Cosmetic Hygiene and Safety Act and Relevant Laws

Taiwan Food and Drug Administration

2021.12

Contents

1 Cosmetic Hygiene and Safety Act

Cosmetic Hygiene and Safety Act

Amended Date：2018-05-02

Category：Ministry of Health and Welfare

Chapter 1 General Provisions

Article 1

This Act is enacted to maintain the hygiene and safety of cosmetics in order to safeguard national health.

Article 2

For purposes of this Act, the term "competent authority" shall mean the Ministry of Health and Welfare at the central government level, the municipal governments at the municipal level, and the county/city governments at the county/city level.

Article 3

The terms used in this Act are defined as follows:

1. "Cosmetics" means products applied externally to the human body, teeth, or oral cavity mucous membranes, and used to moisturize hair and skin, stimulate the sense of smell, improve body odors, change appearance, or cleanse the body. However, this is not applicable to those that are regarded as drugs in accordance with other laws or regulations.
2. "Cosmetics business" means a business engaged in the manufacture, import, or sale of cosmetics.
3. "Product information file" means a number of documents containing data about the quality, safety, and functions of cosmetics.
4. "Cosmetics ingredient" means a single chemical entity or mixture contained in cosmetics.
5. "Label" means a marking object used to bear words, graphics, or symbols for affixation on the container or package of a cosmetic.
6. "Leaflet" means an instruction sheet accompanying a cosmetic.

The scope and categories of cosmetics as defined in Subparagraph 1 of the preceding paragraph shall be publicly announced by the central competent authority.

Chapter 2 Manufacturing, Import, and Management of Factories

Article 4

Cosmetics categories and cosmetics manufacturers or importers of a certain scale that are specified by the central competent authority as per public announcement shall complete product notification and establish product information file prior to the supply, sale, giveaway, public display, or consumer trial offer of cosmetics. The same shall apply to modifications.

Regulations governing the certain scale, the items, contents, procedures, modifications, validity term, revocation, and rescission of product notification, and other matters to be observed with regard to the preceding paragraph shall be prescribed by the central competent authority.

Regulations governing the certain scale, the items, contents, modifications, methods for establishment and maintenance, retention period, location, qualification of signatory for the safety report of product information file, and other matters to be observed with regard to Paragraph 1 shall be prescribed by the central competent authority.

Article 5

For the manufacturing or import of specific purpose cosmetics designated by the public announcement of central competent authority, an application for registration shall be filed with the central competent authority. No manufacturing or import shall be allowed until a license is approved and issued.

Licensed cosmetics of the preceding paragraph shall not modify any of the originally registered particulars without approval of the central competent authority. However, this restriction does not apply to particulars that may be voluntarily modified per public announcement by the central competent authority.

The import of specific purpose cosmetics shall be exempted from application for registration of Paragraph 1 if one of the following conditions applies. Furthermore, the supply, sale, public display, consumer trial offer, or transfer to other uses of said cosmetics shall be forbidden:

1. Import for personal use, the quantity of which complies with public announcement of the central competent authority;
2. Import for the application for registration of Paragraph 1 or for use in research and trial, through special permission of the central competent authority.

For the import of specific purpose cosmetics for personal use of the preceding Subparagraph 1 that exceed the quantity specified in public announcement, their excess portion shall be ordered a return or destruction

within a specified time limit by the customs.

Prior to the enforcement of this Act as amended on April 10, 2018, for the manufacturing or import with a license of cosmetics containing medical or poisonous drugs whose license validity term expires within five years following the enforcement of this Act as amended on April 10, 2018, and where it is necessary to continue the manufacturing or import, an application for extension may be filed within three months before the expiration of validity term and an application for registration in accordance with Paragraph 1 may be exempted.

Regulations governing the issuance, modifications, revocation, and rescission of licenses with regard to Paragraph 1 and Paragraph 2, the application procedure for special permission with regard to Subparagraph 2 of Paragraph 3, the license extension with regard to Paragraph 5, and other matters to be observed shall be prescribed by the central competent authority.

The provisions of Paragraph 1 and Paragraph 2 shall cease to apply starting five years after the date of enforcement of this Act as amended on April 10, 2018.

Article 6

Cosmetics shall not contain mercury, lead, or other ingredients banned for use as per public announcement of the central competent authority. However, this restriction does not apply to residual traces contained therein that are inevitable due to contemporary technical or professional standards, provided that such traces pose no hazard to human health.

The central competent authority may restrict the use of cosmetics ingredients to prevent and avoid causing allergies, irritations, depigmentation, and conditions that pose a hazard to human health.

For the banned use and residual traces in Paragraph 1, and the restriction for use of ingredients or other conditions that pose an impact to the hygiene and safety of the preceding paragraph, their composition, content, applied body part, usage method, and other matters to be observed shall be publicly announced by the central competent authority.

Cosmetics businesses shall not subject animals to testing when conducting safety evaluation of cosmetics or cosmetic ingredients, unless one of the following conditions applies and has been approved by the central competent authority:

1. The ingredient is widely used, and its function cannot be replaced by other ingredients;

2. Those that require animal testing to be conducted, having evaluation data that demonstrate the potential for harming human health.

Cosmetics in violation of the provisions in the preceding Paragraph shall not be provided for sale.

Regulations governing the application procedure for using animals as test subjects and other matters to be observed with regard to Paragraph 4 shall be prescribed by the central competent authority.

Article 7

The outer packaging or containers of cosmetics shall conspicuously label the following information:

1. Product name;
2. Function;
3. Usage and storage instructions;
4. Net weight, volume, or amount;
5. Full ingredient names. For specific purpose cosmetics, the content of specific purpose ingredients contained therein shall be labeled separately;
6. Precautions for use;
7. Name, address, and telephone number of manufacturer or importer; country of origin of imported product;
8. Manufacturing date and shelf life, or manufacturing date and expiration date, or shelf life and expiration date;
9. Lot number;
10. Other information required to be labeled as per public announcement of the central competent authority.

The information to be labeled as specified in the preceding paragraph shall be provided in Chinese or internationally common symbols. However, the information of Subparagraph 5 may be labeled in English.

For the information of each subparagraph in Paragraph 1, if it cannot be labeled due to the surface area of outer packaging or container being too small or other special circumstances, said information shall be stated on the label, in the leaflet, or by other means.

The format and method of labeling and other matters to be observed with regard to the preceding three paragraphs shall be publicly announced by the central competent authority.

Sellers of cosmetics shall not alter or modify the labels, leaflets, outer packaging, or containers of cosmetics for sale.

Article 8

Manufacturing facilities for cosmetics shall comply with the Establishment Standards for Cosmetics Manufactory. Except those specified jointly by the central competent authority and central competent industry authority as per public announcement, factory registration shall be completed.

For cosmetics categories that are specified by the central competent authority as per public announcement, their manufacturing facilities for cosmetics shall comply with cosmetic Good Manufacturing Practice Regulations. The facilities are subject to on-site inspection by the central competent authority.

The provisions of the preceding paragraph may be applied mutatis mutandis to foreign manufacturing facilities.

The standards referred to in Paragraph 1 shall be formulated jointly by the central competent authority and central competent industry authority. The regulations referred to in Paragraph 2 shall be formulated by the central competent authority.

Article 9

Licensed pharmacists or personnel with professional skills in the field of cosmetics shall be hired and stationed at the factory to supervise the dispensation and manufacturing of cosmetics.

The qualifications, training, responsibilities of personnel with professional skills in the field of cosmetics, and other matters to be observed with regard to the preceding paragraph shall be prescribed by the central competent authority.

Chapter 3 Advertising and Logistics Management

Article 10

The contents of the labeling, promotion, and advertisement of cosmetics shall not be deceptive or exaggerated.

Cosmetics shall not be so labeled, promoted, or advertised as having medical efficacy.

A mass media enterprise being commissioned to publish or broadcast a cosmetics advertisement shall maintain the particulars of its principal, including name, national identification card number or establishment registration document number of company, business, corporation or group, domicile or address, telephone number, etc., for six months from the date of such advertisement, and shall not evade, obstruct, or refuse when requested by the competent authority for such particulars.

Regulations for the determination criteria of deceptive or exaggerated contents referred to in Paragraph 1, medical efficacy referred to in Paragraph 2, promotion or advertisement contents and methods, and other matters to be observed shall be prescribed by the central competent authority.

Article 11

Cosmetics businesses shall establish and maintain data on direct supply sources and destinations of products. However, this provision shall not apply to data on products directly sold to consumers.

Regulations governing the scope, items, contents, methods for establishment and maintenance, retention period of data, and other matters to be observed with regard to the preceding paragraph shall be prescribed by the central competent authority.

Article 12

Cosmetics businesses shall report the serious adverse effects generated by cosmetics under conditions of normal or reasonable use, or the findings when product could possibly pose a hazard to hygiene and safety or a risk of harm, and handle them in accordance with the provisions of Article 10 of the Consumer Protection Act.

Serious adverse effects mentioned in the preceding paragraph shall refer to one of the following conditions:

1. Death;
2. Life-threatening;
3. Temporary or permanent disability/incapacity;
4. Congenital anomaly/birth defect of fetus/infant;
5. Resulting in hospitalization of users for treatment.

Regulations on reporting population, methods, contents, deadlines, and other matters to be observed with regard to Paragraph 1 shall be prescribed by the central competent authority.

Chapter 4 Sampling Check, Test, and Control

Article 13

Competent authorities may dispatch personnel to enter the premises of cosmetics businesses to conduct sampling checks of their facilities, product information files, data on product supply sources and destinations, relevant records and documents, or sampling tests of cosmetics or their raw materials used.

Cosmetics businesses shall give their cooperation, and shall not evade, obstruct, or refuse.

In conducting sampling tests referred to in the preceding paragraph, the competent authorities shall sample amounts not to exceed quantities sufficient for conducting sampling tests and shall provide dockets to the cosmetics business.

In carrying out their official duties for conducting sampling checks or sampling tests, the personnel shall present evidentiary documents in relation to the performance of their duties.

Article 14

In order to enhance border control for cosmetics imports, the central competent authority may make public announcement about certain cosmetics categories or items that could possibly pose a hazard to hygiene and safety and may only be imported after sampling checks and sampling tests show compliance.

Regulations governing the methods, techniques, items, scope of sampling checks and sampling tests, and other matters to be observed with regard to the preceding paragraph shall be prescribed by the central competent authority.

Article 15

Competent authorities shall immediately initiate investigations and may order cosmetics businesses to suspend the manufacture, import, or sale, or order their products to be withdrawn from the market or to be sealed and stored if the cosmetics businesses are suspected to have violated the provisions of this Act or the cosmetics have one of the following conditions:

1. Expiration date exceeded;
2. Source unclear;
3. Other conditions sufficiently harmful to human health.

When competent authorities conduct investigations as specified in the preceding paragraph or other sampling checks or sampling tests referred to in this Act, they may order cosmetics businesses to provide testing specifications, testing methods, and testing reports of original manufacturers, as well as information, samples, reference standards, and relevant data necessary for testing. Cosmetics businesses shall give their cooperation, and shall not evade, obstruct, or refuse.

Penalties shall be rescinded and products shall be unsealed in the absence of any conditions specified in Paragraph 1 after investigations.

Article 16

Cosmetics businesses shall not supply, sell, give away, publicly display, or offer consumer trial cosmetics that are in violation of the provisions if one of the following conditions applies:

1. Violation of Paragraph 1 of Article 4;
2. Violation of the regulations prescribed pursuant to Paragraph 2 or Paragraph 3 of Article 4, pertaining to the provisions of items, contents, modifications, or methods for establishment and maintenance, retention period, and location of product notification or information file that could possibly pose a hazard to hygiene and safety as determined by competent authorities;
3. Violation of Paragraph 1 or Paragraph 2 of Article 5;
4. Violation of Paragraph 1 or the public announcement made pursuant to Paragraph 3 of Article 6;
5. Violation of Paragraph 1, Paragraph 2, Paragraph 3, or Paragraph 5, or the public announcement made pursuant to Paragraph 4 of Article 7;
6. Violation of Paragraph 1 of Article 8 in failing to apply for factory registration;
7. Violation of the Establishment Standards for Cosmetics Manufactory specified in Paragraph 1 or the Good Manufacturing Practice Regulations specified in Paragraph 2 of Article 8, and said violation could possibly pose a hazard to hygiene and safety as determined by competent authorities;
8. Violation of the labeling provisions specified in Paragraph 1 or Paragraph 2 of Article 10;
9. Product notification or product license revoked or rescinded by the central competent authority.

The same shall apply to cosmetics that have exceeded expiration date, are of unclear source, or pose other hazards to hygiene and safety as per public announcement of the central competent authority.

Article 17

Cosmetics manufacturers or importers shall immediately notify sellers and recall violating products from the market within a time period specified by competent authorities if one of the following conditions applies:

1. Violation of Paragraph 1 or the regulations prescribed pursuant to Paragraph 2 or Paragraph 3 of Article 4, pertaining to the provisions of items, contents, modifications, or methods for establishment and maintenance, retention period, and location of product notification or information file, and failure to make corrections within the time limit specified by competent authorities;

2. Violation of Paragraph 1, Paragraph 2, or Paragraph 3 of Article 5, and failure to make corrections within the time limit specified by competent authorities;
3. Violation of Paragraph 1 or the public announcement made pursuant to Paragraph 3 of Article 6;
4. Violation of Paragraph 1, Paragraph 2, Paragraph 3, or Paragraph 5, or the public announcement made pursuant to Paragraph 4 of Article 7;
5. Violation of Paragraph 1 of Article 8 in failing to apply for factory registration;
6. Violation of the Establishment Standards for Cosmetics Manufactory specified in Paragraph 1 of Article 8 or the Good Manufacturing Practice Regulations specified in Paragraph 2, and said violation could possibly pose a hazard to hygiene and safety as determined by competent authorities;
7. Violation of the labeling provisions specified in Paragraph 1 or Paragraph 2 of Article 10;
8. Product notification or product license revoked or rescinded by the central competent authority.

The same shall apply to cosmetics that are of unclear source or pose other hazards to hygiene and safety as per public announcement of the central competent authority.

Sellers shall cooperate with manufacturers and importers in the recall of cosmetics with regard to the preceding two paragraphs.

Regulations for cosmetics that shall be recalled, their classification, handling methods, implementation methods for recall operations, deadlines for completion, contents of protocol and report, record retention, and other matters to be observed with regard to Paragraph 1 and Paragraph 2 shall be prescribed by the central competent authority.

Article 18

Violating cosmetics shall be confiscated and destroyed if one of the following conditions applies:

1. Violation of Paragraph 1 or the regulations prescribed pursuant to Paragraph 2 or Paragraph 3 of Article 4, pertaining to the provisions of items, contents, modifications, or methods for establishment and maintenance, retention period, and location of product notification or information file, and said violation poses a hazard to hygiene and safety as determined by competent authorities;
2. Violation of Paragraph 1, Paragraph 2, or Paragraph 3 of Article 5, and said violation poses a hazard to hygiene and safety as determined by competent authorities;
3. Violation of Paragraph 1 or the public announcement made pursuant to Paragraph 3 of Article 6;

4. Violation of Paragraph 1, Paragraph 2, Paragraph 3, and Paragraph 5, or the public announcement made pursuant to Paragraph 4 of Article 7, and said violation poses a hazard to hygiene and safety as determined by competent authorities;
5. Violation of Paragraph 1 or Paragraph 2 of Article 8, and said violation poses a hazard to hygiene and safety as determined by competent authorities;
6. Violation of Paragraph 1 of Article 9, and said violation poses a hazard to hygiene and safety as determined by competent authorities;
7. Violation of Paragraph 1 or Paragraph 2 of Article 10, and said violation poses a hazard to hygiene and safety as determined by competent authorities;
8. Product notification or product license revoked or rescinded by the central competent authority.

The same shall apply to cosmetics that have exceeded expiration date, are of unclear source, or pose other hazards to hygiene and safety as per public announcement of the central competent authority.

Article 19

The competent authority shall keep strictly confidential the particulars of, and may at its discretion grant reward to, anyone informing against cosmetics, labels, promotional materials, advertisements, or cosmetics businesses that are found to have violated the provisions of this Act.

