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# Safety and Technical Standard for Cosmetics

## 2015 Version

### Foreword

"Safety and Technical Standard for Cosmetics" ("Technical Standard" for short) is revision of "Hygienic Standard for Cosmetics (Version 2007)" ("Hygienic Standard" for short). In order to meet requirement of cosmetics safety supervision, and by following of industry development and improvement of scientific knowledge, China Food and Drug Administration (CFDA) organized the revision work of Hygienic Standard, and generate the Technical Standard (2015 Version). It passed the examination of Cosmetics Standard Expert Committee Plenary Meeting in Nov 2015, and has been approved and announced by CFDA. It will be in force on 1st Dec 2016.

Technical Standard (2015 Version) contains 8 chapters. The 1st chapter is *summary*, including Scope, Terms and explanations, General requirements on the safety. The 2nd chapter is *the requirement on cosmetics prohibited ingredient list and restricted ingredient list*, including 1388 cosmetics prohibited ingredients and 47 restricted ingredients. The 3rd chapter is *positive ingredient list*, including requirement on 51 preservatives, 27 UV filters, 157 colorants and 75 hair dyes. The 4th chapter is *physical-chemical testing method*, including 77 testing methods. The 5th chapter is *microbiological test methods*, including 5 testing methods. The 6th chapter is *toxicological test methods*, including 16 testing methods. The 7th chapter is *human safety test method*, including 2 testing methods. The 8th chapter is *efficacy Evaluation in Human*, including 3 testing methods.

This version of standard mainly revised following contents based on "Hygienic Standard":

**Define the term and explanation.** Provide explanation of involved terms and define relevant concept and connotation.

**Refine general safety and technical requirements for cosmetics.** Refer to the safety assessment result of heavy metals and safety hazard substances in cosmetics, it adjusted the limited requirement of lead from 40mg/kg to 10mg/kg, adjusted the limited requirement of As from 10mg/kg to 2mg/kg, added the limited requirement of Cd as 5 mg/kg, included the limited requirement of 2 hazard substances according to the requirement of standard technical documents from CFDA, that was dioxane should be no more than 30 mg/kg, and Asbestos should be not detected.

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**The Appendix incorporates revisions made to attached lists regarding prohibited and restricted substances.** The main revisions include the following: Comparing with Hygienic Standard for Cosmetics (Version 2007), there are totally 1,388 prohibited substance, within them 133 are supplemented items and 137 are revised items. There are totally 47 restricted substances within them 1 is supplemented item, 31 are revised items, and 27 are deleted items. There are totally 51 preservative, within them 14 are revised items and 5 are deleted items. There are totally 27 UV-filter items, within them 6 are revised items and 1 is deleted item. There are totally 157 colorants, within them 1 is supplemented item and 69 are revised items. There are totally 75 hair dyes, within them 63 are revised items and 21 are deleted items.

**Revised the physical and chemical test methods in the cosmetic inspection and evaluation methods.** Added and included over 60 newly-issued test methods for the relevant prohibited and restricted substances in cosmetics on the basis of the original test methods as stipulated in the "Hygienic Standards"; systematically standardized, classified and composed the texts and styles of the test methods for easy reading and utilizing. Deleted the contents not within the range of standardized version management from the "Hygienic Standards", such as the two test methods for strontium and total fluorine; corrected a few mistakes in the "Hygienic Standards"; performed language standardization and format adjustment to the microbiological and toxicological test methods; revised the test method for human safety and effect assessment, dividing it into the test method for human safety and test method for ergonomics assessment; added the preparation method for high SPF standards (P2 and P3) to the test method for ergonomics SPF evaluation.

This edition of "Standards" is characterized in that:

**The safety of cosmetics is further guaranteed.** Based on the comparison and analysis made over the "Hygienic Standard" and the regulations and standards in relation to cosmetics in other countries and regions in the world (including the EU, United States, Japan, Korea, Canada, Chinese Taiwan, etc.), following the principle of being scientific and reasonable as well as safety assurance, adjusted the requirements for the prohibited and restricted components within cosmetics, and adjusted the limitation requirements and restrictive conditions for part of the approved components. At the same time, adjusted the administrative limitation requirements for lead and arsenic in accordance with the results of the risk assessment for part of the hazardous materials and added the administrative limitation requirement for cadmium, and included the administrative limitation requirements for dioxane and asbestos in accordance with the requirement of the normative technical documents issued by CFDA.

