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Herbal cosmetic products— General requirements

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Foreword

Rwanda Standardsarepreparedby Technical Committees and approved by Rwanda Standards Board (RSB) Board of Directors in accordance with the procedures of RSB, in compliance with Annex 3 of the WTO/TBT agreement on the preparation, adoption and application of standards.

The main task of technical committees is to prepare national standards. Final Draft Rwanda Standards adopted by Technical committees are ratified by members of RSB Board of Directors for publication and gazettment as Rwanda Standards.

DRS 333 was prepared by Technical Committee RSB/TC 011, *Cosmetics and related products*.

The assistance derived from the above source is hereby acknowledged with thanks.

This thirdedition cancels and replaces the first edition (RS 333:2018), of which has been technically revised.

Committee membership

The following organizations were represented on the Technical Committee on *Cosmetics and related products* (RSB/TC 011) in the preparation of this standard.

Paragraph of participants

University of Rwanda/College of Science and Technology (UR-CST)

Rwanda Food and Drugs Authority (Rwanda-FDA)

Rwanda Inspectorate, Competition and Consumer protection Authority (RICA)

Rwanda Forensic Laboratory (RFL)

Kipharma

SULFO Industries Rwanda

ORIBUT Company Ltd

Uburanga products

Rwanda Medical Supply (RMS)

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Rwanda Standards Board(RSB) – Secretariat

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Herbal cosmetic products — General requirements

1 Scope

This Draft Rwanda Standard primarily provides general requirements for herbal cosmetic products aimed at ensuring the safety, efficacy and quality of these products for consumers.

This document does not apply to cosmetic products intended to be used for medicinal purpose.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the editioncited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

RS EAS 346, *Labelling of cosmetics — General requirements*

RS EAS 377*(all parts)*, *Cosmetic and cosmetic products*

RS 278, *Cosmetics — Methods of sampling*

3 Terms and definitions

For the purposes of this standard, the following terms and definitions apply.

3.1

cosmetic

any substance or preparationintended to beplaced in contact with the variousexternal parts of the human body (epidermis, hair system, nails, lips and externalgenitalorgans) or with the teeth and the mucous membranes of the oral cavitywith a viewexclusively or mainly to cleaningthem, perfumingthem, changingtheirappearance and/or correcting body odours and/or protectingthem or keepingthem in good condition.

3.2

herbs

crude plant materialsuch as leaves, flowers, fruit, seeds, stems, wood, bark, roots, rhizomes or other plant parts, whichmaybeentire, fragmented or powdered

3.3

herbal material

whole plants or parts of medicinal plants in the crude state. Theyincludeherbs, freshjuices, gums, fixedoils, essential oils, resins and dry powders of herbs.

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3.4

herbal preparations

preparationsobtained by subjectingherbal substances to treatmentssuch as extraction, distillation, expression, fractionation, purification, concentration, fermentation or otherphysical or biological process. Theseincludecommuted or powderedherbal substances, extracts, tinctures,essential oils, expressedjuices and processedexudates of herbalmaterials. Theyalsoincludepreparations made by steeping or heatingherbalmaterials in alcoholbeverages and/or honey, or in othermaterials

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3.5

herbalcosmetics

productsformulatedusingvarious permissible cosmeticingredients and to form the base in which one or more herbs/ herbalingredient are used to providedefinedcosmeticbenefits.

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4 Requirements

4.1 Herb(s)/ Herbal preparation

4.1.1 Theherb(s) herbal preparationused in the products shall include one or more of the following forms:

a) fresh herbs;

b) juices/pastes/oleoresins/gums made from whole or part(s) of plants;

c) herbal extracts;

d) dried powdered herbs;

e) cold expressed and/or solvent extracted, fixed oils/fats from herbs, and

f) distillates/essential oils of herbs.

NOTE: Good Agricultural practices (GAP) are an integral part of quality control

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4.1.2 The proportion of herbal preparations shall be not less than 15% in the product and records shall be kept, and availed when requested.

