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DRAFT EAST AFRICAN STANDARD

Glycerine for cosmetic industry — Specification

EAST AFRICAN COMMUNITY

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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. XXXXXX.

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 071, Cosmetics and related products.

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Glycerine for cosmetic industry — Specification

1 Scope

This Draft East African Standard specifies requirements, sampling and test methods for glycerine for cosmetic industry.

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.

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

EAS 847-2, *Oils for cosmetic industry — Methods of test — Part 2: Determination of moisture content*

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

EAS 847-15, *Cosmetics — Analytical methods — Part 15: Determination of ash content*

EAS 847-16, *Oils for cosmetic industry — Methods of test — Part 16: Determination of heavy metal content*

EAS 346, *Labelling of cosmetics — General requirements*

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

ISO 24153, *Random sampling and randomisation procedures*

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>

specific gravity

ratio of the density of a material to the density of a standard material such as water (for liquids) or air (for gases)

4 Requirements

4.1 General requirements

4.1.1 The raw material shall comply with the requirements of all parts of EAS 377.

4.1.2 The product shall be:

- a) a clear syrupy liquid containing essentially of glycerol and having a sweet warm taste;
- b) free from free from sediment, suspension and other foreign matter; and
- c) miscible in all proportions with water and with ethyl alcohol (90 % v/v) and shall not be soluble in diethyl ether, chloroform and fatty oils

4.1.3 The product shall be produced, prepared and handled in accordance with ISO 22716.

4.2 Specific quality requirements

The product shall comply with the requirements given in Table 1 when tested in accordance with the test methods prescribed therein.

Table 1 — Specific quality requirements for glycerine for cosmetic industry

Characteristic	Requirement	Test method
Glycerol, % by mass, min.	98	Annex A
Moisture content, % by mass, max.	2	EAS 847- 2
Specific gravity, at 25 °C	1.2490 - 1.2636	EAS 847-7
Ash, % by mass, max.	0.01	EAS 847-15
Alkalinity (as Na ₂ O), % by mass, max.	0.01	Annex B
Chlorides (as Cl), mg/l, max.	10	Annex C
Sulphates (as SO ₄), mg/l, max.	10	Annex D
Fatty acids and esters (as Na ₂ O), % by mass, max.	0.06	Annex E

5 Heavy metal requirements

Glycerine shall comply with the heavy metal requirements given in Table 2 when tested in accordance with the test methods specified therein.

Table 2 — Specific quality requirements for glycerine for cosmetic use

Heavy metals,	Limit mg/l, max.	Test method
Lead	5	EAS 847-16
Arsenic	2	
Mercury	2	

6 Packaging

The container (including the closure) in which the glycerine is packaged shall not react chemically with the glycerine and shall be strong enough to protect the product adequately during handling, transportation and storage.

7 Labelling

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

- a) manufacturer's name and physical address;
- b) product name as "Glycerine";
- c) net content of the product when packed;
- d) batch number;
- e) country of origin;
- f) instructions for use;
- g) date of manufacture and expiry; and
- h) precaution/warning, if any.

8 Sampling

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

Annex A (normative)

Determination of glycerol content

A.1 Apparatus

A.1.1 Burette

A.1.2 Pipette

A.1.3 Conical flasks with glass stopper, 500-ml capacity

A.1.4 Weighing pipette/bottle

A.2 Reagents

A.2.1 Sodium hydroxide solution, 0.1 N, accurately standardized

A.2.2 Sodium hydroxide, 0.05 N

A.2.3 Phenol red indicator, 0.05 % m/v. Dissolve 0.05 g of phenol red in 10 ml of ethyl alcohol and make up to 100 ml with water.

A.2.4 Dilute sulphuric acid, 0.2 N

A.2.5 Sodium metaperiodate solution. Dissolve 70 g of sodium metaperiodate in one litre of water containing 10 ml of 1 N sulphuric acid and store the solution in an amber coloured bottle in the dark. Sodium metaperiodate shall be a white crystalline powder containing not less than 98 percent sodium metaperiodate.

A.2.6 Ethylene glycol, neutral and free from glycerol

A.2.7 Standard glycerol

A.3 Procedure

A.3.1 Using a weighing pipette or bottle, transfer into a conical flask a well-mixed and accurately weighed sample.

A.3.2 Add 100 ml of carbon dioxide-free water and three drops of phenol red indicator solution and acidify with sulphuric acid solution to definite yellow colour. Heat to boiling and cool to room temperature.

A.3.3 Adjust the pH value to 8.0 ± 0.1 using 0.05 N sodium hydroxide solution dropwise until the colour changes to just pink. If the colour of the original solution interferes with the detection of colour change of the indicator, use a pH meter.

A.3.4 Pipette accurately 50 ml of sodium metaperiodate solution, replace the glass stopper, mix by swirling gently and allow the flask to stand in the dark for 30 min.

A.3.5 Wash down the sides of the flask with water, add 5 ml of ethylene glycol, replace the stopper, swirl gently and allow the flask to stand in the dark for further 20 min and titrate with standardized 0.05 N sodium hydroxide solution.

A.3.6 Carry out a blank test simultaneously under similar test conditions.

A.4 Calculation

The glycerol content, expressed as percent by mass, shall be calculated as follows:

$$\frac{9.209(S - B)N}{M}$$

where

S is the volume, in millilitres, of standard sodium hydroxide solution required for the sample;

B is the volume, in millilitres, of standard sodium hydroxide solution required for the blank;

N is the normality of standard sodium hydroxide solution; and

M is the mass, in grams, of the sample taken for test.

Each millilitre of 0.05 N sodium hydroxide is equivalent to 9.210 mg of C₃H₈O₃.

