



# Enforcement Rule of the Cosmetics Act (Ordinance of the Prime Minister No. 1795, Feb. 18, 2022)

## 화장품법 시행규칙

Ministry of Food and Drug Safety (MFDS)

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*Translated by ChemLinked*

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## ENFORCEMENT RULE OF THE COSMETICS ACT

[Enforcement Date 18. Feb, 2022.] [Ordinance of the Prime Minister No.1795, 18. Feb, 2022., Partial Amendment]

Ministry of Food and Drug Safety

### Article 1 (Purpose)

The purpose of these Rules is to prescribe matters delegated by the Cosmetics Act and its Decree, and other matters necessary for the enforcement thereof.

### Article 2 (Scope of Functional Cosmetics)

“Cosmetics determined by Ordinance of the Prime Minister” in subparagraph 2 of Article 2 of the Cosmetics Act (hereinafter referred to as "the Act"), other than its items, means the following: <Amended by Ordinance of the Prime Minister No. 1010, Mar. 23, 2013; Ordinance of the Prime Minister No. 1357, Jan. 12, 2017; Ordinance of the Prime Minister No. 1636, Aug. 5, 2020>

1. Cosmetics which have efficacy helpful in skin-whitening by curbing the formation of marks, freckles, etc. through prevention of skin pigmentation of melanin;
2. Cosmetics which have efficacy helpful in skin-whitening by fading melanin pigmentation in skin;
3. Cosmetics which have efficacy in smoothing or improving skin wrinkles by firming skin;
4. Cosmetics which have efficacy in tanning skin gently by screening strong sun light;
5. Cosmetics which have efficacy in protecting skin from ultraviolet rays by intercepting or scattering them;
6. Cosmetics with the function of changing (including the function of bleaching or removing) the color of hair: excluding: however, the products which temporarily change the color of hair;
7. Cosmetics with the function of removing body hair: excluding, however, products which remove body hair in a physical manner;

ChemLinked Team, REACH24H Consulting Group | <http://cosmetic.chemlinked.com>

14F, #3 Bldg., Haichuang Technology Center, No. 1288 Wenyi West Road, Hangzhou, China. PC: 311121

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8. Cosmetics which help alleviate alopecia: excluding, however, products which make hair look thick in a physical manner such as coating;
9. Cosmetics which help alleviate acneiform skin conditions: limited, however, to kinds of products for cleaning human body;
10. Cosmetics which help restore the skin barrier (referred to as the topmost layer of the stratum corneum which is the outermost part of skin) function to relieve the skin itching;
11. Cosmetics which help thinning red lines caused by striae distensa.

**Article 2-2 (Exceptions of Custom Cosmetics)** The “cosmetics prescribed by the Ordinance of the Prime Minister, such as solid soap, etc.” under the subparagraph 3-2 (b) of Article 2 of the Act refer to the solid soap for washing face (hereinafter referred to as “cosmetic soap”). [<Amended by Ordinance of the Prime Minister No.1795, 18. Feb, 2022>](#)

[\[Newly inserted by Ordinance of the Prime Minister No. 1627, Jun. 30, 2020\]](#)

**Article 3 (Registration, etc. of Manufacturing Business)** (1) Deleted [<Amended by Ordinance of the Prime Minister No. 1529, Mar. 14, 2019>](#)

(2) A person who intends to register the cosmetic manufacturing business as prescribed in the former part of Article 3 (1) shall submit an application (including an application in the form of an electronic document) for cosmetic manufacturing business in Appendix 1 to the head of a local food and drug safety office having jurisdiction over the location of the manufacturing factory, together with the following documents (including electronic documents): [Amended by Ordinance of the Prime Minister No. 1529, Mar. 14, 2019>](#)

1. A diagnostic certificate of a specialized medical doctor, which evidences that the person who intends to register the cosmetic manufacturing business (referring to the representative in cases of a corporation; hereafter the same shall apply in this paragraph) does not falls under the main sentence of subparagraph 1 of Article 3-1 of the Act, or a diagnostic certificate of a medical doctor, which evidences that the person falls under the proviso of subparagraph 1 of Article 3-3 of the Act;

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2. A diagnostic certificate of a medical doctor, which evidences that the person who intends to register the cosmetic manufacturing business does not fall under subparagraph of Article 3-3;

3. A document stating the specifications of facilities.

(3) The head of a local food and drug safety office in receipt of an application pursuant to paragraph (2) shall verify the certificate of registered matters of the corporation (limited to where the applicant is a corporation) through administrative data matching under Article 36 (1) of the Electronic Government.

(4) Where requirements for registration under paragraph (2) are satisfied, the head of a local food and drug safety office shall record the following matters in the register of cosmetics manufacturing business and issue a certificate of completed registration of cosmetics manufacturing business of Appendix

2: <Amended by Ordinance of the Prime Minister No. 1097, Sep. 24, 2014; Ordinance of the Prime Minister No. 1529, Mar. 14, 2019>

1. Registration number and registration date;
2. Name and birth date of the cosmetic manufacturer (hereinafter referred to as the person who registered the cosmetics manufacturing business) (referring to the name and birth date of the representative where the applicant is a corporation);
3. Trade name of the cosmetic manufacturer (referring to the name of the corporation where the applicant is a corporation);
4. Location of the manufacturing factory;
5. Type of manufacturing.

