



Taiwan Cosmetic Hygiene and Safety Act

化粧品衛生安全管理法

Taiwan Food and Drug
Administration

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Cosmetic Hygiene and Safety Act

Chapter 1 General Provisions

Article 1

This Act is enacted to maintain the hygiene and safety of cosmetics in order to safeguard national health.

Article 2

For purposes of this Act, the term "competent authority" shall mean the Ministry of Health and Welfare at the central government level, the municipal governments at the municipal level, and the county/city governments at the county/city level.

Article 3

The terms used in this Act are defined as follows:

1. "Cosmetics" means products applied externally to the human body, teeth, or oral cavity mucous membranes, and used to moisturize hair and skin, stimulate the sense of smell, improve body odors, change appearance, or cleanse the body. However, this is not applicable to those that are regarded as drugs in accordance with other laws or regulations.

2. "Cosmetics business" means a business engaged in the manufacture, import, or sale of cosmetics.

3. "Product information file" means a number of documents containing data about the quality, safety, and functions of cosmetics.

4. "Cosmetics ingredient" means a single chemical entity or mixture contained in cosmetics.

5. "Label" means a marking object used to bear words, graphics, or symbols for affixation on the container or package of a cosmetic.

6. "Leaflet" means an instruction sheet accompanying a cosmetic.

The scope and categories of cosmetics as defined in Subparagraph 1 of the preceding paragraph shall be publicly announced by the central competent authority.

Chapter 2 Manufacturing, Import, and Management of Factories

Article 4

Cosmetics categories and cosmetics manufacturers or importers of a certain scale that are specified by the central competent authority as per public announcement shall complete product notification and establish product information file prior to the supply, sale, giveaway, public display, or consumer trial offer of cosmetics. The same shall apply to modifications.

Regulations governing the certain scale, the items, contents, procedures, modifications, validity term, revocation, and rescission of product notification, and other matters to be observed with regard to the preceding paragraph shall be prescribed by the central competent authority.

Regulations governing the certain scale, the items, contents, modifications, methods for establishment and maintenance, retention period, location, qualification of signatory for the safety report of product information file, and other matters to be observed with regard to Paragraph 1 shall be prescribed by the central competent authority.

Article 5

For the manufacturing or import of specific purpose cosmetics designated by the public announcement of central competent authority, an application for registration shall be filed with the central competent authority. No manufacturing or import shall be allowed until a license is approved and issued.

Licensed cosmetics of the preceding paragraph shall not modify any of the originally registered particulars without approval of the central competent authority. However, this restriction does not apply to particulars that may be voluntarily modified per public announcement by the central competent authority.

The import of specific purpose cosmetics shall be exempted from application for registration of Paragraph 1 if one of the following conditions applies. Furthermore, the supply, sale, public display, consumer trial offer, or transfer to other uses of said cosmetics shall be forbidden:

1. Import for personal use, the quantity of which complies with public announcement of the central competent authority;
2. Import for the application for registration of Paragraph 1 or for use in research and trial, through special permission of the central competent authority.



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