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Mouthwash — Specification

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Reference number

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Foreword

Rwanda Standards are prepared by 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.

DRS 453 was prepared by Technical Committee RSB/TC 011, *Cosmetics and related products*.

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

ISO 16408 Dentistry— Oral care products — Oral rinses

The assistance derived from the above source is hereby acknowledged with thanks.

Committee membership

The following organizations were represented on the Technical Committee on *Cosmetics and related products of TC* (RSB/TC 011) in the preparation of this standard.

Paragraph of participants

University of Rwanda/ College of Sciences and Technology (UR/CST)

Rwanda Forensic Laboratory (RFL)

SULFO industries Ltd

Rwanda Inspectorate, Competition and Consumer Protection Authority (RICA)

MORIJA Cosmetics Ltd

Better Home Ltd

UBURANGA Products Ltd

BARANYUZWE Cosmetics Ltd

Better Home Ltd

ORIBUT Company Ltd

Rwanda Standards Board (RSB) – Secretariat

Introduction

A mouthwash (mouth rinse or oral rinse) is a liquid solution that you swish around your entire mouth, teeth, gums and tongue to help promote oral hygiene, reduce oral discomfort, provide moisture to oral tissues or help with bad breath. Oral rinses may be purchased over-the-counter (OTC) or via prescription, and can be categorized as cosmetic, therapeutic or a combination of the two.

While not a replacement for daily brushing and flossing, use of mouthwash (mouth rinse) may be a helpful addition to the daily oral hygiene routine for some people because mouthwash offers the benefit of reaching areas not easily accessed by a toothbrush.

Cosmetic mouthwashes may temporarily control or reduce bad breath (halitosis), rinse away oral debris, diminish bacteria in your mouth and leave it with a pleasant, refreshing taste. Cosmetic mouthwashes mask rather than eliminate bad breath. Their odor-masking effects typically last no more than three hours. Some mouthwashes also contain whiteners to help whiten the teeth.

Cosmetic mouthwashes that contain some of the active ingredients found in rinses designed to treat oral health conditions (i.e. fluoride to help strengthen teeth and prevent cavities) also double as therapeutic rinses

Therapeutic mouthwashes available in non-prescription and prescription formulations contain added active ingredients to help prevent or treat various oral health conditions and diseases. Therapeutic mouthwashes are either anti-plaque/anti-gingivitis, anti-cavity, anti-tartar or antibacterial.

Mouthwash — Specification

1 Scope

This Draft Rwanda standards specifies physical and chemical requirements, sampling and test methods for liquid mouthwash.

This Draft Rwanda standards is not applicable to other delivery systems (e.g. mouth sprays, foams, powders). It is not applicable to mouthwash for prescription only.

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.

ISO 1942, *Dentistry — Vocabulary*

RS ISO 3696, *Water for analytical laboratory use — Specification and test methods*

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

RS EAS 847-17, *Cosmetics — Analytical methods — Part 17: Determination of pH*

3 Terms and definitions

For the purposes of this standard, the terms and definitions given in ISO 1942 and the following apply.

3.1
mouthwash
mouth rinse
oral rinse

liquid formulation used by the public for oral care purposes

4 Classification

Mouthwash shall be classified according to their application by the user as follows:

— **Type 1:** ready-for-use solutions;

— **Type 2:** concentrated solutions for use after dilution with water;

— **Type 3:** solutions for use after mixing.

5 Requirement

5.1 General requirements

5.1.1 Compatibility with oral tissues

Mouthwash shall not cause irritation or damage to the oral hard and/or soft tissue, when used in accordance with the manufacturer's recommendation for frequency and duration of use and experience with known side effects.

5.1.2 Stability against ageing

Mouthwash shall show no signs of deterioration, such as agglomeration or change in clarity, after being subjected to the determination of stability to ageing procedure specified in Annex A.

5.1.3 Container and/or dispensing system

The container and/or dispensing system shall neither contaminate nor permit contamination of the mouthwash after being subjected to the determination of stability to ageing described in Annex A.

5.1.4 Readily fermentable carbohydrates

Mouthwash shall not contain readily fermentable carbohydrates.

5.1.5 Visual inspection

Before and after agitation, examine the mouthwash under a bright light with normal visual acuity without magnification.

5.2 Specific requirements

The product shall also comply with the requirements given in table when tested in accordance with the methods indicated therein.

