DRAFT TANZANIA STANDARD

Draft for comments only CDC3(5131)P3 Rev of TZS1133:2010

Skin care oils - Specification

TANZANIA BUREAU OF STANDARDS

Skin care oils – Specification

0 Foreword

This draft Tanzania standard is being prepared by the Cosmetics and Creameries Technical Committee, under the supervision of Chemicals Divisional Standards Committee and it is in accordance with the procedures of the Bureau.

This Draft Tanzania Standard is the first revision of TZS 1133:2010 Skin care oils – Specification"

Oil is used as an ingredient for skin conditions. It also provides numerous essential nutrients required to maintain normal functions of skin glands and promote natural skin care. When mixed in different proportions, oil blends are used for massage for relaxation purpose.

While there are many oils that can be used to condition the skin, the type of oil or combination that one selects should be chosen wisely, keeping in mind a lot of things. In fact the blending is a result of long term research.

Oils are a group of neutral liquids comprising three main classes:

a) Fixed (fatty) oils from animal, vegetable and marine sources; consisting chiefly of glycerides and esters of fatty acids.

b) Mineral oils derived from petroleum, coal, etc., consisting of hydrocarbons.

c) Essential oils, volatile products mainly hydrocarbons with characteristic odour derived from certain plants.

In reporting the results of a test or analysis made in accordance with this draft Tanzania Standard, if the final value observed or calculated is to be rounded off, it shall be done in accordance with TZS 4.

During the preparation of this draft standard, assistance was derived from 76/768/EEC Cosmetic Directive, published by EEC.

1 Scope

This draft Tanzania Standard prescribes the requirements for skin care oils based on refined vegetable oils blends, vegetable oils, mineral oils or mixture of the vegetable oils and mineral oil meant for application on the skin.

This draft Tanzania standard also covers vegetable oils mixed in different proportions meant for massage. It does not cover skin creams, lotions and pure essential oils. These products are covered by different standards.

This draft standard does not cover skin care oil for which therapeutical claims are made.

2 Normative references

The following referenced documents are indispensable for the application 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.

2.1 TZS 638 (Part 1) /EAS 377 (Part 1) Cosmetics and cosmetic products — Part 1: List of substances prohibited in cosmetic products.

2.2 TZS 638 (Part 2):4 /EAS 377 (Part 2) Cosmetic and cosmetic products — Part 2: List of substances which cosmetic products must not contain except subject to the restrictions laid down.

2.3 TZS 638 (Part 3) /EAS 377(Part 3) Cosmetics and cosmetic products — Part 3: List of colorants allowed in cosmetic products.

2.4 TZS 638 (Part 4) /EAS 377 (Part 4) Cosmetics and cosmetics products — Part 4: List of preservatives allowed in cosmetic products.

2.5 TZS 638 (Part 5) 4/EAS 377 (Part 5) Cosmetics and cosmetic products — Part 5: Use of UV filters in cosmetic products.

2.6 FTZS 1826:/ISO 22717 Cosmetics — Microbiology — Detection of *Pseudomonas aeruginosa.*

2.7 FTZS 1827/ISO 22718Cosmetics — Microbiology — Detection of S*taphylococcus aureus.*

2.8 FTZS 1830:2016/ISO 18416:2007 Cosmetics — Microbiology — Detection of *Candida albicans.*

2.9 TZS 314 Cosmetics and toiletries products – methods of sampling

3 Types

There shall be three types of skin oil, namely;

a) Type 1 – Based on vegetable oils or its blends;
b) Type 2 – Based on mineral oils; and
c) Type 3 – Based on a mixture of vegetable oil(s) and mineral oils.

4 Requirements

4.1 General requirements

4.1.1 Skin care oils shall be free from any sediment, suspended matter and separated water.

4.1.2 All ingredients used including dyes, pigment and colours shall conform to TZS 638 (all Parts) /EAS 377(all Parts) Cosmetics and cosmetic products.

4.1.3 The oils shall be dermatologically safe and shall not cause irritation or harm to the skin when used as intended by the manufacturer. It shall be the responsibility of the manufacturer to ensure the dermatological safety of the formulation before releasing the product for sale.

4.2 Specific requirements

Skin care oils shall conform to the requirements specified in table 1, when tested according to the method indicated therein.

