



Safety and Technical Standards for Cosmetics

化妆品安全技术规范

China Food and Drug Administration (CFDA)

Disclaimer

This is an unofficial document provided by ChemLinked (chemlinked.com), a division of REACH24H Consulting Group, as an informational service to assist non-Chinese companies.

This document should only be used as a reference and in case of any discrepancy between the English and Chinese versions the original Chinese version shall prevail.

ChemLinked is a unique portal to must-know Asia Pacific Chemical, Cosmetic, Food, Agrochemical regulatory issues.

Nondisclosure:

You may not disclose this document to anyone else without the written permission of ChemLinked.

For further clarification and questions, please contact us:
cosmetic@chemlinked.com

Preface

Safety and Technical Standard for Cosmetics (hereinafter "Technical Standard") is a revised version of *Hygienic Standard for Cosmetics* issued by the former Ministry of Health (2007 Edition, hereinafter "Hygienic Standard"). In order to meet the actual needs of China cosmetics supervision, combined with the development of the industry and the improvement of scientific understanding, the former China Food and Drug Administration (CFDA) has completed the revision of "Hygienic Standard" and compiled "Technical Standard" (2015 edition). In November 2015, it was reviewed and passed by Plenary Meeting of the Expert Committee on Cosmetic Standards and issued by the former CFDA. It takes effects on December 1, 2016.

Technical Standard (2015 edition) is divided into eight chapters. The first chapter is an overview, including scope, terminology, interpretation, and universal requirements for cosmetic safety. The second chapter is the requirements for cosmetic prohibited and restricted ingredients, including requirements for 1388 cosmetic prohibited ingredients and 47 restricted ingredients. The third chapter is the requirements for cosmetic permitted ingredients, including requirements for 51 permitted preservatives, 27 permitted sunscreens, 157 permitted colorants and 75 permitted hair dyes. The fourth chapter is the physical and chemical testing method, which contains 77 methods. The fifth chapter is the microbiological testing method, which contains five methods. The sixth chapter is the toxicology testing method, which contains 16 methods. The seventh chapter is the human body safety testing method, which contains 2 methods. The eighth chapter is the testing method for human body efficacy evaluation, which contains three methods.

On the basis of "Hygienic Standard", this edition mainly revised the following main contents:

Making clear explanations of certain terms. Provide explanations of the nouns and terms involved, and clarify related concepts and their connotations.

Detailing cosmetic safety technical universal requirements. According to the risk assessment results of heavy metals and safety risk substances in cosmetics, the limit requirement of lead is adjusted from 40mg/kg to 10mg/kg, the limit requirement of arsenic is adjusted from 10mg/kg to 2mg/kg, and the limit of cadmium is newly set as 5mg/kg. According to the requirements of the former CFDA's normative technical documents, the limit requirements for two kinds of hazardous substances are

included, respectively, dioxane shall not exceed 30mg/kg, and no asbestos should be tested out.

Revising lists of cosmetic prohibited and restricted ingredients and lists of cosmetic permitted ingredients. Compared with "Hygienic Standard", this edition has a total of 1388 prohibited ingredients, including 133 newly added ones and 137 revised ones. There are a total of 47 restricted ingredients, including 1 new ingredient, 31 revised ones, and 27 deleted ones. A total of 51 permitted preservatives, of which 14 were revised and 5 were deleted. There are 27 permitted sunscreens, of which 6 were revised and 1 was deleted. There are 157 permitted colorants, including 1 new colorant, 69 revised ones. There are a total of 75 permitted hair dyes, of which 63 were revised and 21 were deleted.

Revising physical-chemical testing methods in cosmetic inspection and evaluation methods.

- 60 kinds of testing methods for prohibited and restricted ingredients in cosmetics are newly added and the style of which is standardized and classified for more convenient reference.
- Testing methods in the "Hygienic Standard" but beyond the scope of this edition, including 2 testing methods for strontium and total fluorine, have been deleted and a few mistakes in the previous standard have also been corrected.
- Language standardizing and format adjusting of microbiological test methods and toxicological test methods has been conducted.
- Human body safety and efficacy evaluation testing methods have been revised and split into human body safety testing method and human body efficacy evaluation testing method.
- New preparation methods of high SPF standard product (P2 and P3) have been added in the human body efficacy SPF evaluation testing method.

