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Mineral oil for cosmetic industry — Specification

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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.

DRS92 was prepared by Technical Committee RSB/TC 011, *Cosmetics and related products*.

This secondedition cancels and replaces the firstedition (RS 92:2018), 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.

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)

Beauty Makers Association (BMA)Rwanda Standards Board(RSB) – Secretariat

Introduction

Oils and fats are among the most important cosmetic ingredients and are frequently used for a variety of external applications. They can be used directly as skin and hair care products but also as the basic substances for the manufacture of cosmetic products. Many of the cosmetic and hair care products on the market today rely on hydrocarbon molecules, derived from either mineral or vegetable oils, to provide antistatic, plasticiser and viscosity properties.

Due to their excellent skin tolerance, their distinct caring and protecting properties as well as their high cleansing performance, mineral oils are particularly well suited for many cosmetic products. Moreover, they have film-forming and hydrophobic properties. In lipsticks mineral oils support, for instance, gloss formation. Moreover, they can provide the cosmetic product with a certain solidity and protect the skin from the loss of moisture. Substances which are similar to mineral oils have also been shown in the human skin or in natural fats and waxes as well as in plant oils and beeswax.

Mineral oil is a common ingredient in baby lotions, cold creams, ointments and cosmetics. It is a light weight inexpensive oil that is odourless and tasteless. It can be used on eyelashes to prevent brittleness and breaking and, in cold cream, is also used to remove cream make-up and temporary tattoos. One of the common concerns regarding the use of mineral oil is its presence on several lists of comedogenic substances. These lists of comedogenic substances were developed many years ago and are frequently quoted in the dermatological literature. The type of highly refined and purified mineral oil found in cosmetic and skincare products is non-comedogenic (does not clog pores).

Mineral oil for cosmetic industry — Specification

1 Scope

This Rwanda Standard specifies the requirements, sampling and test methods for mineral oil for cosmetic industry.

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

ISO 3448, *Industrial liquid lubricants — Classification*

RS 278, *Cosmetics — Method of sampling*

RS EAS 847-9, *Cosmetics — Analytical methods — Part 9: Determination of colour*

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

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

RS ISO 3104, *Petroleum products — Transparent and opaque liquids — Determination of kinematic viscosity and calculation of dynamic viscosity*

RS 278, *Cosmetics — Methods of sampling*

RS ISO 24153, *Random sampling and randomisation procedures*

ISO 4320, *Non-ionic surface active agents — Determination of cloud point index — Volumetric method*

ASTM D5002 – 16, *Standard Test Method for Density and Relative Density of Crude Oils by Digital Density Analyzer*

RS ISO 3657, *Animal and vegetable fats and oils — Determination of saponification value*

RS EAS 847-21, *Cosmetics — Analytical methods — Part 21: Determination of free acid in oils*

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

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

3 Terms and definitions

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

3.1

mineral oil/paraffin oil/ white oil

any of various colourless, odourless, light mixtures of higher alkanes from a mineral source, particularly a distillate of petroleum.

4 Types

The types of mineral oil shall be as per ISO viscosity grading number ISO 3448, as tabulated in Table 1.

There shall be three types of mineral oil,

a) light,

b) medium, and

c) heavy.

Table 1—Types of mineral oil

ISO Viscosity Grading (ISO VG)	Mid- point kinematic viscosity cSt at 40 °C	Kinematic viscosity at 40 °C
ISO VG 2	2.2	1.98- 2.42
ISO VG3	3.2	2.88- 3.52
ISO VG5	4.6	4.14- 5.06
ISO VG7	6.8	6.12
ISO VG10	10	9.00- 11
ISO VG15	15	13.5- 16.5
ISO VG22	22	19.8- 24.2
ISO VG 32	32	28.8- 35.2
ISO VG46	46	41.4- 50.6
ISO VG68	68	61.2- 74.8
ISO VG100	100	90.0- 100
ISO VG150	150	135- 165
ISO VG 220	220	198- 242

ISO VG320	320	288- 352
ISO VG460	460	414- 506
ISO VG 680	680	612- 748
ISO VG 1000	1000	900- 1100
ISO VG 1500	1500	1350- 1650
NOTE Conversion: 1cSt= 1 mm^2/s= 10^{-6} m^2/s 1 Pa.s= 1 cPs= 1cSt x density		

5 Requirements

5.1 General requirements

5.1.1 The product shall consist wholly of highly refined mineral oil, free from turbidity, sediment, water, foreign matter and visible impurities.

5.1.2 It shall be colourless, odourless and free from fluorescence.

5.1.3 The productshall be immiscible in water and alcohol, and in ether and chloroform.

5.1.4 The colour of oil shall not be inferior than 1.2Y+0.3R *Lovibond units* when measured in 18inch cell according to the method prescribed in RS EAS 847-9.

5.2 Specific requirements

5.2.1 The product shall comply with the requirements given in Table 2 when tested in accordance with the methods specified therein.

