



Export Compliance: Toothpaste in China

ZMUni Compliance Centre

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On December 1, 2023, the ***Measures for Toothpaste Supervision and Administration*** (hereinafter referred to as the ***Measures***) officially came into effect in China, stipulating that toothpaste shall be subject to filing in accordance with provisions regarding general cosmetics in the ***Cosmetic Supervision and Administration Regulation (CSAR)***.

Regulation	Remark	Effective Date
<i>Cosmetic Supervision and Administration Regulation (CSAR)</i>	Toothpastes should be managed with reference to the provisions on general cosmetics in <i>CSAR</i> .	Jan. 1, 2021
<i>Technical Guidelines for Cosmetic Safety Assessment</i>	Toothpastes filers shall carry out product safety assessment in accordance with <i>Technical Guidelines for Cosmetic Safety Assessment</i> and submit a product safety assessment report during filing.	May 1, 2021
<i>Administrative Measures on Cosmetics Labeling</i>	Toothpastes' Chinese name, warning labeling, and the use of permitted efficacy claims in conjunction with other terms shall comply with the provisions in <i>Administrative Measures on Toothpastes and Administrative Measures on Cosmetics Labeling</i> .	May 1, 2022
<i>Measures for Toothpaste Supervision and Administration</i>	The regulation stipulates the responsibilities of all stakeholders, toothpaste' s definition, the management requirements for toothpaste products and new ingredients, the ongoing use of the existing toothpaste production licensing system, and the requirements for toothpaste safety assessment, efficacy claims and labeling.	Dec. 1, 2023
<i>Provisions on the Management of Toothpaste Filing Materials</i>	The regulation stipulates the documentation requirements for toothpastes notification.	Dec. 1, 2023

1. Definition

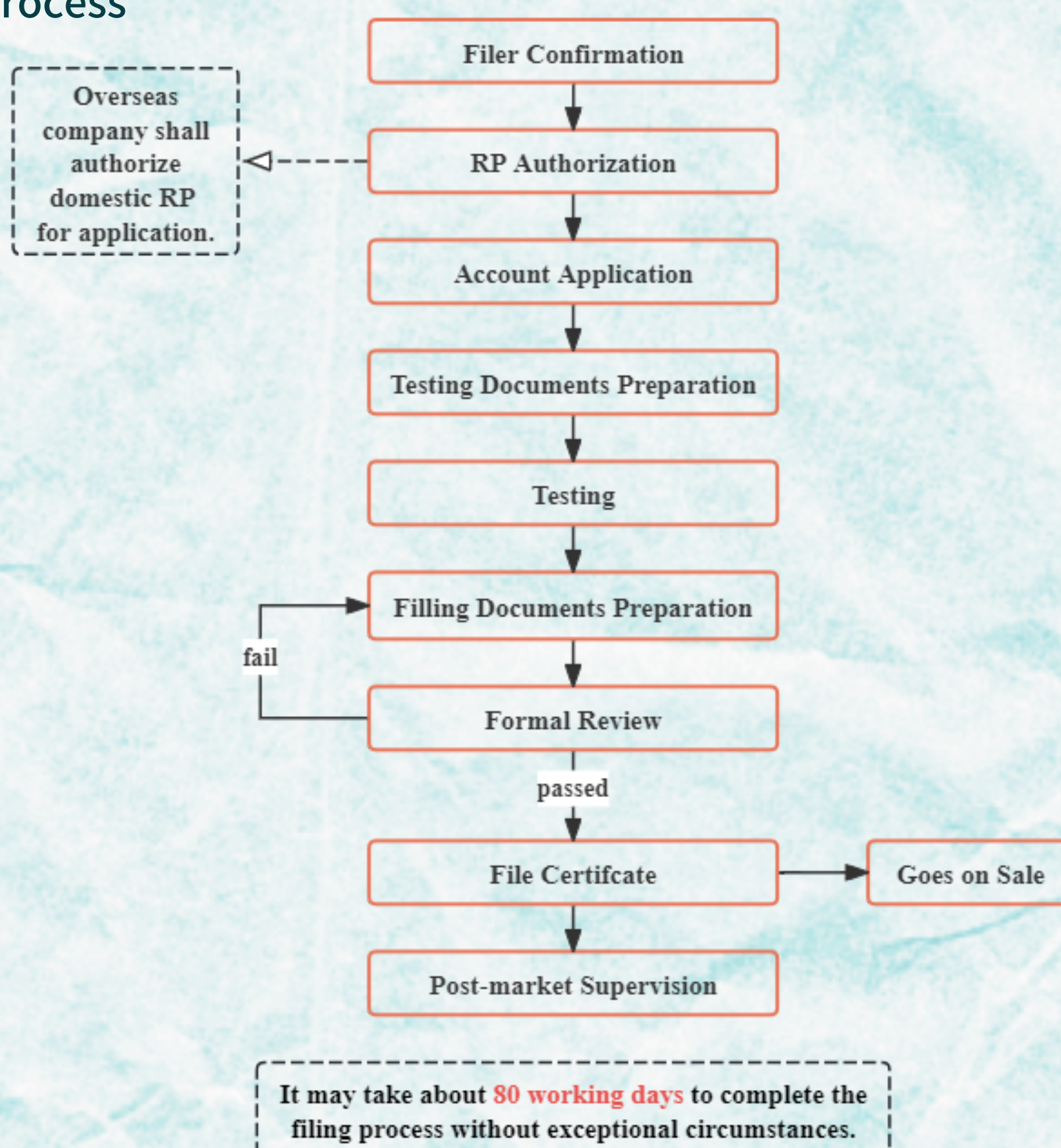
Under the *Measures*, toothpaste is defined as a paste applied to the surface of human teeth by friction for cleaning.

