SRI LANKA STANDARD 742:2021

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SPECIFICATION FOR
SKIN CREAMS AND LOTIONS FOR BABIES
(*SECOND REVISION)*

SRI LANKA STANDARDS INSTITUTION

Sri Lanka Standard
SPECIFICATION FOR SKIN CREAMS AND LOTIONS FOR BABIES
(*Second Revision)*

SLS 742:2021

Gr. 9

SRI LANKA STANDARDS INSTITUTION
17, Victoria Place
Elvitigala Mawatha
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
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FOREWORD

This Sri Lanka 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 1986 and First Revision was issued in 2014. In this Second Revision, the requirement for pH has been changed. The method of test for the determination of peroxide value has been modified. A guideline for skin irritation test has been included.

Skin creams and lotions for babies are emollients and protective products used to soften, relief and prevent chapping of the skin exposed to cold and low humidity.

It is necessary that the raw materials used in skin creams and lotions for babies are in such concentrations that after interaction with other raw materials, the finished product is free from any harmful effect for the user. It should be the responsibility of the manufacturer to ensure the physiological and dermatological safety of this product using appropriate protocols.

This Specification is subject 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 4011 Methods of test for safety evaluation of cosmetics
Standards for fragrances published by the International Fragrance Association (IFRA)

1 SCOPE

1.1 This Standard prescribes the requirements and methods of sampling and test for skin creams and lotions for babies with or without herbs/ herbal extracts.

1.2 Skin gels are not covered by this Standard.

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

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 1488	Cosmetics - Microbiology - Detection of *Candida albicans* in cosmetics
SLS 1489	Cosmetics - Microbiology - Detection of *Escherichia coli* in cosmetics
SLS 1587	Cosmetics – Packaging and labeling

3 DEFINITION

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 REQUIREMENTS

4.1 General requirements

4.1.1 Skin creams and lotions for babies shall be a homogenous emulsion or unctuous mass and shall be free from objectionable odour.

4.1.2 The skin creams and lotions for babies shall be manufactured by a process adhering to Good Manufacturing Practices (GMP) complying with **SLS ISO 22716**.

NOTE: *Guideline for skin irritation test is given in Appendix* **G.**

4.1.3 The skin creams and lotions for babies shall meet performance and requirements of this specification 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**.

4.1.4 It shall be the responsibility of the manufacturers of finished skin creams and lotions for babies, 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.

4.2 Raw materials

4.2.1 All raw materials used in the manufacture of skin creams and lotions for babies shall comply with the provisions of Part **1** and Part **2** of **SLS 457**.

4.2.2 Formaldehyde or substances which release formaldehyde shall not be used.

4.2.3 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.

4.3 Other requirements

4.3.1 The skin creams and lotions for babies 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 skin creams and lotions for babies

Sl. No. (1)	**Characteristic** (2)	**Requirement** (3)	**Method of Test** (4)
i)	pH at 27 ± 2 ^{0}C	4.5 – 7.0	Appendix **B**
ii)	Non-volatile matter at 105 ^{0}C, per cent by mass, min.	15	Appendix **C**
iii)	Water content, per cent by mass, max.	85	Appendix **D**
iv)	Peroxide value, milliequivalents/kg, max.	10.0	Appendix **E**
v)	Thermal stability	To pass the test	Appendix **F**

4.4 Microbiological limits

The skin creams and lotions for babies 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), 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**
v)	*Candida albicans*, per g	Absent	**SLS 1488**

4.5 Limits for heavy metals

The skin creams and lotions for babies shall also comply with the limits for heavy metals given in Table **3** when tested in accordance with **ISO /TR 17276**.

TABLE 3 – Limits for heavy metals

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 PACKAGING AND LABELING

5.1 Packaging

The skin creams and lotions for babies shall be packed in suitable, well closed containers. A number of such containers, as agreed to between the purchaser and the supplier, shall be suitably packed.

5.2 Labeling

5.2.1 The following information shall be legibly and indelibly marked on each container:

a) Name of the product as "Baby cream/ Baby lotion";
b) Name and address of the manufacturer for locally manufactured products;
c) Name and address of the distributor in Sri Lanka / importer including the country of origin; in the case of imported products;
d) Registered trade mark, if any;
e) Brand name, if any;
f) Net content;
g) Batch or code or lot identification number;
h) Date of manufacture;
j) Best before / date of expiry;
k) List of ingredients;
m) Instruction, for use where necessary; and
n) Special precautions to be observed in use, if required; and
o) Specific warning statement necessary or appropriate.