Table 1 – Requirement for skin oils

S/N	Characteristics	Requirement	Method of test
1	Acid value, max	1.0	Annex A
2	Peroxide value, *max*	7.5	Annex B
3	Rancidity	To pass the test	Annex C
4	Thermal stability	To pass the test	Annex D
5	Lead, ppm, *max*	20	Annex E
6	Arsenic, ppm, *max*	2	Annex F
7	Mercury, ppm, *max*	2	Annex G
8	Microbiological examination (Total Plate Count) cfu/g Micro-organism* per g, *max*	100	Annex H
9	*Staphylococcus, aureus*	Not detectable in 0.5 g of cosmetic product	FTZS 1827:2016
10	*Pseudomonas aeruginosa* and		FTZS 1826:2016
11	*Candida albicans* MPN/g		FTZS 1830:2016
12	Moisture and volatile matter, % by mass, *max*	0.5	Annex I

* Micro-organism includes both pathogenic and non-pathogenic
Note: Total heavy metals when present as impurities, shall not exceed 20ppm

5 Packaging

Skin care oil shall be packed in suitable containers to ensure stability of the contents.

6 Marking

The packages shall be securely closed, legibly and indelibly marked in Kiswahili and English, and any other language as agreed between the manufacturer and supplier with the following information:

a) Manufacturer's name and address
b) Name of the product, "Skin care oil"
c) The batch or code number
d) Storage instructions
e) Net content
f) expiry date

g) Country of origin
h)Manufacture date

7 Sampling

Representative samples for test shall be drawn from the market, factory or anywhere else following the procedure of random selection in accordance with TZS 314. The containers shall only be opened during testing.

Annex A

Determination of acid value

A.1 Reagents

A.1.1 Ethyl Alcohol – 95 % by volume, neutralized to mixed indicator solution (A.1.2).

NOTE: 50/50 ethanol/ether mixture and titrating with phenolphthalein indicator may also be used.

A.1.2 Mixed indicator solution – Dissolve 1 g of phenolphthalein in 100 ml of ethyl alcohol and add to it 1 ml of 0.1 percent solution of methyl blue in water.

A.1.3 Standard aqueous potassium hydroxide or sodium hydroxide solution – 0.1 N.

A.2 Procedure

Weigh accurately a suitable quantity of the oil in a 200 ml conical flask. The mass of the oil taken shall be such that the volume of alkali required for the titration does not exceed 10 ml. Add 50 ml of hot ethyl alcohol and 1 ml of the mixed indicator solution. Boil the mixture for about 5 min and titrate while hot with standard alkali solution, shaking vigorously during titration.

A.3 Calculation

If potassium hydroxide is used for titration;

$$\text{Acid value} = \frac{56.1VM}{m}$$

If NaOH is used for titration;

$$\text{Acid value} = \frac{40VM}{m}$$

where,
V, is volume in ml of standard alkali solution used;
M, is molarity of standard alkali solution; and
m, is mass in g of materials taken for the test.

Annex B

Determination of peroxide value

B.1 Reagents

B.1.1 Glacial acetic acid

B.1.2 Chloroform

B.1.3 Potassium iodide solution – saturated freshly prepared.

B.1.4 Standard sodium thiosulphate solution – 0.01 N freshly standardized.

B.1.5 Starch indicator 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 one liter water. Boil for three minutes. Allow to cool and decant off the supernatant clear liquid.

B.2 Procedure

Weigh accurately about 5 g of the material in a 250 ml glass-stopper conical flask and dissolve by shaking in 30 ml of mixed solvent containing 3 parts by volume of glacial acetic acid and two parts by volume of chloroform. Add 0.5 ml of saturated potassium iodide solution, allow solution to stand for exactly 1 min with occasional shaking then add 30 ml of water and titrate with standard sodium thiosulphate solution.

Add thiosulphate solution until the colour of the titrated solution becomes light yellow. Then add 1 ml of starch indicator solution and continue the titration till the disappearance of the blue colour. Carry out a blank determination without using the sample.

B.3 Calculation

$$\text{Peroxide value, mg/1000g)} = \frac{1000(V_1 - V_2)N}{m}$$

where,

V_1, is the volume in ml of standard sodium thiosulphate solution required with the sample;

V_2, is the volume in ml of standard sodium thiosulphate solution required with the blank;

N, is the normality of standard sodium thiosulphate solution; and

m, is the mass in g of materials taken for the test.

Annex C

Test for rancidity

C.1 Reagents

C.1.1 Concentrated hydrochloric acid – analytical reagent grade.

C.1.2 Phloroglucinol solution – Dissolve 1 g of phloroglucinol in 100 ml of diethyl ether.

