



**RWANDA
STANDARD**

**DRS
361**

Second edition

2023-mm-dd

Herbal jelly — Specification

ICS 71.100.70

Reference number

DRS 361: 2023

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Foreword

Rwanda Standards are prepared by 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.

DRS361 was prepared by Technical Committee RSB/TC 011, *Cosmetic and related products*.

This second edition cancels and replaces the first edition (RS 361:2018), of which has been technically revised.

Committee membership

The following organizations were represented on the Technical Committee on *Cosmetic 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)

Rwanda Standards Board(RSB) – Secretariat

Herbal jelly — Specification

1 Scope

This Draft Rwanda Standard specifies the requirements, sampling and test methods for herbal petroleum jelly.

It does not apply to 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 edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

RS333, *Herbal cosmetics products – General requirements*

RS EAS 342, *Pomades and solid brilliantine – Specification*

RS ISO 18664, *Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine*

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

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

RS EAS 847-6, *Cosmetics — Analytical methods — Part 6: Determination of melting point*

RS EAS 847-22, *Cosmetics — Analytical methods — Part 22: Determination of sulphur and sulphides in oils*

RS EAS 847-13, *Cosmetics — Analytical methods — Part 13: Determination of rancidity*

RS EAS 847-18, *Cosmetics — Analytical methods — Part 18: Determination of thermal stability*

RS EAS 847-16, *Cosmetics — Analytical methods — Part 16: Determination of lead, mercury and arsenic content*

RS ISO 18416, *Cosmetics — Microbiology — Detection of *Candida albicans**

RS ISO 21149, *Cosmetics --Microbiology --Enumeration and detection of aerobic mesophilic bacteria*

ISO 22717, *Cosmetics — Microbiology — Detection of *Pseudomonas aeruginosa**

ISO 22718, *Cosmetics — Microbiology — Detection of *Staphylococcus aureus**

RS 278, *Cosmetics – Methods of sampling*

RS EAS 123, *Distilled water - Specification*

ASTM D217 – 10, *Standard Test Methods for Cone Penetration of Lubricating Grease*

3 Terms and definitions

For the purposes of this standard, the terms and definitions given in RS 333 apply.

3.1

herbal petroleum jelly

petroleum jelly formulated using various permissible ingredients and to form the base in which one or more herb(s)/ herbal ingredient(s) are used to provide defined product benefits.

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3.2

petroleum jelly

mixture of mineral oils and waxes, which form a semi solid jelly-like substance

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4 Requirements

4.1 General requirements

4.1.1 To ensure the quality of the product and the well-being of the consumer, herbal petroleum jelly shall conform to requirements specified in RS 333.

4.1.2 The product shall not contain less than 2 % of herbal content. The manufacturer should set the maximum limit of herbal content based on scientific researches and according to the type of herbs used in formulation.

4.1.3 All ingredients used shall comply with the requirements in RS EAS 377 (all parts)

4.2 Physical requirements

4.2.1 Solubility

Herbal jelly shall be insoluble in water and ethanol (96 %), but soluble in ether and chloroform. In cosmetic spirit (boiling range 40 °C – 60 °C) the solution sometimes shows a slight opalescence.

4.2.2 Colour

The colour of herbal petroleum jelly shall be characteristic of plant used.

4.2.3 Odour

The odour of the product shall not be objectionable when rubbed on the skin.

4.3 Specific requirements

4.3.1 Herbal petroleum jelly shall comply with the specific requirements given in Table 1 when tested in accordance with the test methods specified therein.

Table 1— Specific requirements for herbal petroleum jelly

S/N	Characteristics	Requirements	Test method
i.	Melting point, °C	45-60	RS EAS 847-6
ii.	Sulphated ash, % by mass, max	0.1	Annex A
iii.	Sulphur and sulphides	To pass test	RS EAS 847-22
iv.	Cone penetration value at 25°C, 1/10mm in checking for consistency and hardness of jellies	100-275	ASTM-D 217
v.	Test for rancidity	shall be free from rancidity	RS EAS 847-13
vi.	Bleed number	5-15	Annex B
vii.	Stability	To pass test	RS EAS 847-18

4.3.2 Heavy metals contaminants

Herbal petroleum jelly shall comply with the limits for heavy metal contaminants in Table 1 when tested in accordance with the test methods specified therein.