5.2.2 The following information shall be legibly and indelibly marked on each package:

a) Name of the product as "Baby cream/ Baby lotion";
b) Name and address of the manufacturer for locally manufactured products;
c) Name and address of the distributor in Sri Lanka / importer including the country of origin; in the case of imported products;
d) Registered trade mark, if any;
e) Brand name, if any;
f) Number of containers; and
g) Batch or code or lot identification number.

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

6 SAMPLING

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

7 METHODS OF TEST

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

7.2 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 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 schemes of sampling and inspection should be adopted.

A.1 LOT

In any consignment all the containers of the same size containing skin creams and lotions of one batch of manufacture shall constitute a lot.

A.2 SCALE OF SAMPLING

A.2.1 Samples shall be tested from each lot for ascertaining the conformity of the material to the requirements of this Specification.

A.2.2 The number of packages to be selected from a lot shall be in accordance with Table **4**.

TABLE 4 - Scale of sampling

No. of packages in the lot (1)	**No. of packages to be selected** (2)
3 to 50	3
51 to 200	4
201 to 400	5
401 to 650	6
651 and above	7

A.2.3 The packages shall be selected at random. In order to ensure randomness of selection, random number tables as given in **SLS 428** shall be used.

A.3 PREPARATION OF SAMPLE

Two containers shall be drawn from each package selected as in **A.2**. The containers so selected shall be divided into two equal sets, each set having containers from each package selected to draw containers. One set of containers shall constitute individual samples and the contents of the other set shall be mixed to form a composite sample.

A.4 NUMBER OF TESTS

A.4.1 Each package selected as in **A.2** and each container selected as in **A.3** shall be inspected for packaging and labeling requirements.

A.4.2 The individual samples prepared as in **A.3** shall be tested for microbiological limits given in Table **2** of this Specification**.**

A.4.3 The composite sample prepared as in **A.3** shall be tested for the requirements specified in Table **1** and Table **3** of this Specification.

A.5 CONFORMITY TO STANDARD

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

A.5.1 Each package and each container inspected as in **A.4.1** satisfies the relevant requirements.

A.5.2 Each container tested as in **A.4.2** conforms to the microbiological limits.

A.5.3 The test results on the composite samples satisfy the relevant requirements.

APPENDIX B
DETERMINATION OF pH

B.1 APPARATUS

A pH meter, preferably equipped with a glass electrode.

B.2 PROCEDURE

B.2.1 For oil – in - water emulsion creams

Weigh to the nearest 0.1 g, approximately 5 g of the material into a 100 ml beaker. Add 45 ml of water and disperse the cream in it. Determine the pH of the suspension at 27 ± 2 °C using the pH meter.

B.2.2 For water – in – oil emulsion creams

Weigh to the nearest 0.1 g, approximately 10 g of the material and add 90 ml of rectified spirit previously adjusted to pH 6.5 to 7.0. Warm if necessary, to 45 °C and stir thoroughly for 15 min. Filter the alcoholic layer through a filter paper and measure the pH of the filtrate at 27 ± 2 °C using the pH meter.

APPENDIX C
DETERMINATION OF NON-VOLATILE MATTER AT 105 ^{0}C

C.1 PROCEDURE

Weigh, to the nearest 1 mg, approximately 5 g of the material in a tared evaporating dish and heat on a steam-bath until most of the volatile matter has escaped. Continue heating of 105 ± 2 ^{0}C in an oven for 2 hours. Cool in a desiccator and weigh. Repeat heating, cooling and weighing until the difference in mass between two successive weighings does not exceed 5 mg.

$$\text{Non-volatile matter at } 105\ ^0\text{C, per cent by mass} = \frac{(m_2 - m_3)}{(m_1 - m_3)} \times 100$$

where,

m_1 is the mass, in grams, of the dish with the sample before heating;
m_2 is the mass, in grams, of the dish with the sample after heating; and
m_3 is the mass, in grams, of the empty dish.

APPENDIX D
DETERMINATION OF WATER CONTENT

D.1 APPARATUS

The apparatus, shown in Figure **1** consists of the following:

a) Flask, 500 ml capacity, made of heat resistant glass;

b) Trap, the cylindrical portion of the receiving tube is 146 mm to 156 mm in length, graduated to contain a volume of 10 ml and is sub-divided into 0.1 ml divisions; and
c) Condenser, approximately 400 mm in length and the bore diameter of the inner tube is 16 mm to 17 mm. The condenser is connected to the trap as shown in the figure.