Due to the same usage, Tooth Gel can be regarded as toothpaste. The following tooth products are explicitly not classified as toothpaste: **mouthwash, tooth powder, tooth stickers, children's foam dental cleansers, etc.**

2. Requirements of Filing

According to the *Measures*, domestically produced toothpaste in China must be filed with the local Medical Products Administration (MPA) before it goes on sale. Imported toothpaste from overseas must be filed with the National Medical Products Administration (NMPA) before importation. The NMPA may, by law, delegate the import toothpaste filing management work to the local MPA with the corresponding capabilities.

(1) Filing Process



2. Requirements of Filing

(2) Filing Documents

- Name, Address and Contact Information of the Filler (including authorized Domestic RP)
- Name, Address and Contact Information of the Manufacturer
- Product Name
- Product Category
- Product Formula
- Product Executive Standards
- Product Label Sample
- Product Testing Report
- Product Safety Assessment Documents
- Imported Toothpaste: Proof of the product being already marketed and sold in the manufacturing country (region) must be provided, as well as documentation proving that the overseas manufacturer complies with the quality management standards for cosmetic production.
- Other Documents Useful for Filing



3. Requirements of Naming

- (1) The product name of a toothpaste generally consists of three parts: the trademark, the generic name, and the attribute name.
- (2) The attribute name of toothpaste should uniformly use "toothpaste" for expression. Non-toothpaste products cannot deceive or mislead consumers by labeling "toothpaste" in any way.
- (3) When the names of different products are the same, additional information should be specified after the attribute name, including color, fragrance, or specific user groups. However, the labeling content added must correspond to the actual additives of products.
- (4) The suffix of the product name should not use the names of active ingredients or terms indicating product efficacy. For instance, if a toothpaste contains probiotics, the product name cannot show "probiotics" or promote the effectiveness of probiotics. However, it can be separately labeled that the product contains probiotics.
- (5) If the product name contains terms such as **lysozyme, enzymes, active peptides**, etc., documents confirming the claimed efficacy of the ingredients should be provided, including the efficacy basis of the ingredients and efficacy reports of the products.
- (6) It is prohibited to imply medical effects in generic names by using drug names such as **Xiasangju** or **Shuanghuanglian**. However, herbal names such as **Panax notoginseng, Watermelon frost, and Zanthoxylum nitidum** can be used as generic names.
- (7) For imported products, both Chinese and foreign language names must be provided.



4. Requirements of Labeling

Toothpaste labeling requirements must comply with *Measures* and *Administrative Measures on Cosmetics Labeling*. The following content is prohibited from toothpaste labeling:

- (1) Content that expressly or impliedly has a medical function, for instance, this product has antibacterial and anti-inflammatory functions, or this product can remove dental calculus;
- (2) False or misleading content, such as recommended by the government agencies or certain dental institutions, etc.
- (3) Content that violates social morality and customs;
- (4) Other content prohibited by laws, administrative regulations, mandatory national standards, and technical specifications from being labeled.

5. Requirements of New Ingredient Use

Regarding the *Measures*, natural or artificial ingredients used for the first time in toothpaste in China are considered new toothpaste ingredients. The management of new toothpaste ingredients refers to the relevant regulations on the management of new cosmetic ingredients.

