



## General Requirements of Safety and Technical for Toothpastes (Draft for Comments) and Explanatory Notes

《牙膏安全通用技术要求(征求意见稿)》及编制说明

National Medical Products Administration

Release Date: Mar 30, 2026  
Implementation Date: /

*Translated by ChemLinked*

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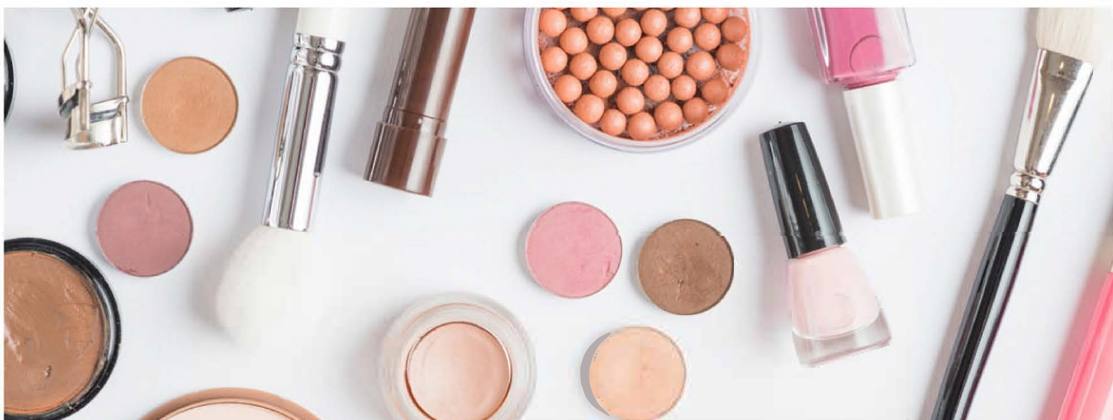
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## General Requirements of Safety and Technical for Toothpastes

(Draft for Comments)

When submitting feedback, please attach the relevant patents that you are aware of along with supporting documents.

Issued on 201X-XX-XX

Implemented on 201X-XX-XX

Issued by  
State Administration for Market Regulation  
National Standardization Administration

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## Foreword

This document was drafted in accordance with the provisions of GB/T 1.1-2020 *Directives for Standardization - Part 1: Rules for the Structure and Drafting of Standardizing Documents*.

Attention is drawn to the possibility that some of the contents of this document may be the subject of patent rights. The issuing body of this document shall not be held responsible for identifying any or all such patent rights.

This document was proposed by and is under the jurisdiction of National Medical Products Administration (NMPA).

## General Requirements of Safety and Technical for Toothpastes

### 1 Scope

This document specifies the general requirements and product requirements for toothpastes.

This document applies to the toothpastes produced and operated within the territory of the People's Republic of China.

This document does not apply to the toothpastes for sale solely outside the People's Republic of China.

### 2 Normative References

The following referenced documents are indispensable for the application 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.

GB/T 603 *Chemical Reagent - Preparations of Reagent Solutions for Use in Test Methods*

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

GB/T 8372 *Toothpaste*

GB 22115 *General Requirements on Raw Materials of Toothpastes*

GB/T 32115 *Determination of Ethylene Glycol and Diethylene Glycol in Oral Care Products*

GB/T 40002 *Oral Hard Tissue Safety Evaluation of Toothpastes*

*Safety and Technical Standards for Cosmetics (STSC)*

*Technical Guidelines for Cosmetic Safety Assessment (NMPA Announcement No. 51 of 2021)*

### 3 Terms and Definitions

For the purposes of this document, the following terms and definitions apply.

#### 3.1 Toothpastes

Paste products applied to the surface of human teeth by means of friction, primarily for the purpose of cleaning.

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- + Cosmetic formula and label compliance review
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- + Functional cosmetic registration
- + Ingredients registration by ICID



- + Marketing license application
- + Cosmetics notification
- + Ingredients analysis and full ingredient list translation
- + Cosmetic test service
- + Label & advertisement review



- + Responsible Person (RP) service in the EU & UK
- + Cosmetic Product Notification Portal (CPNP)
- + Cosmetic Product Safety Report (CPSR)
- + Preparation of Product Information File (PIF)



- + Cosmetic formula and label compliance review
- + FDA Voluntary Cosmetic Registration Program (VCRP)
- + California Safe Cosmetics Program (CSCP)
- + Toxicological Risk Assessment (TRA)
- + INCI application

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## 牙膏安全通用技术要求

General Requirements of Safety and Technical for Toothpastes

(征求意见稿)

在提交反馈意见时，请将您知道的相关专利连同支持性文件一并附上。

201X-XX-XX 发布

201X-XX-XX 实施

国家市场监督管理总局

国家标准化管理委员会

发布

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## 前 言

本文件按照GB/T 1.1—2020《标准化工作导则 第1部分：标准化文件的结构和起草规则》规定起草。

请注意本文件的某些内容可能涉及专利。本文件的发布机构不承担识别这些专利的责任。

本文件由国家药品监督管理局提出并归口。

## 牙膏安全通用技术要求

### 1 范围

本文件规定了牙膏的一般要求和产品要求。

本文件适用于中华人民共和国境内生产、经营的牙膏。

本文件不适用于仅供中华人民共和国境外销售的牙膏。

### 2 规范性引用文件

下列文件对于本文件的应用是必不可少的。凡是注日期的引用文件，仅所注日期的版本适用于本文件。凡是不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

GB/T 603 化学试剂 试验方法中所用制剂及制品的制备

GB/T 6682 分析实验室用水规格和试验方法

GB/T 8372 牙膏

GB 22115 牙膏用原料规范

GB/T 32115 口腔护理产品中乙二醇与二甘醇的测定方法

GB/T 40002 牙膏对口腔硬组织的安全评价

化妆品安全技术规范

化妆品安全评估技术导则（国家药品监督管理局2021年第51号公告）

### 3 术语和定义

下列术语和定义适用于本文件。

#### 3.1 牙膏 toothpastes

以摩擦的方式，施用于人体牙齿表面，以清洁为主要目的的膏状产品。

#### 3.2 儿童牙膏 children's toothpastes

适用于年龄在12岁以下（含12岁）儿童的牙膏。

#### 3.3 单元容器 single-unit container



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