



# FINAL DRAFT International Standard

## ISO/FDIS 11609

### Dentistry — Dentifrices — Requirements, test methods and marking

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

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CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

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# Contents

Page

<b>Foreword</b>	<b>iv</b>
<b>Introduction</b>	<b>v</b>
<b>1 Scope</b>	<b>1</b>
<b>2 Normative references</b>	<b>1</b>
<b>3 Terms and definitions</b>	<b>2</b>
<b>4 Requirements relative to the physical and chemical properties of dentifrices</b>	<b>2</b>
4.1 Total fluoride	2
4.1.1 Total fluoride concentration	2
4.1.2 Total fluoride in a single-unit container	3
4.2 Heavy metals (elemental impurities)	3
4.3 pH	3
4.4 Microbiology	3
4.5 Abrasivity	3
4.6 Stability	3
4.7 Readily fermentable carbohydrates	3
<b>5 Test methods</b>	<b>4</b>
5.1 Determination of pH	4
5.2 Determination of dentine abrasivity	4
5.3 Determination of enamel abrasivity	4
5.4 Determination of stability	4
<b>6 Marking and labelling</b>	<b>4</b>
<b>7 Packaging</b>	<b>5</b>
<b>Annex A (informative) Abrasivity test procedure — American Dental Association (ADA) method</b>	<b>6</b>
<b>Annex B (informative) Determination of relative dentifrice abrasivity to enamel and dentine by a surface profile method</b>	<b>13</b>
<b>Annex C (informative) A testing of total fluoride in dentifrices</b>	<b>19</b>
<b>Bibliography</b>	<b>22</b>

## Foreword

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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](http://www.iso.org/directives)).

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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 use 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](http://www.iso.org/members.html).

## Introduction

Dentifrices should not cause any adverse reactions to the oral soft tissues 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 the US Food and Drug Administration<sup>[3]</sup>, the American Dental Association<sup>[4]</sup> and the Commission Work Project (8-95) of the FDI World Dental Federation<sup>[5]</sup>.

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