Regulations for the reward of informing with regard to the preceding paragraph shall be prescribed by the central competent authority.

Chapter 5 Penal Provisions

Article 20

Those in violation of Paragraph 1 or the regulations prescribed pursuant to Paragraph 4 of Article 10, pertaining to the provisions of promotion or advertisement contents and methods, shall be imposed a fine ranging from NT$40,000 to NT$200,000; violation of Paragraph 2 of the same article shall be imposed a fine ranging from NT$600,000 to NT$5,000,000. In case of severe violation, the business may be ordered to terminate business operations or revoke all or part of the items listed in the registration of its company, business, or factory.

Violators of cosmetics promotion or advertisement specified in Paragraph 1 or Paragraph 2, or the regulations prescribed pursuant to Paragraph 4 of Article 10, pertaining to the provisions of contents and

methods, shall be fined successively until the violation is corrected or the publication or broadcast is terminated.

Severe violation of the provisions pertaining to promotion or advertisement specified in Paragraph 1 or Paragraph 2 of Article 10 shall not only be penalized in accordance with the preceding two paragraphs, the competent authorities shall also order the termination of supply, sale, giveaway, public display, or consumer trial offer of the advertised products.

Violators of the provisions pertaining to advertisement specified in the preceding paragraph shall publish or broadcast a corrective advertisement of the same length and in the same space and time slot as the original advertisement at a specified frequency within 30 days after receipt of the sanction order. Said corrective advertisement shall state an official apology and correct false information.

Violators of the preceding two provisions who continue to supply, sell, give away, publicly display, or offer consumer trial, or fail to publish or broadcast a corrective advertisement shall be imposed a fine ranging from NT$120,000 to NT$2,000,000.

Article 21

Media businesses in violation of Paragraph 3 of Article 10 shall be imposed a fine ranging from NT$60,000 to NT$300,000 and may be fined successively.

Article 22

Cosmetics businesses shall be imposed a fine ranging from NT$20,000 to NT$5,000,000 and may be fined successively if one of the following conditions applies. In case of severe violation, the businesses may be subject to a suspension of business operations for not less than one month nor greater than one year, or ordered to revoke all or part of the items listed in the registration of their company, business, or factory, or to revoke or rescind notifications or licenses for the said cosmetics.

1. Violation of Paragraph 1 or the public announcement made pursuant to Paragraph 3 of Article 6;
2. Violation of Paragraph 1 of Article 8;
3. Violation of Paragraph 2 of Article 8, with corrections not made after being ordered to make corrections within a specified time limit.

In case of revocation of notifications or licenses for cosmetics of the preceding paragraph, re-notification or re-application for registration of said products shall not be permitted within one year.

Article 23

Cosmetics businesses shall be imposed a fine ranging from NT$10,000 to NT$1,000,000 and may be fined successively if one of the following conditions applies. In case of severe violation, the businesses may be subject to a suspension of business operations for not less than one month nor greater than one year, or ordered to revoke all or part of the items listed in the registration of their company, business, or factory, or to revoke or rescind notifications or licenses for the said cosmetics.

1. Violation of Paragraph 1 of Article 4;
2. Provision of false information in product notification or information file referred to in Paragraph 1 of Article 4;
3. Violation of the regulations pertaining to items, contents, modifications, or methods for establishment and maintenance, retention period, and location of product notification or information file prescribed pursuant to Paragraph 2 or Paragraph 3 of Article 4, with corrections not made after being ordered to to make corrections within a specified time limit;
4. Violation of Paragraph 1, Paragraph 2, or Paragraph 3 of Article 5;
5. Provision of false information during the application for registration specified in Paragraph 1 or Paragraph 2 of Article 5;
6. Violation of Paragraph 4 or Paragraph 5 of Article 6;
7. Violation of Paragraph 1, Paragraph 2, Paragraph 3, or Paragraph 5, or the public announcement made pursuant to Paragraph 4 of Article 7;
8. Violation of Paragraph 1 of Article 9;
9. Provision of false data on sources or destinations as specified in Paragraph 1 of Article 11;
10. Violation of Paragraph 1 of Article 13;
11. Violation of Paragraph 2 of Article 15;
12. Violation of Article 16 by supplying, selling, giving away, publicly displaying violating cosmetics or offering consumer trial.

In case of revocation of notifications or licenses for cosmetics of the preceding paragraph, re-notification or re-application for registration of said products shall not be permitted within one year.

Article 24

Cosmetics businesses shall be imposed a fine ranging from NT$10,000 to NT$1,000,000 and may be fined successively if one of the following conditions applies and failing to make corrections within a specified time limit after being ordered to do so. In case of severe violation, the businesses may be suspended from operating for not less than one month nor greater than one year, or ordered to revoke all or part of the items listed in the registration of their company, business, or factory, or to revoke or rescind notifications or licenses for the said cosmetics.

1. Violation of Paragraph 1 or the regulations pertaining to scope, items, contents, methods for establishment and maintenance, and retention period of data as prescribed pursuant to Paragraph 2 of Article 11;
2. Violation of Paragraph 1 or the regulations pertaining to reporting methods, contents, or deadlines as prescribed pursuant to Paragraph 3 of Article 12;
3. Violation of Paragraph 1 or Paragraph 2 for failing to notify sellers or recall within time limit, or violation of Paragraph 3 or the regulations pertaining to handling methods, implementation methods for recall operations, deadlines for completion, contents of protocol and report, or record retention as prescribed pursuant to Paragraph 4 of Article 17.

In case of revocation of notifications or licenses for cosmetics of the preceding paragraph, re-notification or re-application for registration of said products shall not be permitted within one year.

Article 25

In case of violation specified in the preceding five articles, the competent authorities may, based on the circumstances of the offense, the extent of harm, and the scope of impact, make public the names and addresses of businesses, products, and conditions of the violation.

Article 26

The penalties prescribed in this Act, with the exception of revocation or rescission of notifications or licenses for cosmetics that shall be imposed by the central competent authority, shall be imposed by municipal or county/city competent authorities for the remaining penalties. The central competent authority may impose the penalties if deemed necessary.

Article 27

The revocation of all or part of the items listed in the registration of company, business, or factory as specified in this Act shall be forwarded for execution by the competent industry or commerce authority or its competent government authority after the termination of business operations has been ordered and confirmed by municipal or county/city competent authorities.

Chapter 6 Supplementary Provisions

Article 28

Competent authorities may authorize subordinate agencies or commission relevant institutions/organizations, corporations, or groups to carry out inspections, sampling checks or sampling tests of cosmetics and cosmetics businesses, or to issue manufacturing and sale certificates.

The central competent authority may carry out accreditation of the commissioned institutions/organizations, corporations, or groups in the preceding paragraph. The accreditation tasks may be authorized to subordinate agencies or commissioned to relevant institutions/organizations, corporations, or groups.

Regulations governing the qualifications and requirements for organizations, corporations, or groups to undertake commission or accreditation, the procedures of tasks for commission or accreditation, and other relevant matters of those commissioned with regard to the preceding two paragraphs shall be prescribed by the central competent authority.

Article 29

Cosmetics businesses may submit applications of manufacturing and sale certificate or GMP compliance certificate to the central competent authority for the cosmetics they have notified or acquired licenses, or for cosmetics manufacturing facilities that comply with the cosmetic Good Manufacturing Practice Regulations as determined by the central competent authority.

Regulations governing the application criteria, review procedures and standards, validity term, revocation, return, cancellation, and other matters to be observed with regard to the issuance of certificates in the preceding paragraph shall be prescribed by the central competent authority.

Article 30

Cosmetics businesses shall pay the fees for cosmetics notification, applications for registration, applications for inspection of compliance with the cosmetic Good Manufacturing Practice Regulations, applications for sampling checks and sampling tests on border importation of cosmetics, and applications for certificates that are made in accordance with this Act.

Article 31

The enforcement rules of this Act shall be prescribed by the central competent authority.

Article 32

The date for enforcement of this Act shall be set by the Executive Yuan, with the exception of Paragraph 4 through Paragraph 6 of Article 6, and Subparagraph 6 of Paragraph 1 of Article 23, which shall be enforced from November 9, 2019.

2 Enforcement Rules of Cosmetic Hygiene and Safety Act

Enforcement Rules of Cosmetic Hygiene and Safety Act

Amended Date：2019-06-27

Category：Ministry of Health and Welfare

Article 1

This rule (the "Rule") is enacted per Article 31 of Cosmetic Hygiene and Safety Act (the "Act").

Article 2

Cosmetics product notification and product information file stipulated under Paragraph 1 of Article 4 and the product recall as set forth under Paragraph 1 of Article 17 of the Act shall be completed by the cosmetics manufacturers or importers.

The contract manufacturers are not deemed as the cosmetics manufacturers or importers stipulated under the preceding Paragraph.

Article 3

Country of origin of imported products stipulated under Sub-paragraph 7 of Paragraph 1 of Article 7 of the Act shall refer to regions or countries final products manufactured or processed per the Regulations Governing the Determination of Country of Origin of an Import Goods.

Article 4

Manufacturing facilities stipulated under Paragraph 1 and 2 of Article 8 of the Act shall refer to the plants conducting cosmetics manufacturing or packaging operation.

The plants for the further combination of cosmetics products which have fulfilled the labeling requirements of Article 7 of the Act shall be excluded from the manufacturing facilities prescribed in the preceding Paragraph.

Article 5

The requirement of hiring and stationing licensed pharmacists or personnel with professional skills in the field of cosmetics at the factory to supervise the dispensation and manufacturing of cosmetics stipulated under Paragraph 1 of Article 9 of the Act shall not apply to the manufacturing facilities that factory

registration is not necessary as specified jointly by the central competent authority and central competent industry authority per Paragraph 1 of Article 8 of the Act.

Article 6

Products sealed and stored per Article 15 of the Act shall be additionally sealed or labeled by the competent authority. Those products shall be taken photos or videotaped. A list of items and numbers of sealed and stored products shall be made and confirmed by the on-site business by signing or affixing its stamp.

Products sealed and stored per the preceding Paragraph may be designated to be adequately retained by the business. Business shall not, without authorization, replace, remove, conceal or dispose of the products.

Article 7

Unclear source cosmetics stipulated under Sub-paragraph 2 of Paragraph 1 of Article 15, Paragraph 2 of Article 16, Paragraph 2 of Article 17, and Paragraph 2 of Article 18 of the Act shall refer to one of the followings:

1. Proof of source failed to be provided.
2. Provided source or its proof confirmed to be false.
3. No indication of the name or address of the manufacturers or the importers stated on the outer packaging or containers and no product notification information to be verified.

Article 8

Severe violation stipulated under Paragraph 1 and 3 of Article 20 of the Act shall refer to one of the followings:

1. Failing to cease medical efficacy claims in its promotion or advertisements after punished consecutively by the competent authority.
2. Its promotion or advertisements mislead the public and cause harm to human health or cause death.
3. Other situations determined by the competent authority having impact equivalent to preceding two Sub-paragraphs.

Article 9

If cosmetics notification information or originally approved information is amended, and the original information labeled is inconsistent with amended information, the cosmetics with original labels manufactured or imported before the amendment date are allowed for sale within the product expiration date.

If the renewal application for the license of specific purpose cosmetics or cosmetics product notification is not filed or renewal is not granted, the cosmetics manufactured or imported before the due date of the license or notification are allowed for sale within the product expiration date.

Article 10

The Rules shall take effect on July 1, 2019, except for Article 3 and Paragraph 2 of Article 4 of the Rules shall take effect on July 1, 2021.

3 Table of Scope and Category of Cosmetics

Table of Scope and Category of Cosmetics

Effective Date: 2019-07-01

Category: Ministry of Health and Welfare

Category	Scope of Products
I. Hair cleansing products	1. Shampoos, lotions,creams,gels,and powders 2. Other
II. Face cleansing and makeup removing products	1. Face cleansing lotions, creams, gels,foams,and powders 2. Makeup removing oils, lotions, and liquids 3. Other
III. Bath and shower products	1. Body cleansing oils, lotions, gels, foams, and powders 2. Bath salts 3. Other
IV. Bar soaps	1.Bar soaps 2. Other
V. Hair products	1. Hair nourishing liquids,lotions,creams,gels,and oils 2. Styling sprays, styling creams, hair gels, hair waxes, hair oils 3. Conditioners 4. Colorants 5. Hair dyes 6. Bleaching and decoloring agents 7. Perming agents 8. Other
VI. Toner, oil, cream, lotion products	1. Toners, makeup oils 2. Skin care lotions, creams, gels, oils 3. Shaving liquids, creams, and foams 4. Aftershave toners, aftershave facial creams 5. Hand lotions, creams, gels, and oils 6. Tanning lotions, creams, gels, and oils 7. Sunscreen lotions, creams, gels, and oils 8. Paste masks (mud packs) 9. Face masks

	10. Other
VII. Aromatic products	1. Perfumes, aromatic balms, aromatic powders 2. Talcum powders 3. Underarm deodorants 4. Other
VIII. Antiperspirant and deodorant products	1. Antiperspirants 2. Deodorants 3. Other
IX. Lip products	1. Lipsticks 2. Lip glosses, oils 3. Lip masks 4. Other
X. Covering products	1. Liquid foundations, foundation creams 2. Powder pastes, powder cakes 3. Loose powders 4. Facial (excluding the eye) makeup 5. Makeup fixatives 6. Other
XI. Eye products	1. Eye creams, eye gels 2. Eyeshadows 3. Eyeliners 4. Eye makeup removing oils and lotions 5. Eye masks 6. Mascaras 7. Eyebrow pencils, powders, pastes, and gels 8. Other
XII. Manicuring products	1. Nail polish 2. Nail polish removers 3. Nail lotions and creams 4. Other

XIII. Teeth whitening products	1. Teeth whitening agents 2. Whitening toothpastes
XIV. Non-therapeutic toothpaste and mouthwash products	1. Non-therapeutic toothpastes 2. Non-therapeutic mouthwashes

Issued by: Public Announcement of Ministry of Health and Welfare

Issued on: April 1st, 2016

Issuance number: Ministry of Health and Welfare Order Bu-Shou-Shi-Zi No. 1051601670

Subject: Announcement to include wet wipes for infants in the cosmetic categories

Reference: Paragraph 1, Article 154 of Administrative Procedure Act

The announcements are:

1. Competent Authority: Ministry of Health and Welfare
2. Announcement reference: Article 3 of Cosmetics Hygiene and Safety Act
3. Establishing regulations to include wet wipes for infants in the cosmetic categories and these regulations shall be effective starting from June 1st, 2017. Starting from the effective date, wet wipes for infants shall be complied with the regulations of Cosmetic Hygiene and Safety Act. This case shall be announced on the public announcement website of the Ministry of Health and Welfare(website:http://www.mohw.gov.tw) and Food and Drug Administration (website:http://www.fda.gov.tw).
4. The “infants” in “wet wipes for infants” refers to the definition defined by the World Health Organization (WHO). Infants are considered children anywhere from birth to 1 year old.

4 Regulations for Issuance of License of Specific Purpose Cosmetics

Regulations for Issuance of License of Specific Purpose Cosmetics

Announced Date：2019-05-28

Category：Ministry of Health and Welfare

Chapter I General Provisions

Article 1

These Regulations are prescribed pursuant to Paragraph 6 of Article 5 of the Cosmetics Hygiene and Safety Act (the "Act").

Article 2

Before the enforcement of the Act, cosmetics have obtained the license of medical or poisonous drugs per the Statute for Control of Cosmetic Hygiene shall be deemed as Specific Purpose Cosmetics within the valid term of such license.

Article 3

The terms used in these Regulations are defined as follows:

1. Specific purpose cosmetics: refers to cosmetics designated by public announcement of the central competent authority per Paragraph 1 of Article 5 of the Act, and used for sunscreen, hair-dyeing, permanent waving, antiperspirant, deodorant, tooth-whitening or other purposes.
2. Authorization letter: refers to a certificate issued by the original overseas manufacturer, the headquarter, or its contract manufacturer of specific purpose cosmetics, allows registration applicant to import and distribute such cosmetics.
3. Manufacture and Free Sale Certificate ("MFSC"): refers to a certificate issued by the country of origin proves the approved manufacturing and free sale.
4. Ingredients list: refers to a formula table of full ingredients issued by the manufacturer or the headquarter identifying names and content of ingredients.
5. Certificate of analysis: refers to documentation identifying characteristic, active ingredients, identification methods, quantitative methods, an acceptable range of content, test results, and other determination data.

