for 10 minutes. It is deemed to pass the test if it shows no tarnishing when the Copper strip is compared with a freshly polished Copper strip.

APPENDIX D
DETERMINATION OF STABILITY

D.1. APPARATUS

D.1.1 Ultra Violet lamp

D.2 PROCEDURE

D.2.1 Take 50 ml of the sample in a clean beaker, place under the ultraviolet lamp and expose it for a total period of 6 h. Measure the colour of the sample either in Lovibond units (see **ISO 15305**).

D.2.2 The sample shall be taken to have passed the test if there is no colour change.

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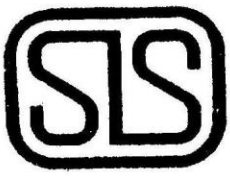
SLS CERTIFICATION MARK

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.*



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SRI LANKA STANDARDS INSTITUTION

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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.

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