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பொதுசனக் கருத்துரைக்கான கட்டளை வரைவு

DRAFT STANDARD FOR PUBLIC COMMENT

(වෙනස්වීමට ඉඩ ඇත. திருத்தத்திற்குட்படக்கூடியது. Liable to alteration)

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අදහස් එවියයුතු අවසාන දිනය
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Draft Sri Lanka Standard Specification for
Herbal Cosmetics
(DSLS ..... : .....)

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

අදහස් එවිය යුත්තේ : ශ්‍රී ලංකා ප්‍රමිති ආයතනය, 17, වික්ටෝරියා පෙදෙස, ඇල්විටිගල මාවත, කොළඹ 08.

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

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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
Sri Lanka Standards Institution,
17, Victoria Place,
Elvitigala Mawatha,
Colombo 08.

Draft Sri Lanka Standard
GUIDELINES FOR HERBAL COSMETICS

DSLS ……:

Gr.

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

Draft Sri Lanka Standard
GUIDELINES FOR HERBAL COSMETICS

FOREWORD

This Standard was approved by the Sectoral Committee on Chemical and Polymer Technology and was authorized for adoptions and publication as a Sri Lanka Standard by the Council of the Sri Lanka Standards Institution on ……..

Nowadays herbal cosmetic products are growing rapidly and are manufactured using better and convenient modern technology. Herbal preparations are obtained mainly from plant materials by physical processes, fermentation or by other procedures including traditional ones. Therefore, it is necessary to ensure the safety and efficacy of herbal cosmetics, through proper quality controls and safety assessment protocols. This Guideline provides set of recommendations for safe use of botanical raw materials and finished products claimed and/or labelled as 'Herbal Cosmetics'.

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

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

IS 4011 Methods of test for safety evaluation of cosmetics
IS 15735 Herbal cosmetics -General guidelines
ASEAN Botanical Safety Assessment Guidance Document
Standards for fragrances published by the International Fragrance Association (IFRA)

1 SCOPE

1.1 This Standard guideline provides recommendations for products generally claimed and/or labelled as 'Herbal Cosmetics'.

1.2 Cosmetics that uses active materials with plant origin, claiming for traditional medicine systems (eg: Ayurveda, Chinese traditional medicines) are excluded from the Scope of this Standard.

1.3 This Standard guideline does not cover products which do not qualify under the criteria for "cosmetics"(See **5.2.12** of **SLS 1587**.)

2 REFERENCES

ISO 16128	Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products Part 1: Definitions for ingredients Part 2: Criteria for ingredients and products
ISO/TR 18811	Cosmetics — Guidelines on the stability testing of cosmetic products

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	1587	Cosmetics - packaging and labeling
SLS ISO	22716	Good Manufacturing Practices (GMP) for Cosmetics

3 DEFINITIONS

For the purpose of this Standard the following definitions should apply:

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

3.2 herbal cosmetics: Products formulated, using permissible cosmetic ingredients to form the base in which one or more herb(s)/herbal ingredient are included to provide defined cosmetic benefits with a label declaration as 'Herbal Cosmetic'

3.3 herbal ingredients: any part or parts of a plant / herb / shrub / tree, or extracts thereof (includes plant juices, oils, etc.). Algae, Fungi and preparations or extracts thereof.

4 RAW MATERIALS

4.1 Herbal ingredients

4.1.1 Herbal ingredients for manufacturing cosmetic products should be obtained from plants including fungi and algae, and those obtained from these materials by:

a) physical processes (e.g. grinding, drying, distillation, etc.),
b) fermentation reactions occurring in nature and leading to molecules which occur in nature, and
c) other procedures of preparation including traditional ones (e.g. extraction using solvents) without intentional chemical modification.

4.1.2 The 'herb(s)/herbal ingredient(s)' for manufacture of cosmetic products in cosmetic products should include one or more of the following:

a) fresh herbs/juices/pastes/oleoresins made from whole or part(s) of plants,
b) dried powdered herbs,
c) herbal extracts,
d) cold expressed and/or solvent extracted, fixed oils/fats from herbs, and
e) distillates/essential oils of herbs.

4.1.3 Herbal ingredients should be processed in compliance with GAP (Good Agricultural Practices) to minimize contaminations such as micro biological, mycotoxins, pesticides, heavy metals etc., as appropriate.

4.1.4 Herbal ingredients for cosmetics should comply with the provisions of **Part 1** and **Part 2** of **SLS 457**.

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

4.1.6 Appropriate risk assessment process should be carried out to evaluate the safety of all botanical raw materials used in herbal cosmetic product.(See Appendix **A**, Guidance for risk assessment based on the profile of botanical raw material.)