Chapter II Manufacture and Import

Article 4

An applicant applies for the registration of the license for manufacturing specific purpose cosmetics per Paragraph 1 of Article 5 of the Act shall submit an application with following documents, and pay the fee to the central competent authority:

1. A copy of the factory registration certificate.
2. A copy of the license of the pharmacist in charge of supervision of manufacturing, or employment certificate and qualification of personnel who is stationed at the factory to supervise the dispensation and manufacturing.
3. Drafts of product labels, leaflets, and packaging.
4. The certificate of analysis.
5. For the contract manufacturer, a copy of company registration or business registration certificate of the applicant and the OEM agreement.

A cosmetic manufacturing facility receives the certificate of cosmetic Good Manufacturing Practice by law, and applies for specific purpose cosmetics license for the same dosage form stated in such certificate, the certificate of analysis mentioned in Sub-paragraph 4 of the preceding Paragraph may be replaced with such certificate.

Article 5

An applicant applies for the registration of the license for importing specific purpose cosmetics per Paragraph 1 of Article 5 of the Act shall submit an application with following documents, information, and pay the fee to the central competent authority:

1. A copy of company registration or business registration certificate.
2. Drafts of product labels, leaflets, and packaging.
3. The authorization letter issued within the past two years.
4. The MFSC issued within the past two years.
5. An ingredient list issued within the past two years.
6. The certificate of analysis.
7. For the contract manufacturer, a certificate identifies the relationship between the hiring firm and contract manufacturer.

Article 6

The authorization letter stipulated under Sub-paragraph 3 of the preceding Article shall state the following information:

1. The name and address of the authorization letter submitter. If the letter is not issued by the original manufacturer, it shall additionally state the name and address of the original manufacturer.
2. The name and address of the agent.
3. The name and item of authorized products.
4. The intention of authorization.

The information mentioned in the preceding Paragraph shall be consistent with the application. If the authorization letter is written in the language other than Chinese or English, the Chinese or English translation shall be attached.

Article 7

The MFSC stipulated under Sub-Paragraph 4 of Article 5 shall state the following information:

1. The name of the product.
2. The name and address of the manufacturer.

The MFSC shall be authenticated by the overseas diplomatic mission. The MFSC issued by the government of the country of origin, or notarized by the local notary public may be exempted from authentication.

If MFSC is written in the language other than Chinese or English, the Chinese or English translation shall be attached.

The MFSC may be replaced with the free sale certificate issued by the country of the hiring firm and the manufacture certificate issued by the country of the contract manufacturer.

The MFSC may be issued by either the authorities of the country of the hiring firm or contract manufacturer if specific purpose cosmetics is imported by the OEM.

If the country of origin of cosmetics in Japan and the MFSC only states the information of the vendor rather than the manufacturer, the copy of the manufacturing certificate carrying the name and the address of the manufacturer and the name of the product issued by the hygiene authority of the country of origin may be provided as substitution, while free sale certificate shall be attached.

Article 8

Ingredient list stipulated under Sub-paragraph 5 of Article 5 shall state the following information:

1. The name of the product.

2. The name and content of active ingredients, preservatives, pigments, or other ingredients.

The name of ingredients mentioned in the Sub-paragraph 2 of the preceding Paragraph shall refer to the International Nomenclature of Cosmetic Ingredients ("INCI") or its common chemical name in English. Its content shall be made by weight or volume percentage (i.e., W/W% or W/V%); provided that the content may be labeled as "appropriate amount" for other ingredients and pigments with no limits on the usage of same.

Ingredient list shall be authenticated by an overseas diplomatic mission. The list issued by the government of the country of origin, or notarized by the local notary public may be exempted from authentication.

Article 9

The certificate of analysis stipulated under Sub-paragraph 4 of Article 4 and Sub-paragraph 6 of Article 5 shall state the following information:

1. Characteristic: appearance, color, shape, and dosage form of the product.

2. Active ingredients: specific purpose ingredients in the product.

3. Method for identifying active ingredients.

4. Method for quantifying active ingredients.

5. Acceptable content range of active ingredients, and it shall be within 90% to 110% of the content.

6. The test results.

7. Other determination data.

If the active ingredients of oxidative hair- dyeing products are too low or unstable and therefore cannot be quantified precisely, the active ingredients stipulated under Sub-Paragraph 4 and 5 of the preceding Paragraph may be replaced with freebase (Alkalinity) or free ammonia (limited to active ingredients containing ammonia)

Article 10

When central competent authority designates specific purpose cosmetics by the public announcement per Paragraph 1 of Article 5 of the Act, the content of public announcement shall contain the names, scopes,

and limitations of active ingredients.

The active ingredient of cosmetics are not stipulated under preceding Paragraph; however, it is identified the characteristic of specific purpose cosmetic by the authorities of countries (areas) or regions recognized by the central competent authority, the applicant may apply for registration per the Act and attach the certificates used by those countries (areas) or regions.

Article 11

Applying for the license of specific purpose cosmetic shall attach relevant information per the Appendix if active ingredient of cosmetic is new substance, with new purpose or new maximum concentration. However, the condition mentioned in Paragraph 2 of the preceding Article shall exempt from it.

Article 12

Cosmetics applied for the license of specific purpose cosmetics shall not contain any ingredient prohibited from using per the public announcement made pursuant to Paragraph 1 of Article 6 of the Act.

Cosmetics mentioned in the preceding Paragraph contain bovine and sheep tissue composition shall attach certificates of products or raw materials from Bovine Spongiform Encephalopathy-free countries, regions, or zones.

Article 13

The license may be jointly applied if specific purpose cosmetics come from the same manufacturer, with the same purpose, same active ingredients and dosage form.

The joint application stipulated under the preceding Paragraph shall attach documents and data mentioned in Paragraph 1 of Article 4 and Article 5 separately in accordance with different products, except for those documents or data mentioned in Sub-Paragraph 1, 2, and 5 of Paragraph 1 of Article 4 and Sub-Paragraph 1 of Article 5.

Article 14

The central competent authority shall notify the applicant the result of the application stipulated under Article 4 and 5. The applicant, within three months after the arrival date of the notice, shall provide electronic files of approved labels, leaflets, and packaging, and pay the fee to the central competent

authority to obtain the license.

Article 15

The items of registration stipulated under the preceding Article shall be as follows:

1. Product item.

2. Product name; model number and color code for serial products.

3. Active ingredients and content percentage.

4. Dosage form.

5. Leaflets, labels, packaging, and specifications.

6. Purpose.

7. Name of the applicant.

8. Name and address of the manufacturer.

Article 16

The license stipulated under Article 14 shall state validity term and items mentioned in Sub-paragraph of the preceding Article except for the items of Sub-paragraph 5.

Article 17

If the document or data attached to the application is deficient, or the fee is unpaid, the central competent authority shall request the applicant for the correction within the time limit.

The applicant who fails to correct the deficiency within the time limit under the preceding Paragraph may request an extension in writing to the central competent authority with reasons before the expiration of the time limit. The extension is one month upon the next day of the expiration of correction.

If the applicant fails to correct the deficiency per the preceding two Paragraphs, the application shall be refused.

Article 18

The application shall be disapproved if one of the following conditions applies:

1. Attached document or data is inconsistent with the content of the application.

2. Containing prohibited ingredients per Paragraph 1 of Article 6 of the Act, or the ingredients violate the

limit on usage of ingredients set forth under Paragraph 2 of Article 6 of the Act.

3. The labeling of packaging, labels or, leaflets violates Article 7 of the Act.
4. Text or picture of the product name, packaging, labels or, leaflets has deception, exaggeration, or involving medical efficacy as set forth under Paragraph 1 and 2 of Article 10 of the Act.
5. Any conditions that may harm human health.
6. Other violation of laws, regulations or public announcement made by the central competent authority.

Article 19

If the license of specific purpose cosmetics is damaged or lost, the applicant may pay the fee to the central competent authority and apply for the replacement or reissue. The original license shall be attached if applying for the replacement.

Chapter III Modification of Registration and Transfer and Modification of License

Article 20

If there is any change of the information of registration or license mentioned in Article 15 or 16, the applicant shall provide the original license and relevant documents and pay the fee to the central competent authority to apply for the modification per Paragraph 2 of Article 5 of the Act. After the central competent authority reviews and approves, the original license shall additionally state the modified registration, date, and returned the license with the stamp.

If the Modification mentioned in the preceding Paragraph is to increase items or color systems, those products shall be made by the same manufacturer, same active ingredients, same dosage form and purpose, and conforming to the limit on usage of specific purpose ingredients as set forth by the central competent authority.

Article 21

Applying for transfer of the license of specific purpose cosmetics, the transferor and transferee shall file a joint application with the original license and relevant certificates, and pay the fee to the central competent authority to apply for the approval.

The original license shall identify the name of the transferee and the approval date when the central competent authority makes an approval mentioned in the preceding Paragraph.

Article 22

Applying for the revocation of the license of specific purpose cosmetics, the application with the original license and relevant documents shall be submitted to the central competent authority.

Chapter IV Extension of License

Article 23

Applying for an extension of the term of validity of the license of specific purpose cosmetics per Paragraph 5 of Article 5 of the Act, the applicant shall submit an application with the following documents, and pay the fee to the central competent authority:

1. The original license.
2. The copy of the company or business registration certificate.
3. The Authorization letter issued within the past two years except for domestic manufacturing.

Article 24

If the extension is not applied before the expiration of the term of the license of specific purpose cosmetics per the preceding Article, the application shall re-apply for registration and license per Paragraph 1 of Article 5 of the Act. However, the applicant may submit an application with the following documents, and pay the fee to the central competent authority if re-apply license within six months after the term expired:

1. The original license.
2. The copy of the company or business registration certificate.
3. For domestic contract manufacturer, the manufacture agreement. For foreign contract manufacturer and import, the certificate identifies the relationship between the hiring firm and contract manufacturer.
4. For importer, MFSC, ingredient list and authorization letter issued within the past two years.

The license with the new license number will be issued after the approval of the application mentioned in the preceding Paragraph.

Chapter V Supplementary

Article 25

The Regulations shall take effect on July 1, 2019.

Appendix: Required Technical Information for registration of specific purpose cosmetics containing new substance, new purpose or new maximum concentration

item	information	New substance	New purpose	New maximum concentration (elevating maximum concentration)
origin of substances, research and develop history,foreign application status	origin of substances, research and develop history	○	○	○
	foreign application status	○	○	○
	Characteristic comparison information	○	○	○
Characteristics, specification of analysis	Chemical structure	○	×	×
	Physical/chemical Characteristics	○	×	×
	specification and method of analysis	○	○	○
Stability test	Long-term test	○	○	○
	Stress test	○	○	○
	Acceleration test	○	○	○
Safety test report	Acute toxicity test	○	△	△
	subacute toxicity test	○	△	△
	Chronic toxicity test	○	△	△
	Local sensitizing test	○	△	△
	Antigenicity test	○	△	×
	*Mutagenicity test	△	×	×
	*Carcinogenicity test	△	×	×
	*Reproductive toxicity test	△	×	×
Test report of Absorption,Distribution, Metabolism,Excretion	Absorption	△	△	△
	Distribution	△	△	△
	Metabolism	△	△	△
	Excretion	△	△	△
Purpose-related information	Functionality or efficacy data	○	○	○

	Human test data	○	○	○
	Approval document Of other country	△	△	△

Notes：

1.「○」means that the information under that item shall be provided「△」means that it depends via a case-by-case basis.「╳」means that the information under that item is not necessary to be provided.

2.「Foreign application status」: No need to provide if developed domestically.

3.「Test specifications and results」: Including materials and preparations.

4.「Stability test」:Including materials and preparations. No need to provide preparations for the ones bearing「*」mark.

5.Antigenicity tests shall include skin allergen tests and photoallergic tests; local irritation tests shall include skin irritation tests and mucosal stimulation tests.

6.Operation of stability tests may refer to international guideline or「Guidelines on the Drug Stability Study」as announced by the central health competent authority.

7.To conduct safety evaluation of cosmetics or cosmetic ingredients, cosmetics businesses shall comply with paragraph 4 and paragraph 6 of article 6 of the Act.

5 Regulation for Authorizing the Applications of Import of Non-licensed Specific Purpose Cosmetics

Regulation for Authorizing the Applications of Import of Non-licensed Specific Purpose Cosmetics

Announced Date：2019-05-28

Category：Ministry of Health and Welfare

Article 1

This Regulation is enacted pursuant to Paragraph 6 of Article 5 of Cosmetics Hygiene and Safety Act (the "Act").

Article 2

Specific purpose cosmetics comply with one of the following Sub-paragraphs may, according to the Sub-paragraph 2 of Paragraph 3 of Article 5 of the Act, apply special permission to the central competent authority:

1. Cosmetics business imports for the application for registration.
2. Cosmetics business, university, academic research institute, trial site, sponsor, academic medical association, or teaching hospital imports for use in research and trial.

Article 3

Applying for the special permission of the Sub-paragraph 1 of the preceding Article, the applicant shall file the application and attach the following documents and information:

1. Company or business registration certificate.
2. The certificate of representative issued by the foreign company within the past two years.
3. Packaging, container, leaflet, and required quantity.
4. Other documents and information designated by the central competent authority.

Article 4

Applying for the special permission of the Sub-paragraph 2 of Article 2, the applicant shall file the application and attach the following documents and information:

1. The registration certificate of the company, business, university, corporation, association, or organization.
2. The research trial project included the purpose, method, and length of the research, and the usage,

application, and required quantity.

3. Packaging, container, leaflet, and required quantity.

4. Other documents and information designated by the central competent authority.

Article 5

Required quantity stipulated under Paragraph 3 of Article 3 and Paragraph 2 of the preceding Article shall not exceed the following rule for each product:

1. Application for registration: 12 bottles (boxes, cans, bags, packages, pieces)

2. Research and trial：the estimation of required quantity mentioned in the research trial project and related certification.

Article 6

If the document or information attached by the applicant is incomplete and may be corrected, the competent authority shall request for the correction within the time limit. Fail to correct or correct incompletely within the time limit, and the application shall be refused.

Article 7

The application of special permission per this Regulation shall not be granted if one of the following conditions met:

1. Attached document or information is inconsistent with the content of the application.

2. Attached document or information is deceptive or false.

3. The product contains ingredient banned for use as per public announcement of the central competent authority.

4. The product ingredient fails to conform to the restriction for use as per public announcement of the central competent authority unless the specific purpose cosmetics for research trial use.

5. The applicant had applied the same product for the license of specific purpose cosmetics unless it is deemed as necessary by the central competent authority.

6. The applicant had applied the same product per Paragraph 1 of Article 2 within six months and obtained approval.

7. Other violation of laws or rules publicly announced by the central competent authority.

Article 8

After the special permission of importing specific purpose cosmetics is granted, the central competent authority may revoke or rescind the grant if one of the following conditions met:

1. Attached document or information is deceptive or false.

2. Actual usage is inconsistent with the content of approval.

3. The potential for harming human health.

The grant is revoked or rescinded per Sub-paragraph 1 or 2 of the preceding Paragraph, the new application submitted within two years shall be refused.

Article 9

After the special permission of importing specific purpose cosmetics is granted, the applicant shall record the using or processing by the actual quantity, and keep the record properly at least three years.

Article 10

The Regulation shall take effect on July 1, 2019.

6 Regulations Governing Notification of Cosmetic Products

Regulations Governing Notification of Cosmetic Products

Announced Date：2019-05-30

Category：Ministry of Health and Welfare

Article 1

This Regulation is enacted pursuant to Paragraph 2 of Article 4 of Cosmetics Hygiene and Safety Act (the "Act").

