DRAFT UGANDA STANDARD

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Baby oils — Specification



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Foreword

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The work of preparing Uganda Standards is carried out through Technical Committees. A Technical Committee is established to deliberate on standards in a given field or area and consists of key stakeholders including government, academia, consumer groups, private sector and other interested parties.

Draft Uganda Standards adopted by the Technical Committee are widely circulated to stakeholders and the general public for comments. The committee reviews the comments before recommending the draft standards for approval and declaration as Uganda Standards by the National Standards Council.

The committee responsible for this document is Technical Committee UNBS/TC 5, Chemicals and Environment products.

Baby oils — Specification

1 Scope

This draft Uganda standard specifies requirements, sampling and test methods for baby oils intended for use on the babies.

Products for which therapeutic claims are made are not covered by this standard. Such products shall be registered with the Ministry of Health.

2 Normative references

The following referenced documents 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.

FDEAS 846, Glossary of terms relating to the cosmetic industry

FDEAS 847- 2: Oils for cosmetic industry — Methods of test — Part 2: Determination of Moisture Content

FDEAS 847-7, Oils for cosmetic industry — Methods of test — Part 7: Determination of specific gravity

FDEAS 847- 13: Cosmetics — Analytical methods — Part 13: Determination of rancidity

FDEAS 847-16, Oils for cosmetic industry — Methods of test — Part 16: Determination of Heavy metal Content

FDEAS 847-18, Cosmetics — Analytical methods — Part 18: Determination of thermal stability

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

FDUS ISO 18416, Cosmetics — Microbiology — Detection of candida albicans

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

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

US EAS 346, Labelling of cosmetics — General requirements

US EAS 377-1, Cosmetics and cosmetic products — Part 1: List of substances prohibited in cosmetic products

US EAS 377-2, Cosmetics and cosmetic products — Part 2: List of substances which cosmetic products must not contain except subject to the restrictions laid down

US EAS 377-3, Cosmetics and cosmetic products — Part 3: List of colorants allowed in cosmetic products

US EAS 377-4, Cosmetics and cosmetic products — Part 4: List of preservatives allowed in cosmetic products

US EAS 377-5, Cosmetics and cosmetic products — Part 5: Use of UV filters in cosmetic products

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

3.1

acid value

number of milligrams of potassium hydroxide (KOH) required to neutralize 1 g of a sample under specified test conditions.

3.2

peroxide value

quantity of those substances in the sample, expressed in terms of active oxygen, that oxidize potassium iodide under the specified conditions.

3.3

rancidity

decomposition of fats or oils by oxidation or hydrolysis

4 Requirements

4.1 Types

The baby oil shall be one of the following types;

- a) type 1 —Based on refined vegetable oil.
- b) type 2—Based on mineral oil.
- c) type 3—Based on a mixture of mineral oils and refined vegetable oils.

4.2 Description

When examined visually, the product shall be a clear oily liquid, free from sediments, suspended matter and separated water. It shall be insoluble in water.

4.3 Odour

The oil shall not have any objectionable odour.

4.4 Raw materials

- 4.4.1 All raw materials used shall conform to all Parts of US EAS 377.
- 4.4.2 The perfume used shall be of refined cosmetic grade.

4.5 Weights and measures

The fill and volume of the material shall comply with the requirements of the Weights and Measures Act.

4.6 Performance

The product shall possess lubricity and spreadability so that on application to areas of the body, it shall leave a protective film.

