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Lactose free milk — Specification

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In order to keep abreast with the progress in the industry, Kenya Standards shall be regularly reviewed. Suggestions for improvements to published standards, addressed to the Managing Director, Kenya Bureau of Standards, are welcome.

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Foreword

This Kenya Standard was prepared by the Milk and Milk Products Technical Committee under the guidance of the Standards Projects Committee and it is in accordance with the procedures of the Kenya Bureau of Standards.

Lactose is a type of sugar or carbohydrate in milk and milk products that can be difficult for some people to digest and is normally hydrolyzed during digestion by the enzyme lactase. People deficient in this enzyme can experience gastrointestinal symptoms including nausea, cramps, bloating and diarrhea. In commercially manufactured lactose-free milk and milk products, most of the lactose has already been broken down into glucose and galactose which are now well tolerated.

This Kenya Standard specifies the safety and quality requirements for the Lactose free milk.

During the preparation of this standard, reference was made to the following documents:

EAS 27, UHT Milk- Specification
EAS 69, Pasteurized Milk-Specification

Acknowledgement is hereby made for the assistance derived from these sources.

Lactose free milk— Specification

1 Scope

This Draft Kenya Standard specifies requirements, sampling and test methods for Lactose free milk.

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.

AOAC Method 984.15. Enzymatic hydrolysis of lactose to glucose and galactose at pH 6.6 by β-galactosidase.
AOAC 999.10, Official method for lead, cadmium, zinc, copper, and iron in foods Atomic Absorption Spectrophotometry after microwave Digestion
KS EAS, UHT Milk- Specification
KS EAS 39, General principles for food hygiene
KS 1552, Code of hygienic practice for milk and milk products
KS EAS 38, Labelling of pre- packaged foods — General requirements
KS EAS 803, Nutrition labelling — Requirements
KS ISO 707, Milk and milk products — Guidance on sampling
KS ISO 2446, Milk — Determination of fat content
KS ISO 4832, Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of coliforms — Colony count technique
KS ISO 4833-1, Microbiology of the food chain — Horizontal method for the enumeration of microorganisms — Part 1: Colony count at 30 degrees C by the pour plate technique
KS ISO 5764, Milk — determination of freezing point — Thermistor cryoscope method (Reference method)
KS ISO 6579-1, Microbiology of the food chain — Horizontal method for the detection, enumeration and serotyping of Salmonella — Part 1: Detection of Salmonella spp
KS ISO 6731, Milk, cream and evaporated milk — Determination of total solids content (Reference method)
KS ISO 6888-3, Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) — Part 3: Detection and MPN technique for low numbers
KS ISO 8968-4, Milk and milk products — Determination of nitrogen content — Part 4: Determination of protein and non-protein nitrogen content and true protein content calculation (Reference method)
KS ISO 14501, Milk and milk powder — Determination of aflatoxin M1 content — Clean-up by immunoaffinity chromatography and determination by high-performance liquid chromatography
KS ISO 22662, Milk and milk products — Determination of lactose content by high-performance liquid chromatography (Reference method)

3 Terms and definitions

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

3.1 pasteurized milk
milk which has been subjected to pasteurization either by batch method, flash pasteurization or High Temperature Short Time method (HTST)

3.2 homogenization process by which milk fat globules are finely divided and interspersed to form a homogeneous product so as to prevent the fat from floating on the surface and adhering to the inside of the container

3.3 UHT milk
milk that is treated under ultra-high temperatures (at 135° – 150° centigrade for 2 secs - 6 sec), homogenized, filled and sealed aseptically into sterile retail containers in order to maintain commercial sterility under room temperatures

3.4 commercial sterility
condition achieved by application of heat sufficient, alone or in combination with other appropriate treatment to render food free from microorganisms capable of growing in the food as normal non-refrigerated conditions at which the food is likely to held during distribution and storage

3.5 reconstituted milk
product resulting from the addition of water to the dried or concentrated form of the product in the amount necessary to re-establish the appropriate water to solids ratio.

3.6 recombined milk
product resulting from the combining of milkfat and milk-solids-non-fat in their preserved forms with or without the addition of water to achieve the appropriate milk product composition.

3.7 toned milk
product prepared by a mixture of cow milk with skimmed milk or powdered milk in the amount necessary to reestablish the appropriate milk product composition.

Lactose free milk
shall mean the product prepared from any type of milk specified in section 4. (1) below, in which, lactose content has been reduced significantly through hydrolysis by enzymatic or any other appropriate process.