Table 1: Specific requirements for mouthwash

S/N	Characteristics	Requirements	Test method
i)	Stability against ageing	Pass the test	Annex A
ii)	Total fluoride concentration, max. mass fraction %	0.15	Annex B

iii)	pH	3.0-10.5	RS EAS 847-17
iv)	Unintended heavy metals, mg/kg	20	RS EAS 847-16
v)	Microbial contamination, CFU(Colony-Forming Units), per gram	100	

6 Sampling

The mouthwashes used for testing shall be representative of actual manufactured mouthwash and shall not be altered in any way.

Eight containers of mouthwash from the same manufacturing tracking code (e.g. batch code, lot number) shall be tested before the determination of stability to ageing (see Annex A).

7 Packaging and labelling

7.1 Packaging

Packaging should ensure the integrity of the contents of the container during storage and transportation. The packaging system for mouthwash is left to the discretion of the manufacturer.

7.2 Labelling

The following information, where appropriate, shall be given on the primary container, and also on the secondary container, if it exists:

a) name of the product

b) the manufacturer's name and address;

c) trade name;

d) the wording "mouthwash" or equivalent, as defined in Clause 3;

e) the manufacturer's tracking code (e.g. batch code, lot number);

f) country of origin

g) a list of ingredients

h) net volume, in millilitres;

i) if the mouthwash contains alcohol, the declaration of alcohol content, as volume fraction;

j) if the mouthwash contains fluoride, the concentration of fluoride, in milligrams per kilogram (mg/kg) or ppm (parts per million; 10^{-6}) by mass of fluoride ion;

k) instructions and warning for proper use with children;

l) the statement: Not suitable for children under 6 years of age unless medically recommended;

m) for mouthwash of Type 2, the statement: “Dilute according to the manufacturer’s instructions for use”;

n) for mouthwash of Type 3, the statement: “Mix according to the manufacturer’s instructions for use”;

o) the warning: “Do not swallow”;

p) information on common side- effects,

q) manufacture date and best before date,

r) recommended storage conditions.

Annex A
(normative)

Determination of stability against ageing

A.1 Test

One of the following two tests shall be performed:

a) Accelerated test

Store the mouthwash at (40 ± 2) °C for 3 months at (75 ± 5) % relative humidity or under such conditions of time and temperature as will simulate storage at room temperature for 30 months.

b) Real time test

Store the mouthwash at (23 ± 2) °C at (60 ± 15) °C relative humidity for 30 months or for the period indicated by the expiry date listed on the product label.

A.2 Compliance

Examine by visual inspection (5.1.5) of the mouthwash if requirement 5.1.2 is fulfilled.

Annex B
(normative)

Determination of fluoride in mouthwash containing ionic fluoride compounds

B.1 Principle

This test method is used for the determination of fluoride in mouthwash containing ionic fluoride compounds.

B.2 Reagents and/or materials

During the analysis, unless otherwise stated, use only reagents of recognized analytical grade.

B.2.1 Deionized water, in accordance with ISO 3696, grade 2.

B.2.2 Fluoride standard solution, commercially available or prepared with sodium fluoride (NaF).

B.2.3 Total Ionic Strength Adjustment Buffer (TISAB) solution, with cyclohexanediamine tetra-acetate (CDTA). Other buffer solutions such as ammonium acetate buffer, applicable to fluoride analysis, may also be used.

Ammonium acetate buffer (pH 5.3) is prepared by dispersing of 16 g of ammonium chloride, 23 g of ammonium acetate and 0,4 g of *trans*-1,2-cyclohexanediamine-*N,N,N',N'*-tetraacetate monohydrate in about 80 ml of water and by dissolving this solution after mixing and heating. The pH value of this buffer is adjusted to 5,3 with acetic acid, and the buffer is diluted with deionized water to 100 ml.

B.3 Apparatus

The following apparatus shall be used.

B.3.1 Laboratory balance, with a reading accuracy of 0.01g.

B.3.2 Flask, of capacity 20mL

B.3.3 Fluoride ion selective electrode (F-ISE), with reference electrode or combination F-ISE/reference electrode pair

B.3.4 Graduated cylinder, of capacity 15 ml to 50 ml.

B.3.5 Magnetic stirring apparatus, with PTFE-coated magnetic stirring bar and magnetic stir plate.

B.3.6 pH/mV-electrometer (pH meter), with an accuracy of ±0,05 pH units (±0,1 mV), calibrated**.**

B.3.7 Pipette, of capacity (1,0 ± 0,1) ml.