Annex B (normative)

Test for alkalinity

B.1 Apparatus

B.1.1 Conical flask, 500-ml capacity

B.1.2 Burette

B.2 Reagents

B.2.1 Standardized hydrochloric acid, 0.1 N

B.2.2 Phenolphthalein indicator solution

B.3 Procedure

B.3.1 Weigh accurately about 100 g of a well-mixed sample into 500-ml conical flask and add 150 ml of carbon dioxide-free water.

B.3.2 Titrate with standardized 0.1 N hydrochloric acid using phenolphthalein indicator.

B.4 Calculation

The alkalinity (Na_2O), expressed as percent by mass, shall be calculated as follows:

$$\frac{3.1 \times A \times N}{M}$$

where

A is the volume, in millilitres, of standardized 0.1 N hydrochloric acid;

N is the normality of standardized 0.1 N hydrochloric acid; and

M is the mass in grams of sample taken.

Annex C (normative)

Determination of chlorides (Volumetric method)

C.1 Apparatus

Conical flasks, 250-ml capacity

C.2 Reagents

C.2.1 Nitric acid solution, 35 % v/v

C.2.2 Nitrobenzene

C.2.3 Silver nitrate solution, 0.05 N accurately standardized

C.2.4 Ammonium thiocyanate solution, 0.05 N accurately standardized

C.2.5 Ferric ammonium sulphate solution, saturated, aqueous

C.3 Procedure

C.3.1 Weigh accurately about 20 g of the sample in a 250-ml conical flask and add about 100 ml of water.

C.3.2 To this solution, add 5 ml of nitric acid, a few drops of nitrobenzene and 5 ml of standard 0.05 N silver nitrate solution.

C.3.3 Swirl and titrate with standardized 0.05 N ammonium thiocyanate solution using 1 ml of ferric ammonium sulphate solution as indicator. Carry out a blank test using the same reagents.

C.4 Calculation

The chlorides (as Cl) content, expressed as parts per million, shall be calculated as follows:

$$\frac{35500(B - S)N}{M}$$

where

B is the volume, in millilitres, of standard ammonium thiocyanate solution required for the blank;

S is the volume, in millilitres, of standard ammonium thiocyanate solution required for the sample;

N is the normality of standard ammonium thiocyanate solution; and

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

Annex D (normative)

Determination of sulphates

D.1 Apparatus

- D.1.1 Nessler cylinders, 25-ml capacity
- D.1.2 Pipette, 1-ml capacity with 0.01-ml graduations

D.2 Reagents

- D.2.1 Hydrochloric acid, 1:1 solution of hydrochloric acid in water
- D.2.2 Barium chloride solution, 10 % (m/v), aqueous
- D.2.3 Standard sulphate solution. Dissolve 1.479 g of anhydrous sodium sulphate in water and make up to one litre in a volumetric flask. Dilute this stock solution 10 times immediately before use. One millilitre of this solution contains 0.000 1 g of sulphate (SO₄).

D.3 Procedure

- D.3.1 Weigh accurately about 10 g of the sample into a Nessler cylinder, add 1 ml of hydrochloric acid and 2 ml of barium chloride solution, and make up to 25 ml with water. Allow to stand for 30 min. A dull white turbidity is produced if sulphates are present.
- D.3.2 Simultaneously, introduce 0.5 ml, 0.75 ml, 1.0 ml and 1.25 ml of standard sulphate solution into four separate Nessler cylinders. In each, add 1 ml of hydrochloric acid and 2 ml of barium chloride solution, and make up to 25 ml with water. Allow to stand for 30 min.
- D.3.3 Note which one of these four solutions has a turbidity most closely matching that produced by the test material (see D.3.1). Repeat the test and note the volume of standard sulphate solution required to produce a turbidity exactly matching that of the test sample.

D.4 Calculation

The sulphates (as SO₄) content, expressed as parts per million, shall be calculated as follows:

$$\frac{100 \times V}{M}$$

where

V is the volume, in millilitres, of standard sulphate solution used; and

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

Annex E (normative)

Determination of fatty acids and esters.

E.1 Apparatus

E.1.1 Round-bottomed flask, 500-ml capacity

E.1.2 pH meter

E.2 Reagents

E.2.1 Sodium hydroxide solution, 0.25 N accurately standardized

E.2.2 Sulphuric acid, 0.25 N accurately standardized

E.2.3 Phenolphthalein indicator solution

E.3 Procedure

E.3.1 Weigh accurately about 50 g of the sample into a 500-ml round-bottomed flask. Add 100 ml of hot, carbon dioxide-free water and 1 ml of phenolphthalein indicator solution. If the solution is alkaline, neutralize it with sulphuric acid

E.3.2 Add exactly 15.0 ml of standard sodium hydroxide solution, connect the flask to a reflux condenser and heat to boiling. Boil for 5 min, allow to cool slightly and wash down the condenser with a little water. Disconnect the flask, close it with a stopper carrying a sodalime tube, and cool.

E.3.3 Titrate with standardized 0.25 N sulphuric acid and perform a blank determination.

E.4 Calculation

The fatty acids and esters (as Na₂O) content, expressed as percent by mass, shall be calculated as follows:

$$\frac{3.1(B-S)N}{M}$$

where

B is the volume, in millilitres, of standard sulphuric acid required for the blank;

S is the volume, in millilitres, of standard sulphuric acid required for the material;

N is the normality of standard sulphuric acid; and *M* is the mass, in grams, of the material taken for the test.

Bibliography

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- [6] USP 29- NF 24 page 1011, *pharmacopeial forum volume 28 (4) page 12450*.

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