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DRAFT EAST AFRICAN STANDARD

Petroleum jelly for cosmetic use — Specification

EAST AFRICAN COMMUNITY

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East African Community
P.O. Box 1096,
Arusha
Tanzania
Tel: + 255 27 2162100
Fax: + 255 27 2162190
E-mail: eac@eachq.org
Web: www.eac-quality.net

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Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

The Community has established an East African Standards Committee (EASC) mandated to develop and issue East African Standards (EAS). The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the public and private sector organizations in the community.

East African Standards are developed through Technical Committees that are representative of key stakeholders including government, academia, consumer groups, private sector and other interested parties. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the Principles and procedures for development of East African Standards.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

The committee responsible for this document is Technical Committee EASC/TC 71, *Cosmetics and related products*.

Attention is drawn to the possibility that some of the elements of this document may be subject of patent rights. EAC shall not be held responsible for identifying any or all such patent rights.

This second edition cancels and replaces the first edition (EAS 126:1999), which has been technically revised.

Petroleum jelly for cosmetic use — Specification

1 Scope

This Draft East African Standard specifies requirements, sampling and test methods for petroleum jelly for cosmetic use.

This standard does not cover petroleum jelly for industrial use.

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.

ASTM D217-19b, *Standard test methods for cone penetration of lubricating grease*

EAS 123, *Distilled water — Specification*

EAS 346, *Labelling of cosmetics — General requirements*

EAS 377 (all parts), *Cosmetics and cosmetic products*

EAS 846, *Glossary of terms relating to the cosmetic industry*

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

ISO 2137, *Petroleum products and lubricants — Determination of cone penetration of lubricating greases and petrolatum*

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

ISO 24153, *Random sampling and randomization procedures*

3 Terms and definitions

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

petroleum jelly

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

3.2

pure petroleum jelly

petroleum jelly without any additives

3.3

perfumed petroleum jelly

petroleum jelly containing a fragrance

3.4

herbal Petroleum jelly

petroleum jelly containing herbal extracts/powder

3.5

foreign matter

any extraneous matter other than petroleum jelly comprising of “inorganic matter” which includes metallic pieces, dust, sand, gravel, stones, dirt, pebbles, lumps or earth, clay, mud and animal filth, etc; and “organic matter” consisting of husks, straws

4 Requirements

4.1 General requirements

4.1.1 All the ingredients used shall comply with the requirements given in EAS 377(all parts).

4.1.2 Petroleum jelly shall:

- a) be insoluble in water and ethanol (96 %), but soluble in diethyl ether, dichloromethane, benzene, carbon disulphide, hexane and chloroform;
- b) not be of objectionable odour at room temperature when rubbed on the skin; and
- c) not bleed under normal conditions of storage.
- d) be free from foreign matter.

4.1.3 Petroleum jelly may contain additives. .

4.2 Specific requirements

Petroleum jelly shall comply with the requirements given in Table 1 when tested in accordance with the test methods specified therein.

Table 1 — Specific requirements for petroleum jelly

Characteristic	Requirement		Test method
	Pure petroleum jelly	Petroleum jelly with additives	
Melting point, °C	38 – 60	38 – 60	Annex A
Saponifiable matter	Nil	Nil	Annex B
Organic acids, ml,max.	1	1	Annex C
Sulphated ash, %, bymass, max.	0.10	0.2	Annex D
Sulphur and sulphides	To pass the test	To pass the test	Annex E
Iodine value (Wijs),max.	1.5	1.5	Annex F
Cone penetration value at 25 °C	100 - 275 1/10 mm in checking for consistency and hardness of jellies	100 - 275 1/10 mm in checking for consistency and hardness of jellies	ISO 2137 or ASTM D217-19b

NOTE Additives may include colour, perfume, herbal extracts, emollients, moisturizers and vitamins.

4.3 Heavy metal contaminants

Petroleum jelly shall comply with the limits for contaminants given in Table 2 when tested in accordance with the test methods specified therein.

Table 2 — Limits for heavy metal contaminants

S/N	Heavy metal contaminant ^a	Maximum limit, mg/kg	Test method
i.	Lead	10	EAS 847-16
ii.	Arsenic	2	
iii.	Mercury	2	

^a The total amount of heavy metals as lead, mercury and arsenic, in combination, in the finished product shall not exceed 10 mg/kg.

4.4 Microbiological limits

Petroleum jelly shall comply with the microbiological limits given in Table 3 when tested in accordance with the test method specified therein.

Table 3 — Microbiological limits of petroleum jelly

Microorganism	Maximum limit	Test method
Total viable count, CFU/g or CFU/ml	100	ISO 21149

5 Packaging

Petroleum jelly shall be packaged in suitable well-sealed containers that shall protect the contents during transportation, handling and storage and shall not cause any contamination or react with the product.

6 Labelling

In addition to the labelling requirements specified in EAS 346, the package shall be legibly and indelibly marked with the product name as “Pure petroleum jelly”, or “Perfumed petroleum jelly” or “Herbal petroleum jelly”, or “Herbal perfumed petroleum jelly” or Petroleum jelly with “X” where X is the name of the additive(s).

