



South Korea Cosmetic Safety Standard

화장품 안전기준 등에 관한 규정

Ministry of Food and Drug Safety (MFDS)

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Cosmetic Safety Standard

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Ministry of Food and Drug Safety (Cosmetics Policy Division), 043-719-3410

Chapter 1 General Provisions

Article 1 (Purpose)

The purpose of this Notice is to provide reasonableness in the manufacture or import of cosmetics and their safety control by setting forth the raw materials that may not be used in cosmetics, standards for the use of raw materials that require usage restrictions, and matters concerning the safety control standards of distributed cosmetics pursuant to the provisions of Article 8 of the Cosmetics Act.

Article 2 (Scope of Application)

The regulations in this Notice shall apply to all cosmetics that are manufactured, imported, or distributed domestically.

Chapter 2 Raw Materials That May Not Be Used in Cosmetics and Standards for the Use of Raw Materials That Require Usage Restrictions

Article 3 (Raw Materials That May Not Be Used)

Raw materials that may not be used in cosmetics shall be as specified by Appendix 1.

Article 4 (Standards for the Use of Raw Materials That Require Usage Restrictions)

Raw materials that require restrictions on using them in cosmetics and the

standards for their use shall be as specified by Appendix 2. Disinfectants, preservatives, sunscreen, etc. other than the raw materials in Appendix 2 shall not be used.

Chapter 3 Safety Control Standards of Distributed Cosmetics

Article 5 (Safety Control Standards of Distributed Cosmetics)

Distributed cosmetics shall comply with the safety control standards in paragraphs (1) through (4), and based on the type of distributed cosmetics, safety control standards in paragraphs (5) through (7) shall additionally apply. Moreover, tests shall be carried out with a test method specified by Appendix 4, but when it is considered appropriate scientifically and rationally, they may be carried out with a company-specific standard.

(1) Although the following substances have not been artificially added during the manufacture of cosmetics, if it is confirmed through an objective data that they have originated unintentionally such as by packing materials during the manufacturing or storing processes, where its complete removal is not technically possible, permissible detection limit of the pertinent substance shall be as follows:

1. Lead: No greater than 50 $\mu\text{g/g}$ for a powder product which uses clay as its raw material. For other products, no greater than 20 $\mu\text{g/g}$
2. Nickel: No greater than 35 $\mu\text{g/g}$ for eye make-up products, 30 $\mu\text{g/g}$ for color make-up products, 10 $\mu\text{g/g}$ for other cosmetics
3. Arsenic: No greater than 10 $\mu\text{g/g}$
4. Mercury: No greater than 1 $\mu\text{g/g}$
5. Antimony: No greater than 10 $\mu\text{g/g}$
6. Cadmium: No greater than 5 $\mu\text{g/g}$
7. Dioxane: No greater than 100 $\mu\text{g/g}$
8. Methanol: No greater than 0.2 (v/v) %; for wet tissue, 0.002 (v/v) %
9. Formaldehyde: No greater than 2000 $\mu\text{g/g}$; for wet tissue, no greater than 20 $\mu\text{g/g}$
10. Phthalates (applicable only to dibutyl phthalate, butyl benzyl phthalate, and diethyl hexyl phthalate): Net total shall be no greater than 100 $\mu\text{g/g}$.

(2) When raw materials that may not be used as shown by Appendix 1 are detected due to a reason that falls under paragraph (1), for which a permissible detection limit has not been set up, whether there is any harm or not shall be determined after conducting a risk assessment pursuant to Article 17 of the Enforcement Rule of the Cosmetics Act.

(3) Limit of microorganisms shall be as follows:

1. Total aerobic viable cell count for infant and children's products and eye make-up products shall be no greater than 500/g(mL).
2. For wet tissues, bacteria and fungus count shall each be no greater than 100/g(mL).
3. For other cosmetics, the amount shall be no greater than 1000/g(mL).
4. Escherichia Coli, Pseudomonas aeruginosa, and Staphylococcus aureus shall not be detected.

(4) Standards of net content shall be as follows:

1. When conducting a test with three products, the average net content shall be no less than 97% of the indicated amount.
2. If the standards of subparagraph 1 is not met: when conducting a test by adding six more products, average net content of nine products shall be no less than the standards of subparagraph 1.
3. Other special products: Korean Pharmacopoeia (Ministry of Food and Drug Safety Notice) shall apply.

(5) Products for infants and children (excluding infants and children's shampoo, conditioner, cleansing product, and bathing product); eye make-up products; color make-up products; hair products (excluding shampoo and conditioner); shaving products (excluding shaving cream and shaving foam); and among base make-up products (excluding make-up remover products such as cleansing water, cleansing oil, cleansing lotion, cleansing cream, etc.), the liquid, lotion, cream and liquid products of a similar form shall have pH standards of 3.0 – 9.0: however, this shall not apply to products that do not contain water, or products that are washed with water immediately after their use.

(6) For functional cosmetics, content of the main raw materials which result in the manifestation of the relevant functions shall comply with the standards that are examined and reported pursuant to Article 4 of the Cosmetics Act and Article 9 or Article 10 of the Enforcement Rule thereof.



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