



## **Korea Cosmetic Safety Standard (2016 Version)**

韩国化妆品安全标准等的相关规定  
(2016 年版 )

Ministry of Food and Drug Safety (MFDS)

Compiled by Chemlinked

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## **Regulation on Safety Standards of Cosmetics**

### **Chapter 1 General provisions**

**Article 1 (Purpose)** This regulation, pursuant to Article 8 of the Cosmetics Law, is to ensure the management of manufacture (import) and safety management by defining standards of negative ingredients, restrictive ingredients used in cosmetics and by determining the matters related to cosmetic safety management standards in market.

**Article 2 (Application scope)** This regulation shall be applied all the cosmetics of manufacture, import or distribution.

### **Chapter 2 Standards of negative ingredients, restrictive ingredients used in cosmetics**

**Article 3 (Negative ingredients)** Ingredients to not be allowed to use of cosmetics shall refer to Annex 1.

**Article 4 (Restrictive ingredients used in cosmetics)** Ingredients needs to be restricted to use for cosmetics and its use standards shall refer to Annex 2 and Disinfectants/Preservatives and UV filters cannot used without listed in Annex 2.

### **Chapter 3 Safety Standards of cosmetics in market**

**Article 5 (Safety management of cosmetics in market)** Cosmetics in market shall be suitable for safety management standards from Article 1 to 4 and additionally suitable for the standards from Article 5 to 7 per product types. In addition, the test methods will follow Annex 4 but the other scientific and reasonable methods can be used if they are verified.

① Following ingredients are not intentionally added when manufacturing cosmetics, but it is unintentionally derived by transition from packaging during manufacture or storage and identified as being technically complete removal is impossible through objective data, their detection limits are as follows.

1. Pb: less than 50µg/g (powders using clay), less than 20µg/g (the others)
2. Arsenic: less than 10µg/g
3. Hg: less than 1µg/g
4. Antimony: less than 10µg/g
5. Cadmium: less than 5µg/g
6. Dioxane: less than 100µg/g
7. Methanol: less than 0.2(v/v)% , wipes: less than 0.002%(v/v)
8. Formaldehyde: less than 2000 µg/g ; wipes: less than 20µg/g
9. Phthalates(Dibutylphthalate, Butylbenzylphthalate and Diethylhexylphthalate): less than 100µg/g as total sum

② When negative ingredients of Annex 1 are identified because of Article 1 but their detection limits are not defined yet, they shall decide its risk after go through risk assessment process for the evaluation according to Article 17 of Enforcement regulations of Cosmetics Act.

③ Microbial limits are as follows.

1. Total aerobic count for children-use and eye makeup products must be less than 500 CFU/g (mL)
2. wipes: bacterial count and fungi count less than 100 per g(ml)
- 3.the other cosmetics must be less than 1000 CFU/g (mL)

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