C.2 Procedure

Shake 10 ml of the material (melt if necessary) with 10 ml of concentrated hydrochloric acid and 10 ml of phloroglucinol solution. Shake for 1 minute.

C.3 Results

The material shall be taken to have passed the test if no pink colour develops.

Annex D

Test for stability
(Method 1)

D.1 Apparatus

Ultra-violet lamp – with emission at 360 nm.

D.2 Procedure

Place 50 ml of the material in a 100 ml glass beaker. Turn on the ultra violet lamp and expose the samples at a distance of 12 to 14 cm below the lamp for 6 hours. After the specified time, remove the sample, cool to room temperature and compare for any change in odour or colour. The same volume of material shall be employed for all tests so that comparison is ensured on a reproducible basis.

NOTE – The output of the ultra-violet lamp diminishes with time in service. A log of number of hours of the lamp in use should be maintained. The lamp is to be replaced after the specified hours of service, as recommended by the lamp manufacturer.

D.3 Evaluation

Evaluation is done by comparing the test material against an unexposed specimen from the same sample.

Alternatively the following method can be used**.**

(Alternative method)

D.4 Procedure

Place the original unopened sample in a thermostatically controlled oven at 40 ± 2º C for 48 hours.

D.5 Results

The sample will be taken to have passed the test if it does not develop any disagreeable odour from the original smells or changes its physical appearance after the 48 hours in the oven.

Annex E

Test for lead using flame atomic absorption spectrophotometer (FAAS)

E.1 Principle

The sample is passed through wet digestion using pressure decomposition. The amount of lead is then determined using AAS.

E.2 Reagents

The reagents used should be of analytical grade. Water must be distilled or de-ionized.

E.3 Procedure

Weigh accurately about 0.4 g of sample and put this into a 50 ml decomposition pressure tube. Add 7.0 ml of concentrated nitric acid. Add 20 ml of water. Close the pressure tube, and apply between 15-20 N/m^2 of pressure. Digest for about 2 hours. Transfer to 200 ml volumetric flask and make to the mark.

Prepare the standard solutions for lead. Aspirate into the flame each of the standard solutions in ascending order of concentration. Take the absorbance reading for each concentration using the FAAS. Plot a calibration graph of the concentration of lead in the standard solutions against the corresponding values of absorbance.

Aspirate into the flame the sample solution. Take the absorbance reading from the FAAS and give it a value X. From the graph, use the value of absorbance X to read the corresponding value of concentration. Let this value of concentration be C.

E.4 Calculation

$$\text{Amount of lead} = \frac{\text{C x D}}{\text{M}}$$

where D = Dilution factor;
C = Concentration of sample solution;
M = Mass sample in g.

Annex F

Test for arsenic using flame atomic absorption spectro Photometer (FAAS)

F.1 Principle

The sample is passed through wet digestion using pressure decomposition. The sample is further prepared using vapour generation method. The amount of arsenic is then determined using AAS.

F.2 Reagents

The reagents used should be of analytical grade. Water must be distilled or de-ionized.

F.3 Procedure

Weigh accurately 0.4 of sample and put this into a 50 ml decomposition pressure tube. Add 7.0 ml of concentrated nitric acid. Add 20 ml of water. Close the pressure vessel and apply between 15-20 N/m^2 of pressure. Digest for about 2 hours. Transfer to a 200 ml volumetric flask and make to the mark. Further prepare the sample using the hydride vapour generation method. In this method, arsenic compounds are reduced to the trivalent state and AsH_3 is generated.

Prepare the standard solutions for arsenic. Measure the absorbance for each concentration of the standard solutions in ascending order using the FAAS. Plot a calibration graph of the concentration of arsenic in the standard solutions against the corresponding values of absorbance.

Measure the absorbance of the sample solution using FAAS and give it a value X. From the graph, use the value of absorbance X to read the corresponding value of concentration. Let this value of concentration be C.

F.4 Calculation

$$\text{Amount of arsenic} = \frac{\text{C x D}}{\text{M}}$$

where

C= Concentration of the sample solution;
M = Mass of the sample in grams;
D = Dilution factor.

Annex G

Test for mercury using atomic absorption spectrophotometer (AAS)

G.1 Principle

The sample is passed through wet digestion using pressure decomposition. The sample is further prepared using vapour generation method. The amount of mercury is then determined using (AAS).

G.2 Reagents

The reagents used should be of analytical-reagent grade. Water must be distilled or de-ionized.