4.1.3 All the ingredients used shall conform to the requirements in RS EAS 377 (all parts).

4.2 Selection of herbs

4.2.1 Selection of herbal ingredients

4.2.1.1 Selection of herbal ingredients for the standardization of herbal cosmetics products involves several other steps like source and quality of raw materials, good agricultural practices and good manufacturing practices. These practices shall play a pivotal role in guaranteeing the quality and stability of herbal preparations.

4.2.1.2 The quality of a plant product is determined by the prevailing growth conditions and accepted GoodAgricultural Practices (GAP) shall control this. These include:

a) seed selection;

b) growth conditions;

c) fertilizers application;

d) harvesting;

e) drying;

f) and storage.

NOTE In fact, GAP procedures are an integral part of quality control.

4.2.1.3 Using cultivated plants under controlled conditions instead of those collected from the wild could minimize most of these factors. Sometimes, the active principles are destroyed by enzymic processes that continue for long periods from collection to marketing, resulting in a variation of composition. Thus, proper standardization and quality control of both the raw material and the herbal preparations shall be conducted.

4.2.1.4 Formulators shall also apply adequate care in selecting the forms in which the herbs shall be used as an 'ingredient' in the products. Formulators shall use new herbal ingredients provided, adequate datais available on such ingredients

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4.2.2 Quantity/proportions of herbs used

4.2.2.1 Formulators shall have adequate data justifying the proportion of the herbs or the herbal ingredient(s) for which claims are made, used in the product**.**

4.2.2.2 In the absence of scientific data, availability of the quantity of herb in a product to provide the intended cosmetic benefits, such data shall be scientifically generated using appropriate methods and/or based on the known knowledge, published literature, and reported knowledge.

4.3 Herbal cosmetic benefits claims

4.3 Herbal Cosmetic benefits claims

4.3.1 The cosmetic benefit claims made for products shall be true, factual and based on the data as described in 4.2.2.

4.3.2 Factors such as the use of fresh plants, age and part of plant collected, period, time and method of collection, temperature of processing, exposure to light, availability of water, nutrients, drying, packaging, transportation of raw material and storage can greatly affect the quality and hence, the benefit of herbal preparation. Apart from these criteria, factors such as the method of extraction, contamination with microorganisms, heavy metals, and pesticides which can alter the quality, safety, and efficacy of herbal preparations shall be controlled and records shall be kept.

4.3.3 No formulators/marketers shall make any cosmetic benefit claims which are false, exaggerated or misleading. However, in cases where cosmetic benefit claims are linked specifically to herb/herbs ingredients, the formulator/marketer 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.

4.3.4 Formulators/marketers who are incorporating herbal ingredient(s) for variant purposes shall ensure any cosmetic benefit claim made shall be delivered by the product as a whole, even though such benefits are not attributable to any specific herbal ingredient, and such cosmetics shall be governed by the Rwandan regulations. However, no formulator/marketers shall make any cosmetic benefit claim, which is not delivered by the product.

4.4 Physical requirements

4.4.1 The herbal cosmetic product shall have:

a)a characteristic colourof the plant material.

b) an acceptable odour at room temperature when rubbed on the skin.

4.4.2 Foreign organic matter

It is not possible to collect herbal ingredients without small amounts of related parts of plant or other plants. Procedure shall be set in order to limit the percentage of such unwanted plant contaminants.

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4.5 Chemical requirements

4.5.1 Herbal cosmetic formulator shall have chemical evaluation procedure which will cover screening, isolation, identification and purification of the chemical components.

4.5.2 Chemical analysis of the herbal cosmetic shall be done to assess the potency of plant material in terms of its active principles**.**

4.5.3 The chemical screening or tests shall include colour reaction test, which helps to determine the identity of the active substance and possible adulteration.

4.5.4 ***Ash values*****:** incineration of herbal ingredients produces ash which constitutes inorganic matter. Treatment of the ash with hydrochloric acid results in acid-insoluble ash which consists mainly of silica and should be used to act as a measure of soil present. Limits shall be set for ash and acid-insoluble ash of herbal ingredients.

