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DRAFT TANZANIA STANDARD

Lanolin, anhydrous for cosmetics industry — Specification

TANZANIA BUREAU OF STANDARDS

Foreword

This Draft Tanzania Standard has been 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 second edition cancels and replaces the first edition of TZS 1427:2011 *Lanolin, anhydrous for cosmetics industry* with minor changes and technical change of deleting requirement for colour.

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

Lanolin, anhydrous for cosmetics industry - Specification

1. Scope

This Draft standard specifies the requirements, sampling and test methods for anhydrous lanolin for cosmetic industry.

2. Normative references

The following referenced documents are indispensable for the application of this Tanzania Standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

TZS 54 *Methods of sampling and tests for oils and fats (Part 1) Sampling, physical and chemical tests.*

TZS 774 *Labelling of cosmetics products - General requirements*

3. Terms and definition

For the purposes of this standard, the following term and definition shall apply;

Lanolin
fat substance found naturally in sheep's wool extracted as yellowish viscous mixture of esters and used as a base for ointment

4. Requirement

4.1 General requirement

4.1.1 Description

The material shall be in the form of pale yellow, tenacious, unctuous mass, having a slightly characteristic odour.

4.1.2 Solubility

The material shall be sparingly soluble in 95% ethyl alcohol and freely soluble in ethyl ether and chloroform. Further it shall mix without any separation of layers, with twice its mass of water.

4.2 Specific requirements

The material shall comply with the requirements given in Table 1.
Table 1 – **Specific requirements for Lanolin**

S/N	Characteristic	Requirement	Test method
i.	Melting point, ºC	36 - 45	TZS 54
ii.	Loss on drying, percent by mass, *max*	0.5	TZS 54
iii.	Acid value, *max*	2	TZS 54
iv.	Iodine value	18 - 32	TZS 54
v.	Saponification value	92 - 106	TZS 54
vi.	Petrolatum	To pass the test	Annex A
vii.	Sulphated ash, percent by mass, *max*	0.15	Annex B
viii.	Chlorides,	To pass the test	Annex C
ix.	Water soluble oxidizable substances	To pass the test	Annex D

5. Packaging and labelling

5.1 Packing;

The product shall be packaged in suitable well-sealed containers that shall protect the contents and shall not cause any contamination with the product.

5.2 Labelling;

Each container shall be labeled according to TZS 774 (see clause 2)

6. Sampling

6.1 General precautions and directions

In drawing, preparing, storing, and handling samples the following precautions and directions shall be observed.

6.1.2 Samples shall be taken in a protected place not exposed to damp air, dust or soot.

6.1.3 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination.

6.1.4 The samples shall be placed in a clean and dry glass container. The Sample containers shall be of such a size that they are almost completely filled by the sample.

6.1.5 Each container shall be sealed air tight after filling and marked with full details of sampling date of sampling, batch or code number, name of manufacturer and other important particulars of the consignment.

6.1.6 Samples shall be stored in such a manner that the temperature of the material does not vary unduly from the normal temperature.

6.2 Scale of sampling

6.2.1 *Lot*;
All the containers in a single consignment of the material drawn from a single batch of manufacture shall constitute a lot. If the consignment is declared to consist of different batches of manufacturer, the batches shall be marked separately and the groups of containers in each batch constitute lots.

6.2.2 Samples shall be tested from each lot for ascertaining conformity of the material to the requirements of the specification.

6.2.3 The number of containers (*n*) to be chosen from the lot shall depend on the size of the lot (*N*) and shall be given in Table 2.

Table 2: Number of Containers to be selected for Sampling

Lot size (*n*)	**No. of containers to be selected (*N*)**
Up to 50	3
51 to 200	4
201 to 400	5
401 to 650	6
651 to 1000	7
1001 and above	8

6.2.4 The containers to be selected for sampling shall be chosen at random as follows; Starting from any container in the lot, count them as 1, 2, 3,.., up to r and so on in one order, where r is the integral part of *N/n*, *N* being the lot size and n the sample size. Every r^{th} container thus counted shall be drawn from the lot so as to constitute the required sample size.