4.7 quality requirements

The oil shall also conform to the requirements specified in Table1

Table 1 — quality requirements for baby oils

Characteristic	Requirement	Test method
Moisture content, % m/m, max.	0.5	FDEAS 847- 2
Acid value, max	1.0	FDEAS 847- 4
Specific gravity,25°C	0.800 -0.960	FDEAS 847-7
Rancidity	shall be free from rancidity	FDEAS 847- 13
Thermal stability	To pass test	FDEAS 847-18
Sulphur and sulphides	To pass test	FDEAS 847-22
Peroxide value, mg/1 000 g, max	7.5	Annex A
Total viable count for aerobic mesophyllic micro-organisms per g, max.	100	Annex B
Pseudomonas aeruginosa	Not detectable in 0.5 g of cosmetic product	FDUS ISO 22717
Staphylococcus aureus		FDUS ISO 22718
Candida albicans		FDUS ISO 18416
Heavy metals, ppm , Max	Lead – 10	
	Arsenic – 1	FDEAS 847-16
Call	Mercury-1	

5 packing and labelling

5.1 Packing

The product shall be packed in suitable containers that are securely closed, are impervious to the product or shall not be corroded by the product, and shall be sufficiently strong to prevent contamination of the product arising from the ordinary risks of transportation, handling and storage

5.2 Labelling

In addition to the labelling requirements outlined in US EAS 346, the package shall be legibly marked with the following information:

- a) manufacturer's name and physical address;
- b) product name, "Baby oil";
- c) net mass of the material when packed;
- d) batch number;
- e) instructions for use;

- f) ingredients;
- g) country of origin;
- h) date of manufacture and expiry;
- i) storage conditions; and
- j) Precaution/warning.

6 Sampling

Random samples of the product shall be drawn for test in accordance with FDUS ISO 24153 from the market, factory or elsewhere.

Annex A

(normative)

Determination of peroxide value

A.1 Principle

The sample is treated in solution with a mixture of acetic acid and a suitable organic solvent and then with a solution of potassium iodide. The liberated iodine is titrated with a standard solution of sodium thiosulfate

A.2 Reagents

- A.2.1 Glacial acetic acid
- A.2.2 Chloroform
- A.2.3 Potassium iodide solution

Saturated, freshly prepared

A.2.4 Standard sodium thiosulphate solution

0.01 N freshly standardized

A.2.5 Starch indicator solution

Mix 5 g of starch and 0.01 g mercuric iodide with 30 ml of cold water and slowly pour it while stirring into one litre of boiling water. Boil for three minutes. Allow to cool and decant off the supernatant clear liquid.

A.3 Procedure

- A.3.1 Weigh accurately about 5 g of the sample in a 250 ml glass stoppered conical flask and dissolve by shaking in 30 ml of a mixed solvent containing 3 parts by volume of glacial acetic acid and 2 parts by volume of chloroform. Add 0.5 ml of saturated potassium iodide solution, allow the solution to stand for exactly one minute with occasional shaking, then add 30 ml of water and titrate with standard sodium thiosulphate solution.
- A.3.2 Add the thiosulphate solution until the colour of the titrated solution becomes light yellow. Then add 1 ml of starch indicator and continue the titration until the disappearance of the blue colour.
- A.3.3 Carry out a blank determination without using the sample.

A.4 Calculation

Peroxide Value, mg/1000g =
$$\frac{1000(V1-V2)N}{M}$$

Where,

V₁= volume of standard sodium thiosulphate solution required with the sample,

 V_2 = volume of standard sodium thiosulphate solution required with the blank,

N = Normality of standard sodium thiosulphate solution and

M =mass of the sample in grams taken for the test.

Annex B (normative) Determination of total viable count

B.1 Outline of the method

The test consists of plating a known dilution of the sample or any digest agar medium (soya bean casein is recommended) suitable for the total count of bacteria and fungi after incubating them for a specified period to permit the development of visual colonies.

IMPORTANT Take precaution in ascertaining that only fresh samples, from carefully sealed containers that had not been opened before, are used for this test. This is very necessary for getting accurate results.