G.3 Procedure

Weigh accurately 0.4 g of sample and put this into a 50 ml decomposition pressure tube. Add 7.0 ml of concentrate acid. Add 20 ml of water. Close the pressure vessel and apply between 15-20 N/m^2 of pressure. Digest for about 2 hours. Transfer to 200 ml volumetric flask and make to the mark. Further prepare the sample using the cold vapour generation method.

Prepare the standard solutions for mecury. Measure the absorbance for each concentration of the standard solutions in ascending order using the AAS. Plot a calibration graph of the concentration of mercury in the standard solutions against the corresponding values of absorbance.

Measure the absorbance of the sample solution using AAS and give it a value X. From the graph, use the value of absorbance X to read the corresponding value of concentration. Let this value of concentration be C.

G.4 Calculation

$$\text{Amount of mercury} = \frac{\text{C x D}}{\text{M}}$$

where

C = Concentration of the sample solution;
M = Mass of the sample in grams;
D = Dilution factor.

Annex H

Microbiological examination

H.1 Principle

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

NOTE – 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.

H.2 Apparatus

H.2.1 Tubes – of resistant glass, provided with closely fitting metal caps.

H.2.2 Autoclaves – of sufficient size, capable of keeping 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.

H.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.

H.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 diameters. In order to ensure uniformity of conditions during counting, illumination equivalent to that provided by the Quebec colony counter shall be employed.

H.2.5 Analytical balance

H.2.6 pH meter

H.2.7 Water bath

H.2.8 Incubator – capable of being maintained at 32°C to 35°C.

H.3 Media buffer

H.3.1 Soya bean casein digest agar medium

Dissolve15 g of pancreatic digest of casein 5 g papacy digest of soya bean meal, and 5 g of sodium chloride in 100 ml of distilled water contained in a 2 L beaker by heating on 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 autoclaved at 122°C for 20 minutes. After autoclaving, store the tubes in a cool place and use them within three weeks.

H.3.2 Stock solution pH 7.2

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

H.3.3 Dilute phosphate buffer solution pH 7.2

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

H.4 Sterilization of apparatus

H.4.1 Tubes – sterilized at 122°C temperature and 1.05 kg/cm^2 pressure for 20 minutes or in a hot air oven at 160°C for 1 h.

H.4.2 Petri-dishes – packed in drums and autoclaved at a temperature of 122°C and a pressure of 1.05 kg/cm^2 for 20 minutes individually wrapped in Kraft paper and sterilized in a hot air oven at 160°C for one hour.

H.4.3 Pipettes – in piped cones (copper, stainless steel or aluminum) after plugging the breaded end with cotton and be sterilized at 122°C temperature and 1.05 kg/cm^2 pressure for 20 minutes or in a hot air oven at 160°C for one hour.

H.5 Procedure

H.5.1 Melt a sufficient number of soya bean casein digest agar medium tubes in a hot water bath and transfer while hot into a constant temperature water bath maintained at 48±2°C.

H.5.2 Weigh and transfer aseptically 1 g of the sample to a conical flask containing sterile 50 ml of 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 the plates to mix thoroughly. Incubate the plate at 32°C for 72 hours in an inverted position.

H.6 Expression of results

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

Annex I
Determination of moisture content and volatile matter

I.1 Principle

A known mass of the sample is evaporated to constant weight and the moisture and volatile matter content is determined as the difference in weights for the sample before and after evaporation.

The air-oven method is applicable to all the ordinary oils and fats which have a relatively low moisture content (below one percent), but not to drying or semi-drying oils or oils of the coconut oil group.

I.2 Apparatus

I.2.1. Moisture disk, provided with tight-fitting slip-over cover

I.2.2 Desiccator, containing an efficient desiccant, such as phosphorus pentoxide

I.2.3 Air oven, preferably electrically heated, with calibrated temperature control device

I.3. Procedure

Weigh approximately 10 g (W_1) of the oil into a moisture dish which has been dried previously, cooled in the desiccator and then weighed. Place the dish in the air-oven for approximately one hour at 105 °C ± 1 °C. Remove the dish from the oven, cool in the desiccator to room temperature and weigh (W_2). Repeat this procedure but keep the dish in the oven only for half an hour each time until the difference between the two successive weighings does not exceed one milligram.

I.4 Calculation

The moisture and volatile matter content, percent by weight, shall be expressed as follows:

$$\frac{W_1 - W_2}{W_1} \times 100$$

where,

W_1 mass, in grams, of the material taken for the test, and

W_2 mass, in grams, of the material upon drying.