The characteristics of this version mainly embody the following:

- The safety assurance of cosmetics has been further improved. On the basis of comparative analysis of the relevant regulations and standards concerning cosmetics in world's major countries and regions (including the European Union, the United States, Japan, South Korea, Canada and China Taiwan) and on the principles of scientific rationality and safety, the requirements for prohibited/restricted ingredients in cosmetics and the limitation requirements and restrictions of some

permitted ingredients are adjusted. Meanwhile, the management limit requirements for lead and arsenic are adjusted and that for cadmium are newly added in accordance to the risk assessment conclusions of some safety risk substances; while that for dioxane and asbestos are included in the standard in accordance to the requirements of the former CFDA's normative technical documents.

- Adaptability and operability have been further improved. The standard provides definitions for involved nouns and terms, details and clarifies related concepts, and focuses on increasing technical requirements of cosmetic products and general testing methods and other technical standards and requirements closely related to cosmetic quality and safety. On the basis of retaining the original relevant test methods of the previous *Hygienic Standard for Cosmetics*, 60 inspection methods issued by the former CFDA for the prohibited/restricted substances in cosmetics were included in this standard to meet the needs of cosmetics technology research and development and safety supervision.

Based on scientific and normative nature and advancement, "Technical Standard" focuses on strengthening the management of safety risk substances and permitted ingredients in cosmetics, and fully drawing on international cosmetics quality and safety control technology and experience, which completely reflects the current situation in China that the development of the cosmetics industry and the improvement of inspection technology, will play an important role in promoting China's cosmetics scientific supervision, promoting the healthy development of the cosmetic industry, and enhancing the authority and international influence of China's cosmetics technical standards.

Content

CHAPTER 1 OVERVIEW	10
CHAPTER 2 PROHIBITED/RESTRICTED INGREDIENTS USED IN COSMETICS	17
1 PROHIBITED INGREDIENTS USED IN COSMETICS⁽¹⁾⁽²⁾ (LIST 1)	17
2 PROHIBITED PLANT/ANIMAL INGREDIENTS USED IN COSMETICS⁽¹⁾⁽²⁾⁽³⁾ (LIST 2)	103
3 RESTRICTED INGREDIENTS USED IN COSMETICS (LIST 3)	108
CHAPTER 3 PERMITTED INGREDIENTS USED IN COSMETICS	131
1 PERMITTED PRESERVATIVES USED IN COSMETICS⁽¹⁾ (LIST 4)	131
2 PERMITTED SUNSCREENS USED IN COSMETICS⁽¹⁾ (LIST 5)	139
3 PERMITTED COLORANTS USED IN COSMETICS⁽¹⁾ (LIST 6)	142
4 PERMITTED HAIR DYES USED IN COSMETICS⁽¹⁾⁽²⁾ (LIST 7)	163
CHAPTER 4 PHYSICAL AND CHEMICAL TESTING METHODS FOR COSMETICS	173
1 GENERAL PRINCIPLES	173
1.1 PH	178
1.2 Mercury	182
1.3 Lead	195
1.4 Arsenic	205
1.5 Cadmium	215
1.6 Li and 36 kinds of elements	220
1.7 Nd and 14 kinds of elements	229
1.8 Ethanolamine and other 4 kinds of components	235
1.9 Test in vitro of protection against UVA	245
2 TESTING METHODS OF PROHIBITED INGREDIENTS	248
2.1 Fluconazole and other 8 kinds of components	248
2.2 Minocycline hydrochloride and other 6 kinds of components	258
2.3 Enoxacin and other 9 kinds of components	262
2.4 Estriol and the Other 6 kinds of Components	270
2.5 Minoxidil and other 6 kinds of components	285
2.6 6-Methyl coumarin	292

