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SPECIFICATION FOR BABY SOAP (First Revision)

SRI LANKA STANDARDS INSTITUTION

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SLS 547 : 2009

Gr. 5

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Sri Lanka Standard SPEIFICATION FOR BABY SOAP (First Revision)

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 2009-06-23.

This specification was first published in 1981. This is the First Revision to SLS 547 where the amendments issued to **SLS 547 : 1981** are incorporated into this standard. In this specification, ISO test methods are introduced under methods of test and additional marking requirements have been included.

Baby soap is distinguished from toilet soap by its higher emollient content, finer texture and softness. It also contains a very low free caustic alkali content to ensure dermatological safety for the delicate skin of infants. It may be white or coloured. It may contain antioxidants, chelating agents, colouring matter, medicaments and mild perfume(s).

It is necessary that the raw materials used are such that in the concentrations in which they would be present in the baby soap, after interaction with the other raw materials used in the formulation, are free from any harmful effects. It is the responsibility of the manufacturer to ensure the dermatological safety of the product.

This specification is subject to the restrictions imposed under the Cosmetics, Devices and Drugs Act No.27 of 1980, Consumer Affairs Authority Act No. 09 of 2003 and the Regulations framed there under.

For the purpose of deciding whether a particular requirement of this specification is complied with, the final value, observed or calculated, expressing the results of a test or 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 specification.

In the preparation of this specification, the assistance obtained from the following publication is gratefully acknowledged:

IS 10523 : 1983 Indian Standard Specification for baby toilet soap

1 SCOPE

This specification prescribes the requirements and methods of sampling and test for baby soap.

2 REFERENCES

- ISO 456 Surface active agents Analysis of soaps Determination of free caustic alkali
- ISO 457 Soaps Determination of chloride content Titrimetric method
- ISO 673 Soaps Determination of content of ethanol insoluble matter
- ISO 684 Analysis of soaps Determination of total free alkali
- ISO 685 Analysis of soaps Determination of total alkali content and total fatty matter content
- SLS 102 Rules for rounding off numerical values
- SLS 428 Random sampling methods
- SLS 457 Classification of cosmetic raw materials and adjuncts
 Part 1 : Dyes, colours and pigments recognized as safe
 Part 2 : Raw materials and adjuncts other than dyes, colours and pigments not recognized as safe
- SLS 1316 Code of good manufacturing practices for cosmetic industry

3 REQUIREMENTS

3.1 General Requirement

3.1.1 Baby soap shall be a well saponified and a homogenized product. It shall be free from objectionable odour and shall not develop such odours during storage within the declared shelf life. It shall have good lathering and cleansing properties.

3.1.2 The baby soap shall be manufactured by a process adhering to Good Manufacturing Practices (GMP) complying with **SLS 1316**.

3.1.3 Baby soap 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 on the results of stability.

3.2 Raw materials

3.2.1 The dyes, colourants and pigments used, if any shall comply with the provisions of SLS 457 : Part 1.

3.2.2 The raw materials and adjuncts other than dyes, colourants and pigments shall comply with provisions of **SLS 457 : Part 2**.

3.2.3 Baby soap shall made of a soap base of no objectionable odour to which super-fatting agents shall be added. These shall be non-injurious in use with soap. It shall contain a nut oil (coconut oil, palm kernel oil and palm kernel olein) content of not less than 15 per cent.

3.3 Other Requirements

3.3.1 Baby soap shall be free from grittiness, sandiness or hard lumps before and after abrading, when tested according to the method prescribed in **6.1**.

3.3.2 Baby soap shall also comply with the requirements given in Table 1, when tested in accordance with the relevant methods given in Column (4) and the results re-calculated according to **7.1** for characteristics (ii) to (vi) of the table.

Sl. No.	Characteristic	Requirement	Method of test
(1)	(2)	(3)	(4)
i)	Total fatty matter, per cent by mass, min.	78.0	ISO 685
ii)	Freedom from rosin	to pass the test	Appendix B
iii)	Matter insoluble in ethanol, per cent by mass, max.	1.5	ISO 673
iv)	Free caustic alkali, (as NaOH) per cent by mass, max.	0.04	ISO 456
v)	Total free alkali, (as NaOH) per cent by mass, max.	0.1	ISO 684
vi)	Chlorides, (as NaCl) per cent by mass, max.	1.0	ISO 457

TABLE 1 - Requirements for baby soap

3.3.3 Mass of soap

Net mass of baby soap indicated on the wrapper shall be complied with the recalculated mass of soap as given in **7.2**.

4 PACKAGING AND MARKING

4.1 Each cake or tablet shall be well wrapped and the wrapper shall be marked legibly and indelibly with the following :

a) Name of the product as "Baby Soap";

b) Name and address of the manufacturer including country of origin (**NOTE**: *Name and address of the manufacturer and the distributor should be marked on imported products*);

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c) Registered trade mark, if any ;

- d) Brand name, if any ;
- e) Net mass in gram at declared TFM;

f) Batch or code or lot identification number ; and

g) Date of manufacture and best before / shelf life (**NOTE** : *Date of manufacture may be used as the batch no. /lot identification no. / code no. if one batch is manufactured during the day.*).

4.2 Where more than one cake or tablet is packed into container, each container shall be marked legibly and indelibly with the following :

a) Name of the product as "Baby Soap";

b) Name and address of the manufacturer including country of origin (**NOTE:** *Name and address of the manufacturer and the distributors need to be marked on imported products*);

c) Registered trade mark, if any ;

d) Number of soap tablets / cakes in each container ; and

e) Batch or code or lot identification number (**NOTE** : *Date of manufacture may be used as the batch no. /lot identification no. / code no. if one batch is manufactured during the day.*).