Article 2

The cosmetics manufacturers or importers of a certain scale under Paragraph 1 of Article 4 of the Act (the "Cosmetics Manufacturers or Importers") shall refer to below entities in the business of manufacturing or importing cosmetics products:

1. A corporate or a firm to be established and registered pursuant to Company Act and/or Business Registration Act.
2. A factory to be registered pursuant to Paragraph 1 of Article 8 of the Act.
3. The groups and corporations which engage in cosmetics manufacturing or importing, except the handmade soap entities which are exempt from industry registration, excluding the entities mentioned in preceding two subparagraphs.

Article 3

Cosmetics Manufacturers or Importers shall, while manufacturing or importing cosmetics under Paragraph 1 of Article 4 of the Act, complete data notification via the platform provided by the central competent authorities.

Article 4

Data notification specified in the preceding Article shall include:

1. Notification number of products.
2. Chinese and English names of products provided that no need to notify the English name of domestic products.
3. Category and usage of products.

4. Type of products. Model number and color code for series products.

5. Dosage of products.

6. Precautions of products.

7. Names, addresses and telephone numbers of manufacturers or importers of products.

8. Names, addresses nationalities of the premises where products manufactured and other criteria conforming to cosmetics Good Manufacturing Practice (GMP).

9. Full components of products. Weight or capacity percentage identifying its content inclusion if limitation of usage set forth by the central competent authorities.

10. Other relevant descriptions.

The aforesaid data notify shall be made in Chinese, English, numbers or international symbols.

Article 5

No false data notify shall be provided by Cosmetics Manufacturers or Importers.

Article 6

Data notification shall be made separately for different data provided for each Sub-paragraph of Paragraph 1 of Article 4, except for the followings:

1. Multiple product names carrying same component formula, dosage and usage.

2. Same series products carrying same dosage and usage with only difference in pigments or spices and/or essence of component formula.

3. Combination products referring to those products including more than two cosmetics products which are not able to be supplied, sold, gave away, public display, or offered consumer trial.

Article 7

Changes of cosmetics product data notification may be by amendment except for the change involving components, which shall be made by re-notification its data notification.

Article 8

The valid period for cosmetics product data notification is three years. If after the three year term, products are still supplied, sold, gave away, public display, or offered consumer trial, the data notification valid

period shall be extended three months prior to its expiration.

Article 9

The data notification shall be disapproved if there is any of the following:

1. Data notification denied pursuant to Paragraph 2 of Article 22, Paragraph 2 of Article 23, Paragraph 2 of Article 24 of the Act.
2. Products containing any components prohibited to be used via the announcement made by the central competent authorities.
3. Incomplete data notification pursuant to Article 4.

Article 10

Data notification made by those Cosmetics Manufacturers or Importers who are dissolved or have closed its business, or whose corporation registration, business registration, factory registration or other equivalent registration or permits were withdrawn or abolished, shall be revoked.

Cosmetics Manufacturers or Importers may revoke data notification of a product if the product is no longer supplied, sold, gave away, public display, or offered consumer trial.

Article 11

The central competent authorities shall rescind the data notification if found products, after completion of data notification, are not cosmetics defined under Sub-paragraph 1 of Paragraph 1 of Article 3 of the Act.

Article 12

The Regulations shall take effect on July 1, 2019.

7 Cosmetic Categories for Which Shall Complete the Product Notification and the Effective Date

Cosmetic Categories for Which Shall Complete the Product Notification and the Effective Date

Effective Date：2019-07-01

Category：Ministry of Health and Welfare

The categories of cosmetics and the enforcement date for which manufacturers or importers shall complete product notification:

1. Non-specific purpose cosmetics shall be implemented after two years from the effective date of Cosmetic Hygiene and Safety Act.
2. Specific purpose cosmetics shall be implemented after five years from the effective date of Cosmetic Hygiene and Safety Act.

8 Regulations for Cosmetic Product Information File Management

Regulations for Cosmetic Product Information File Management

Announced Date：2019-05-30

Category：Ministry of Health and Welfare

Article 1

The regulations are prescribed pursuant to Paragraph 3 of Article 4 of the Cosmetic Hygiene and Safety Act (hereinafter referred to as "the Act").

Article 2

The cosmetics manufacturers or importers of a certain scale (hereinafter referred to as " cosmetics manufacturers or importers ") mentioned in Paragraph 1 of Article 4 of the Act shall mean the following entities which engage in cosmetics manufacturing or importing:

1. The companies and businesses which shall apply for registration according to the Company Act and Business Registration Act.
2. The factories which shall complete registration according to Paragraph 1 of Article 8 of the Act.
3. The groups and corporations which engage in cosmetics manufacturing or importing, except the handmade soap entities which are exempt from industry registration, excluding the entities mentioned in preceding two subparagraphs.

Article 3

Cosmetic product information file shall establish the following information in Chinese or English:

1. Basic information of the product: the name of the product, the category of the product, dosage form, purpose, the names and addresses of manufacturing facilities, information of product manufacturers or importers.
2. Evidentiary documents of completing product notification.
3. Full ingredient names and the individual content.
4. The outer packaging of the products, containers, labels or leaflets.
5. GMP compliance certificates or self-declarations which the manufacturing facilities comply with cosmetic Good Manufacturing Practice Regulations
6. Manufacturing methods and procedures.

7. Usage methods, body parts, dosage, frequencies and the targeted population.

8. Adverse effects of the product application.

9. Physical and chemical characteristics of the products and individual ingredients.

10. Toxicological data of the ingredients.

11. The product stability test reports.

12. The microbiological test reports.

13. The antimicrobial effectiveness test reports.

14. Supporting information of the functional assessments.

15. Information about the packaging materials which have contact with the products.

16. Product safety information:

(1) Safety evaluation conclusion and suggestion which has the signature of the signatory for the safety report and the date.

(2) Qualification certificates which the signatory for the safety report complies with Article 4, 5 and 6.

If the original information of the file in the preceding paragraph is established in the language other than Chinese or English, the Chinese or English translation shall be attached Cosmetic products which are manufactured in separate processes, the names and addresses of manufacturing facilities mentioned in the Subparagraph 1 of the previous paragraph shall include all of the manufacturing facilities in the processes and their operation procedures.

Cosmetic product information file shall be renewed in accordance with Paragraph 1 when it changes.

The information mentioned Subparagraph 11 to 13 of Paragraph 1, when the signatory for the safety report evaluates the characteristics or specialty of the product and makes reasoning in Subparagraph 16 of the same Paragraph, may be exempt from establishment.

Article 4

A person who graduated from department of medicine, department of pharmacy, toxicology, cosmetic and other related departments or graduate schools at the domestic university or the foreign university which complies with Regulations Governing the Assessment and Recognition of Foreign Academic Records by Institutions of Higher Education (hereinafter referred to as " domestic or foreign university"), and has taken cosmetic safety evaluation training courses which are provided by domestic or foreign university, or by central competent authority, the person may serve as a signatory for the safety report of product information

file mentioned in Subparagraph 16 of Paragraph 1 of the preceding article.

The content and hours of cosmetic safety evaluation training courses mentioned in the preceding paragraph shall be:

1. Cosmetic management regulations: including cosmetic hygiene management regulations of R.O.C (Taiwan), international cosmetic hygiene regulations, and the system of cosmetic product information file in R.O.C. (Taiwan); at least 4 hours.
2. Applications and risks of cosmetic ingredients: including the action principles and safety of whitening, sunscreen, antiperspirant, deodorant, hair-dyeing, permanent waving and other ingredients, and common cosmetic adverse effects and violations; at least 8 hours.
3. Methods of cosmetic safety evaluation: including skin anatomy and physiology, cosmetic percutaneous absorption capacity, skin irritation, the mechanism and symptom of photoaging and photoallergy, the safety evaluation of nanomaterials, the safety evaluation of natural substance cosmetic, the cosmetic risk assessment, toxicological evaluation methods(skin irritation, skin sensitization, skin corrosivity, eye irritation and genetic toxicity and mutagenicity test), systemic toxicity and margin of safety, and alternative methods of animal testing; at least 36 hours.
4. Concluding the product safety evaluation: at least 6 hours.

Article 5

The signatory for the safety report of product information file shall take at least eight hours courses yearly which are provided by the domestic or foreign university, or by central competent authority, and the courses shall relate to Paragraph 2 of the preceding article.

Article 6

The countries (regions) or areas which have signed the cooperation agreements of the signatory for the safety report of product information file with R.O.C (Taiwan), their signatories are exempted from the application of Paragraph1 of Article 4 and the preceding article.

Article 7

The cosmetic product information file may be stored by written records or the means of electronic data storage media.

The file stated in the preceding paragraph shall be kept for at least five years from the next day of the date of the product lastly available in the market.

Article 8

The cosmetics manufacturers or importers shall store the product information file at the address mentioned in Subparagraph 7 of Paragraph 1 of Article 7 of the Act and provide it for the competent authority inspection.

The competent authority shall send a notification at least seven days before it assigns officers to inspect the file mentioned in the preceding paragraph unless the emergency or the need of public interests.

Article 9

The Regulations shall take effect on July 1, 2019.

9 Labeling requirements for cosmetic packaging, containers, labels or directions

This Rule has been translated into English according to the original Chinese version. If there is any inconsistency or ambiguity between these two versions, the Chinese version shall prevail.

1	The Rule is established pursuant to Paragraph 4 of Article 7 of Cosmetic Hygiene and Safety Act (here-in-after referred to as the Act).
2	Outer packaging or the container of cosmetics shall be labelled clearly the information stipulated per Paragraph 1 of Article 7 of the Act. Cosmetics with both outer packing and the container shall at least be labelled its product name in Chinese or other language on the container in addition to its Chinese product name that has been clearly labelled on the outer packaging.
3	The font size of information to be labelled stipulated Paragraph 1 of Article 7 of the Act shall comply with the following provisions: (1) If the net weight or volume of a product exceeds 800 g or 800mL, the length and width of the font size of information to be labelled shall be at least 2.0mm. (2) If the net weight or volume of a product exceeds 300 g or300 mL and less than (is equivalent to) 800g or 800mL, the length and width of the font size of information to be labelled shall be at least 1.6mm. (3) If the net weight or volume of a product less than (is equivalent to) 300 g or 300 mL, the length and width of the font size of information to be labelled shall be at least 1.2mm.
4	Outer packaging or containers of the maximum surface area less than 40 square centimeters shall be labelled the information stipulated Paragraph 1 of Article 7 of the Act, and such information may be labelled on its label, leaflet, card, tag, or description. The outer packaging, label, or containers of cosmetics mentioned in the preceding paragraph shall at least be labelled the following information : (1) Product name; (2) Function; (3) Name of the manufacturer or the importer (4) Manufacturing date and shelf life; manufacturing date and expiration date; shelf life and expiration date.
5	Full ingredient names shall be labelled in Chinese or English with reference to the pharmacopoeia or official reference books, including International Nomenclature of Cosmetic Ingredients (INCI), Chinese Pharmacopoeia, United States Pharmacopoeia, and European Pharmacopoeia.

6	Colorant ingredients may refer to the Color Index (CI) and EC Directive Annex IV of U.S. FDA.
7	Essence and spices may be labelled as Essence, Spices, Flavor , Fragrance, Parfum, Perfume or Aroma.
8	Ingredients shall be labelled in a descending order according to their concentration (weight or volume). Provided that if the ingredients refer to one of the Sub-paragraphs, the concentration of ingredients may be labelled in a random order following the ingredients of more than 1 percent concentration. (1) The concentration of the ingredients is equal to or less than 1 percent. (2) Colorant ingredients in makeup products.
9	Makeup products include colorants shall list colorants names and those colorants may be included shall be labelled as the following: (1) +\– (2) may contain (3) may include colorants
10	The information stipulated Sub-paragraph 8 of Paragraph 1 of Article 7 of the Act shall be stamped, printed in permanent ink, pressed, etc. onto the outer packaging, the container or the label. The date labelled per the preceding Paragraph shall be made customarily decipherable. The manufacturing date and the expiration date may only label the year and the month which shall refer to the last day of that month as the end date.
11	The information stipulated Paragraph 1 of the preceding Article may be labelled on the label, and all information shall be stamped or printed in permanent ink onto the same label.

10 Cosmetic Categories for Which Shall Establish the Product Information File and the Effective Date

Cosmetic Categories for Which Shall Establish the Product Information File and the Effective Date

Effective Date：2019-07-01

Category：Ministry of Health and Welfare

The categories of cosmetics and the enforcement date for which manufacturers or importers shall establish product information file:

1. Specific purpose cosmetics shall be implemented after five years from the effective date of Cosmetic Hygiene and Safety Act.
2. Non-specific purpose cosmetics for infants, lip, or eye shall be implemented after six years from the effective date of Cosmetic Hygiene and Safety Act.
3. Non-specific purpose cosmetics (except specific purpose cosmetics, Non-specific purpose cosmetics for infants, lip, or eye) shall be implemented after seven years from the effective date of Cosmetic Hygiene and Safety Act

11 Regulations for Qualifications and Training of Cosmetics Professional Technicians

Regulations for Qualifications and Training of Cosmetics Professional Technicians

Announced Date：2019-06-27

Category：Ministry of Health and Welfare

Article 1

The Regulations have been established according to Paragraph 2 of Article 9 of the Cosmetic Hygiene and Safety Act (the "Act").

Article 2

Cosmetics professional technicians stipulated under Paragraph 1 of Article 9 of the Act (the "professional technicians") shall possess one of the following qualifications:

1. A person graduated and obtained a diploma from the cosmetic, pharmacy and relevant departments, graduate schools or degree courses at the domestic public or private university, or the foreign university which complies with the "Regulations Governing the Assessment and Recognition of Foreign Academic Records by Institutions of Higher Education" and recognized by the Ministry of Education.
2. A person graduated and obtained a diploma from the chemistry, chemical engineering and relevant departments, graduate schools or degree courses at the domestic public or private university, or the foreign university which complies with the "Regulations Governing the Assessment and Recognition of Foreign Academic Records by Institutions of Higher Education" and recognized by the Ministry of Education. The person shall also engage in cosmetics manufacturing works at least three years.
3. A person graduated and obtained a diploma from the domestic public or private university, or the foreign university which complies with the "Regulations Governing the Assessment and Recognition of Foreign Academic Records by Institutions of Higher Education" and recognized by the Ministry of Education. The person shall also engage in cosmetics manufacturing works at least five years.

The cosmetics manufacturing works stipulated under the Subparagraph 2 and Subparagraph 3 of the preceding Paragraph means engaging in production, dispensation, processing or other works related to manufacturing.

Article 3

Professional technicians shall attend at least 24 hours pre-service training which is held by the competent authority or its accredited institution and obtain a certification:

1. Cosmetic hygiene and safety regulations.
2. Professional ethics of cosmetics manufacture.
3. The scope and content of duties mentioned in Article 4.
4. Other courses related to cosmetics manufacture and quality control.

Article 4

The duties of professional technicians are as follows:

1. To station at the factory and supervise the dispensation and manufacturing of cosmetics.
2. To inspect and guide the maintenance of cosmetics manufacturing facilities, equipment, and device.
3. To draft and supervise the enforcement of an operational plan which complies with Cosmetics Good Manufacturing Practice Regulations.

Article 5

Professional technicians, within the term of employment, shall attend at least eight hours training for cosmetics manufacturing and Good Manufacturing Practice Regulations which is held by the competent authority or its accredited institution.

Article 6

The Regulations shall take effect on July 1, 2019.

12 Regulations Governing the Source and the Flow Data of Cosmetic Products

Regulations Governing the Source and the Flow Data of Cosmetic Products

Announced Date：2019-05-22

Category：Ministry of Health and Welfare

Article 1

The Regulations have been established according to Paragraph 2 of Article 11 of the Cosmetic Hygiene and Safety Act (the “Act”).

Article 2

Cosmetics manufacturers or importers establish data on direct supply sources and destinations in accordance with Paragraph 1 of Article 11 of the Act, the scope, items, and contents are as follows:

1. Information and certificate of manufacture or import:

(1) The product name, notification number or license number, packaging specification and net weight or volume.

(2) Lot number.

(3) Amount.

(4) Date of customs import declaration, and declaration form number.

2. Information and certificate of destinations:

(1) The receiver’s name, address and the contact person’s name, phone number.

(2) The product name, notification number or license number, packaging specification and net weight or volume.