2.7 8-methoxypsoralen and other 3 kinds of components	303
2.8 Psoralen and other 3 kinds of components	310
2.9 4-Aminoazobenzene and Benzidine	316
2.10 Biphenyl-4-ylamine and its salts	323
2.11 Acid Yellow 36 and other 4 kinds of components	331
2.12 α -Chlorotoluene	340
2.13 Aminocaproic Acid	346
2.14 Cantharidin	352
2.15 Benzo [a] pyrene	355
2.16 Acrylamide	360
2.17 Chlormethine	366
2.18 Desloratadine and other 14 kinds of components	370
2.19 Dioxane	379
2.20 Diethylene glycol	391
2.22 Methanol	404
2.23 Procainamide and other 6 kinds of components	414
2.24 Diethyl maleate	423
2.25 Minoxidil	430
2.26 Hydroquinone and phenol	437
2.27 Asbestos	447
2.28 Tretinoin and Isotretinoin	462
2.29 Vitamin D2 and Vitamin D3	469
2.30 Dimethyl phthalate and 9 kinds of components	474
2.31 Dibutylphthalate and 7 kinds of components	482
2.32 Dichloromethane and other 14 kinds of components	490
2.33 Ethanol and other 36 kinds of components	498
3 TESTING METHODS OF RESTRICTED INGREDIENTS	532
3.1 α -Hydroxy Acid	532
3.2 Selenium Disulfide	543
3.3 Hydrogen peroxide	548
3.4 Resorcinol	555
3.5 Soluble zinc salt	559
3.6 Quinine	562
3.7 Boric Acid and Borate	565

3.8 Oxyquinoline	569
3.9 Thioglycollic Acid	573
3.10 Salicylic acid	584
3.11 Musk ketone	588
3.12 Free Hydroxide	592
3.13 Total Selenium	594
4 TESTING METHODS OF PRESERVATIVES	598
4.1 Benzyl alcohol	598
4.2 Benzoic acid and sodium benzoate	609
4.3 Phenoxyisopropanol	621
4.4 Benzalkonium chloride	625
4.5 Ammonium chloride, Benzethonium chloride and Cetalkonium Chloride	629
4.6 Formaldehyde	633
4.7 Chloromethyl Isothiazolinone and Other 11 kinds of Components	644
4.8 Chlorphenesin	651
4.9 Triclocarban	655
4.10 Sorbic Acid and Dehydroacetic	659
4.11 Salicylic acid and other 4 kinds of components	663
5 TESTING METHODS OF SUNSCREENS	668
5.1 Phenylbenzimidazole Sulfonic Acid and Other 14 Kinds of Components	668
5.2 Denzophenone	679
5.3 Titanium dioxide	683
5.4 Diethylamino Hydroxybenzoyl Hexyl Benzoate	687
5.5 Diethylhexyl butamido triazone	691
5.6 Benzylidene camphor sulfonic acid	695
5.7 Zinc oxide	700
6 TESTING METHODS OF COLORANTS	704
6.1 Basic orange 31 and other 6 kinds of components	704
6.2 Colorant CI 59040 and other 9 kinds of components	710
7. TESTING METHODS OF HAIR COLORANTS	719
7.1 p-Phenylenediamine and other 7 kinds of components	719
7.2 p-Phenylenediamine and Other 31 Kinds of Components	724
CHAPTER 5 METHODS OF MICROBIOLOGICAL TEST	733