7 Sampling

Sampling shall be carried out in accordance with ISO 24153.

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Annex A normative

Determination of melting point

A.1 Melt a quantity of the sample slowly while stirring until it reaches a temperature of 90 °C - 92 °C. Remove the source of heat and allow the molten sample to cool to a temperature of 8 °C - 10 °C above the expected melting point. Chill the bulb of a thermometer (range: 1 °C - 100 °C) to 5 °C, wipe it dry and while it is still cold, dip it into molten sample so that approximately half of the bulb is "submerged". Withdraw it immediately and hold it vertically away from heat until the wax surface dulls, then dip it for 5 min into a water bath having a temperature not higher than 16 °C.

A.2 Fix the thermometer prepared in A.1 securely in a test tube so that its lowest point is about 15 mm above the bottom of the test tube. Suspend the test tube in a water bath adjusted to 16 °C, and raise the temperature of the bath at a rate of 1 °C/min and note the temperature at which the first drop of the melted sample leaves the thermometer. Repeat the determination twice on a freshly melted portion of the sample. If the variation in three determinations is less than 1 °C, take the average of three as the melting point. If the variation in the three determinations is more than 1 °C, make two additional determinations and take the average of the five

Annex B (normative)

Determination of saponifiable matter

B.1 Reagents

- B.1.1 Methyl ethyl ketone, analytical grade, stored in amber coloured bottle
- B.1.2 Standard alcoholic potassium hydroxide solution, 0.5 mol/L standardized before use
- B.1.3 Petroleum ether, boiling range 80 °C - 100 °C
- B.1.4 Standard hydrochloric acid, 0.5 mol/L accurately standardized
- B.1.5 Phenolphthalein indicator solution, 1 % solution in 95 % rectified spirit

B.2 Procedure

B.2.1 Accurately weigh in flask about 5 g of the sample and add 25 ml \pm 1 ml of methyl ethyl ketone, followed by 25 ml standard alcoholic potassium hydroxide solution from a burette. Connect the flask to a condenser and heat for half an hour after refluxing begins. Disconnect the condenser, add 50 ml of petroleum ether and titrate the solution while hot (without heating) with standard hydrochloric acid, using three drops of phenolphthalein indicator. When the indicator colour is discharged add three drops more of the indicator. If this addition restores the colour, continue the titration. Proceed in this manner until the end point is reached when the indicator colour is discarded and does not immediately reappear upon the addition of three more drops of indicator.

B.2.2 Run a blank under identical conditions.

B.2.3 The sample shall be taken to have passed the requirement specified in Table 1 if the blank reading does not differ from the sample reading by more than 0.1 ml.

Annex C (normative)

Determination of organic acids

C.1 Reagents

C.1.1 Dilute rectified spirit, prepared by diluting one volume of 95 % rectified spirit with two volumes of water, and neutralized to phenolphthalein indicator

C.1.2 Phenolphthalein indicator, same as in B.1.5

C.1.3 Standard sodium hydroxide solution, exactly 0.1 mol/L

C.2 Procedure

C.2.1 Add 100 ml of dilute rectified spirit to 20 g of the sample, agitate thoroughly, and heat to boiling. Add 1 ml of phenolphthalein indicator and titrate rapidly with standard sodium hydroxide solution with vigorous agitation to a sharp pink endpoint in the alcohol water layer.

C.2.2 The material shall be taken to have passed the test if not more than 1 ml of standard sodium hydroxide solution is required for the titration

Annex D (normative)

Determination of sulphated ash

D.1 Reagents

Dilute sulphuric acid, approximately 2.5 mol/L

D.2 Procedure

Heat a platinum dish to redness for 10 min; allow to cool in a desiccator and weigh. Place 1 g of the sample in the dish, moisten with sulphuric acid, and ignite gently by means of a Bunsen burner. Again, moisten with sulphuric acid and ignite at about 800 °C in a muffle furnace. Cool and weigh. Again, ignite for 15 min and repeat this procedure until two successive weighings do not differ by more than 0.5 mg.

D.3 Calculation

Sulphated ash, expressed as percent by mass, shall be calculated using the formula below:

$$\frac{m_1}{m_2} \times 100$$

where

m_1 is the mass, in grams, of the residue; and

m_2 is the mass, in grams, of the sample taken for the test

Annex E (normative)

Determination of sulphur and sulphides

E.1 Reagents

Copper strips, 1 cm in width, and freshly polished

E.2 Procedure

E.2.1 Melt in a beaker about 100 g of the sample and keep on a water bath at a temperature of 95 °C. Then place a strip of copper in the melted sample so that it is partially immersed in it and allow to remain for 10 min.

E.2.2 The material shall be taken to have passed the test if the copper strip used in the test shows no tarnishing when compared with another freshly polished copper strip.

Annex F (normative)

Determination of iodine value

F.1 Apparatus

Thermometer, an engraved stem thermometer, calibrated between 10 °C and 65 °C in 0.1-degree intervals and with the 0 °C point marked on the stem is recommended. The thermometer shall have an auxiliary reservoir at the upper end, and length of about 370 mm and diameter of about 6 mm.

