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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 42761-2023

**Screening method for erosion potential of oral rinses on dental
hard tissues**

口腔清洁护理液对牙齿硬组织潜在腐蚀性的评估方法

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Foreword

This document was issued on 23 May 2023 by the State Administration for Market Regulation; Standardization Administration of the PRC and takes effect on 1 December 2023.

It is a GB/T standard: recommended rather than compulsory, but it is the text a Chinese reviewer applies when assessing a submission.

1 Scope

GB/T 42761-2023 screens a mouthwash or other oral rinse for its potential to erode teeth, using an acid-etching model on enamel, on dentine, or on both, with terms taken from GB/T 9937-2020. The requirements clause frames the work as a risk assessment and a preliminary screening of fluoride-free rinses rather than as a clinical finding. Reagents and materials - calcium chloride dihydrate, citric acid, potassium hydroxide and the rest, analytically pure - and the instruments, down to the borosilicate beakers and the range of the pipette, are fixed so the etching conditions are the same from one laboratory to the next. The analytical procedure starts at sampling: two representative samples from each of three different batches, six in all, so a formulation is judged rather than one lucky bottle. An evaluation report clause lists what has to be stated, beginning with full identification of the rinse tested, and an informative annex maps the clause numbering against ISO 28888:2013. Rinses are acidic because acid keeps actives soluble and stable, and a

product used twice a day for years can soften enamel and expose dentine in a way no single use reveals. Oral care manufacturers, formulators, contract laboratories and regulators are the users.

This document describes a method for evaluating the erosion potential of oral rinses on dental

hard tissues using enamel and (or) dentine acid-etching models.

This document is applicable to the evaluation of erosion potential of oral rinses on dental hard

tissues.

This document does not apply to the evaluation of oral rinses containing fluoride.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only

versions with a specified date are applicable to this document. In terms of references without a

specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 6682 Water for Analytical Laboratory Use - Specification and Test Methods (GB/T 6682-

2008, ISO 3696:1987, MOD)

GB/T 9937-2020 Dentistry - Vocabulary (ISO 1942:2009, MOD)

3 Terms and Definitions

What is defined in GB/T 9937-2020, and the following terms and definitions are applicable to

this document.

3.1 tooth erosion; dental erosion

Tooth erosion / dental erosion refers to the progressive loss of calcified dental tissue by chemical processes that do not involve bacterial action.

[source: GB/T 9937-2020, 2.292]

4 Requirements

4.1 Overview

This document is a risk assessment of enamel and dentine acid-etching caused by oral rinses

and a preliminary screening of the erosion potential of all fluoride-free oral rinses. If the product

fails the screening, adopt a more complex and clinically relevant test method specified in the

product standard for the testing.

4.2 Maximum pH Drop Value

The maximum pH drop value allowed in this document is 1.0.

If the pH drop value is greater than 1.0, then, the oral rinse fails the screening test. Under this

circumstance, a more complex and clinically relevant test method should be selected, so as to

determine the erosion effect of the oral rinse.

5 Reagents and Materials

5.1 Calcium chloride dihydrate ($\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$), analytically pure.

5.2 Citric acid ($\text{C}_6\text{H}_8\text{O}_7$), analytically pure.

5.3 Potassium hydroxide (KOH), analytically pure.

5.4 Hydrochloric acid (HCl), analytically pure.

5.5 Trisodium citrate dihydrate ($\text{C}_6\text{H}_5\text{Na}_3\text{O}_7 \cdot 2\text{H}_2\text{O}$), analytically pure.

5.6 Potassium dihydrogen phosphate (KH_2PO_4), analytically pure.

5.7 Distilled water (H_2O), Grade-2 water in compliance with GB/T 6682.

5.8 For citric acid control buffer solution, in accordance with 7.2.3, prepare the following three

standard citric acid buffer solutions:

---Solution 1: 1.0% citric acid solution, pH is 3.60 at 25 °C;

---Solution 2: 0.25% citric acid solution, pH is 3.68 at 25 °C;

---Solution 3: 0.07% citric acid solution, pH is 3.77 at 25 °C.

6 Instruments and Equipment

6.1 Beaker, 50 mL, made of borosilicate glass.

6.2 Beaker, 100 mL, made of borosilicate glass.

6.3 Pipette, with a measuring range of 0.01 mL ~ 1 mL.

6.4 Volumetric flask, 100 mL, 1 L.

6.5 Analytical balance, with an accuracy of 0.0001 g or higher.

6.6 Magnetic stirrer, equipped with a stirring magneton coated with polytetrafluoroethylene (PTFE).

6.7 Thermometer, with an accuracy of 0.1 °C or higher.

6.8 pH meter (pH electrode), calibrated, with an accuracy unit of ± 0.05 pH.

Use standard buffer solutions with pH of 2.0, 4.0 and 6.0 at 25 °C, or standard buffer solutions

with pH of 1.68, 4.01 and 6.86, or pH buffer solutions prepared in accordance with national standards for the calibration. In addition, check the linear response, and the slope per pH unit

shall be at least 58 mV.

NOTE: commercially available pH standard buffer solutions that comply with national standards

and with attached certificates can be used.

7 Analytical Procedures

7.1 Sample Selection

From three different batches of oral rinses, take two representative samples from each batch

(six samples in total).

7.2 Preparation of Solutions

7.2.1 Preparation of stock solutions

---Stock solution A (1 mol/L CaCl₂): add 147.01 g of CaCl₂ · 2H₂O (5.1) to 1 L of water (5.7);