B.2 Apparatus

- B.2.1 Tubes, of resistant glass, provided with closely fitting metal caps
- **B.2.2** Autoclaves, of sufficient size. They shall keep uniform temperature within the chamber up to and including the sterilizing temperature of 122 °C. They shall be equipped with an accurate thermometer, located so as to register the minimum temperature within the sterilizing chamber, a pressure gauge and properly adjusted safety valves.
- B.2.3 Petri dishes, of 100 mm diameter and 15 mm depth. The bottom of the dishes shall be free from bubbles and scratches and shall be flat so that the medium is of uniform thickness throughout the plate.
- B.2.4 Colony counter, an approved counting aid, such as Quebec colony counter. If such a counter is not available, counting may be done with a lens giving a magnification of 1.5 diameter. In order to ensure uniformity of conditions during counting, illumination equivalent to that provided by Quebec colony counter shall be employed.
- **B.2.5** Balance
- B.2.6 pH meter
- **B.2.7 Water bath**
- **B.3 Medial buffer**

B.3.1 Soya bean casein digest agar medium

Dissolve 15 g of pancreatic digest of casein 5 g of papaic digest of soya bean meal, and 5 g of sodium chloride in 100 ml of distilled water contained in a 2-litre beaker by heating in a water bath. Add 15 g of powdered agar and continue boiling until the agar is completely digested. Adjust the pH to 7.5 with sodium hydroxide solution. Distribute in 20-ml quantities, close the tubes with metal caps and autoclave at 123 °C for 20 min. After autoclaving, store the tubes in a cool place and use them within three weeks.

B.3.2 Stock solution pH 7.2 phosphate buffer

Dissolve 34 g of monobasic potassium phosphate in about 100 mL of water contained in a 500-ml volumetric flask. Adjust the pH 7.2 ± 0.1 by the addition of 4 % sodium hydroxide solution. Add water to volume and mix. Sterilize at 122 °C for 20 min. Store under refrigeration.

B.3.3 Dilute phosphate buffer solution pH 7.2

Dilute 1 ml of stock solution with distilled water in the ratio of 1:800. Fill 50 ml in each of the conical flask of 100 ml capacity. Plug the flasks with cotton and sterilize at 122 °C for 20 min.

B.4 Sterilization of apparatus

B.4.1 Tubes

These shall be sterilized in the autoclave at 122 °C temperature and 1.05 kg/cm₂ pressure for 20 min or in a hot oven at 160 °C for one hour.

B.4.2 Petri dishes

These shall be packed in drums and autoclaved at 122 °C temperature and 1.05 kg/cm₂ pressure for 20 min or individually wrapped in Kraft paper and sterilized in a hot air oven at 160 °C for one hour.

B.4.3 Pipettes

These shall be placed in pipette cones (copper, stainless steel or aluminium) after plugging the breeder end with cotton and sterilized in the autoclave at 122 °C temperature and 1.05 kg/cm₂ pressure for 20 min, or at 160 °C for one hour in the air oven.

B.5 Procedure

- B.5.1 Melt a sufficient number of soya bean casein digest agar medium tube in a hot water bath and transfer while hot in to a constant temperature water bath maintained at 48 $^{\circ}$ C \pm 20 $^{\circ}$ C.
- B.5.2 Weigh and transfer aseptically 1 g of the sample to a conical flask containing sterile 50 ml or any suitable dilution factors of dilute phosphate buffer at pH 7.2. Shake well. Pipette out in 1 ml portions into three sterile petri dishes. Pour melted and cooled (at 45 °C) soya bean casein digest agar medium over it, and rotate to mix thoroughly. Incubate the plate at 32 °C for 72 h in an inverted position.

B.6 Expression of results

Get the average number of colonies on soya bean casein digest agar medium plates and determine the number of micro-organisms per gram of the sample. If no colony is recovered from any of the plates it can be stated as less than 50 micro-organisms per gram

Bibliography

- [1] FDEAS 836: 2015 Sesame (simsim) oil for cosmetic industry specification
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- [4] FDEAS 839: 2015, Ground nuts (peanut) oil for cosmetic industry specification
- [5] Is 7299:1974, mineral oils for cosmetics.
- [6] IS 11376:1985, Specification for sesame oil for cosmetic industry
- [7] IS 11486:1985, Specification for castor oil for cosmetic industry
- [8] JS 250-1:2000, Baby skin care products. Part 1: General requirements
- [9] JS 250-4:2000, Baby skin care products. Part 4: baby oils

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