Table2— Specific requirements for mineral oil

S/N	Characteristics		Requirement	Test method
i.	Cloud point, °C, max		50	RS ISO 4320
ii.	Colour in a 1” cell on the Lovibond scale, expressed as Y + 5R, max. deepness		4.0	RS EAS 847-9
iii.	Viscosity at 40 °C - 0 °C	Light	8-30	RS ISO 3104
		Medium	31-63	
		Heavy	≥64	
iv.	Relative density at 25 °C		0.815-0.910	ASTM D5002-16
v.	Free acid and alkali		To pass the test	RS EAS 847-21
vi.	Saponification value		Nil	RS ISO 3657
vii.	Sulphur and sulphides		To pass the test	RS EAS 847-22

viii.	Carbonizable substances	To pass the test	Annex A
ix.	Ash, % by mass, max.	0.01	RS EAS 847-15
x.	Ultra violet absorption test, extinction, max.	0.5	Annex B
xi.	Stability test	To pass the test	RS EAS 847-18

5.2.2 The products shall comply with the limits for heavy metal contaminants in accordance with Table 3, when tested in accordance with the methods specified therein.

Table 3 — Limits for heavy metals contaminants for mineral oil

S/N	Characteristics	Maximum limit, mg/kg, max	Test method
i.	Lead	10	RS EAS 847-16
ii.	Arsenic (As_2O_3)	2	
iii.	Mercury	2	
- The total amount of heavy metals as lead, mercury and arsenic, in combination, in the finished product shall not exceed 10 mg/kg. - The heavy metals including lead, mercury and arsenic may be as a result of contamination during processing andshould not be deliberately added as ingredients.			

6 Packaging

The product shall be packaged in suitable a container which does not react or denaturize the content.

7 Labelling

Each container shall be suitably marked with the following information:

a) name “Mineral oil” and the grade;

b) name of the manufacturer or his registered trademark;

c) batch or code number;

d) volume of contents

e) storage conditions

f) manufacture date

g) expiry date, and

g) country of origin

h)

8 Sampling

Sampling shall be done in accordance with RS 278.

Annex A
(normative)

Test for carbonizable substances

A.1 Apparatus

A.1.1 Test tubes, of heat-resistant glass fitted with a well-ground glass stopper, the stopper and the tube bearing identical and indestructible numbers. The tube shall be 140 ± 3 mm in length and 14 ± 1 mm in outside diameter, and shall be calibrated at the 5.0 ± 0.2 mL liquid levels. The capacity of the tube stopper inserted shall be 16 ± 0.1 mL. A rolled edge may be provided for suspending the tube on the cover of the

A.1.2 Water-bath,suitable for immersing the test-tube above the 10 mL line and equipped tomaintain a temperature of 100 ºC ± 0.5 ºC. The bath shall be provided with a cover of any suitable material with holes approximately 16 mm in diameter through which the test tubes may be suspended.

A.1.3 Colour comparator,a colour comparator of suitable type for observing the colour of the acid layer in comparison with the reference standard colour solution. The size and shape of the comparator are optional but the size and shape of the apertures shall conform to the dimensions of the test tube.

A.2 Reagents

A.2.1 ***Concentrated sulphuric acid***, nitrogen-free, which is tested as follows: Dilute a small amount of the acid with an equal volume of water and superimpose 10 mL of the cooled liquid upon diphenylamine solution (1 g of diphenylamine in 100 mL of concentrated sulphuric acid). Blue colour should not appear at the zone of 1h.

A.2.2 ***Cobaltous chloride solution, 5 N,*** dissolve about 65 g of cobaltous chloride (CoCl2.6H2O) in enough dilute hydrochoric acid (1:39) to make 1000 mL of solution. Transfer exactly 5 mL of this solution to a flask; add 16 mL of sodium hydroxide solution (1:5) and 5 mL of hydrogen peroxide. Boil for 10 min, cool and add 2 g of potassium iodide and 20 mL of sulphuric acid (1:4). When the precipitate has dissolved, titrate the liberated iodine with 0.1 N sodium thiosulphate solution using starch as indicator. Each mL of sodium thiosulphate solution consumed is equivalent to 0.023799 g of $CoCl_2.6H_2O$. Adjust the final volume of cobalt chloride by the addition of dilute hydrochloric acid (1:39) so that 1 mL contains 59.5 mg of $CoCl_2.6H_2O$.

A.2.3 ***Ferric chloride solution, 0.5 M***,dissolve about 55 g of ferric chloride (FeCl3.6H2O) in enough diluted hydrochloric acid (1:39) to make 100 mL of solution. Transfer exactly 10 mL of the solution to a flask, add 5 mL of concentrated hydrochloric acid, 25 mL of water and about 3 g of potassium iodide. Stopper and allow the mixture to stand for 5 minutes. Dilute the mixture with 50 mL of water and titrate the liberated iodine with 0.1 M sodium thiosulphate solution using starch solution as indicator. Each mL of 0.1 M thiosulphate solution is equivalent to 0.02703 g of FeCl3.6H2O. Adjust with hydrochloric acid so that 1 mL contains 45.0 mg of FeCl3.6H2O.