5 SAMPLING

Representative samples of baby soap for carrying out tests shall be drawn as specified in Appendix A.

6 METHODS OF TEST

Tests shall be carried out as prescribed in 6.1 and Column (4) of Table 1.

6.1 A cake or tablet of soap shall be washed in a bowl of water at ambient temperature, keeping the tablet fully immersed during abrading. Washing shall be continued until 2 mm to 3 mm of soap has been removed from the surface. The feel of the surface of soap shall be assessed for the presence of grittiness, sandiness of hard lumps.

6.2 During the analysis, unless otherwise stated, use only reagents of recognized analytical grade and only distilled water or water of equivalent purity.

7 CALCULATION OF RESULTS

7.1 Baby soap is liable to lose moisture on storage. The results for different characteristics obtained by the specified methods of analysis shall therefore be recalculated in relation to the specified minimum total fatty matter by means of equation:

Recalculated result = Actual result x <u>Minimum specified total fatty matter (see Note)</u> Actual total fatty matter

NOTE : *Minimum specified total fatty matter* = 78.0 *as given in* i), *Column* (3) *of Table* 1.

7.1.1 In each of the characteristics (ii) to (vi) of Table **1**, the requirement of the characteristic will be met if the recalculated result obtained as above is within the specified limits.

7.2 The mass of soap shall be recalculated from the equation:

Recalculated mass of soap	=	Actual mass of	Х	Actual total fatty m	natter
before drain		soap	D	eclared total fatty m	natter

NOTE: Attention is drawn to certification marking facilities offered by the Sri Lanka Standards Institution. See the inside back cover of the standard.

APPENDIX A COMPLIANCE OF A LOT

The sampling scheme given in this Appendix shall 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, appropriate schemes of sampling and inspection shall be adopted based on manufacturer's control systems coupled with types, tests and testing procedures.

A.1 LOT

All cakes or tablets of the same brand and size manufactured by the same organization under relatively similar conditions of manufacture shall be grouped together to form a lot.

A.2 SCALE OF SAMPLING

A.2.1 Samples shall be tested from each lot separately fro ascertaining the conformity of the soap to the requirements of this specification.

A.2.2 The number of cakes or tablets to be selected from the lot shall depend on the size of the lot and shall be in accordance with Columns (1) and (2) of Table 2.

No. of cakes of tablets	No. of cakes or tablets	Acceptance number	Sub-sample size	
in the lot	to be selected			
(1)	(2)	(3)	(4)	
Up to 100	05	0	2	
101 to 500	08	0	3	
501 to 1 000	13	1	3	
1 001 to 5 000	20	1	5	
5 001 and above	32	2	5	

TABLE 2 – Scale of sampling

A.2.3 Where the soap is packed in containers, the number of containers to be selected for taking required number of samples shall be half the number given in Column (2) of Table 2. At least 2 cakes or tablets shall be drawn from each container selected to form a sample.

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 assessed based on manufacture's control system coupled with type and check tests or any other procedure appropriate schemes of sampling and inspection should be adopted.

A.2.4 The required number of containers, cakes or tablets shall be chosen at random. A random number table specified in **SLS 428** shall be used in order to ensure randomness of selection.

A.3 NUMBER OF TESTS

A.3.1 The wrapper of each cake or tablet selected as in A.2.2 shall be inspected for marking (see 4.1) requirements.

A.3.2 Each container selected as in A.2.3 shall be inspected for marking (see 4.2) requirements.

A.3.3 The mass of each cake or tablet selected as in **A.2.2** shall be determined and recalculated as given in **7.2** (see **3.3.3**).

A.3.4 A sub-sample of size as in Column (4) of Table 2 shall be drawn and tested for requirements given in 3.3.1.

A.3.5 Remaining cakes or tablets shall be cut into halves along their longer axes. One half of each cake or tablet shall be sliced finely and mixed together to form a composite sample.

A.3.5.1 Tests for the requirements given in 3.3.2 shall be carried out on this composite sample.

A.4 CRITERIA FOR CONFORMITY

A lot shall be considered to be in conformity with the requirements of this specification if the following conditions are satisfied:

A.4.1 Each soap wrapper examined as in A.3.1 satisfies the marking requirements.

A.4.2 Each container examined as in A.3.2 satisfies the marking requirements.

A.4.3 The number of defective cakes or tablets is less than or equal to the corresponding acceptance number given in Column (3) of Table 2.

NOTE : A defective is a cake or tablet of which the recalculated mass determined as in **7.2** is less than the mass indicated on the wrapper.

A.4.4 Each cake or tablet of the sub-sample tested as in A.3.4 satisfies the relevant requirement.

A.4.5 The composite sample tested as in A.3.5.1 satisfies the relevant requirements.

APPENDIX B DETERMINATION OF ROSIN

B.1 REAGENTS

- **B.1.1** Acetic anhydride
- B.1.2 Sulphuric acid, sp. Gr. 1.53

B.2 PROCEDURE

Dissolve 40 g to 50 g of the soap in 400 ml of hot water in a beaker and add gradually an excess of dilute sulphuric acid to this solution.

Heat the beaker and draw off the water underneath the liberated fatty acids which would have formed a clear layer on the top. Wash the fatty acids twice with 500 ml portions of boiling water. Filter the fatty acid through dry paper. Boil a few drops of the fatty acids with 2 ml to 3 ml of acetic anhydride in a dish, allow to cool and add sulphuric acid drop by drop. If rosin is present, the characteristic violet colour is produced which changes to brown.

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.

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SRI LANKA STANDARDS INSTITUTION

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