



SLOVENSKI STANDARD SIST EN ISO 11609:2000

01-januar-2000

Zobozdravstvo - Zobne paste - Zahteve, preskusne metode in označevanje (ISO 11609:1995)

Dentistry - Toothpastes - Requirements, test methods and marking (ISO 11609:1995)

Zahnheilkunde - Zahnpasten - Anforderungen, Prüfverfahren und Kennzeichnung (ISO 11609:1995)

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Produits et matériel pour l'art dentaire - Dentifrice - Prescriptions, méthodes d'essai et marquage (ISO 11609:1995)

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Ta slovenski standard je istoveten z: EN ISO 11609:1998

ICS:

11.060.01	Zobozdravstvo na splošno	Dentistry in general
71.100.70	Kozmetika. Toaletni pripomočki	Cosmetics. Toiletries

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11609

March 1998

ICS 11.060.10

Descriptors: see ISO document

English version

Dentistry - Toothpastes - Requirements, test methods and
marking (ISO 11609:1995)

Produits et matériel pour l'art dentaire - Dentifrice -
Prescriptions, méthodes d'essai et marquage (ISO
11609:1995)

Zahnheilkunde - Zahnpasten - Anforderungen,
Prüfverfahren und Kennzeichnung (ISO 11609:1995)

This European Standard was approved by CEN on 14 February 1998.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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EN ISO 11609:1998

Foreword

The text of the International Standard from Technical Committee ISO/TC 106 "Dentistry" of the International Organization for Standardization (ISO) has been taken over as a European Standard by Technical Committee CEN/TC 55 "Dentistry", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 1998, and conflicting national standards shall be withdrawn at the latest by September 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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Endorsement notice
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The text of the International Standard ISO 11609:1995 has been approved by CEN as a European Standard without any modification.

SIST EN ISO 11609:2000

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NOTE: Normative references to international publications are listed in annex ZA (normative).



Annex ZA (normative)**Normative references to international publications
with their relevant European publications**

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 3696	1987	Water for analytical laboratory use - Specification and test methods	EN ISO 3696	1995

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INTERNATIONAL STANDARD

ISO
11609

First edition
1995-12-15

Dentistry — Toothpastes — Requirements, test methods and marking

*Produits et matériel pour l'art dentaire — Dentifrice — Prescriptions,
méthodes d'essai et marquage*

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Reference number
ISO 11609:1995(E)

ISO 11609:1995(E)**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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 11609 was prepared by Technical Committee ISO/TC 106, *Dentistry*, in collaboration with the International Dental Federation (FDI).

Annex A forms an integral part of this International Standard. Annexes B and C are for information only.

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Case postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

Dentistry — Toothpastes — Requirements, test methods and marking

1 Scope

This International Standard specifies requirements and test methods for physical and chemical properties, and for the marking and/or labelling of toothpastes for daily use by the public with a toothbrush to promote oral hygiene.

NOTE 1 It is anticipated that guidelines on claimed or implied efficacy of toothpastes for the prevention or control of oral conditions will be published as an FDI Technical Report.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1942:1989, *Dental vocabulary*.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*.

BS 5136:1981, *Specification for toothpastes*.

CTFA, *International Cosmetic Ingredients Dictionary*.¹⁾

SHELLIS, R.P. A synthetic saliva for cultural studies of dental plaque. *Archives Oral Biol.*, **23**, pp. 485-489, 1978.

POPE, D.G. Accelerated stability testing for production of drug product stability. *Drugs and Cosmetics*, pp. 54-62, 1980.

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 1942 and the following definitions apply.

3.1 dentifrice: Any substance or combination of substances specially prepared for the public for cleaning the accessible surfaces of teeth.

3.1 toothpaste: Any semi-solid dentifrice preparation presented in the form of a paste, cream or gel.

NOTE 2 The product's main constituents generally are an abrasive, humectants, a binder, a surfactant and a flavouring. Secondly, the product may contain agents for oral health maintenance.

4 Requirements

4.1 Total fluoride

The total fluoride concentration shall not exceed the limits set by national laws and regulations and in no case shall the total fluoride concentration exceed 0,15 % (*m/m*). When using containers, for example dispensing systems of various sorts, the total fluoride content per single unit shall not exceed 300 mg.

Test in accordance with one of the procedures given in annex B or the EEC method^[22]. Other validated methods of similar sensitivity and accuracy may be used (see references [20] and [21]).

1) See note 4, clause 6.