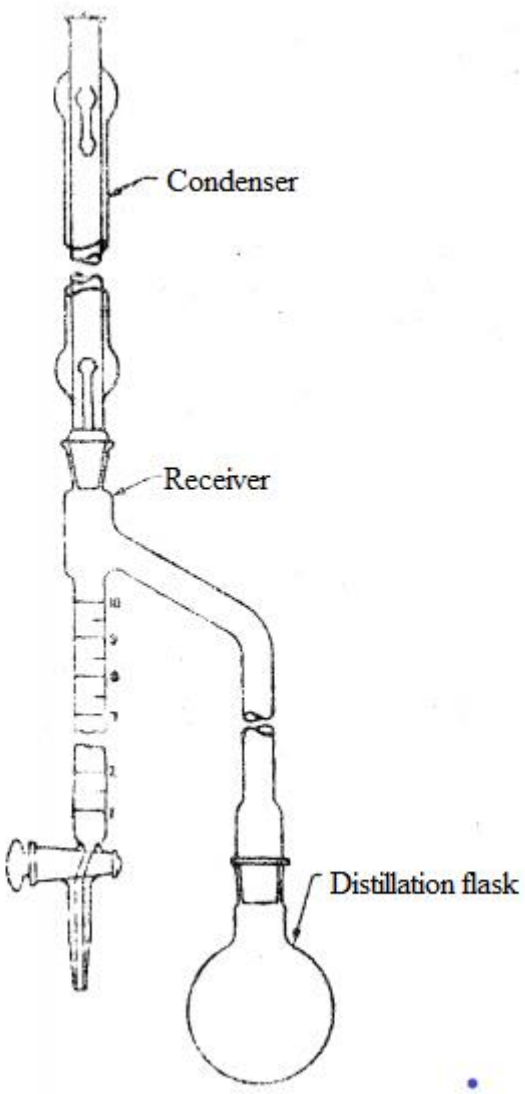

Figure 1- Entrainment distillation of water

D.2 REAGENTS

D.2.1 Toluene, treated with excess water and distilled

D.3 PROCEDURE

Weigh to the nearest 0.1 g approximately 10 g of the material into the flask. Add about 200 ml of Toluene and a few pieces of dry pumice stone. Connect the apparatus and fill the receiving end of the trap with the solvent, poured through the top of the condenser. Heat the flask gently for 15 min, and then the solvent begins to boil, reflux at a rate of 2 drops per second until most of the water has passed. Increase the rate to about 4 drops per second. When all water has apparently distilled, rinse the inside of the condenser tube with solvent while brushing down the tube with a tube brush attached to a copper wire and saturated with the solvent. Continue the distillation for 5 min, then remove the source of heat, and allow the receiving tube to cool to room temperature. If any droplets of water are seen adhering to the wall of the receiving tube, scrub down with a brush consisting of a rubber band wrapped around a Copper wire and dipped with the solvent. When the water and solvent have separated, read the volume of water.

D.4 CALCULATION

Water content, per cent by mass = $\frac{V \times d \times 100}{m}$

where,

V is the volume of water, in ml, at room temperature collected in the receiving tube;
d is the density of water, at room temperature; and
m is the mass, in grams, of the material taken for the test.

APPENDIX E
DETERMINATION OF PEROXIDE VALUE

E.1 PRINCIPLE

E.1.1 The peroxide value is the quantity of those substances in the sample, expressed in milliequivalents of active Oxygen per kilogram of oil, which oxidize Potassium iodide under the conditions described.

E.2 REAGENTS

All reagents and distilled water shall be free from dissolved oxygen.

E.2.1 Chloroform, AR grade, freed from Oxygen by flushing with a current of pure, dry inert gas

E.2.2 Glacial acetic acid, freed from Oxygen by flushing with a current of pure, dry inert gas

E.2.3 Aqueous Potassium iodide solution, fresh, saturated, and free from free iodine and iodates

NOTE:
*Make sure the solution remains saturated as indicated by the presence of undissolved crystals. Store in the dark. Test daily by adding 2 drops of starch solution (***E.2.5***) to* 0.5 m1 *of Potassium iodide solution in 30* ml *of Acetic acid - Chloroform (3 volumes: 2 volumes) solution. If a blue colour is formed which requires more than 1 drop of* 0.01 M *Sodium thiosulphate solution to discharge, discard the iodide solution and prepare a fresh solution.*

E.2.4 Sodium thiosulphate solution 0.005 M, standardized just before use.

