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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 42763-2023

**Guideline for safety assessment of oral care and cleansing
products**

口腔清洁护理用品安全评估指南

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Foreword

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1 Scope

GB/T 42763-2023 gives guidance on the safety assessment of oral care and cleansing products. Toothpaste and mouthwash are an unusual exposure case: the product is applied to a highly permeable mucosa, twice a day for a lifetime, beginning in infancy, and a proportion of every dose is swallowed - which is why the assessment cannot be borrowed from cosmetics applied to skin. The standard sets the information required for the assessment, covering the physicochemical properties of the raw materials, the toxicological information and the human safety data, and then the safety assessment of the raw materials with the assessment itself and the procedure to be followed. It took effect on 1 December 2023.

This document provides general principles, procedures and conditions for the safety assessment of finished products and raw materials of oral care products (toothpaste and mouthwash) guide: This document is applicable to the safety assessment of finished oral care products and raw materials:

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text: Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document:

GB 22115 Specification for Toothpaste Raw Materials

GB/T 35919 Classification and Terminology of Oral Cleaning and Care Products

3 Terms and Definitions

The following terms and definitions defined in GB/T 35919 apply to this document: 3:

1 Act on human teeth, oral mucosa or dentures by scrubbing, gargling, rubbing, spraying, scraping, sticking or other similar methods to achieve Daily products for cleaning, reducing bad odors, grooming, maintaining and keeping them in good condition:

Note: This document refers specifically to toothpaste and mouthwash: [Source: GB/T 35919-2018, 2:2:1] 3:2 hazard hazard The property of a chemical (raw material or hazardous substance) to have an adverse effect on the human body under exposure conditions: 3:3 risk risk Under exposure conditions, the possibility and characteristics of a chemical (raw material or risk substance) causing harmful effects or adverse reactions to users: 3:4 risk assessment risk assessment The process of systematically and scientifically analyzing the possibility of adverse health effects or adverse reactions resulting from

exposure to a hazardous factor or condition:

Note: It usually includes four steps: hazard identification, dose-response relationship assessment, exposure assessment and risk characterization: 3:5 A level of exposure to a chemical that is not expected to present a risk to human health:

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