(3) Lot number.

(4) Amount.

(5) Delivery date.

Article 3

Cosmetics sellers establish data on direct supply sources and destinations in accordance with Paragraph 1 of Article 11 of the Act, the scope, items, and contents are as follows:

1. Information and certificate of supply sources:

(1) The supplier’s name, address and the contact person’s name, phone number.

(2) The product name, notification number or license number, packaging specification and net weight or volume.

(3) Lot number.

(4) Amount.

(5) Date of receipt.

2. Information and certificate of destinations:

(1) The receiver’s name, address and the contact person’s name, phone number.

(2) The product name, notification number or license number, packaging specification and net weight or volume.

(3) Lot number.

(4) Amount.

(5) Delivery date.

Article 4

Cosmetic businesses shall record the data mentioned in preceding two articles completely and establish the databases in written or electronic form to store the data well and comprehensively. The records shall be kept for at least five years after the next day of the date of the manufacture, import or supply.

Article 5

The Regulations shall take effect on July 1, 2019.

13 Regulations for Reporting Cosmetics Serious Adverse Effects and Hazards to Hygiene and Safety

Regulations for Reporting Cosmetics Serious Adverse Effects and Hazards to Hygiene and Safety

Announced Date：2019-05-22

Category：Ministry of Health and Welfare

Article 1

The Regulations have been established according to Paragraph 3 of Article 12 of the Cosmetic Hygiene and Safety Act (the “Act”).

Article 2

When the regular or reasonable use of cosmetics generated serious adverse effects on the human bodies, or the cosmetics businesses found the products may have hygiene and safety hazards or risks of harm, they shall visit and report to the network system which is established by the central competent authority within 15 days from the day of awareness of the event.

In the case of emergency, the report of the preceding Paragraph shall use oral or other methods to report immediately and shall visit the network system for a correction within the time limit stipulated under the preceding Paragraph.

Article 3

The report of the preceding Article shall include the following information, documents and data:

1. The name, address and telephone number of the reporter.
2. The date that the reporter knew the event mentioned in Paragraph 1 of the preceding Article.
3. The name of the product.
4. Product notification number or license number.
5. The situations of serious adverse effects, hygiene and safety hazards or risks of harm.
6. Necessary documents or information required by the central competent authority.

If contents of the report mentioned in the preceding Paragraph are incomplete and may be corrected, the competent authority shall request for the correction within the time limit.

Article 4

The cosmetics businesses shall keep the certificates, documents or information which could prove content of the report mentioned in Paragraph 1 of the preceding Article at least five years from the day of reporting.

Article 5

The Regulations shall take effect on July 1, 2019.

14 Regulations for Cosmetics Recall

Regulations for Cosmetics Recall

Announced Date：2019-05-22

Category：Ministry of Health and Welfare

Article 1

The Regulations have been established according to Paragraph 4 of Article 17 of the Cosmetic Hygiene and Safety Act (the "Act").

Article 2

Operational procedure of cosmetics recall shall be classified in three classes according to the risks to health as follows:

1. Class 1
   (1) Violation of Paragraph 1 of Article 6 of the Act, which cosmetics contain mercury, lead, or other ingredients banned for use as per the public announcement of the central competent authority.
   (2) Violation of Paragraph 3 of Article 6 of the Act, which cosmetics use ingredients that pose a hazard to human health or impact the hygiene and safety.
   (3) Violation of Paragraph 1 of Article 8 of the Act, which cosmetics are manufactured by non-registered factories.
   (4) According to Subparagraph 8 of Paragraph 1 of Article 17 of the Act, the product notification or license was revoked or rescinded by the central competent authority.
   (5) According to Paragraph 2 of Article 17 of the Act, cosmetics that are of the unclear source; or pose hazards to hygiene and safety as per the public announcement of the central competent authority.
2. Class 2
   (1) Violation of Paragraph 1 of Article 4 of the Act in failing to complete product notification or failing to establish the product information file that are made in accordance with Subparagraph 1 of Paragraph 1 of Article 17 of the Act in failing to make corrections within the time limit specified by the competent authority.
   (2) Violation of the regulations prescribed pursuant to Paragraph 2 or Paragraph 3 of Article 4 of the Act, pertaining to the provisions of items, contents, modifications, or methods for establishment and maintenance, retention period, and location of product notification or information file that are made in

accordance with Subparagraph 1 of Paragraph 1 of Article 17 of the Act in failing to make corrections within the time limit specified by the competent authority.

(3) Violation of Paragraph 1 or Paragraph 2 of Article 5 of the Act in failing to apply for a specific purpose cosmetics license or modifying the originally registered particulars without authorization that are made in accordance with Subparagraph 2 of Paragraph 1 of Article 17 of the Act in failing to make corrections within the time limit specified by the competent authority.

(4) Violation of Paragraph 3 of Article 5 of the Act on supplying, selling, publicly displaying, offering consumer trial, or altering the uses of said cosmetics that are made in accordance with Subparagraph 2 of Paragraph 1 of Article 17 of the Act in failing to make corrections within the time limit specified by the competent authority.

(5) Sellers of cosmetics violate Paragraph 5 of Article 7 of the Act, alter or modify the labels, leaflets, outer packaging, or containers of cosmetics for sale.

(6) Violation of the Establishment Standards for Cosmetics Manufactory specified in Paragraph 1 of Article 8 of the Act or the Good Manufacturing Practice Regulations specified in Paragraph 2, and said violation could possibly pose a hazard to hygiene and safety as determined by the competent authority.

(7) Violation Paragraph 1 or Paragraph 2 of Article 10 of the Act, the labels of cosmetics are deceptive, exaggerated or having medical efficacy.

3. Class 3: The outer packaging or containers of cosmetics violate Paragraph 1, Paragraph 2 or Paragraph 3 of Article 7 of the Act or public announcement of labeling regulations prescribed pursuant to Paragraph 4 of Article 7 of the Act.

Article 3

The deadlines for recall completion mentioned in Paragraph 1 and Paragraph 2 of Article 17 of the Act are as follows:

1. Class 1: Within one month after the next day of the date when cosmetics manufacturers or importers receive a notification from the competent authority. The competent authority may reduce to 14 days if necessary.
2. Class 2: Within two months after the next day of the date when cosmetics manufacturers or importers receive a notification from the competent authority.
3. Class 3: Within six months after the next day of the date when cosmetics manufacturers or importers receive a notification from the competent authority.

Article 4

Whenever the municipal or county (city) competent authority notifies a cosmetics manufacturer or an importer of the recall, it shall inform central and other municipal or county (city) competent authorities.

Article 5

For the recalled cosmetics, the competent authority may disclose the following information on the website of the authority or to the public media:

1. The name of the product.
2. Product notification number or license number.
3. Batch number or serial number for identification and coding of the product.
4. The name, address and telephone number of the manufacturer or importer.
5. The reason for the recall.

Article 6

Cosmetics manufacturers or importers shall establish the operating procedure of cosmetics recall, which content shall include the organization of the recall operation, designated personnel and their mission, the proposal of recall operation, notice of the recall messages and the report with documented operation procedures and results regarding recalled products from the market and in the warehouse.

Article 7

For the recall operation, the cosmetics manufacturer or importer shall inform sellers within seven days after the next day of receiving a notification mentioned in Article 3. For the Class 1 recall operation, the municipal or county (city) competent authority may notify the cosmetics manufacturer or importer that the period shall reduce to three days.

The notice in the preceding paragraph shall include the following information:

1. The name, address and telephone number of the manufacturer or importer.
2. The name of the product.
3. Product notification number or license number.
4. Batch number or serial number for identification and coding of the product.

5. The reason for the recall and damage it may cause.

6. Recall methods, time and location for the recalled product delivery.

7. The requirements shall be complied with by sellers.

The sellers in preceding two paragraphs shall be the receiver mentioned in Item 1 of Subparagraph 2 of Article 2 of the Regulations Governing the Source and the Flow Data of Cosmetic Products.

Cosmetics manufacturers or importers shall record the matter mentioned in Paragraph 1, notifiers, recipients, time and the methods for notifications, and keep the record at least five years.

Article 8

For the recall operation, the cosmetics manufacturer or importer shall submit a proposal of recall operation to the municipal or county (city) competent authority within 14 days after the next day of receiving a notification mentioned in Article 3. For the Class 1 recall operation, the municipal or county (city) competent authority may notify the cosmetics manufacturer or importer that the period shall reduce to seven days.

The proposal of recall operation shall include the following information:

1. The name, address and telephone number of the manufacturer or importer.

2. The name of the product.

3. Product notification number or license number.

4. Batch number or serial number for identification and coding of the product.

5. The total quantity, sales quantity, and inventory quantity of the product manufacture or import.

6. The name, address, and their individual sales quantity of the sellers.

7. The reason for the recall and damage it may cause.

8. The scheduled date for recall completion.

9. The methods, contents, and other related procedures taking indicate in the notification to the sellers.

If the proposal of recall operation is incomplete, the municipal or county (city) competent authority may notify the correction within the time limit.

Article 9

Cosmetics manufacturers or importers shall give identification and labels both on the recalled cosmetics and inventory and place them and the conforming products separately.

Article 10

The cosmetics manufacturer or importer which complies with the proposal of recall operation and completes the implementation, it shall draft and submit the report with documented operation procedures and results to the municipal or county (city) competent authority within 14 days after the next day of recall completion. For the Class 1 recall operation, the municipal or county (city) competent authority may notify the cosmetics manufacturer or importer that the period shall reduce to seven days.

The report with documented operation procedures and results shall include the following information:

1. The name, address and telephone number of the manufacturer or importer.
2. The name of the product.
3. Product notification number or license number.
4. Batch number or serial number for identification and coding of the product.
5. The total quantity, sales quantity, and inventory quantity of the product manufacture or import. They shall all be recorded separately into recalled and not recalled items and quantity.
6. The recall items and quantity lists from each recall targets.
7. Recall completion date, the storage location for recalled products, and the follow-up handling method and date.
8. If the recalled products have been destroyed, the report shall attach the photos or video of the destruction process.
9. Follow-up corrective and preventive actions for the reason of the recall.

If the report with documented operation procedures and results is incomplete, the municipal or county (city) competent authority may notify the correction within the time limit.

Article 11

The municipal or county (city) competent authority shall supervise the implementation of recall operation; After receiving the report with documented operation procedures and results, it may inspect the circumstance of the recall at the place of manufacturing, storage, and sale.

Article 12

The Regulations shall take effect on July 1, 2019, except for Item 5 of Subparagraph 2 of Paragraph 1 of Article 2 and Subparagraph 3 of Paragraph 1 of Article 2 shall take effect on July 1, 2021.

15 Regulations Governing the Application of Animal Testing for the Safety Assessment of Cosmetics or Cosmetic Ingredients

Regulations Governing the Application of Animal Testing for the Safety Assessment of Cosmetics or Cosmetic Ingredients

Amended Date：2019-06-28

Category：Ministry of Health and Welfare

Article 1

The present regulations are prescribed pursuant to Paragraph 6 of Article 6 of the Cosmetics Hygiene and Safety Act (the “Act”).

Article 2

Cosmetics manufacturers, importers or sellers shall, in accordance with the provisions of Paragraph 4 in Article 6 of the Act and when applying for testing of animals as subjects for the safety assessment of cosmetics or cosmetic ingredients (hereinafter referred to as the animal test), submit a completed application form along with the following documents and information to the central competent authority for approval before conducting the animal test:

1. Photocopy of registration certificate for the company or business of the animal test applicant.
2. Photocopy of registration document for the legal establishment of the company, business, college/university, juristic person, organization or institution that is a contractor to conduct animal test of the contract party.
3. Photocopy of concurrence document upon review approved by deliberation of the care and use of laboratory animals committee/panel (hereinafter referred to as the animal care committee/panel) established by the one that conducts animal test in accordance with Article 16 of the Animal Protection Act.
4. Explanation and related supporting documents for the necessity to conduct animal test that has the conditions in Subparagraphs 1 and 2 of Paragraph 4 in Article 6 of the Act.
5. Explanation and related documents to demonstrate that there are no other non-animal alternative methods available.
6. Animal test protocol reviewed and approved by the animal care committee/panel in accordance with Article 4 of Regulations for Establishing and Managing the Institutional Animal Care and Use Committee or Panel (hereinafter referred to as the Regulations for Animal Care).

Article 3

The central competent authority shall notify the applicant to make supplement or correction within a given time limit if documents or information of the preceding Article is deficient and may be supplemented or corrected. In case supplement or correction is not made or completely made in the specified time limit, the application shall be refused.

The applicant may, with reasonable justification, apply for an extension before the deadline of the time limit in the preceding Paragraph. Such application is limited to one time only.

Article 4

The central competent authority shall issue an approval document and notify the applicant after the application has been reviewed to be in compliance with the provisions of Paragraph 4 in Article 6 of the Act.

The review in the preceding Paragraph may be conducted by experts and scholars of cosmetics, toxicology, animal protection and other relevant specialized fields invited by the central competent authority.

Article 5

The central competent authority may revoke or cancel the approval document of those who conduct animal test if there is one of the following situations:

1. The application documents or information is found to be fraudulent or untrue.
2. The animal test is conducted in violation of the animal test protocol, provisions of the Statute, the Animal Protection Act or the Regulations for Animal Care, and the circumstances are severe.

Article 6

No application shall be accepted for the next two years after the applicant’s approval document for conducting animal test is revoked or canceled by the central competent authority.

Article 7

In case of loss or damage of an approval document, a completed application form along with the following documents shall be submitted to the central competent authority to apply for reissuance or renewal:

1. Reissuance: Affidavit of Loss.
2. Renewal: Original copy of the approval document.

Article 8

These Regulations shall take effect on November 9, 2019.

16 Establishment Standards for Cosmetics Manufactory

Establishment Standards for Cosmetics Manufactory

Amended Date：2019-08-29

Category：Ministry of Health and Welfare

Article 1

This set of standards promulgated pursuant to Paragraph 4, Article 8 of Cosmetic Hygiene and Safety Act (hereinafter referred to as the Act).

Article 2

The factory of cosmetics manufacturing premises shall be isolated from residential area and public places, and shall not jeopardize public hygiene and safety.

The building of the premises mentioned in the preceding paragraph shall be sturdy, rodent-proofing, insect-proofing, dust-proofing and easy to clean.

Article 3

Except those were announced by the central competent authority in accordance to Paragraph 1 Article 8 of the Act which are exempt from industry registration, The factory of cosmetics manufacture premises shall all comply to the following:

1. The ceilings, walls, and floors shall be implemented with construction materials which are not easy to accumulate dust, to maintain smooth surfaces and free with cracks.
2. The material of pipeline shall be smooth surfaces and the pipes and ducts shall be hidden where possible.
3. The drain shall be implemented with facilities to avoid back flow.

Article 4

The manufacturing production, packaging, storage and other related area in the cosmetics manufacturing premises shall be separated appropriately and labelled clearly; The raw materials, supplies, bulk products, and finished products shall be done the same.

Article 5

Container washing equipment shall be installed in the cosmetics manufacturing premises.

Article 6

All containers and manufacturing equipment in the cosmetics manufacturing premises shall not contain the materials that may release hazardous substance to human body especially for those with contacts to the raw materials or bulk products.

Article 7

The cosmetics manufacturing premises shall be equipped with qualified weighing equipment, and being calibrated regularly.

Article 8

The cosmetics manufacturing premises shall implemented with changing rooms, hand-washing facilities; for those without equipping with disposable working clothes, hat, mask, gloves and shoes shall install washing, sanitizing or sterilizing equipment.

Article 9

The cosmetics manufacturing premises shall install boilers, water pumps, vacuum pumps, compressors, general-use-water treatment systems, equipment for water distillation or purification, equipment for sterilization, dust removal, air ventilating or air cleaning, temperature and moisture control facilities, as needed according to cosmetics classification, characteristics, and process.

Article 10

Relevant facilities in the cosmetics manufacturing premises shall be used for operations in an integrated closed system from the inlet to the outlet of materials as principle. For those operations without being conducted in an integrated close system and involving in causing powder or toxic gas shall be conducted where independent ventilators installed and in negative pressure.