New toothpaste ingredients with functions such as **preservatives** and **coloring** shall be used only after registration by the NMPA; other new toothpaste ingredients shall be subject to filing.

New toothpaste ingredients that have been registered or completed filing shall undergo a 3-year safety monitoring period.

The ingredient list for toothpaste (already in use) is still being formulated. It is anticipated to be released in two batches (general and special ingredients).

6. Requirements for Children's Toothpaste

Children's toothpaste refers to toothpaste suitable for children under the age of 12 (including 12 years old), with cleaning and anti-cavity effects.

(1) Labels such as "suitable for all ages," "family use," or the use of trademarks, patterns, homophones, letters, Pinyin, numbers, symbols, packaging forms, etc., implying that the product is intended for children, fall under the management of children's toothpaste.

(2) Children's toothpaste should include "**Caution**" or "**Warning**" as guiding language, and relevant warning phrases such as "Used under adult supervision," "Do not ingest," "Beware of wallowing," etc., should be visibly marked on the sales packaging.

(3) The Logo of children's toothpaste should be located in the upper left corner of the main display surface. If there is an outer packaging, it is not mandatory to label the logo on the inner packaging. Still, if there is no outer packaging, the packaging directly in contact with the contents must be labeled.

(4) Children's toothpaste should be designed following the principles of safety priority, efficacy necessity, and minimal formulation by the physiological characteristics of children.

(5) Children's fluoride toothpaste should be labeled with the recommended single-use limit.



7. FAQs Collection

Q1: How do overseas toothpaste products get filed in China?

Under the Measures, overseas toothpaste filers shall authorize a domestic enterprise legal entity in China to be the responsible party for filing, assisting in monitoring adverse reactions to toothpaste, implementing product recalls, and cooperating with supervision and inspection efforts by the drug regulatory authorities.

Q2: How should toothpaste efficacy claims be made?

According to the **CSAR**, the toothpaste filers can claim that the toothpaste has effects such as preventing dental caries, inhibiting dental plaque, resisting dentin hypersensitivity, and alleviating gum problems only after having the efficacy evaluation by national and industry standards.

Under the **Measures**, the efficacy claims of toothpaste should have a scientific basis and be consistent with the filed efficacy claims.

The **Provisions on the Management of Toothpaste Filing Materials** (hereinafter referred to as **Provisions**) stipulates that toothpaste that claims only cleaning efficacy are exempt from efficacy evaluation; for claims other than cleaning, such as whitening, specific efficacy evaluations should be made for specific claims.

Q3: How should toothpaste formulated with new ingredients be filed?

According to the **Provisions on the Management of Toothpaste Filing Materials**, when using new ingredients in toothpaste that are still under safety monitoring, the filer or the domestic responsible party should fill in the registration number or filing number of the new ingredient used. They should submit the authorization document from the registrant or filer allowing the use of the new ingredient to confirm the authorized use information of the ingredient.

Q4: Can toothpaste be produced using multiple manufacturing processes?

Yes, according to the **Provisions**, toothpaste can be produced using two or more manufacturing processes simultaneously. Manufacturers should provide a brief description of each production process. If multiple manufacturing processes are used, only one complete product inspection report is required for one of the production processes. Additionally, microbiological and physicochemical test reports for the other production processes should be submitted.

7. FAQs Collection

Q5: Can toothpaste with multiple types of packaging provide label images for just one kind of packaging?

Toothpaste with multiple types of packaging should submit label images for all packaging variations. However, in certain cases, you may only need to upload label images for a kind of packaging if the following situations arise:

- (1) There are differences in net weight only;
- (2) The uploaded packaging has been labeled additionally with information for sales channels, promotions, holiday specials, and gifts only;
- (3) There are differences in color only;
- (4) Already filed products are being sold in sets, gift boxes, and other forms of combination that do not affect the product's content;
- (5) The text description reflects the difference with the uploaded packaging and has been noted.

Cosmetics and Cosmetic Ingredients Compliance Services

- Notification for Imported General Cosmetics
- Registration for Imported Special Cosmetics
- Notification for Imported Children's Cosmetics
- Registration for Imported Children's Cosmetics
- Application for New Cosmetic Ingredients
- Application for Submission Code of Cosmetics Ingredients
- Notification for Toothpaste
- Responsible Person in China
- Safety Assessment for Cosmetics
- Efficacy Claims Review for Cosmetics
- Ingredients/Labeling Review




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