F.2 Reagents

F.2.1 Carbon tetrachloride or chloroform

F.2.2 Acetic acid, glacial, 99 %, having a melting point of 14.8 °C and free from reducing impurities. Determine the melting point of the acetic acid in accordance with F.2.2.1 and test it for reducing impurities in accordance with F.2.2.2.

F.2.2.1 For the melting point determination, take a 15-cm long test tube and fill it to about two thirds with the acetic acid. Insert into the acid a thermometer complying with the requirements specified in F.1 through a cork stopper fitting the test tube. The amount of acid should be at least double the quantity required to cover the bulb of the thermometer when the bottom of the latter is 12 mm from the bottom of the test tube. Suspend this tube within a larger test tube through a cork. Cool the acid by immersing the assembly in ice water until the temperature is 10 °C, then withdraw the assembly from the ice water and stir the acid rather vigorously for a few moments, thus causing the super-cooled liquid to crystallize partially and give a mixture of liquid and solid acid. Take thermometer readings every 15 s and consider the temperature at which the reading remains constant for at least 2 min as the true melting point.

F.2.2.2 For the determination of reducing impurities (potassium permanganate test), dilute 2 ml of acetic acid with 10 ml of water and add 0.1 ml of 0.5 mol/L potassium permanganate solution and maintain at 27 °C ± 2 °C. The test shall be taken as having been satisfied if the pink colour is not discharged at the end of 2 h.

F.2.3 Potassium dichromate, finely ground

F.2.4 Starch solution; mix 5 g of starch and 0.01 g of mercuric iodide with 30 ml of cold water and slowly pour it while stirring into 1 L of boiling water. Boil for 3 min. Allow the solution to cool and decant off the supernatant clear liquid.

F.2.5 Standard sodium thiosulfate solution, 0.2 mol/L

F.2.6 Chlorine gas, dry

F.2.7 Iodine trichloride

F.2.8 Wijs iodine monochloride solution; prepare this solution by one of the following methods, and store in a glass stoppered bottle in a cool place, protected from light and sealed with paraffin until taken for use:

- a) dissolve 3 g of re-sublimed iodine in 1 L of acetic acid, using gentle heat if necessary, and determine the length by titration with standard sodium thiosulfate solution. Set aside 50 ml - 100 ml of solution and introduce washed and dried chlorine gas into the remainder until the characteristic colour change occurs and the halogen content is nearly doubled as ascertained again by titration. If the halogen

content has been more than doubled, reduce it by adding the requisite quantity of the iodine-acetic acid solution. A slightly excess of iodine does not harm, but avoid an excess of chlorine.

Example, if the titration of 20 ml of original iodine-acetic acid solution requires 22 ml of standard sodium thiosulfate solution, then 20 ml of the finished Wijs solution should require between 43 ml and 44 ml (and not more than 44 ml) of the same sodium thiosulfate.

- b) as an alternative method of preparing Wijs solution, dissolve 8 g of iodine trichloride in approximately 450 ml of acetic acid. Dissolve separately 9 g of iodine in 450 ml of acetic acid using heat if necessary. Add gradually the iodine solution to the iodine trichloride solution until the colour has changed to reddish brown. Add 50 ml more of iodine solution and dilute the mixture with acetic acid till 10 ml of the mixture are equivalent to 20 ml standard sodium thiosulfate solution when the halogen content is estimated by titration in the presence of an excess of potassium iodide and water. Heat the solution at 100 °C for 20 min and cool. Prevent access of water vapour in preparing the solution.

F.3 Procedure

F.3.1 Melt the material and filter through the filter paper to remove any impurities and the last trace of moisture. Make sure that the glass apparatus used is absolutely clean and dry. Weigh accurately by difference, about 10 g of the sample, into a clean, dry 500-ml glass stoppered bottle to which 25 ml of carbon tetrachloride or chloroform have been added, and agitate to dissolve the contents. Add 25 ml of Wijs solution (the quantity of Wijs solution added is 50 % - 60 % more than the quantity required).

F.3.2 Replace the glass stopper after wetting with potassium iodide solution, swirl for intimate mixing, and allow to stand in the dark for 45 min. Carry out a blank test simultaneously under similar experimental conditions. After standing, add 15 ml of potassium iodide solution and 100 ml of water, and titrate the liberated iodine with standard sodium thiosulfate solution, swirling the contents of the bottle continuously to avoid any local excess, until the colour of the solution is straw yellow. Add 0.5 ml of starch solution and continue the titration until the blue colour disappears.

F.4 Calculation

The Iodine value, expressed in Wijs, shall be calculated using the formula below:

$$\frac{12.69(V_1 - V_2)M}{m}$$

where

V_1 is the volume, in millilitres, of standard sodium thiosulfate, required for the blank;

V_2 is the volume, in millilitres, of standard sodium thiosulfate solution, required for the material;

M is the molarity, of standard sodium thiosulphate; and

m is the mass, in grams, of the material taken for the test.

Bibliography

- [1] ISO 17516: 2014, *Cosmetics — Microbiology — Microbiological limits*
- [2] EAS 126:1999, *Pure petroleum jelly for cosmetics industry — Specification*
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