E.2.5 Starch solution, Mix 5 g of soluble starch in 30 ml of water, add this mixture to 1 000 ml boiling water and leave boiling for 3 min.

E.2.6 Petroleum ether: Diethyl ether (1:1) solvent mixture

E.2.7 Ethanol, AR grade

E.3 APPARATUS

All equipment used shall be free from reducing or oxidizing substances.

NOTE: *Do not grease ground glass surfaces.*

E.3.1 Flask*s*, of about 500 ml capacity, with ground necks and ground glass stoppers, dried before hand and filled with a pure, dry inert gas (Nitrogen or preferably, Carbon dioxide)

E.3.2 Air condenser

E.3.3 Separatory funnels, 500 ml

E.3.4 Flasks, 250 ml capacity, with ground necks and ground glass stoppers

E.3.5 Measuring cylinders

E.3.6 Evaporating dishes, glass

E.3.7 Filter funnel, glass

E.4 PROCEDURE

E.4.1 Ensure that the sample is taken and stored away from strong sunlight, kept cold and contained in completely filled glass containers, hermetically sealed with ground glass or cork stoppers.

E.4.2 Extraction of oil/fat from test sample

Weigh, around 25 g of cream into a clean, dry flask (**E.3.1**), such that the weighed portion contains approximately 2 g of oil. Add approximately 100 ml of solvent mixture into test portion and swirl gently. Connect the air condenser to flask containing test portion and reflux in heating mantle under low heat for around 45 minutes. Remove the flask from heating block and cool the contents and add 20 ml saturated Sodium chloride solution into the mixture in the flask. Connect the air condenser to the flask containing test portion and reflux in heating mantle under low heat for about 1-1.5 hours.

After cooling transfer all the contents in the flask to a separatory funnel. Rinse the flask twice with distilled water (around 40-50ml) and add these rinsings into the separatory funnel. Stopper the separatory funnel and shake the contents in the funnel, and allow to stand until there is complete separation of the two phases. Add small quantities of Ethanol to eliminate emulsion formation.

After two phases are well separated, remove the lower aqueous layer. Pass the solvent layer in the separatory funnel through glass filter funnel with anhydrous Sodium sulfate layer. Collect the filtered ether layer into an evaporating dish (**E.3.6**).

Kept evaporating dish on a water bath and warm until all ether was evaporated. Dry the oil in the dish in an oven under 40 ± 2 °C for several minutes.

E.4.3 Analysis of peroxide value

Weigh approximately 1.5-2 g of oil into a dry flask (m). Add 10 ml of the Chloroform (**E.2.1**) and dissolve the oil quickly by swirling. Add 15 ml of the Acetic acid (**E.2.2**), then 1 ml of fresh saturated aqueous Potassium iodide solution (**E.2.3**). Immediately stopper the flask (**E.3.1**), shake/stir for about 1 min and leave for exactly 5 minutes away from the light in a cool dark place.

Add about 75 ml of distilled water. Stir vigorously and titrate the liberated iodine in the presence of few drops of the starch solution with the 0.005 M standard volumetric Sodium thiosulphate solution.

Carry out a blank test in parallel with the test sample.

E.5 CALCULATION

$$\text{Peroxide value, milliequivalents per kilogram} = \frac{(V - V_0) \times M \times 1000}{m}$$

where,

V_0 is the volume, in milliliters, of the thiosulphate solution (**E.2.4**) used for the blank;

V is the volume, in milliliters, of the Sodium thiosulphate solution (**E.2.4**) used for the determination;

M is the molarity of the Sodium thiosulphate solution (**E.2.4**) used; and

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

APPENDIX F
TEST FOR THERMAL STABILITY

F.1 APPARATUS

A humidity chamber controlled at 60 per cent to 70 per cent relative humidity and 40 ± 1 °C.

F.2 PROCEDURE

F.2.1 Spread a 20 mm broad, 5 mm thick strip of the material on the internal wall of a beaker. Keep the beaker for 8 hours in the humidity chamber between 60 per cent to 70 per cent relative humidity and 40 ± 1 °C.

F.2.2 The cream shall be considered to have passed the test if no oil separation is observed on removal from the humidity chamber.

