



# Administrative Measures on Toothpaste

## 牙膏监督管理办法

State Administration for Market Regulation

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*Translated by ChemLinked*

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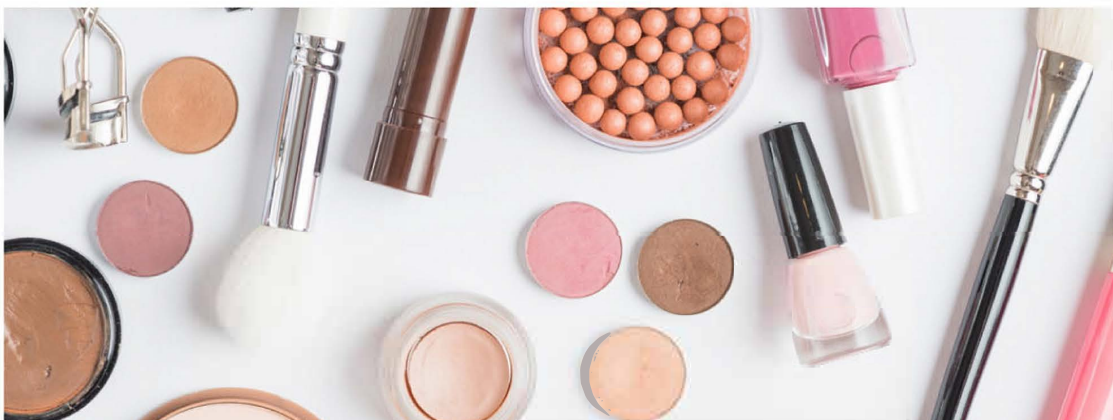
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## Administrative Measures on Toothpaste

(Promulgated by Decree No. 71 of the State Administration for Market Regulation on March 16, 2023, effective as of December 1, 2023)

**Article 1** In order to standardize the production and operation activities of toothpaste, strengthen the supervision and administration and ensure the quality and safety of toothpaste, safeguard the health of consumers, and promote the healthy development of the toothpaste industry, the *Measures* is hereby formulated in accordance with the *Cosmetic Supervision and Administration Regulations* (CSAR).

**Article 2** The *Measures* apply to the production and operation of toothpaste and the supervision and administration thereof within the territory of the People's Republic of China.

**Article 3** The term "toothpaste" as referred to in the *Measures* refers to a paste like product that is applied to the surface of human teeth by friction for the main purpose of cleaning.

**Article 4** The National Medical Products Administration (NMPA) should be responsible for the supervision and administration of toothpaste throughout the country.

The medical products administration departments under the local people's governments at or above the county level should be responsible for the supervision and administration of toothpaste in their respective administrative areas.

**Article 5** Toothpaste are subject to notification administration, and toothpaste notifiers should be responsible for the quality, safety, and efficacy claims of the toothpaste concerned.

Toothpaste producers and operators should engage in production and operation activities in accordance with laws, regulations, mandatory national standards, and technical specifications, strengthen administration, adhere to integrity and self-discipline, and ensure the quality and safety of toothpaste products.

**Article 6** Overseas toothpaste notifiers should designate an enterprise legal person in China as the domestic responsible person to handle the notification, assist in the monitoring of adverse reactions to toothpaste, implement product recalls, and cooperate with the supervision and inspection work of the medical products administration departments.

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## 牙膏监督管理办法

(2023 年 3 月 16 日国家市场监督管理总局令第 71 号公布 自 2023 年 12 月 1 日起施行)

第一条 为了规范牙膏生产经营活动，加强牙膏监督管理，保证牙膏质量安全，保障消费者健康，促进牙膏产业健康发展，根据《化妆品监督管理条例》，制定本办法。

第二条 在中华人民共和国境内从事牙膏生产经营活动及其监督管理，适用本办法。

第三条 本办法所称牙膏，是指以摩擦的方式，施用于人体牙齿表面，以清洁为主要目的的膏状产品。

第四条 国家药品监督管理局负责全国牙膏监督管理工作。

县级以上地方人民政府负责药品监督管理的部门负责本行政区域的牙膏监督管理工作。

第五条 牙膏实行备案管理，牙膏备案人对牙膏的质量和功效宣称负责。

牙膏生产经营者应当依照法律、法规、强制性国家标准、技术规范从事生产经营活动，加强管理，诚信自律，保证牙膏产品质量安全。

第六条 境外牙膏备案人应当指定我国境内的企业法人作为境内责任人办理备案，协助开展牙膏不良反应监测、实施产品召回，并配合药品监督管理部门的监督检查工作。

第七条 牙膏行业协会应当加强行业自律，督促引导生产经营者依法从事生产经营活动，推动行业诚信建设。

第八条 在中华人民共和国境内首次使用于牙膏的天然或者人工原料为牙膏新原料。

牙膏新原料应当遵守化妆品新原料管理的有关规定，具有防腐、着色等功能的牙膏新原料，经国家药品监督管理局注册后方可使用；其他牙膏新原料实行备案管理。



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