**The adaptability and maneuverability are further improved.** Provided interpretation for the phrases and terms involved in the "Technical Standards", refined the relevant concepts, and especially added the content of technical requirements for cosmetic product and general test methods as well as the technical standards and requirements closely related to the quality and safety of cosmetics. On the basis of the existing test

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methods in the "Hygienic Standard", collected 60 test methods issued by CFDA for the prohibited and restricted substances in cosmetics to satisfy the needs of cosmetics technology R&D and safety regulation.

In addition to maintaining a scientific nature, advancement and normalization, this edition of "Standard" focuses on the administration of the hazardous materials and approved components in cosmetics; it makes full use of the international cosmetics quality & safety control technology and experiences and comprehensively reflects the development of China's current cosmetics industry and the improvement of China's inspection and test techniques, thus playing an important role in advancing the scientific supervision of China's cosmetics, promoting the healthy development of cosmetics industry and raising the authoritativeness and international influence of China's technical standards of cosmetics.

## **Chapter 1 Summary**

### **1. Scope**

This standard specifies the safety and technical requirements of cosmetic products, including the general requirements, requirements on prohibited and restricted substances, requirements of approved substances and inspection and evaluation methods etc.

This standard is applicable to the cosmetic products produced and sold within the territory of the People's Republic of China (excluding the products only for overseas sales).

### **2. Terms and explanations**

The following terms and explanations are applicable thereto.

- 2.1 Raw materials of cosmetic products: the ingredients used in the formula of cosmetic products.
- 2.2 New raw materials of cosmetic products: the natural or artificial raw materials that are used for the first time in PRC.
- 2.3 Prohibited substances: substances that cannot be used as the raw materials of cosmetic products.
- 2.4 Restricted substances: substances that can be used as the raw materials of cosmetic products under the restricted conditions.

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- 2.5 Preservative agents: substances that are added to the cosmetic products for the purpose of inhibiting the growth of microorganisms in cosmetic products
  - 2.6 Sunscreen agents: substances that are added to the cosmetic products to protect the skin from the harmful effects of certain UV rays or to product the product itself, by means of light absorption, reflection, or scattering.
  - 2.7 Colorant agents: substances that are added to the cosmetic products to develop a color in the cosmetic products or their application site, by means of absorption or reflection of the visible light, excluding the hair dyes specified in Table 7 of Chapter 3.
  - 2.8 Hair dyes: substances that are added to the cosmetic products to change the color of hair.
  - 2.9 Rinse-off cosmetic products: products that are immediately rinsed off after use on human body surface (skin, hair, fingernails and lips etc.).
  - 2.10 Leave-on cosmetic products: products other than the rinse-off cosmetic products.
  - 2.11 Eye cosmetic products: cosmetic products claimed to be applied on the skin in the vicinity of the eyes and eyelashes.
  - 2.12 Lip cosmetic products: cosmetic products claimed to be applied on the lips.
  - 2.13 Body cosmetic products: cosmetic products claimed to be applied on the body skin (excluding the head skin).
  - 2.14 Skin cosmetic products: cosmetic products claimed to be applied on the skin.
  - 2.15 Cosmetic products for children: cosmetic products claimed to be used in the children.
  - 2.16 Professional use: operated and used at a specialized site by personnel who have received professional training.
  - 2.17 Packaging materials: the packaging container materials that have direct contact with the raw materials or the cosmetic products.
  - 2.18 Substances with safety risks: the substances brought in by the raw materials or packaging materials, generated or brought in during the production, transporting and storage, may cause potential harms to human health when exposing to the human body.

### **3. General requirements on the safety of cosmetic products**

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### 3.1 General requirements

- 3.1.1 Safety risk assessment should be done on the cosmetic products, and they should be guaranteed to create no harm to human health under the normal, reasonable and predictable use conditions.
- 3.1.2 The production of cosmetic products should conform to the requirements of cosmetic manufacturing practice. The manufacturing process of the cosmetic products should be scientific and reasonable, and the safety of the products should be guaranteed.
- 3.1.3 Before marketing, necessary inspections should be performed on the cosmetic products. The inspection methods include relevant physical and chemical inspection methods, microbiological testing method, toxicological testing methods and human safety testing methods etc.
- 3.1.4 The cosmetic products should conform to relevant requirements of product quality and safety and can be released after inspection qualification.

### 3.2 Requirements on formula

- 3.2.1 The prohibited substances listed in chapter 2, Table 1 and Table 2 hereof should not be used in the formula of the cosmetic products.