4 Requirements

4.1 Raw materials

Raw materials for Lactose free milk may include:
UHT milk;
reconstituted milk;
recombined milk;
pasteurized milk; or
toned milk
lactose free milk powder

4.2 General requirements

Lactose free milk shall:
a) be processed without affecting the composition of the product;
b) have characteristic of texture and colour
c) be free from preservatives, off-flavours and odour; and
d) free from objectionable tastes and foreign Matter

4.3 Specific requirements

Lactose free milk shall comply with the specific requirements given in Table 1 when tested in accordance with tests methods specified therein.

Table 1 — Specific requirements for Lactose free milk

S/N	Characteristic	Requirement	Test method
	Lactose content (%), m/m	have less than 1% lactose	KS ISO 22662/ AOAC Method 984.15
i.	pH	4.0 – 8.5	Annex A
ii.	Titratable acidity, % lactic acid, max.	0.02	Annex B
iii.	Density at 20 °C g/ml,	1.028 - 1.036	Annex C
iv.	Milk fat (%), m/m		
	a) Whole milk/full cream milk, min.	3.25	KS SO 2446
	b) Fat reduced milk/semi skimmed	1.51 - 3.24	
	c) Low fat milk/skimmed milk	0.51 - 1.50	
	d) Fat free milk, max.	0.50	
v.	Milk Solids Non-Fat, %, min.	8.5	KS ISO 6731
vi.	Protein content, %, min.	3	KS ISO 8968-4
vii.	Freezing point, °C	-0.550 to -0.525 I	KS ISO 5764

5 Hygiene

5.1 Lactose free milk shall be produced and handled in accordance with KS 1552 and KS EAS 39.

5.2 Lactose free milk shall comply with microbiological limits given in Table 2 when tested in accordance with the test methods specified therein.

Table 2 — Microbiological requirements for Lactose free milk

S/N	Micro-organisms	Maximum limits	Test method
i.	Total plate count, CFU/ ml	10	KS ISO 4833-
ii.	Coliform, CFU/ ml	absent	KS ISO 4832
iii.	iii. Staphylococcus aureus (coagulase positive), CFU/ ml	absent	KS ISO6888-3
iv.	Salmonella spp, per 25 ml	Absent	KS ISO 6579-1

6 Contaminants

6.1 Pesticide residues

Lactose free milk shall comply with maximum limits residues set by Codex Alimentarius Commission.

6.2 veterinary drug residues

Lactose free milk shall comply with the maximum residue limits set by the Codex Alimentarius Commission.

6.3 Heavy Metal

When tested in accordance with AOAC 999.10, the level of Lead (Pb) shall not exceed 0.02 mg/kg

6.4 Mycotoxins

When tested in accordance with ISO 14501, the level of aflatoxin M1 shall not exceed 0.50 µg/kg.

8 Packaging

8.1 The packaging material used for lactose free milk shall be food grade and shall:

a) be lightproof;
b) be gas-proof;
c) be mechanically strong;
d) be non-toxic;
e) not impart any off-flavour to the milk;
f) be able to withstand aseptic packaging pre-treatment procedure; and
g) allow hermetic sealing.

8.2 The lactose free milk shall be packaged aseptically into sterile packaging material.

8.3 The Lactose free milk packages shall not be deformed, creased, dented or have crushed corners.

9 Labelling

The containers shall be labelled in compliance with the requirements of KS EAS 38 and KS EAS 803. In addition, the following particulars shall be legibly and indelibly labelled on the container:

a)

b) fat content; categories as either:

(i) whole milk/full cream milk;

(ii) fat reduced milk/semi skimmed milk/low fat milk; or

(iii) fat free milk/skimmed milk

c) net content in SI units;

d) name and physical address of manufacturer;

e) batch or code number;

f) the fat content;

g) nutritional information;

h) the date of manufacture and expiry date;

i) instruction for storage and use; and

j) country of origin;

9 Sampling

Sampling for Lactose milk shall be done in accordance with KS ISO 707.

Annex A (normative)

Determination of pH variation

A.1 Apparatus

A.1.1 Incubator adjusted at 55 °C ± 1 °C

A.1.2 pH meter

A.2 Procedure

A.2.1 Determine the pH of 50 ml of the sample in the flask, with a glass electrode at 20 °C and note reading. Then incubate another 50 ml of the sample at 55 °C ± 1 °C for five days. Examine the flask each day, then shake and replace it in the incubator. If any physical alteration of the contents is observed (coagulation with, or without exudation, grittiness, flocculation, formation of bubbles or scum peptonization or proteolysis) the result of the test shall be considered positive and the sample as nonsterile.

A.2.2 If no alteration takes place during the five days' incubation at 55 °C ± 1 °C remove the sample from the incubator and cool to room temperature. Take a small portion of it and measure the pH in the pH meter with glass electrode at 20 °C. From this pH value subtract the initial pH value (A.2.1).

A.3 Interpretation of results

A sample which does not show any physical alteration during incubation at 55 °C ± 1 °C for five days and where the pH does not show a difference of more than 0.3 unit from the initial pH is considered sterile.