4.6 Contaminants of herbal ingredients

Herbal ingredients of high quality shall be free from insects, animal matter and excreta. It is usually not possible to remove completely all contaminants; hence specifications shall be set in order to limit them:

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4.6.1 Microbial contamination

Aerobic bacteria and fungi are normally present in plant material and may increase due to faulty growing, harvesting, storage or processing. Herbal ingredients, particularly those withhigh starch content, shall be prone to increase microbial growth. Pathogenic organisms includingEnterobacter, Enterococcus, Clostridium, Pseudomonas, Shigella and Streptococcus have been shown tocontaminate herbal ingredients. Limits shall therefore be set for microbial contamination.

4.6.2 Pesticides

Herbal ingredients, particularly those grown as cultivated crops, may be contaminated byDDT (dichlorodiphenyltrichloroethane) or other chlorinated hydrocarbons, organophosphates, carbamates orpolychlorinated biphenyls. Limit tests shall be necessary for acceptable levels of pesticide contamination ofherbal ingredients.

4.6.3 Fumigants

Ethylene oxide, methyl bromide, phosphine or others fumigants should be used to controlpests which contaminate herbal ingredients. Limit tests shall be necessary for acceptable levels of fumigantresidues contamination.

4.6.4 Heavy metals

Lead, cadmium, mercury, thallium and arsenic have been shown to be contaminants ofsome herbal ingredients. Limit tests for such toxic metals are essential for herbal ingredients.

4.6.5 Radioactive contamination

There are many sources of ionization radiation, including radionuclides,occurring in the environment. Hence, a certain degree of exposure is inevitable and limit tests shall benecessary for acceptable levels of radioactive contamination.

4.6.6 Other contaminants

As standards increase for the quality of herbal ingredients and tests to limitother contaminants such as endotoxins and mycotoxins shall be utilized to ensure high quality for herbalcosmetic purposes.

4.7 Quality assurance

4.7.1 It is recognized that testing of herbal ingredients in herbal cosmetics is not easy and practicable due the multi-component nature of herbal ingredients. Formulators 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 an herb/herbal ingredient is used.

4.7.2 Use of herb/herbal ingredients shall be done through ‘Certification by addition’ during manufacturing and such certification documentation shall be recorded and maintained in the relevant ‘Master product ‘specification’ duly authenticated by the production and quality personnel. Written procedures shall be available for it and records shall be maintained for having applied the procedures and their results of compliance

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4.8 Shelf-life data

4.8.1 Formulators may adopt suitable shelf-life study protocols which ensure product integrity throughout the intended shelf-life period through appropriate data. Visible 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.

4.8.2 Samples of the products exposed to pre-decided challenge conditions of storage shall also be testedfor confirming the claimed cosmetics benefits. Finger printing technique or any other suitable methods wouldbe acceptable while generating shelf-life data.

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

4.9 Safety data

4.9.1 Formulators shall ensure that the finished product is safe. Results of safety data or such studies shall be available with the formulators/marketers and shall be produced, whenever required.

4.9.2 Formulators/marketers shall suitably inform the consumer if there are any precautions to be taken while using the products, which are known to show safety concerns in specific individual/population on the labels of such products.

5 Packaging

Herbal cosmetics shall be packaged in containers that shall protect the contents, effectively screen the content from UV light when stored and shall not cause any contamination or react with the product.

6 Labelling

The containers shall be securely closed and in addition to the labelling requirements of RS EAS 346, the following information shall be indelibly and legibly marked on the container:

a) product name that is “Herbal cosmetic”;

b) net contents;

c) name and physical address of the manufacturer and trade mark if any;

d) list of ingredients;

e) batch number in code or otherwise;

f) the date of manufacture in the form “mm/yyyy”;

g) best before date in the form “mm/yyyy”;

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h) storage conditions; and

i) country of origin.

j) storage conditions

7 Sampling

The samplingof herbal cosmetic products shall be done in accordance with RS 278.

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Bibliography

[1] RS 333:2018, *Herbal cosmetic products- drawings— General requirements*

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