If the prohibited substances are brought into the cosmetic products as impurities and cannot be technically avoided, the national regulations on the limit should be satisfied; if there is no national regulations on the limit, safety risk assessment should be carried out to ensure that no harm is created to human health under the normal, reasonable and predictable use conditions.

- 3.2.2 If the raw materials in the formula of cosmetic products are included in the substances listed in the restricted substances tables in Chapter 2, Table 3 hereof, the use should conform to the requirements in the tables.
- 3.2.3 The preservative agents, sunscreen agents, colorant agents and hair dyes used in the formula of cosmetic products must correspond to substances listed in Chapter 3, Tables 4 to 7 hereof, and the use should conform to the requirements in the tables.

### 3.3 Requirements on microbial indexes

The indexes of microorganisms in cosmetic products should comply with the limit specified in Table 1.

**Table 1 Limit of indexes of microorganisms in cosmetic products**

Indexes of microorganisms	Limit	Remarks
Total numbers of colony (CFU/g or CFU/ml)	≤500	Eye product, lip product and product for children
	≤1000	Other products
Total count of molds and yeasts (CFU/g or CFU/ml)	≤100	
Thermotolerant coliform group /g (or ml)	not detected	
Staphylococcus aureus /g (or ml)	not detected	
Pseudomonas aeruginosa /g (or ml)	not detected	

### 3.4 Requirements on limit of harmful substances

The harm substances in the cosmetic products should not exceed the limit specified in Table 2.

**Table 2 The limit of harmful substances in the cosmetic products**

Harmful substances	Limit (mg/kg)	Remarks
Mercury	1	Excluding the eye cosmetic products containing organomercury preservative
Lead	10	
Arsenic	2	
Cadmium	5	
Methanol	2000	
Dioxane	30	
Asbestos	not detected*	

### 3.5 Requirements on packaging materials

The packaging materials that have direct contact with the cosmetic product should be safe in use, should not have a chemical reaction with the cosmetic products, and should not contain or release the toxic substances that may create harms to human.

### 3.6 Requirements on labeling

3.6.1 As for all the raw materials used in the cosmetic products, if the use conditions

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and precautions are required to be printed on the label according to the requirements hereof, the requirements should be specified.

3.6.2 Other practices should conform to relevant laws and regulations as well as the requirements of rules and standards.

3.7 Requirements on cosmetic products for children

3.7.1 The cosmetic products for children should meet the safety requirements on normal cosmetic products in terms of the raw material, the formula, the manufacturing process, the labeling, the ways of usage and the quality safety control etc. In addition, related specific requirements should be met to ensure the safety of the products.

3.7.2 For the cosmetic products for children, the applicable objects should be specified in the label.

3.8 Requirements on raw materials

3.8.1 Safety risk assessment should be done on the raw materials of cosmetic products, and they should be guaranteed to create no harm to human health under the normal, reasonable and predictable use conditions.

3.8.2 The requirements on quality and safety of raw materials of cosmetic products should conform to the corresponding national regulations, and correspond to the level reached by the production process and detection techniques.

3.8.3 The contents of technical requirements of raw materials include the name of raw materials of cosmetic products, registration number (CAS No. and/or EINECS No., INCI name, latin name etc.), use purpose, scope of application, specifications, detection method the substances with safety risk that probably exist and the corresponding control measures etc.

3.8.4 The processes of packaging, storage and use etc. of raw materials of cosmetic products should not create pollution to the raw materials of cosmetic products.

The materials of containers that have direct contact with the raw materials of cosmetic products should be safe, should not have a chemical reaction with the raw materials, and should not transfer or release the toxic substances that may create harms to the users.

The raw materials that have special requirements on temperature, relatively humidity or others should be stored according to the specified conditions.

3.8.5 The basic information of the raw materials of the cosmetic products should be traced through the labels (including but not limited to the Chinese name of raw

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material standard, INCI name, CAS No. and / or EINECS No.), name of manufacturer, purity or content, production batch No. or production date, shelf life and other Chinese signs.

For the raw materials of cosmetic products belong to the hazardous chemicals, the signs should conform to the regulations of relevant national departments.

- 3.8.6 The raw materials of cosmetic products from animals and plants should have the information of explicit source and use site etc.

As the raw materials of cosmetic products from animal organ tissues and blood products or extracts, the source and quality specification should be ascertained, and such raw materials are not allowed to be used, if they are not approved to be used in the country of origin.

- 3.8.7 The use of new raw materials of cosmetic products should conform to relevant national regulations.