Annex B (normative)

Determination of titratable acidity

B.1 Apparatus

B.1.1 Incubator

B.1.2 Burette; with soda-lime guard tube

B.1.3 Porcelain dishes; white hemispherical of approximately 60 ml

B.1.4 Stirring rods; of glass, flattened at one end

B.2 Reagents

B.2.1 Standard sodium hydroxide solution

Prepare concentrated stock solution of sodium hydroxide by dissolving equal parts of sodium hydroxide (stocks or pellets) in equal parts of water in a flask. Tightly stopper the flask with a rubber bung and allow any insoluble sodium carbonate to settle down for three to four days.

Use the clear supernatant liquid for preparing the standard 0.1 M solution. About 8 ml of stock solution is required per litre of distilled water. The solution should be accurately standardized against acidic potassium phthalate or oxalic acid.

B.2.2 Phenolphthalein indicator solution

Dissolve 1 g of phenolphthalein in 110 ml rectified spirit. Add 0.1 M sodium hydroxide solution until one drop gives a faint pink coloration.

B.2.3 Rosaniline Acetate Stock Solution

Dissolve 0.121 g of rosaniline acetate in approximately 50 ml of rectified spirit, containing 0.5 ml of facial acetic acid. Make up to 100 ml with rectified spirit.

B.2.4 Bench solution

Dilute 1 ml of stock solution to 500 ml with a mixture of rectified spirit and distilled water in equal proportions by volume.

The stock and the bench solutions shall be stored in dark brown bottles securely stoppered with rubber bungs.

B.3 Procedure

B.3.1 Acidity of fresh sample

Weigh 10.0 g of the sample into each of the two white porcelain dishes of approximately 60 ml capacity; add to both 10 ml of water and stir to disperse the sample. Prepare from one dilution a colour control by addingand stirring 2 ml dilute rosaniline acetate solution. Stir 2 ml phenolphthalein solution into the other dilution and while stirring vigorously, add as rapidly as possible sodium hydroxide solution from a 10-ml burette fitted with a soda-lime guard tube, until the colour matches the pink colour of the control. The titration shall be done in bright light.

B.3.2 Acidity after incubation

Incubate another 20 g of sample at 55 °C ± 1 °C for five days. Examine the flask each day, then shake and replace it in the incubator. If any physical alteration of the content is observed the results of the test shall be considered positive and the sample as non-sterile.

If no alteration takes place during the five days' incubation remove the sample from the incubator and cool to room temperature. Weigh 10 g of the incubated sample and determine acidity as described in B.3.1.

B.4 Calculation

B.4.1 Acidity of fresh sample

Titratable acidity (as lactic acid) per cent by weight =

m MV .9/w

Where,

V=is the volume in ml of the standard sodium hydroxide required for titration (see B.3.1)

M=is the molarity of the standard sodium hydroxide solution (see B.3), and

m=is the mass in g of the sample taken for test (see B.3.1).

B.4.2 Acidity after incubation

B.4.2.1 Titratable acidity (as lactic acid) percent by weight =

MV .9/w

Where,

V=is the volume in ml of the standard sodium hydroxide required for titration (see B.2.1),

M=is the molarity of the standard sodium hydroxide solution (see B.2.1),

w=is the weight in g of the sample taken for the test (see B.2.1)

B.4.2.2 Subtract the value obtained in B.4.1 from the value obtained in B.4.2 which would give increase in acidity.

B.5 Interpretation of results

A sample which does not show any physical alteration during incubation at 55 °C ± 1 °C for five days and where the acidity does not show a difference of more than 0.02 g from the initial acidity is considered sterile.

Annex C (normative)

Determination of Density in milk

C.1 General

The density is a relationship between the body mass and the volume this body occupies in the space. The density test is performed in order to be used in the detection of adulteration in the milk since, the addition of water only would cause the decrease in density, whereas the skimming (fat removal) would cause an increased density in the milk, beside supplying important information for the determination of the total dry extract.

C.2 Equipment
The following equipment shall be used:
a) Thermolactodensimeter (TLD); and
b) Test tube (250 mL)
C.3 Methods
The density determination is accomplished by the Thermolactodensimeter because the practicability of this method.

C.4 Procedure

C.4.1 Place the sample to be analyzed in the clean and dry test tube by taking the care of inclining the test tube and allowing the liquid to flow down the walls of the glass for avoiding the incorporation of the air which would reduce the density of the milk.
C.4.2 Immense TLD into the test tube and make it rotate slowly on its own axis.
C.4.3 Perform the reading of both density and temperature of the milk as soon as TLD stabilizes.
C.4.4 Proceed to the correction of the influence from the temperature, by using an adequate scale. The result will correspond to the corrected milk density.