A.2.4 ***Cupric sulphate solution, 0.5 M***, dissolve about 65 g of CuSO4.5H2O in enough hydrochloric acid (1:39) to make 1000 mL of solution. Transfer exactly 10 mL of this solution to a flask, add 50 mL of water, 4mL of acetic acid, and 3 g of potassium iodide. Allow the mixture to stand for 5 min, then titrate the liberatediodine with 0.1 M thiosulphate solution, using starch as indicator. Each mL of 0.1 M thiosulphate solution isequivalent to 0.02497 g of CuSO4.5H2O. Adjust the final volume of copper sulphate solution by the addition of diluted hydrochloric acid (1:39) so that 1 mL contains 62.4 mg CuSO4.5H2O.

A.2.5 ***Reference colorimetric solution***, prepare a reference standard pale amber solution for colour comparison by mixing together 1.5 parts of cobalt chloride solution, 3.0 parts of ferric chloride solution and 0.5 parts of the copper sulphate solution. Measure 5 mL of this mixture into a test tube as specified in C.2.1.

A.2.6 This pale amber reference standard shall then be overlaid with the 5 mL of mineral oil.

A.3 Procedure

A.3.1 Clean a test tube with a chromic acid cleaning solution, rinse with tap water followed by distilled water,and dry in an oven at 105 ºC for 1 h.

A.3.2 Fill the test tube to the 5 mL mark with sulphuric acid (94.7% ± 0.2%). Then add the oil to be tested to the 10 mL mark, insert the stopper loosely, and place the test tube in position in the water bath at 100 ºC ± 0.5ºC.

A.3.3 After the test tube has been in the water-bath for 30 sec., loosen the stopper sufficiently to release any pressure and re-insert, remove the test tube from the bath quickly, hold with a finger over the stopper, and give three vigorous, vertical shakes over an amplitude of about 12 cM, shaking the test tube quickly and at a rate corresponding to 5 shakes per second. Repeat every 30 sec. Do not keep the test tube out of the bathlonger than 3 sec. for each shaking period.

A.3.4 At the end of 10 min from the time the test tube was first placed in the bath, remove the test tube and allow to stand in the room for not less than 10 min, nor more than 30 min. Note any discolouration of the oil layer. Place the test tube in the colour comparator and compare the acid layer with 5 mL of the standard colorimetric solution and 5 mL of the sample mineral oil in the test tube that has been shaken vigorously for 10sec. and allowed to stand just long enough for the contents to separate into two layers.

A.4 Results

A.4.1 The mineral oil shall be reported as passing the test only when the oil layer shows no change in colour and when the acid layer is not darker than the reference standard colorimetric solution.

A.4.2 If the oil layer is discoloured or if the acid layer is darker than the reference standard colorimetric solution, the mineral oil shall be reported as not passing the test.

NOTE A bluish haze in the oil layer should not be interpreted as a change in colour.

Annex B
(normative)

Test for ultra violet absorption

B.1 General

The The extent to which radiation is absorbed in passing through a layer of an absorbing substance is expressedin terms of the extinction, E. This purely optical quantity is defined by the expression:

$E = \log_{10} (I_0 / I)$;

where *I0* is the intensity of the radiation passing into the absorbing layer; and
I isthe intensity of the radiation passing out of it.

For a solution of an absorbing solute contained in an absorption cell having flat parallel optical faces, results are evaluated by the expression:

E1%, 1 cM = (E/c). I;

where c is the concentration of absorbing solute expressed as a percentage (m/v); and
I the thickness of the absorbing layer in centimeters.

Therefore, E1% 1 cM is the extinction of a 1 cM layer of 1 % (m/v) solution of the absorbing solute, its value at a particular wavelength in a given solvent being a property of the solute.

B.2 Procedure

B.2.1 In measuring the extinction of a solution at a given wavelength, the extinction of the solvent cell and its contents shall not exceed 0.4 per cM of path length, and shall in general be less than 0.2 per cM of path length, when measured with reference to air at the same wavelength. The solvent cell shall be of the same batch as that used to prepare the solution and shall be free of fluorescence at the wavelength of measurement. Statements of concentration and thickness of the solution to be used in the determination of the light absorption apply to measurements made with photoelectric instruments. When such details are not given or when measurements are made by a photographic or visual instrument, the concentration and thickness of solution shall be adjusted so that the measured extinction lies within the optimum working range of the apparatus.

B.2.2 For this test it is more convenient to use a recording instrument, a 1 cM layer of 2.0 % (m/v) solution in trimethyl pentane in the wavelength range of 240 to 280 µM. If these conditions are not appropriate for a particular instrument, the thickness should be varied – not the concentration.

B.2.3 When measuring the extinction of an absorption medium the spectral slit width shall be small compared with the half width of the absorption band, otherwise erroneously low extinctions will be measured. Particular care is needed in this respect and the instrumental slit width used should always be such that a further reduction does not result in an increased extinction reading.

Bibliography

[1] RS EAS 92:2018, *Mineral oil for cosmetic industry — Specification*

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