6.3 Test Samples and Reference sample

6.3.1 The material shall be melted, prior to sampling, if already not so.

6.3.2 Lower the sampling tube (closed type sampling tube, undivided) slowly to a requires depth and draw the sample by operating the sampling tube by inserting the instrument when closed and the material is admitted by opening it and finally it is closed and withdrawn from each container selected. The total quantity of the material drawn from each container shall be about 200 mL.

6.3.3 Thoroughly mix all portions of the material drawn from the same container. Out of these portions, equal quantities shall be taken out from each selected container and shall be well mixed up together so as to form a composite sample measuring not less than 600 mL.

6.3.4 The composite sample shall be divided into three equal parts, one for the purchaser, another for the supplier and the third for the referee. These samples shall be transferred to sample containers, which shall then be sealed air tight with stoppers and labeled with all the particulars of the sample given under 6.1.5.

6.3.5 The reference sample, bearing the seals of the purchaser and the supplier, shall be used in case of a dispute between the two. It shall be kept in a place agreed to between the purchaser and the supplier.

6.4 Number of Tests

Tests for all characteristics given in 2 shall be carried out on the composite sample.

6.5 Criteria for Conformity

The material shall be taken to have conformed to this specification, if the composite sample satisfies all requirements given in clause 4.

7. Test methods

Tests shall be carried out according to the methods prescribed in TZS 54 and in Annexes A to D of this standard.

Annex A
(Normative)

Test for Petrolatum

A.1 Reagents

95% ethyl alcohol (*rectified*)

A.2 Procedure

Boil 1.00 g of the material with 80 mL of rectified spirit. Observe the solution

The material shall have passed the test, if the solution is clear or not more than opalescent.

Annex B
(Normative)

Determination of Sulphated Ash

B.1 Reagents

Concentrated sulfuric acid

B.2 Procedure

Weigh accurately 5.00 g of the material in a tarred crucible. Ignite (See note)[1], gently at first until thoroughly charred, then cool and moisten the residue with 1 mL of concentrated sulfuric acid. Ignite gently until the carbon is completely consumed, then heat strongly. When the carbon has completely disappeared, cool the crucible in a desiccator and weigh.

B.3 Calculations

Sulphated ash, percent by mass = $\frac{m \times 100}{M}$

Where

m = mass in g of the residue obtained and
M = mass in g of the material taken for the test.

[1] Note: conduct the ignition in a place protected from air currents and use as low a temperature as possible to affect the combustion of carbon.

Annex C
(Normative)

Test for Chlorides

C.1 Outline of the method

Refluxing the material with alcohol isolates chlorides. The turbidity produced with silver nitrate is compared with that produced by a control standard.

C.2 Apparatus

Nessler cylinders 50 mL capacity

C.3 Reagents

C.3.1 ethyl alcohol - 95% (*rectified spirit*)
C.3.2 Dilute nitric acid - 4M
C.3.3 Silver nitrate - 2%
C.3.4 Standard Hydrochloric acid (HCl) - 0.01M

C.4 Procedure

Boil 2.00 g of the material with 20 mL of rectified spirit under a reflux condenser, cool and filter. Take a filtrate in a Nessler cylinder, add 1 mL of dilute nitric acid and 1 mL of silver nitrate solution and dilute to the mark with water. Carryout control test in another Nessler cylinder using 1.0 mL of standard hydrochloric acid and the same quantities of other reagents as used with the sample. Allow the cylinders to stand for 30 min protected from direct sunlight and compare the turbidity.

C.5 The material shall have be taken to have passed the test, if the turbidity produced with the material is not greater than that in the control test.

Annex D
(Normative)

Test for water soluble oxidizable substances

D.1 Reagent

Potassium permanganate solution 0.01M

D.2 Procedure

Warm 10.00 g of the material with 50 mL of water on a steam bath with constant stirring until it is melted. The fat separates completely on cooling, leaving the water layer almost clear. Separate the water layer, filter it and preserve the filtrate. Take a 10 mL portion of this filtrate and warm it with 0.5 mL of potassium permanganate solution.

The material shall be taken to have passed the test, if it does not completely decolourize the potassium permanganate solution within 10 minutes.