Article 11

Devices in the cosmetics manufacturing premises with functions including pressing, stamping or printing batch numbers and the items listed in Subparagraph 8 Paragraph 1 Article 7 in the Act shall be installed.

Article 12

Cosmetics manufactories producing powder form products shall install the following equipment:

1. Powder milling or ultra-fine powder milling equipment.

2. Screening and dust collecting equipment.

3. Mixing equipment.

4. Quantitative filling (packaging) equipment.

Article 13

Cosmetics manufactories producing liquid form products shall install the following equipment:

1. Liquid blending containers.

2. Settling tanks or ceramic vats.

3. Stirring equipment.

4. Filtrating equipment.

5. Quantitative filling (packaging) equipment.

When there is need for making concentration in the cosmetics manufacturing producing mentioned in the preceding paragraph, vacuum evaporator equipment shall be installed; When there is need for sterilization, autoclave sterilization equipment shall be installed.

Article 14

Cosmetics manufactories producing emulsion form products shall install the following equipment:

1. Stirring emulsion equipment.

2. Blending equipment.

3. Quantitative filling (packaging) equipment.

When there is need for heating in the cosmetics manufacturing producing mentioned in the preceding paragraph, heating equipment shall be installed; When there is need for filtration, filtration equipment shall be installed; When there is need for cooling, cooling equipment shall be installed.

Article 15

Cosmetics manufactories producing oil form products shall install the following equipment:

1. Oil blending containers.

2. Stirring equipment.

3. Quantitative filling (packaging) equipment.

When there is need for filtration in the cosmetics manufacturing producing mentioned in the preceding paragraph, filtration equipment shall be installed.

Article 16

Cosmetics manufactories producing ointment form products shall install the following equipment:

1. Powder milling or ultra-fine powder milling equipment.

2. Screening and dust collecting equipment.

3. Blending equipment.

4. Quantitative filling (packaging) equipment.

When there is need for heating in the cosmetics manufacturing producing mentioned in the preceding paragraph, Double heating kettlesshall be installed; When there is need for ointment tube filling, ointment tube sealing equipment shall be installed.

Article 17

Cosmetics manufactories producing solid form products shall install the following equipment:

1. Powder milling or ultra-fine powder milling equipment.

2. Screening and dust collecting equipment.

3. Blending equipment.

4. Mixing equipment.

5. Molding equipment.

6. Drying or cooling equipment.

7. Quantitative packaging equipment.

Article 18

Cosmetics manufactories producing eyebrow pencils shall install the following equipment:

1. Raw material blending equipment.

2. Equipment for producing pencil core.

3. Equipment for producing pencil barrel.

4. Equipment for painting pencil barrel.

Article 19

Cosmetics manufactories producing spray form products shall install the following equipment:

1. Blending Containers.

2. Pressure filling equipment.

3. Leak testing equipment.

Article 20

Manufactories producing non-handmade soaps shall install the following equipment:

1. Stainless steel storage tanks.

2. Saponification equipment.

3. Drying equipment.

4. Equipment for adding fragrances or colorants.

5. Pressing machines.

6. Molding machines.

7. Cutting machines.

When there is need for salting-out in the cosmetics manufacturing producingnon-handmade soaps mentioned in the preceding paragraph, salting-out equipment shall be installed; When there is need for conveying, conveying equipment shall be installed.

Article 21

Manufactories producing handmade soaps shall install the following equipment:

1. Weighting Equipment.

2. Stainless Steel Vats.

3. Heating Equipment.

4. Mixers.

5. Measuring Cups.

6. Thermometers.

7. Rubber Scrapers.
8. Molds.
9. Soap Cutting Machines.

Article 22

Manufactories processing packaging shall install the following equipment:

1. Measurement equipment and other packaging equipment (such as counting devices, automatic packaging equipment).
2. Damp proof packaging equipment.
3. Bottle capping or sealing equipment.
4. Semi-automatic or automatic printing or labeling equipment.
5. Revolving or regular operation tables.

Article 23

The manufactories produce the types of products other than the types of products listed from Article 12 to the preceding article shall apply mutatis mutandis to the rules of these standards to install the necessary equipment.

Article 24

If the cosmetics manufacturing premises did not install the related equipment listed in Article 5, Article 11 to Article 22, shall prepare relevant documents and data to submit and propose an explanation to the municipality or county (city) the competent authority; installation shall be exempted after receiving the approval from the competent authority.

Article 25

This set of standards shall be effective as of the date of July 1st, 2019.

17 Cosmetics Good Manufacturing Practice Regulations

Cosmetics Good Manufacturing Practice Regulations

Announced Date：2019-08-13

Category：Ministry of Health and Welfare

Chapter 1 General Provisions

Article 1

These regulations are formulated in accordance with the Paragraph 4, Article 8 of the Cosmetic Hygiene and Safety Act (hereinafter referred to as the Act).

These regulations are formulated in reference to the ISO 22716: Cosmetics-Good manufacturing practices (GMP)-Guidelines on good manufacturing practices issued by International Organization Standardization.

Article 2

The definition of terms used in this regulation are defined as follows:

1. Acceptance criteria: the acceptable amount, range, or other suitable measurement methods according to the test result.
2. Auditing: systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives.
3. Batch: the certain produce amount of raw materials, packaging materials, or products from a single or series of manufacturing process.
4. Batch number: The identification of certain batch of products which contains numbers, alphabets, or symbolic combinations.
5. Bulk product: any product that is completed the manufacturing process, but without the final packaging process.
6. Calibration: Under a certain condition, to establish the operation methods and procedures with the known standard reference values to ensure the result values and material testing values of the measurement equipment or measurement system.
7. Control: verification that acceptance criteria are met.

8. Change control: To ensure all manufacturing, packaging, process control and storage of the products to meet the defined acceptance criteria. The amendment plan conducted by the internal organizations and responsible units related to good manufacturing practice.
9. Cleaning: all operations that ensure a level of cleanliness and appearance, consisting of separating and eliminating generally visible dirt from a surface by means of the following combined factors, in variable proportions, such as chemical action, mechanical action, temperature, duration of application.
10. Complaint: external information claiming a product does not meet the defined acceptance criteria.
11. Contamination: occurrence of any undesirable matter such as chemical, physical and/or microbiological matter in the product.
12. Consumables: materials such as cleaning agents and lubricants that are used up during cleaning, sanitization or maintenance operations.
13. Contract acceptor: person, company or external organization to enforce an operation on behalf of another person, company or organization.
14. Deviation: internal organization and responsibilities relative to the authorization to deviate from specified requirements due to a planned or unplanned and, in any case, temporary situation concerning one or several activities covered by the Good Manufacturing Practices.
15. Finished product: cosmetic product that has undergone all stages of production, including packaging in its final container, for shipment.
16. In-process control: controls performed during production in order to monitor and, if appropriate, to adjust the process to ensure that the product meets the defined acceptance criteria.
17. Internal audit: systematic and independent examination made by competent personnel inside the company, the aim of which is to determine whether activities covered by these guidelines and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives.
18. Major equipment: equipment specified in production and laboratory documents, which is considered essential to the process.
19. Maintenance: any periodic or unplanned support and verification operations designed to keep premises and equipment in proper working condition.
20. Manufacturing operation: set of operations from the weighing of raw materials to the making of the bulk products.

21. Out-of-specification: examination, measurement or test result that does not comply with the defined acceptance criteria.
22. Packaging operation: all packaging steps including filling and labeling, which a bulk product has to undergo in order to become a finished product.
23. Packaging material: any material employed in the packaging of a cosmetic product, excluding any outer packaging used for transportation. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.
24. Plant: location for production of cosmetic products.
25. Premises and Facilities: physical location, buildings and supporting structures used to conduct receipt, storage, manufacturing, packaging, control and shipment of product, raw materials and packaging materials.
26. Production: manufacturing and packaging operations.
27. Quality assurance: all those planned and systematic activities necessary to provide confidence that a product satisfies the defined acceptance criteria.
28. Raw material: any substance going into or involved in the manufacturing of a bulk product.
29. Recall: decision made by a company to call back a product batch that has been put on the market.
30. Reprocessing: re-treatment of all or part of a batch of finished product or a bulk product of an unacceptable quality from a defined stage of production so that its quality may be rendered acceptable by one or more additional operations.
31. Return: sending finished cosmetic products which may or may not present quality defect back to manufacturing premises.
32. Sample: one or more representative elements selected from a set to obtain information about that set.
33. Sampling: set of operations relating to the taking and preparation of samples.
34. Sanitization: operation, used to reduce undesirable micro-organisms on inert contaminated surfaces depending on the objectives set.
35. Shipment: set of operations relative to the preparation of an order and its putting in a transport vehicle.
36. Waste: any residue of a production operation, transformation or use, any substance, material, product that its holder intends for disposal.

Article 3

The cosmetics manufacturing premises shall be regulated according to the public announced cosmetics categories listed in Paragraph 2 Article 8 of the Act.

Chapter 2 Management and Personnel

Article 4

The personnel in the cosmetics manufacturing premises shall have an appropriate training to comply the quality of production, control and product storage operation.

Article 5

The personnel in the cosmetics manufacturing premises shall establish the organization according to the following:

1. Regulate the organization and to establish an organization chart to ensure the division of labor and competency according to the scale and diversity of its product of the manufacturing premises.
2. To ensure there are adequate staffing levels and well-trained as well as sufficient personnel in the different scope of activity according to its diversity of products.
3. The quality assurance unit and quality control unit shall be independent to other departments. The responsibility of quality assurance and quality control can be undertaken by a separate quality assurance unit and quality control unit or a single unit accordingly.

Article 6

The cosmetics manufacturing premises shall regulate the key responsibilities as follows:

1. Management level:
   (1) The organization shall be supported by the top management of the company to ensure the enforcement of these regulations.
   (2) To monitor the participation and commitment of the personnel at all level in the manufacturing premises for the following these regulations.
   (3) Management shall categorize the areas in which the authorized personnel are allowed to access.
2. Personnel in each department and each level:
   (1) To ensure the position and department in the organizational structure.

(2) To ensure the scope of responsibilities.

(3) To obtain the related documents within the scope of responsibilities, and follow the regulations indicates in the documents.

(4) Comply with personal hygiene requirements according to Article 8.

(5) To report the irregularities and other non-conformities.

(6) To receive adequate educational training and skills to perform the activities and responsibilities.

Article 7

Personnel of the cosmetics manufacturer involved in production, control, storage and shipment shall acquire the appropriate abilities of working experience and training according to the responsibilities.

1. Appropriate training related to the activities in this regulation shall be provided to all personnel.
2. To ensure training needs of different levels and qualification of the personnel, and to conduct and enforce its related training program.
3. The training program shall be considered and developed according to the expertise, experience, and the scope of responsibilities of the personnel.
4. The cosmetics manufacturer may outsource to a professional group, if necessary, to develop and enforce training program according to the training needs and manufacturing premises resources.
5. The personnel shall receive training normally and continually, and the training content and program shall be updated regularly.
6. Newly recruited personnel shall receive theory and practical training related to this regulation, and specific training according to the duties assigned to them.
7. The effectiveness of receiving the training shall be evaluated during the training process or afterwards.

Article 8

The cosmetics manufacturer shall control the hygiene and health of the personnel, and the following regulation shall apply:

1. To establish and to adapt the need of a hygiene program, these requirements shall be understood and followed by all personnel who entered in the production, control and storage area.
2. Personnel shall be instructed to the hand washing facility.

3. Ensure the personnel who enter production, control and storage to wear appropriate clothing and protection outfit to avoid the contamination of cosmetic products.
4. Avoid the personnel from eating, drinking, chewing, smoking, or to store foods, drinks, smoking products or personal drugs in the production, control, and storage area.
5. Prohibit all the unhygienic practice in the production, control, storage area or in any other area where the product may be adversely affected.
6. Any person affected by an apparent illness or having open wound, a measurement shall be taken to be excluded from direct contact to the products until the condition is corrected or determined by medical personnel that the quality of cosmetic products will not be compromised.

Article 9

Visitor or untrained personnel shall be prohibited to enter production, control and storage area. However, if there is any necessity to enter these areas, they shall be given related precaution in advance, including rules about personal hygiene and the prescribed protective clothing, and closely supervised.

Chapter 3 Premises and Facilities

Article 10

The location, design, construction, and use of the cosmetics manufacturing premises shall be regulated as follows:

1. To make sure the produces are protected.
2. May enforce effective cleaning. Sanitizing and maintenance shall be enforced when necessary.
3. To minimize the risk and control of mix-up of products, raw materials, and packaging materials.

The design of the premises mentioned in the preceding paragraph shall consider the type of the cosmetic product produced, existing condition, cleaning, sanitizing, and other necessary measures.

Article 11

The storage, production, quality control, ancillary, washing and toilets of the cosmetics manufacturing premises shall be separated of identified clearly.

Article 12

There shall be sufficient space to enforce operations such as receiving, storage, production or other related operations in the cosmetics manufacturing premises.

Article 13

The flow of the materials, products, and personnel through the building or between the buildings shall be planned properly to avoid any mix-ups in the cosmetics manufacturing premises.

Article 14

The design and construction of the cosmetics manufacturing premises shall be regulated as follows:

1. The design and construction of floors, walls, ceilings and windows of the production area, shall be implemented with smooth surfaces to tolerate cleaning agents and sanitizers. They shall be easy to clean and sanitized to maintain in a good condition.
2. The windows shall be non-opening design, except if there is insufficient ventilation in the buildings, shall set up with push out casement windows with screens.

Article 15

Sufficient and clean washing and toilet facilities shall be provided in the cosmetics manufacturing premises. The facilities shall be separated from production area. Sufficient shower and clothes changing facilities shall be provided when necessary.

Article 16

The lighting of the cosmetics manufacturing premises shall be regulated as follows:

1. Sufficient lighting facilities shall be installed to provide the needs for operation.
2. The lighting facilities shall be installed properly or other measures be taken to make sure there will not be any fragments from potential breakage to contaminate the products.

Article 17

There shall be sufficient ventilation, or other specific measures to be taken to protect the products in the cosmetics manufacturing premises alternatively.

Article 18

The pipework, drains and ducts in the cosmetics manufacturing premises shall be regulated as follows:

1. Shall be installed properly to avoid any drip and condensation to contaminate the materials, products, equipment, and facilities.
2. Drains shall be kept flowing smoothly and without any back flow.
3. Exposed overhead rood beams, pipes and ducts shall be avoided. Exposed pipes shall be suspended by brackets or separated and not touch the walls for easy cleaning.
4. Specific measures to be taken to protect the products when necessary.

Article 19

The cleaning and sanitation of the facilities of the cosmetics manufacturing premises shall be regulated as follows:

1. To conduct a specific cleaning and sanitation plan for each area, and to keep it in a clean condition.
2. To enforce cleaning and necessary sanitation to ensure the products are not contaminated.
3. To identify the specific kinds of the cleaning agents and sanitizers, and to ensure they work effectively.

Article 20

The cosmetics manufacturing premises and facilities shall be repaired and maintained properly.

Article 21

The cleaning agents and lubricants cosmetics manufacturer used to clean, sanitize or maintain premises and facilities shall not affect the quality of the products.

Article 22

The pest control in the cosmetics manufacturing premises shall be regulated as follows:

1. The design, construction, and maintenance of the premises shall be effective to avoid any insects, birds, pests, rodents and other vermin.
2. A pest control plan shall be conducted.
3. Measures shall be taken to prevent attracting pests at the exterior of the premises.

Chapter 4 Equipment

Article 23

Equipment in the cosmetics manufacturing premises shall meets the intended uses, and easy to clean, sanitize, and maintain if necessary.

Article 24

The equipment design in the cosmetics manufacturing premise shall meet the requirements as follows:

1. The production equipment shall be designed to prevent the products from being contaminated.
2. The container for bulk products shall come with the protection to avoid dusts, moisture and other air contaminants.
3. Transfer hoses and accessories shall be cleaned and sanitized if necessary, kept dry and protected properly from dusts, splash or other contamination.
4. The material of the equipment shall be compatible with the products, cleaning agents, and sanitizer.