4.2 Quantity/ proportions of herbal ingredients used

4.2.1 If finished herbal cosmetics claimed and/or labelled as "natural", formulators/marketers should have adequate evidence justifying that herbal ingredients are of natural origin.

NOTE: Part **1** *of* **ISO 16128** *provides guidance on technical definitions for natural cosmetic ingredients and products.* Part **2** *of* **ISO 16128** *offers a methodology to calculate a value (natural index) indicating whether cosmetic ingredient meets the definition of a natural ingredient as per* Part **1** *of* **ISO 16128.**

4.2.2 Cosmetics claimed and/or labelled as 'Herbal Cosmetics' should contain sufficient amount of herbal ingredients obtained from a single plant or a mixture of plants that can be qualitatively proven by an analytical technique.

5 FINISHED HERBAL COSMETIC PRODUCT

5.1 Herbal cosmetics should be manufactured by a process adhering to Good Manufacturing Practices (GMP) complying with **SLS ISO 22716.**

5.2 Herbal cosmetics should conform to the requirements prescribed in the relevant Sri Lanka Standards.

NOTE: *Finished herbal cosmetics for which no Sri Lanka Standards exist, formulators/marketers may be responsible to provide evidence for the compliance with any other specifications/ their own standards.*

5.3 Safety Assessment

5.3.1 Herbal finished cosmetics should be formulated in such that, the concentrations of all raw materials (ingredients) ensure freedom from any harmful effect after interaction with each other in the finished product.

5.3.2 Results of safety assessments/such studies should be available and should be produced, whenever required.

5.3.2.1 The following data on product use should be considered for exposure assessment:

a) Type of product (leave-on/ rinse-off/ whole body/ face only/ oral care/ hair etc);
b) Quantity of use and/or maximum level of use;
c) Target population (regions/ adults/ children etc.); and
d) Method of application.

5.3.2.2 Toxicology testing should be considered when the characterization data is incomplete and/or does not provide an adequate profile for the risk assessment of the botanical raw material.

Eg: Skin irritation test for skin, hair and lip products- in vitro testing methods (must consider validation status). (See Appendix **B)**

NOTE : *For cosmetic products accepted with known reference to traditional use, local* tolerance *assessment may be sufficient instead of toxicological testing*.

5.4 Stability

5.4.1 Herbal finished cosmetics should meet performance and requirements of the product for the complete duration of life. The date of expiry / best before / shelf life of the finished product should be determined based on appropriate stability tests as per **ISO/TR 18811**.

5.4.2 The products exposed to pre-decided challenge conditions of storage should also be tested for confirming the claimed cosmetics benefits.

6 PACKAGING AND LABELING

6.1 Packaging

6.1.1 Herbal cosmetic products should be packed in suitable well-closed containers/packages which shall not cause any deterioration to the quality throughout its shelf life.

6.2 Labeling

6.2.1 The information should be legibly and indelibly marked on the containers/ packages in accordance with **SLS 1587.**

APPENDIX A
BOTANICAL RAW MATERIALS CHARACTERIZATION

TABLE 1 - Botanical raw materials characterization

Sl. No (1)	**Parameter** (2)	**Description** (3)
i)	Source of botanical raw material	Botanical name of plant source (preferably Scientific name and /or local name);
		Part(s) of plant used;
ii)	Physical Characterization	General description of the organoleptic of the botanical raw materials (powder, liquid, colour, odour, etc.)
iii)	History of traditional use	Reference to any traditional use
iv)	Method of preparation	Ratio plant/ solvent, solubility of the preparation, residual solvent(s), if used.
		Process of extraction/ concentration/ fractionation, if any
		Comparison to any known traditional method
		Aqueous or solvent (specify solvent), if extracted
v)	Chemical characterization (if applicable)	Testing and analyses of at least 2 batches to confirm consistency
vi)	Contamination	Analysis – (e.g.: microbiological, mycotoxins, pesticides, heavy metals, residual proteins, if applicable.)
		Residual pesticide levels may be substantiated using one of the following: - Total organochlorines, organophosphates, carbamates and pyrethroids levels - EU pharmacopeia – analysis of pesticides listed (preferred) - or, use of solvents or purification methods that would exclude the presence of pesticides

vii)		Botanical raw materials are naturally prone to microbial and heavy metal contamination.

APPENDIX B
SKIN IRRITATION TEST

B.1 GENERAL

B.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.

B.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 (Good Laboratory Practices) required for safety testing.

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

B.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.

B.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 **2**, 24 h after removal of the patches. Follow up the reactions if any, one week later to confirm recovery.

B.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.

B.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 **B.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).

B.3.3 Positive control

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

B.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 **2**.

TABLE 2 – 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

B.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.

……