

DRAFT TANZANIA STANDARD

Herbal cosmetics — General guidelines

TANZANIA BUREAU OF STANDARDS

Foreword

This Draft Tanzania Standard is being prepared by Cosmetics and creameries Technical Committee under the supervision of Chemicals Divisional Standards Committee and it is in accordance with the procedures of the Bureau.

During preparation of this Draft Standard, reference was made from the Indian Standard, IS 15735:2006 *Herbal Cosmetics — General Guidelines*, published by Bureau of Indian Standards

Draft Standard for Comments Only

Introduction

The awareness and need for cosmetics with herbs are on the rise, primarily because consumer believes that these products are safe and free from side effects. There is a need to provide assurance to the consumers that such products generally claimed and/or labelled to as “Herbal Cosmetics” are actually delivering the benefit claims, safe and are of standard quality. There is a need for manufacturers of herbal cosmetics to adopt general guidelines by the formulators and marketers of such cosmetics.

Cosmetics claimed and labelled as ‘Herbal’ could be those products which are formulated using cosmetic base into which herbs are added for providing the claimed product benefits. These guidelines address identified areas, which manufacturers of herbal cosmetics need to comply. Manufacturers who claim their cosmetic product(s) as herbal cosmetic by labeling them with such words on the package need to comply with the general guidelines for herbal cosmetics.

This guideline does not stipulate the composition of the herbal cosmetics. However, it is necessary that the raw materials used in formulation of herbal cosmetics are in concentrations which would be present in the finished cosmetics, after interaction with the other raw materials used in the formulation and are free from any harmful effects.

It is a responsibility of the manufacturers of finished cosmetic, to satisfy that their cosmetic products are dermatologically safe.

Herbal Cosmetics — General guidelines

1. Scope

This Draft Tanzania Standard provide general guidelines for herbal cosmetics.

This guideline does not cover herbal products which therapeutical claims are made.

2. Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

TZS 638 (1-5)/EAS 377 (1-5), *Cosmetics and cosmetic products*

TZS 314, *Cosmetics and toilet products – Methods of sampling*

TZS 774/EAS 346, *Labeling of cosmetic products – General requirements*

ISO 24153, *Random sampling and randomization procedures*

ISO 22716, *Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on good manufacturing practices*

ISO 17516, *Cosmetics — Microbiology — Microbiological limits*

3. Terms and definitions

For the purposes of this document, the terms and definitions given in EAS 846 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses: — ISO Online browsing platform: available at <http://www.iso.org/obp>

herbal cosmetics

cosmetic products formulated using various permissible cosmetic ingredients to form the base in which one or more herb(s)/herbal ingredient are used to provide defined cosmetic benefits with a label declaration as 'herbal cosmetic'.

4. Herb(s)/Herbal Ingredient(s)

The herb(s)/herbal ingredient(s) for use in products covered under these guidelines, shall mean to 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 pressed and/or solvent extracted, fixed oils/ fats from herbs, and
- (e) Distillates/Essential oils of herbs

5. Selections of herb

5.1 Manufacturers of herbal cosmetics should carefully select herbs/herbal ingredients based on their known and reported properties (in literature), properties known in cultural heritage or/and traditional use.

5.2 Manufacturers of herbal cosmetics shall apply adequate care in selecting the forms in which the herbs would be used as an ingredient in the products. They may use an herbal ingredient for new uses than known earlier provided; adequate data should be available on that ingredient and its new uses.

6. Quantity/proportions of herbs used

Manufacturers of herbal cosmetics should have adequate data on the proportion of the herbs or the herbal ingredient(s) for which claims are made, used in the product. In the absence of scientific data, on availability of the quantity of herb in a product to provide the intended cosmetic benefits, such data may be based on the known knowledge, published literature, and reported knowledge in traditional books and/ or scientifically generated data using appropriate in-vitro and/or in-vivo (clinical) methods.

7. Herbal cosmetic benefits claims

The cosmetic benefit claims made for products should be true, factual and based on the data in possession with the formulators/marketers. Manufacturers should not make any cosmetic claim/claims, which are false, exaggerated or misleading. However, in cases where cosmetic benefit claims are linked specifically to herbs/herbal ingredients, manufacturer shall do so, based on adequate and appropriate data in their possession justifying that the particular benefit claim is actually provided by the herb/herbal ingredients.

8. Quality assurance

Testing of herbal ingredients in herbal cosmetics is not easy and practicable due the multicomponent nature of herbal ingredients, manufacturers using herb/herbal ingredients shall adopt necessary quality assurance techniques while deciding to use an herb/herbal ingredient. Adequate raw material quality control shall be adopted each time when a herb/herbal ingredient is used. The use of herb/herbal ingredients shall be recorded and maintained in the relevant 'Master product specification' or 'Bill of materials' or 'Weighment sheet' duly authenticated by the production and quality personnel. Written procedures should be available for it and records shall be maintained for having applied the procedures and their results of compliance.

9. Shelf-life data

Manufacturers may adopt suitable shelf-life study protocols which ensure product integrity throughout the intended shelf-life period through appropriate data. Viable signs of degradation such as fermentation, rancidity, change in colour, and such other parameters as applicable to the product shall be used to prove the stability of the product. Samples of the products exposed to pre-decided challenge conditions of storage shall also be tested for confirming the claimed

cosmetics benefits. Finger printing technique or any other suitable methods would be acceptable while generating shelf-life data.

Stability of herbal ingredient(s) proven in a cosmetics formulation base can be justified and extrapolated to cosmetics with similar base formulation with changes within normal ranges from proven product.

10. Data of safety of the product

Manufacturers should ensure that the finished product is safe. Results of safety data/such studies should be available with the manufacturer and shall be produced whenever required. Manufacturer should suitably inform the consumer on the labels of such products if there are any precautions to be taken while using the products which are known to show safety concerns in specific individual/population.

For microbiological evaluation/examination, reference may be made to ISO 17516, For the purpose of hygienic manufacture of cosmetics, reference may be made to ISO 22716 and for sampling details, reference may be made to TZO 314.

11 Packaging and labelling

11.1 Packaging

Herbal cosmetics should be packaged in suitable well-sealed containers that protect the contents and not cause any contamination or react with the product.

11.2 Labelling

In addition to the labelling requirements given in TZO 774/EAS 346, each package of herbal cosmetics should be legibly and indelibly marked with following information:

- a) Name of product
- b) Herbal ingredient contained