Article 25

The installation of the equipment shall be regulated as follows:

1. The design and installation of the equipment shall be easy to drain in order to clean and sanitize.
2. The placement for the equipment shall consider the movement of materials, movement of mobile equipment, and personnel flow, not to pose a risk to the quality.
3. Appropriate access space under, inside and around the equipment shall be provided for cleaning and sanitizing.
4. The major equipment shall be easy to identify.

Article 26

The equipment calibration in the cosmetics manufacturing premises shall be regulated as follows:

1. Laboratory and production measuring instruments related to production quality shall be calibrated regularly.
2. If calibration results of measuring instruments do not meet the acceptance criteria, those shall be identified specifically and removed from service.

3. The condition set forth in the preceding subparagraph shall be investigated to confirm the impact to the production quality and to take appropriate measures afterwards according to the investigation result.

Article 27

The cleaning and sanitation of the equipment in the cosmetics manufacturing premises shall be regulated as follows:

1. All equipment shall be cleaned adequately. A Sanitation plan shall be established if necessary.
2. Cleaning agents and sanitizers shall be specifically identified and work effectively.
3. Where equipment is assigned for continuous production or production of successive batches of the same products, that equipment shall be cleaned and if necessary, a sanitizing period can be established to carry out.

Article 28

The equipment maintenance of the cosmetics manufacturing premises shall be regulated as follows:

1. The equipment shall be maintained regularly.
2. Maintenance operation shall not affect the quality of the products.
3. The defective equipment shall be identified accordingly and excluded from use and isolated, except for any unavoidable condition.

Article 29

The consumable uses for equipment in the cosmetics manufacturing premises shall not affect the quality of the products.

Article 30

The equipment or automated system in the cosmetics manufacturing premises used in production and control shall be access and used by authorized personnel.

Article 31

The cosmetics manufacturer shall prepare an adequate alternative back-up plan for operation system breakdown or failure.

Chapter 5 Raw Materials and Packaging Materials

Article 32

Raw materials and packaging materials purchased by the cosmetics manufacturer shall meet the acceptance criteria.

The acceptance criteria in the preceding paragraph shall be established based on the finished products quality requirements.

Article 33

Raw materials and packaging materials are purchased from the cosmetics manufacturer shall consider the following requirements:

1. The selection and evaluation of the supplier.
2. The establishments of technical clauses such as type of selection to be conducted, acceptance criteria, measures to take in the case of defect or modification, transport conditions or other related items.
3. Setting of the relations and interactions between the company and supplier such as questionnaire, assistance, and audit or other related items.

Article 34

The receiving of the raw materials and packaging materials of the cosmetics manufacturer shall be regulated as follows:

1. The records of the purchase order, the deliver notes and the receiving materials shall all match.
2. The integrity of the raw materials and packaging materials shall be checked. Transportation data shall be inspected if necessary.

Article 35

The raw materials and packaging materials identification and status in the cosmetics manufacturing premises shall be regulated as follow:

1. Shall be labelled in order to identify the material and batch information.
2. The raw materials and packaging materials shows defects that may affect the product quality shall be suspended hold for further decision.

3. The raw materials and packaging materials shall be identified and separated according to its status, such as accepted, rejected or quarantined. Those can be identified by using physical system of identification or others methods that can ensure the same level of identification.

The identification of the raw materials and packaging materials mentioned in the preceding paragraph shall include the following information:

1. Name of the product indicated on the delivery note.
2. Name of the products given by the company. If different from the name or code number given by the supplier, shall be indicated clearly.
3. Batch reference provided by the supplier and the one given at the receipt shall all be presented if there is any difference.
4. Name of the supplier.
5. Date and number of the receipt, if necessary.

Article 36

The release of the raw materials and packaging materials in the cosmetics manufacturing premises shall be regulate as follows:

1. To establish physical or other alternative system to ensure only released raw materials and packaging materials are used.
2. The release of the raw materials shall be enforced by authorized personnel who are responsible for the quality.
3. The analysis certificates provided by the supplier can be accepted as the acceptance criteria, only if the supplier possess the sufficient technology, experience and knowledge, and agree with the test methods adopted by the company, as well as the appropriate inspection and audit conducted by the company.

After measurement, when there are remaining released raw materials mentioned in the preceding paragraph, they shall be contained in a sealed container, labelled adequately and stored properly in the storage.

Article 37

The storage of the raw materials and packaging materials in the cosmetics manufacturing premises shall be regulated as follows:

1. Storage condition shall be set up properly to fit each raw materials and packaging materials. Monitoring and control measures shall be taken to maintain the specific storage if necessary.
2. The raw materials and packaging materials shall be stored and handled properly according to its characteristics.
3. The container of the raw materials and packaging materials shall be sealed and stored off the floor.
4. When repacking the raw materials and packaging materials, the content on the labels shall be identical to the original labels.
5. When raw materials and packaging materials are rejected or quarantined, they shall be stored at a certain location, or use other methods to ensure they can be identified.
6. To establish measures to ensure stock turnover, and stock rotation shall follow the rules of first in, first out.
7. Periodic inventory shall be performed to ensure the inventory information is correct. Any significant discrepancy shall be investigated and corrected.

Article 38

In order to prevent the misuse of materials after the defined period of storage, the cosmetics manufacturer shall establish a re-evaluation system for those materials to determine the suitability for use.

Article 39

The quality of water used in production shall be regulated as follows:

1. The water treatment system shall supply a defined quality of water.
2. The water quality shall be monitored or verified through water quality testing or process parameters.
3. The water treatment system shall permit sanitation.
4. The material used for the water treatment equipment shall be selected to ensure the water quality is not affected; the settlement of the water treatment equipment shall avoid any water stagnation or the risk of contamination.

Chapter 6 Production

Article 40

At each stage of manufacturing production, measures shall be taken to ensure the finished products meet the defined specification.

Article 41

The cosmetics manufacturer, according to the need of every manufacture operation stage, relevant documents and data shall be prepared and available. The documents are:

1. Equipment documents.
2. Formula for the products
3. List of all raw material with the quantities and identified batch numbers.
4. Detailed manufacturing process for each stage, including the addition of the raw materials, temperature, speeds, mixing time, sampling, cleaning, necessary sanitizing, transfer of bulk products and other related items.

Before starting any manufacturing process mentioned in the preceding paragraph, these items have to be ensure:

1. All the relevant documents related to manufacturing and all raw materials are prepared, available and released.
2. Equipment is able to use properly and has been through appropriate cleaning and sanitizing.
3. Operation area is cleaned to prevent from mixing any materials from the previous manufacturing operations.

The identification of the manufacturing operation mentioned in paragraph 1 shall be regulated as follows:

1. All raw materials measured and weighted according to the formula, and placed in a labelled, cleaned and suitable container, or directly put into the manufacturing equipment.
2. Major equipment, raw material containers, and bulk product containers shall be identified easily at any time.
3. The identification on the bulk product container shall include: Name or identification code, batch number and storage condition when such information is critical to assure the quality of the products.

Manufacturing process mentioned in the preceding paragraph shall be regulated as follows:

1. Establish a manufacturing process control plan includes acceptance criteria and to enforce it.
2. To enforce the plan mentioned in the preceding sub-paragraph. Any result does not meet the acceptance criteria shall be and reported and investigated according to the procedure.

Article 42

Every batch of manufactured bulk products shall be assigned a batch number. When the batch number is different from the numbers on the finished products, it shall be easy to identified and related to each other.

The storage of the bulk products mentioned in the preceding paragraph shall be regulated as follows:

1. Use the proper container for to store, and to place it at a specific location with adequate condition.
2. Set up a defined period of storage.
3. Bulk products shall be re-evaluated and not allowed to use when passed the defined period of storage.

Article 43

The cosmetics manufacturer, According to the needs for every stage of packaging operations, the following relevant documentations and data shall be available:

1. Equipment documents.
2. Lists of packaging materials.
3. Operation details in every stages including filling, sealing, labeling, coding or other items.

Before starting any packaging operation mentioned in the preceding paragraph, it shall be ensure that:

1. Prepare the documentations and data listed in the preceding paragraph.
2. Equipment is able to use properly and has been through appropriate cleaning and sanitizing.
3. Operation area is cleaned to prevent from mixing any materials from the previous manufacturing operations.
4. Finishing the establishment of the numbering for product identification information.

Every batch of manufactured bulk products shall be assigned a batch number. When the batch number is different from the numbers on the finished products, it shall be easy to identified and related to each other.

During the packaging operation, according to the actual process, Identification information shall be placed on each operation line; the information includes:

1. Name and identification code of the packaging operation line.
2. Name and identification code of the finished products.
3. Batch number.

The unused packaging materials shall be placed in a sealed container and labelled properly. Then it can be restored to the storage.

When filling and labelling operation does not complete at once, measures such as quarantine and identification shall be taken to avoid mix-up or mislabeling.

Article 44

The packaging mentioned in the preceding article, the in-process control shall be regulated as follows:

1. To establish an in-process control plan including acceptance criteria, and to enforce it.

2. Any result does not meet the acceptance criteria shall be and reported and investigated according to the procedure.

The control mentioned in the preceding paragraph, including those who use on-line control equipment shall be checked regularly according to the established period, items and content.

Chapter 7 Finished Products

Article 45

The finished products of the cosmetics shall meet the acceptance criteria.

The cosmetics manufacturer shall use proper storage, shipment and return methods to ensure the quality of the finished products.

Article 46

The release of finished products shall be regulated as follows:

1. Before releasing to the market, all finished products shall be controlled to make sure to meet to acceptance criteria according to the established test methods.
2. The release of the finished products shall be enforced by authorized personnel who are responsible for the quality.

Article 47

The storage of the finished products shall be regulated as follows:

1. The finished products shall be stored in a specific area in a systematic method according to the storage condition and duration. They shall be monitored and controlled, if necessary.
2. The finished products shall be categorized into release, quarantine or reject and they shall be stored at a certain location, or other ways to ensure they can be identified.
3. The identification of the finished products shall include:
   (1) Name or identification code, batch number and quantity.
   (2) The critical storage condition to assure the quality of the finished products.
4. To establish measures to ensure stock turnover, and stock rotation shall follow the rules of first in, first out.
5. Periodic inventory shall be performed to ensure the list of inventory and quantities are complying with the inventory acceptance criteria. Any significant discrepancy shall be inspected and corrected.

Article 48

Cosmetics manufacturer shall adopt the proper protective measures of shipping methods in order to maintain the quality of the finished products during the shipping process.

Article 49

Cosmetics manufacturer shall handle the returned products according to following the regulations:

1. To identify in a proper way and to store in a specific area.
2. To decide the handling method according to the established evaluation standard.
3. For resale products, shall be handled according to the release procedure.
4. To establish measures to effectively distinguish the reprocessing return, to avoid re-distribution without going through the release procedure.

Chapter 8 Quality Control Laboratory

Article 50

Quality control laboratory shall apply mutatis mutandis to regulations of Chapter 2 Management and Personnel, Chapter 3 Premises and Facilities, Chapter 4 Equipment, Chapter 11 Contracting, Chapter 16 Documentation. Quality control laboratory mentioned in the preceding paragraph shall enforce sampling and testing to the cosmetics materials and the finished products. When conducting sampling, testing or other related activities, related control shall be enforced in order to make sure the materials for use complies with the defined acceptance criteria. Packaging and shipping may be approved when the finished products are complying with the defined acceptance criteria.

Article 51

The test methods mentioned in Paragraph 2 of the preceding article shall be clear, appropriate and workable. The acceptance criteria mentioned in Paragraph 2 of the preceding article shall be defined and established according to types the raw materials, packaging materials, bulk products, and finished products from Quality control laboratory.

Article 52

Test results conducted from quality control laboratory mentioned in the preceding 2 articles shall be reviewed. Decisions of approval shall be made when results complies with the relevant provisions after review; However, rejection or pending shall be made when results does not complies with the relevant provisions after review according to the rules regulated in Article 53.

Article 53

Out-of-specification shall be regulate as follows:

1. Out-of-specification results shall be reviewed and investigated properly by the responsible personnel. Re-testing shall not be performed except with a sufficient and legitimate reason.
2. After the review mentioned in the preceding subparagraph, the decisions shall be made according to the previous article after reviewed as deviation or not.

Article 54

Reagents, solutions, reference standards and culture media shall, at least, be labelled identification information such as name and opening date. If necessary, shall include strength or concentration, storage condition, expiration date, and the name or signature of the person who prepared.

Article 55

The cosmetics manufacturing premises shall perform sampling operation by authorized personnel according to the established sampling operation plan.

The operation plan mentioned in the preceding paragraph shall include the following:

1. Sampling methods.
2. Equipment to be used.
3. Number of the samples.
4. Any precautions to be observed to avoid samples from contamination and deterioration.
5. Identification information of sample.
6. Sampling frequency.

Article 56

Identification information of sample mentioned in Subparagraph 5 of Paragraph 2 of the preceding article shall include the following:

1. Name or identification code.
2. Batch number.
3. Sampling date.
4. The container from which the sample was taken.
5. The sampling point, if applicable.

Article 57

The retention sample shall be regulated as follows:

1. The sample of the finished products shall be retained properly in a specific area.
2. The amount of the retain samples of the finished products shall be sufficient enough to enforce analysis.
3. The samples of the finished products shall be retained with the complete packaging, and retain for an appropriate period according to the storage condition.
4. The samples of the raw materials shall be retained according to the regulations of the manufacturing premises or other relevant regulations.

Chapter 9 Treatment of Product that is Out of Specification

Article 58

The treatment of rejected finished products, bulk products, raw materials and packaging materials of the cosmetics manufacturer shall be regulated as follows:

1. Investigation of rejected products or materials shall be conducted by authorized personnel.
2. Decisions from quality control related authorized personnel to be made to determine any further action of the rejected items including destroying or reprocessing.

Article 59

The reprocessing of the finished products and bulk products according to subparagraph 2 of the preceding article shall be regulated as follows:

1. The performance of reprocessing shall be approved by the quality control related authorized personnel.
2. The method for reprocessing shall be approved by the responsible authorized personnel.

3. To enforce control of finished products and bulk products after re-processing and to be reviewed by the authorized personnel in order to ensure to comply with the defined acceptance criteria.

Chapter 10 Waste

Article 60

The cosmetics manufacturer shall dispose the wastes in a proper and sanitary manner.

Article 61

The cosmetics manufacturer shall identify and categorize the type of waste that may affect the product quality clearly according to the information of production and quality control laboratory.

Article 62

The waste disposal shall be regulated as follows:

1. The flow of the waste disposal shall not affect the operation of production and laboratory.
2. Appropriate measures shall be taken concerning collection, transportation, storage and disposal of the wastes.

Article 63

The containers for waste shall be properly identified as to the contents and other information.

Article 64

The cosmetics manufacturer shall dispose the wastes in a proper way with adequate level of control according to subparagraph 2 of Article 62.

Chapter 11 Contracting

Article 65

The cosmetics manufacturer may appoint these items, including manufacture, packaging, analysis, pest control, cleaning and sanitizing of the premises, and maintenance of the equipment and premises and other related items, to agencies, natural persons, schools, institutions, judicial persons or groups.

The contracting mentioned in the preceding paragraph which means the contract giver shall establish a written contract or agreement with the contract acceptor to indicate the objectives, obligations, responsibilities and contract performance management in the written documents, in order to ensure the products being made or the service being provided can meet the requirements from the cosmetics manufacturer.

The contract acceptor shall retain or provide all the information related the contract of the preceding paragraph to the contract giver.

Article 66

When the cosmetics manufacturer conduct the contracting in the preceding article, the contracting should be regulated as follows:

1. To evaluate the performance ability, legal compliance and productivity of the contract acceptor, to ensure they have all the abilities to enforce the contract and to assure all the contracting items can be carried out according to the contract.
2. To provide the contract acceptor with all the necessary information.

Article 67

The contract acceptor shall be regulated as follows:

1. To ensure the method of performance, experience, and personnel abilities are capable to carry out the requirements indicated in the contract.
2. The contract acceptor shall not out-source the items listed in the contract to the third party, except with the approval from the cosmetics manufacturer; with the approval, the contract acceptor and the third party shall conduct another agreement to ensure the cosmetics manufacturer obtain all the operation information according to the original contract or agreement.
3. To cooperate with the cosmetics manufacturer to conduct investigation and to audit according to the contract or agreement.
4. Except with another agreement in addition to the contract or agreement, or with the approval from the cosmetics manufacturer, the contract acceptor cannot make any change to the contract items which may affect the products or service quality.