#### Article 4 (Registration, etch, of Responsible Cosmetic Distribution Business) (1)

Deleted <Amended by Ordinance of the Prime Minister No. 1627, Jun. 30, 2020>

(2) The person who intends to make a registration of a responsible cosmetic distribution business pursuant to Article 3 (1) of the Act shall submit an application (including an application in the form of electronic document) for responsible cosmetic distribution business in Appendix 3 to the head of a local food and drug safety office having jurisdiction over the location of the manufacturing and sales business place, together with the following documents [the following documents need not to be submitted in cases falling under the

ChemLinked Team, REACH24H Consulting Group | <http://cosmetic.chemlinked.com>

14F, #3 Bldg., Haichuang Technology Center, No. 1288 Wenyi West Road, Hangzhou, China. PC: 311121

Tel: +86 571 8609 4444 | Fax: +86 571 8700 7566 | Email: [contact@chemlinked.com](mailto:contact@chemlinked.com)

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subparagraph 2 d) of Article 2 of the Enforcement Decree of the Cosmetics Act(hereinafter referred to as the Decree)]: [<Amended by Ordinance of the Prime Minister No. 1627, Jun. 30, 2020>](#)

1. Regulations on the standards suitable for the quality control and the responsible post-sale safety control of cosmetics under Article 3 (3) of the Act;

2. A document through which it is possible to verify the qualification for a responsible distribution manager under Article 3 (3) of the Act (hereinafter referred to as a "responsible distribution manager").

(3) The head of a local food and drug safety office in receipt of an application under paragraph (2) shall verify the certificate of registered matters of the corporation (limited to where the applicant is a corporation) through administrative data matching under Article 36 (1) of the Electronic Government.

(4) Where requirements for registration under paragraph (2) are satisfied, the head of a local food and drug safety office shall record the following matters in the register of responsible cosmetic distribution business and issue a certificate of completed registration of responsible cosmetic distribution business in Appendix 4 (hereinafter referred to as a "certificate of completed registration of responsible cosmetic distribution business"): [<Amended by Ordinance of the Prime Minister No. 1097, Sep. 24, 2014; Ordinance of the Prime Minister No. 1529, Mar. 14, 2019>](#)

1. Registration number and registration date;
2. Name and birth date of the responsible cosmetic distributor (hereinafter referring to the person who registered the responsible cosmetic distribution business) (referring to the name and birth date of the representative where the applicant is a corporation);
3. Trade name of the responsible cosmetic distributor (referring to the name of the corporation where the applicant is a corporation);
4. Location of the responsible cosmetic distribution business place;
5. Name and birth date of the responsible distribution manager;
6. Type of the responsible distribution.

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### Article 5 (Registration of Changes in Cosmetic Manufacturing Business, etc.) (1)

The cases where a cosmetic manufacturer or a cosmetic responsible distributor is required to file for registration of a change pursuant to the latter part of Article 3 (1) of the Act shall be as follows: <Amended by Ordinance of the Prime Minister No. 1097, Sep. 24, 2014; Ordinance of the Prime Minister No. 1529, Mar. 14, 2019>

1. Where the cosmetic manufacturer falls under any of the following:

- (a) Change of the cosmetic manufacturer (in cases of a corporation, change of the representative thereof);
- (b) Change of the trade name of the cosmetic manufacturer (in cases of a corporation, change of the name thereof);
- (c) Change of the location of the manufacturing factory;
- (d) Change of the type of manufacturing.

2. Where a cosmetic responsible distributor falls under any of the following:

- (a) Change of the cosmetic responsible distributor (in cases of a corporation, change of the representative thereof);
- (b) Change of the trade name of a cosmetic responsible distributor (in cases of a corporation, change of the name thereof);
- (c) Change of the location of the cosmetic responsible distribution business place;
- (d) Change of the cosmetic responsible distributor;
- (e) Change of the type of responsible sale.

(2) In cases of filing for registration of change under paragraph (1) a cosmetic manufacturer or a cosmetic responsible distributor shall submit an application for registration of change in a cosmetics manufacturing business in Appendix 5 (including an application in the form of an electronic document) or an application for registration of change in cosmetics responsible distribution business in Appendix 6 (including an electronic document) to the head of a local food and drug safety office, together with the certificate of completed registration of manufacturing business or the certificate of completed registration of cosmetic responsible distribution business and other relevant document categorized in

ChemLinked Team, REACH24H Consulting Group | <http://cosmetic.chemlinked.com>

14F, #3 Bldg., Haichuang Technology Center, No. 1288 Wenyi West Road, Hangzhou, China. PC: 311121

Tel: +86 571 8609 4444 | Fax: +86 571 8700 7566 | Email: [contact@chemlinked.com](mailto:contact@chemlinked.com)





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