B.3.8 Plastic vial, or any small beaker or container, 10 ml or more capacity.

B.3.9 Washing bottle.

B.4 Preparation od solutions and calibration curve

B.4.1 Preparation of standard solution for calibration

Make successive dilutions of the fluoride standard solution (B.2.2) to obtain a set of working standards which includes 5 mg/kg, 10 mg/kg (10^{-5} mol/l), 50 mg/kg, 100 mg/kg (10^{-4} mol/l), and 150 mg/kg of fluoride.

B.4.2 Preparation of calibration curve

Use the following procedure to prepare the calibration curve.

a) Pipette 1,0 ml of each standard solution (B.4.1) into a plastic vial (B.3.8).

b) Add 1,0 ml of TISAB solution (B.2.3), and add a magnetic stirring bar (B.3.5) to each plastic vial. Mix thoroughly.

c) Insert the fluoride ion selective electrode (B.3.3) and reference electrodes into the liquid in the plastic vial containing the first standard solution. Make sure no air bubbles have been trapped under the electrode.

d) Record the millivolt reading to 0,1 mV at the steady potential difference with the mV electrometer (B.3.6).

e) Conduct at least two measurements for millivolt readings, until the difference between the two millivolt readings is less than 0,2 mV.

f) Repeat steps c) to e) for each of the other standard solutions.

g) Construct a calibration curve of millivolts versus the log of the fluoride ion concentration of the standard, expressed in milligrams per kilogram.

NOTE The slope of the calibration curve should be linear.

B.4.3 Preparation of sample solution

In duplicate, pipette (1,0 ± 0,1) g of each sample into a 20 ml flask (B.3.2).

Add (9,0 ± 0,1) ml of deionized water (B.2.1) to the flask and mix thoroughly. This is the sample solution.

B.5 Sample analysis

Determine the fluoride ion concentration in the sample solution as follows.

a) Pipette accurately an equal amount of sample solution (B.4.3) and TISAB solution (B.2.3) into a plastic vial (B.3.8) and mix thoroughly.

b) Insert the fluoride ion selective electrode (B.3.3) and reference electrodes into liquid that contains the sample and buffer solution, in the plastic vial (B.3.8). Make sure no air bubbles are trapped under the electrode.

c) Record the millivolt reading to the nearest 0,1 mV at the steady potential difference with the mV electrometer.

d) Use the calibration curve of standard solutions to determine the fluoride ion concentration in the sample solution, in milligrams per kilogram.

B.6 Expression of results

B.6.1 Expression

The fluoride ion concentration shall be expressed in milligrams per kilogram of the oral rinse solution unless otherwise required.

NOTE Regulatory requirements in some regions require the expression of fluoride ion concentration in ppm = parts per million (10^{-6}).

B.6.2 Calculation of fluoride ion concentration

Calculate the fluoride ion concentration of one container of oral rinse using Formula (B.1) (units see B.6.1):

$$C_{OR} = C_S * 10$$

where

cOR is the fluoride ion concentration of mouthwash, in milligram per kilogram (10^{-6});

cS is the fluoride ion concentration of sample solution, in milligram per kilogram (10^{-6}).

B.6.3 Calculation of mass of ionic fluoride

Calculate the mass of ionic fluoride per single container of oral rinse using Formula (B.2) (units see B.6.1):

$m_{OR} = c_{OR} * m$

Where

m_{OR} is the mass of ionic fluoride of mouthwash, in milligram;

c_{OR} is the fluoride ion concentration of mouthwash, in milligram per kilogram (10^{-6});

m is the mass of the solution in one container of mouthwash, in kilogram.

cOR is the fluoride ion concentration of mouthwash, in milligram per kilogram (10^{-6});

cS is the fluoride ion concentration of sample solution, in milligram per kilogram (10^{-6}).

B.6.4 Calculation of mass of ionic fluoride

Calculate the mass of ionic fluoride per single container of oral rinse using Formula (B.2) (units see B.6.1):

$m_{OR} = c_{OR} * m$

Where

m_{OR} is the mass of ionic fluoride of mouthwash, in milligram;

c_{OR} is the fluoride ion concentration of mouthwash, in milligram per kilogram (10^{-6});

m is the mass of the solution in one container of mouthwash, in kilogram.

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Price based on nnn pages