International Standard

ISO 11609

Dentistry — Dentifrices — Requirements, test methods and marking

Médecine bucco-dentaire — Dentifrices — Exigences, méthodes d'essai et marquage

Fourth edition
2026-07

Reference number
ISO 11609:2026(en)

© ISO 2026



COPYRIGHT PROTECTED DOCUMENT

© ISO 2026

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 Requirements relative to the physical and chemical properties of dentifrices ... **2**
4.1 Total fluoride ... 2
4.1.1 Total fluoride concentration ... 2
4.1.2 Total fluoride in a single-unit container ... 2
4.2 Heavy metals (elemental impurities) ... 2
4.3 pH ... 2
4.4 Microbiology ... 2
4.5 Abrasivity ... 2
4.6 Stability ... 3
4.7 Readily fermentable carbohydrates ... 3

5 Test methods ... **3**
5.1 Determination of pH ... 3
5.2 Determination of dentine abrasivity ... 3
5.3 Determination of enamel abrasivity ... 3
5.4 Determination of stability ... 3

6 Marking and labelling ... **4**

7 Packaging ... **4**

Annex A (informative) **Abrasivity test procedure — American Dental Association (ADA) method** ... **5**

Annex B (informative) **Determination of relative dentifrice abrasivity to enamel and dentine by a surface profile method** ... **12**

Annex C (informative) **Testing total fluoride in dentifrices** ... **18**

Bibliography ... **21**

© ISO 2026 – All rights reserved

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 11609:2017), which has been technically revised.

The main changes are as follows:

— edits and clarifications to align with the ISO directives;

— updates for abrasive availability;

— corrections for contacting the manufacturer of the cross-brushing machine;

— correcting Clause 2 and the Bibliography;

— 4.2 has been modified to suggest ISO 21392 for the analysis of five elemental impurities.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

© ISO 2026 – All rights reserved

Introduction

Dentifrices are not expected to cause adverse reactions to oral soft tissue when used in accordance with the manufacturer's recommendation for frequency and duration of use, nor cause any known side effects.

Guidelines on assessing the claimed or implied efficacy of dentifrices for the prevention or control of oral conditions can be found through Reference [19], Reference [20] and Reference [21].

© ISO 2026 – All rights reserved

Dentistry — Dentifrices — Requirements, test methods and marking

1 Scope

This document specifies requirements for the physical and chemical properties of dentifrices and provides guidelines for suitable test methods. It also specifies requirements for the marking, labelling and packaging of dentifrices.

This document is applicable to dentifrices, including toothpastes, destined to be used by consumers on a daily basis with a toothbrush to promote oral hygiene.

This document does not apply to specific qualitative and quantitative requirements for freedom from biological and toxicological hazards. These are covered in ISO 7405 and ISO 10993-1.

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*

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

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 8601-2, *Date and time — Representations for information interchange — Part 2: Extensions*

International Nomenclature of Cosmetic Ingredients (INCI), in International Cosmetic Ingredient Dictionary and Handbook[1)]

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
dentifrice
substance or combination of substances specially prepared for consumers for hygiene of the accessible surfaces of teeth and surrounding tissues

1) Nomenclature developed by the Personal Care Products Council (formerly CTFA). Available at: https://access.personalcarecouncil.org/eweb/DynamicPage.aspx?Site=pcpc&WebKey=4513b14e-2f75-4857-85b4-b3697be5d5d9.

© ISO 2026 – All rights reserved