Table 2— Limits of heavy metals contaminants for herbal petroleum jelly

S/N	Characteristics	Requirements mg/kg, max	Test method
i.	Lead	10	RS EAS 847-16
ii.	Arsenic	2	
iii.	Mercury	2	
NOTE The total amount of heavy metals as lead, mercury and arsenic, in combination, in the finished product should not exceed 10 mg/kg.			

4.3.3 Microbiological limits

Herbal petroleum jelly shall comply with the microbiological limits for given in Table 1 when tested in accordance with the test methods specified therein.

Table 3— Microbiological limits for herbal petroleum jelly

S/N	Micro-organisms	Limits, max. (CFU/g)	Test method
i.	Total viable count aerobic mesophilic microorganisms	100 in 0.5 g ⁽¹⁾	RS ISO 21149
		100 in 0.5 g ⁽²⁾	
ii.	<i>Pseudomonas aeruginosa</i> ⁽³⁾	Not detectable	ISO 22127
iii.	<i>Staphylococcus aureus</i> ⁽³⁾	Not detectable	ISO 22718
iv.	<i>Candida albicans</i> ⁽³⁾	Not detectable	ISO 18416

(1), (2) For products specifically intended for children under 3 years, eye area and mucous membranes for other products
(3) For *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans*, the limits shall not be detectable in 0.5 g for products specifically intended for children under 3 years, eye area and mucous membranes and in 0.1 g for other products

5 Packaging

Herbal petroleum jelly shall be packaged in suitable well-sealed containers that 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

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 jelly"; and
- b) percentage of herbal preparations used.
- c) storage conditions

7 Sampling

The sampling of the herbal petroleum jelly shall be done in accordance with RS 278.

Annex A (normative)

Determination of sulphated ash

A.1 Reagents

Dilute sulphuric acid, approximately 5 N

A.2 Procedure

Heat a porcelain or silica dish of 50 mL to 100 mL capacity to redness; cool in a desiccator and weigh. Place about 20 g of the sample, accurately weighed, in the dish. Heat the dish gently by means of a Bunsen burner until the oil can be ignited at the surface. Remove the burner and allow the oil to burn completely, taking care that all the free carbon on the sides of the dish is completely burnt. Heat the residue with a strong flame or in a muffle furnace until all the carbonaceous matter has disappeared. Cool the dish; add a few drops of dilute sulphuric acid; heat gently to drive off the acid and then heat strongly. Cool the dish again in the desiccator and weigh it. Repeat the heating, cooling and weighing until constant mass is obtained.

A.3 Calculation

The sulphated ash content shall be calculated as follows:

$$\text{Sulphated ash, \% by mass} = \frac{M_2 - M_1}{M} \times 100$$

Where

M_1 is the mass in g of the residue, and

M_2 is the mass in g of the sample taken for the test.

Annex B (normative)

Bleed number

Procedure

Heat the sample to 95 °C. Then allow to cool to 100 °C above its melting point. Dip a glass tube (or internal diameter 4 mm and wall thickness 1 mm) into the sample so that when it is removed with the upper end closed with a finger, it contains approximately 25 mm column of molten sample. From approximately 12 mm above the filter paper (Whatman No. 1 or equivalent), allow 5 evenly spaced drops of the sample to fall separately on the paper. The droplets should have a diameter of 6 mm - 8 mm. When the droplets solidify, place the paper on a watch glass and insert in an oven kept at 30 °C for 24 h. After 24 h, determine the diameter of each droplet plus the oil ring which surrounds it. Subtract the diameter of the droplet from the oil ring and record the result in mm. Calculate the average of these result in millimetres.

Bibliography

RS 361:2018, *Herbal petroleum jelly — Specification*

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