ISO/FDIS 11609

ISO/TC 106/SC 7

Secretariat: JISC

Date: 2025-07-03

Dentistry — Dentifrices — Requirements, test methods and marking

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

iTeh Standards

FDIS stage

ISO/FDIS 11609

https://standards.iteh.ai/catalog/standards/iso/a7abb441-2c2d-4050-91aa-f1b1b82b1e45/iso-fdis-11609

Edited DIS MUST BE USED
FOR FINAL
DRAFT

© ISO 2025

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 E-mail: copyright@iso.org Website: www.iso.org

Published in Switzerland

iTeh Standards (https://standards.iteh.ai) Document Preview

ISO/FDIS 11609

https://standards.iteh.ai/catalog/standards/iso/a7abh441-2c2d-4050-91aa-f1b1b82b1e45/iso-fdis-11609

Formatted: FooterPageRomanNumber, Space Before: 0 pt, Line spacing: single, Tab stops: Not at 487.6 pt

Formatted: Font: 11 pt

© ISO 2025 – All rights reserved

Contents

Forew	ordiv	
Introductionv		
1	Scope	
2	Normative references	
3	Terms and definitions	
4 4.1 4.2 4.3 4.4 4.5 4.6 4.7	Requirements relative to the physical and chemical properties of dentifrices 3 Total fluoride 3 Heavy metals (elemental impurities) 3 pH 3 Microbiology 3 Abrasivity 3 Stability 4 Readily fermentable carbohydrates 4	
5 5.1 5.2 5.3 5.4	Test methods	
6	Marking and labelling5	
7	Packaging5	
Annex	4.5 Abrasivity	
Annex		
Annex	C (informative) A testing of total fluoride in dentifrices21	
Bibliography		

Formatted: Font: 10 pt

Formatted: FooterCentered, Left, Space Before: 0 pt, Tab stops: Not at 487.6 pt

Formatted: Font: 10 pt

Formatted: FooterPageRomanNumber, Left, Tab stops: Not at 487.6 pt

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: Formatted: Font: Cambria, English (United Kingdom) Editsedits and clarifications to meet align with the ISO directives: Formatted: List Continue 1 updates for abrasive availability; Formatted: List Continue 1, No bullets or numbering corrections for contacting the manufacturer of the cross-brushing machine; correcting the Normative Reference list Clause 2 and the Bibliography. 4.24.2 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 Formatted: English (United Kingdom) complete listing of these bodies can be found at www.iso.org/members.html, www.iso.org/members.html Formatted: English (United Kingdom) Formatted: FooterPageRomanNumber, Space Before: 0 pt, Line spacing: single, Tab stops: Not at 487.6 pt Formatted: Font: 11 pt © ISO 2025 – All rights reserved

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[3], the American Dental Association[4] and the Commission Work Project (8-95) of the FDI World Dental Federation[5].

iTeh Standards (https://standards.iteh.ai) Document Preview

ISO/FDIS 11609

https://standards.iteh.ai/catalog/standards/iso/a7abb441-2c2d-4050-91aa-f1b1b82b1e45/iso-fdis-11609

Formatted: Font: 10 pt

Formatted: FooterCentered, Left, Space Before: 0 pt, Tab stops: Not at 487.6 pt

Formatted: Font: 10 pt

Formatted: FooterPageRomanNumber, Left, Tab stops: Not at 487.6 pt

© ISO-2024-2025 – All rights reserved