1 GENERAL PRINCIPLES	733
2 AEROBIC BACTERIAL COUNT	737
3 THERMOTOLERANT COLIFORM BACTERIA	741
4 PSEUDOMONAS AERUGINOSA	746
5 STAPHYLOCOCCUS AUREUS	751
6 MOLDS AND YEAST COUNT	755
CHAPTER 6 METHODS OF TOXICOLOGICAL TEST	758
1 GENERAL PRINCIPLES	758
2 ACUTE ORAL TOXICITY TEST	760
3 ACUTE DERMAL TOXICITY TEST	764
4 DERMAL IRRITATION/CORROSION TEST	768
5 ACUTE EYE IRRITATION/CORROSION TEST	773
6 SKIN SENSITISATION TEST	779
7 SKIN PHOTOTOXICITY TEST	786
8 SALMONELLA TYPHIMURIUM/REVERSE MUTATION ASSAY	790
9 IN VITRO MAMMALIAN CELLS CHROMOSOME ABERRATION TEST	802
10 IN VITRO MAMMALIAN CELL GENE MUTATION TEST	807
11 IN VIVO MAMMALIAN BONE MARROW CELL CHROMOSOME ABERRATION TEST	813
12 MAMMALIAN ERYTHROCYTE MICRONUCLEUS TEST	818
13 TESTICLE CELLS CHROMOSOME ABERRATION TEST	823
14 SUBCHRONIC ORAL TOXICITY TEST	828
15 SUBCHRONIC DERMAL TOXICITY TEST	834
16 TERATOGENICITY TEST	840
17 COMBINED CHRONIC TOXICITY / CARCINOGENICITY TEST	845
CHAPTER 7 HUMAN BODY SAFETY TESTING METHOD	853
1 GENERAL PRINCIPLES	853
2 HUMAN SKIN PATCH TEST	854
3 SAFETY EVALUATION OF USING TESTS OF COSMETICS ON HUMAN BODY	858
CHAPTER 8 HUMAN BODY EFFICACY EVALUATION TESTING METHOD	861
1 GENERAL PRINCIPLES	861
2 DETERMINATION METHODS OF SUN PROTECTION FACTOR (SPF) *	862

3 DETERMINATION METHODS OF SUNSCREEN WATER RESISTANT PERFORMANCE *	873
4 DETERMINATION METHODS FOR PFA OF SUNSCREEN COSMETICS	876

Chapter 1 Overview

1. Scope

This standard specifies the technical safety requirements, including the general requirements, restricted and forbidden ingredients, and test and evaluation methods.

This standard applies to all the cosmetics that are manufactured and operated in the People's Republic of China, except those only for sale abroad.

2. Terms and definitions

This standard adopts the following terms and definitions:

2.1 Cosmetic ingredient: ingredient used in the cosmetics formula.

2.2 New cosmetic ingredient: natural or synthetic ingredient that are used in the cosmetic production for the first time in China.

2.3 Prohibited ingredient: substance forbidden to use in cosmetics.

2.4 Restricted ingredient: substance that can be used in cosmetics under certain conditions.

2.5 Preservative: ingredient added in cosmetics to restrain the growth of the microbes.

2.6 Sunscreen: ingredient added in cosmetics to protect the skin from being harmed by specific ultraviolet ray or to protect the product itself, by absorbing, reflecting and scattering the sunlight.

2.7 Coloring agent: ingredient added in cosmetics to present certain colors by absorbing and reflecting the light. Hair dyes in List 7 of chapter 3 are excluded.

2.8 Hair dyeing agent: ingredient added in cosmetics to change the color of the hair.

- 2.9 Rinse-off cosmetics: cosmetics should be washed off after use on human surface (skin, hair, fingernail, lip and so on).
- 2.10 Leave-on cosmetics: cosmetics other than rinse-off cosmetics.
- 2.11 Eye cosmetics: cosmetics used on the skin around the eye and eyelash.
- 2.12 Lip cosmetics: cosmetics used on the lip.
- 2.13 Body cosmetics: cosmetics used on the body skin, excluding the head skin.
- 2.14 Skin cosmetics: cosmetics used on the skin.
- 2.15 Children cosmetics: cosmetics for children.
- 2.16 Professional use: should be operated by trained professionals in specific places.
- 2.17 Packaging materials: materials that directly contact the cosmetic ingredients or cosmetics containers.
- 2.18 Safety risk materials: materials having potential risks to human health when exposed to human body that are brought in with the cosmetic ingredients or packaging materials or are generated during the production, transportation and storage.

3. General safety standards of cosmetics

3.1 General requirements

- 3.1.1 All cosmetics should go through safety risk assessment to ensure they do not have adverse effect to human health under normal, appropriate and foreseeable use conditions.
- 3.1.2 Manufacture of cosmetics should comply with Hygienic Standard for Production Enterprises of Cosmetics. The manufacturing process should be scientific and