APPENDIX G
SKIN IRRITATION TEST

G.1 GENERAL

G.1.1 Raw material purity

The purity of raw materials used in a formulation must be established by physicochemical analysis and specifications established for use, before the products containing them are subjected to safety testing.

G.1.2 Facilities

The testing should be carried out by the manufacturer in-house or in reputed laboratories both national and international, which maintain high standards such as compliance to GLP required for safety testing.

The tests should be carried out by trained personnel under the supervision of toxicologists.

G.2 PRINCIPLE

Irritants are substances that may damage the skin. The damage will depend upon the nature, concentration and duration of exposure. Irritation is manifested as inflammatory responses such as erythema (redness), oedema (swelling), vesiculation and finally to an intense suppurate reaction without the involvement of immune system. The irritation potential of a substance can be assessed in human patch test. This patch test is carried out on human volunteers in the manner given below.

G.3 PROCEDURE

Apply the neat cosmetic product sample as such on the upper arm of human subjects, under occlusive patch for duration of 24 h. In ease of rinse off products, rinse the treated sites with water to remove any residue. However, if the volunteer experiences unbearable discomfort with any of the patches, the volunteer is instructed to remove such patches any time prior to the targeted 24 h contact. Mark such sites with a blue/black marker to facilitate evaluation later. The volunteer is also requested to note down the signs and symptoms of the discomfort and the time of removal of the patch and hand it over to the investigator. Assess the skin reactions subjectively using the Draize scale, given in Table **5**, 24 h after removal of the patches. Follow up the reactions if any, one week later to confirm recovery.

G.3.1 Human subjects

Select 24 healthy adult human subjects, preferably equal number of males and females who do not have any previous history of adverse skin conditions and are not under any medication likely to interfere with the results. Pregnant ladies and breast feeding mothers should be excluded. Explain the test procedure to volunteers and obtain a signed informed consent from each of them.

G.3.2 Test patches for topical treatment

Ideally use ready-made standard test patches (Finn Chambers) measuring about 1 cm diameter. Fix three such test patches on a transparent porous surgical adhesive tape of sufficient length (approximately 14 cm) and breadth, take 0.04 ml of the sample using a micropipette on the patch and apply the patch on the upper arm as mentioned in **G.3**. Alternatively if such patches are not available, use 1 cm diameter discs made out of chromatography paper (Whatman No.3) taken on a slightly bigger polythene sheet having about 0.25 cm hole punched at the centre and fixed on the adhesive tape. Keep about 2.5 cm distance between the two adjacent test patches (filter paper discs).

G.3.3 Positive control

Use Sodium lauryl sulphate, analytical grade, at 3 per cent (w/w) concentration in distilled water as the positive control.

G.4 OBSERVATION AND SCORING

Assess the skin reaction under a constant artificial daylight source, 24 h after the removal of the patches. Score the reactions, namely, erythema (including dryness, scaliness and wrinkles) on a 0-4 point scale and oedema on another 0-4 point scale as per the Draize Scale given in Table **5**.

TABLE 5 – Draize scale for scoring the treatment sites

Sl No.	Score for Erythema/ dryness/wrinkles	Reaction	Score for Oedema	Reaction
(1)	(2)	(3)	(4)	(5)
i)	0	No reaction	0	No reaction
ii)	1	Very slight erythema/ dryness with shiny appearance	1	Very slight oedema
iii)	2	Slight erythema/ dryness/wrinkles	2	Slight oedema
iv)	3	Moderate erythema/ dryness/wrinkles	3	Moderate oedema
v)	4	Severe erythema/ wrinkles/ scales	4	Severe oedema

G.5 RESULT

The combined mean scores and standard deviation of the 24 subjects are calculated:

a) Positive control must give a combined score of greater than 4. If it is less than 4, then the test need to be repeated on another group of newly recruited volunteers.
b) A combined mean score of 2.0/8.0 will mean that product is non-irritant.

c) Usage of cosmetic product with a score up to 4.0/8.0 which is mildly irritating may be reviewed by manufacturer for safety of the formulation.

d) No cosmetic product should be marketed which has irritation score above 4.0/8.0.

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SLS CERTIFICATION MARK

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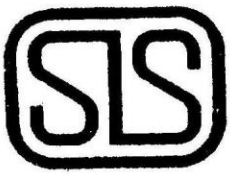

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SRI LANKA STANDARDS INSTITUTION

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