Chapter 12 Deviation

Article 68

When the cosmetics manufacturer discovers any deviations, the decisions shall be made according to the support of sufficient data.

Article 69

The cosmetics manufacturer shall take corrective action to prevent recurrence of the deviation.

Chapter 13 Complaints and Recalls

Article 70

Cosmetics manufacturer shall review, investigate and follow-up on, as appropriate when handling product complaints.

Article 71

Cosmetics manufacturer shall handle product complaints according to the following regulations:

1. To assign authorized personnel to handle complaints.
2. The handling of complaints and all the detailed shall be recorded and preserved.
3. Appropriate follow-up on the concerning batch shall be completed.
4. The investigation and follow-up of the complaints shall include:
   (1) Measures to be taken to prevent any recurrence of defect.
   (2) To check other batch of the products to ensure whether if they are affected.
5. The amount and content of complaints shall be reviewed periodically, to ensure for trends or recurrence of defect.

Article 72

When there is contracting for cosmetics manufacturing, the manufacturer and contract acceptor shall handle the complaints under the established contracts or agreements and not to violate the regulations of the previous 2 articles.

Article 73

Recall of the products shall be regulated as follows:

1. Appropriate measures shall be taken and to enforce the correction according to these regulations.
2. The responsible personnel shall negotiate the recall process.
3. The operation of the product recall shall be initiated promptly and in a timely manner.
4. The related authorities shall be notified of recalls which might cause the impact of consumer safety.
5. The recalled products shall be identified and stored in a safe area.
6. The product recall process shall be reviewed and evaluated periodically.

Chapter 14 Change Control

Article 74

When there is any change to be done which might affect the product quality, the cosmetics manufacturer shall assign authorized personnel to check and approve with sufficient data support.

Chapter 15 Internal Audit

Article 75

The Cosmetics manufacture premises shall enforce internal audit in order to comply with these regulations, and take necessary corrective measures according to the results of internal audit.

Article 76

The enforcement of internal audit mentioned in the preceding article shall be regulated as follows:

1. To assign a responsible competent personnel to conduct internal audit independent and detailed manner, periodically or on demand.
2. Observed results from internal audit shall be evaluated and notify the appropriate management.

Article 77

The cosmetics manufacturer shall ensure the corrective measures mentioned in Article 75 are achieved or implemented.

Chapter 16 Documentation

Article 78

The cosmetics manufacturer shall design, establish, install and maintain its own documentation systems according to its organization structure and the type of the products.

The documentation systems mentioned in the preceding paragraph is an internal part of Good Manufacturer Practices. The documentation shall record all the operation activities according to these regulations to prevent risks of misinterpretation, loss of information, confusions or error.

Electronic systems may be established and managed documents mentioned in the documentation systems in Paragraph 1.

Article 79

The content of documentation systems mentioned in the preceding article shall include: procedures, instructions, specifications, protocols, reports, methods, and records.

The content of the documentation mentioned in the preceding paragraph shall be kept in hard-copy papers or electronic data processing records.

Article 80

All activities in these regulations such as operation details, measures to be taken, and precautions to be taken shall be detailed documented. The title, nature and purpose shall be stated in every document.

Documents mentioned in the preceding paragraph shall be written legibly and comprehensively. The authorized responsible personnel shall sign and indicate the date as approval before the announcement, and update, annul, distribute, and archive accordingly.

The documents mentioned in Paragraph 1 shall be obtained from the appropriate personnel in the company, and to ensure the annulled documents are deleted, destroyed and not being used again.

Article 81

The required hand written records in the documentation mentioned in Paragraph 1 Article 79 shall be regulated to write legibly with permanent ink. The recorder shall sign and indicated the date of the record. Any correction shall require the same consent.

The correction of the written records mentioned in the preceding paragraph shall leave the original entry readable, if necessary, the reason of the correction shall be recorded.

Article 82

The documents shall be updated if necessary. For those are updated, shall indicate the revision number and the reasons for each revision shall be retained.

Article 83

Archiving of the documentation shall be regulated as follows:

1. The controlled copies each revision of the documents mentioned in the preceding articles shall be used, and the original records shall be archived.
2. The duration of archiving original documents shall be defined according to the related regulations.
3. The storage of original documents shall be properly secured.
4. The documents shall be stored electronically or as hard-copy papers, and to ensure their legibility.
5. The documents shall be back-upped regularly and stored in a separated safe location.

18 Specified Cosmetic Categories Shall Comply with Cosmetics Good Manufacturing Practice Regulations

Specified Cosmetic Categories Shall Comply with Cosmetics Good Manufacturing Practice Regulations

Effective Date：2019-07-01

Category：Ministry of Health and Welfare

The categories of cosmetics and the enforcement date for which manufacturers or importers shall comply with Good Manufacturing Practice Regulations(GMP):

1. Specific purpose cosmetics shall be implemented after five years from the effective date of Cosmetic Hygiene and Safety Act.
2. Non-specific purpose cosmetics for infants, lip, or eye shall be implemented after six years from the effective date of Cosmetic Hygiene and Safety Act.
3. Non-specific purpose cosmetics (except specific purpose cosmetics, Non-specific purpose cosmetics for infants, lip, or eye) shall be implemented after seven years from the effective date of Cosmetic Hygiene and Safety Act.

19 Ingredients Limitation and Hygiene Standards of Cosmetic Products

19.1 List of Specific Purpose Ingredients in Cosmetic Products

List of Specific Purpose Ingredients in Cosmetic Products

Effective Date：2020-01-01

Category：Ministry of Health and Welfare

Sunscreen

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
1	2-Ethylhexyl 4-(dimethylamino)benzoate/ Padimate O	Ethylhexyl dimethyl PABA	21245-02-3		8%		
2	2-Hydroxy-4-methoxybenzophenone/ Oxybenzone	Benzophenone-3	131-57-7		6% (When used for product protection purposes: 0.5%)		Precautions(exception concentration≦ 0.5% or used for product protection purposes):Contains Benzophenone-3
3	2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid and its sodium salt/ Sulisobenzone	Benzophenone-4/ Benzophenone-5	4065-45-6/ 6628-37-1		5% (as acid)		
4	Benzoic acid, 2-hydroxy-,3,3,5-trimethylcyclohexyl ester/ Homosalate	Homosalate	118-56-9		10%		

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
5	2-Ethylhexyl 4-methoxycinnamate/ Octinoxate	Ethylhexyl methoxycinnamate	5466-77-3		10%		
6	2-Ethylhexyl salicylate/ Octisalate	Ethylhexyl salicylate	118-60-5		5%		
7	2-Phenylbenzimidazole-5-sulfonic acid and its potassium, sodium and triethanolamine salts/ Ensulizole	Phenylbenzimidazole sulfonic acid	27503-81-7		8% (as acid)		
8	1-(4-tert-Butylphenyl)-3-(4-methoxyphenyl) propane-1,3-dione/ Avobenzone	Butyl methoxydibenzoylmethane	70356-09-1		5%		
9	3,3'-(1,4-Phenylenedimethylene)bis(7, 7-dimethyl-2-oxobicyclo-[2.2.1]hept-1-ylmethanesulfonic acid) and its salts/	Terephthalylidene dicamphor sulfonic acid	92761-26-7/ 90457-82-2		10% (as acid)		

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
	Ecamsule						
10	2-Cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester/ Octocrilene	Octocrylene	6197-30-4		10% (as acid)		
11	Zinc oxide	Zinc oxide	1314-13-2		25% (when used as astringent the limit would be less than 10%)		
12	Phenol,2-(2H-benzotriazol-2-yl)-4-methyl-6-(2-methyl-3-(1,3,3,3-tetramethyl-1-(trimethylsilyl)oxy)disiloxanyl)propyl)	Drometrizole trisiloxane	155633-54-8		15%		
13	2,2'-Methylene-bis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)/ Bisoctrizole	Methylene bis-benzotriazolyl tetramethylbutylphenol	103597-45-1		10%		

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
14	2,2'-(6-(4-Methoxyphenyl)-1,3,5-triazine-2,4-diyl)bis(5-((2-ethylhexyl)oxy)phenol)/ Bemotrizinol	Bis-ethylhexyloxyphenol methoxyphenyl triazine	187393-00-6		10%		
15	Dimethicodiethylbenzalmalonate	Polysilicone-15	207574-74-1		10%		
16	2,4,6-Trianilino-(pcarbo-2'-ethylhexyl-1'-oxy)-1,3,5-triazine	Ethylhexyl triazone	88122-99-0		5%		
17	Benzoic acid, 2-[-4-(diethylamino)-2-hydroxybenzoyl]-, hexylester	Diethylamino hydroxybenzoyl hexyl benzoate	302776-68-7		10%		
18	alpha-(2-Oxoborn-3-ylidene)-toluene-4-sulphonic acid and its salts	Benzylidene camphor sulfonic acid	56039-58-8		6% (as acid)		
19	N,N,N-Trimethyl-4-(2-oxoborn-3-ylidenemethyl)anilinium methyl sulfate	Camphor benzalkonium methosulfate	52793-97-2		6%		

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
20	Benzoic acid, 4,4-((6-((4-(((1,1-dimethylethyl)amino)carbonyl)phenyl)amino)-1,3,5-triazine-2,4-diyl)diimino)bis-, bis(2-ethylhexyl)ester/ Iscotrizinol	Diethylhexyl butamido triazone	154702-15-5		10%		
21	Sodium salt of 2,2'-bis(1,4-phenylene)-1Hbenzimidazole-4,6-disulfonic acid)/ Bisdisulizole disodium	Disodium phenyl dibenzimidazole tetrasulfonate	180898-37-7		10% (as acid)		
22	Isopentyl-4-methoxycinnamate/ Amiloxate	Isoamyl p-methoxycinnamate	71617-10-2		10%		
23	3-(4-Methylbenzylidene)-d1 camphor/ Enzacamene	4-Methylbenzylidene camphor	38102-62-4/ 36861-47-9		4%		
24	Ethoxylated ethyl-4-aminobenzoate	PEG-25 PABA	116242-27-4		10%		
25	Polymer of N-{(2 and 4)-[(2-oxoborn-	Polyacrylamidomethyl benzylidene	113783-61-2		6%		

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
	3-ylidene)methyl]benzyl}acrylamide	camphor					
26	1,3,5-Triazine, 2,4,6-tris[1,1'-biphenyl]-4-yl-	Tris-biphenyl triazine	31274-51-8		10%	Not to be used in spray products	
※When used as protecting agent of the product instead of sunscreen, which does not indicate the efficacy, may be regulated as general cosmetic.							

Hair dye

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
1	p-Phenylenediamine and its salts	p-Phenylenediamine/ p-Phenylenediamine HCl/ p-Phenylenediamine sulfate	106-50-3/ 624-18-0/ 16245-77-5	2% (as free base)			
2	1,4-Benzenediamine, 2-methyl-/ 2,5-Diaminotoluene sulphate	Toluene 2,5-diamine/ Toluene-2,5-diamine sulfate	95-70-5/ 615-50-9	2% (as free base) 3.6% (as sulfate salt)			
3	5-Amino-o-cresol	4-Amino-2-hydroxytoluene	2835-95-2	1.5%			
4	m-Aminophenol and its salts	m-Aminophenol/ m-Aminophenol HCl/ m-Aminophenol sulfate	591-27-5/ 51-81-0/ 68239-81-6/ 38171-54-9	1.2%			
5	4-Aminophenol	p-Aminophenol	123-30-8	0.9%			
6	1,4-Diaminoanthraquinone	Disperse Violet 1	128-95-0		0.5%		
7	2,4-Diaminophenoxyethanol, its hydrochloride and its sulphate	2,4-Diaminophenoxyethanol HCl/ 2,4-Diaminophenoxyethanol sulfate	70643-19-5/ 66422-95-5/ 70643-20-8	2% (as hydrochloride)			
8	Naphthalene-1,5-diol	1,5-Naphthalenediol	83-56-7	1%	1%		
9	Pyridine-2,6-diyldiamine	2,6-Diaminopyridine	141-86-6	0.15%			
10	5-[(2-Hydroxyethyl)amino]-o-cresol	2-Methyl-5-hydroxyethylaminophenol	55302-96-0	1.5%		Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb);	

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
						Keep in nitrite-free containers	
11	p-Methylaminophenol and its sulphate	p-Methylaminophenol/ p-Methylaminophenol sulfate	150-75-4/ 55-55-0/ 1936-57-8	0.68% (as sulfate)		Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
12	4-Nitro-1,2-phenylenediamine	4-Nitro-o-phenylenediamine	99-56-9	0.5%			
13	N-Phenyl-p-phenylenediamine	N-(4-aminophenyl)aniline	101-54-2	3%			
14	N-Phenyl-p-phenylenediamine acetate	-	-	3%			
15	N-phenylbenzene-p-diamine monohydrochloride (CI 76085)	N-phenyl-p-phenylenediamine HCl	2198-59-6/ 56426-15-4	3%			
16	2-Amino-4,6-dinitrophenol and 2-Amino-4,6-dinitrophenol, sodium salt	Picramic acid and sodium picramate	96-91-3/ 831-52-7	0.6%	0.6%		
17	2-Amino-6-chloro-4-nitrophenol	2-Amino-6-chloro-4-nitrophenol	6358-09-4	2%	2%		
18	4-Amino-m-cresol	4-Amino-m-cresol	2835-99-6	1.5%			
19	3-Amino-2,4-dichlorophenol and its hydro-	3-Amino-2,4-dichlorophenol/	61693-42-3/ 61693-43-4	1.5% (as hydrochloride)	1.5% (as hydrochloride)		

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
	chloride	3-Amino-2,4-dichlorophenol HCl					
20	2-[(3-Amino-4-methoxyphenyl)amino] ethanol and its sulphate	2-Amino-4-hydroxyethylaminoanisole/ 2-Amino-4-hydroxyethylaminoanisole sulfate	83763-47-7/ 83763-48-8	1.5% (以 sulfate 計)		Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
21	4-Amino-3-nitrophenol	4-Amino-3-nitrophenol	610-81-1	1.5%	1%		
22	4,4'-[1,3-Propanediylbis(oxy)]bisbenzene-1,3-diamine and its tetrahydrochloride salt	1,3-bis-(2,4-Diaminophenoxy)propane/ 1,3-bis-(2,4-Diaminophenoxy)propane HCl	81892-72-0/ 74918-21-1	1.2% (as free base) 1.8%(as tetrahydrochloride salt)	1.2% (as free base) 1.8%(as tetrahydrochloride salt)		
23	2,2'-[(4-Aminophenyl)imino]bis(ethanol) sulphate	N,N-bis(2-Hydroxyethyl)-p-phenylenediamine sulfate	54381-16-7	2.5%(as sulfate)		Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
24	Phenol, 2-Chloro-6-(ethylamino)-4-nitro-	2-Chloro-6-ethylamino-4-nitrophenol	131657-78-8	1.5%	3%	Do not use with nitrosating agents; Maximum	

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
						nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
25	1,3-Benzenediol,4-Chlororesorcinol (CI 76510)	4-Chlororesorcinol	95-88-5	2.5%			
26	6-Hydroxy-3,4-dimethyl-2-pyridone	2,6-Dihydroxy-3,4-dimethylpyridine	84540-47-6	1%			
27	2,6-Dimethoxy-3,5-pyridinediamine and its hydrochloride	2,6-Dimethoxy-3,5-pyridinediamine/ 2,6-Dimethoxy-3,5-pyridinediamine HCl	56216-28-5/ 85679-78-3	0.25% (as hydrochloride)			
28	Ethanol, 2,2'-[[4-[(4-aminophenyl)azo]phenyl]imino]bis-	Disperse Black 9	20721-50-0		0.3%	The mixture in the ratio 1:1 of 2,2’-[4-(4-aminophenylazo)phenylimino]diethanol and lignosulfate	
29	2,2'-[[4-[(2-Hydroxyethyl)amino]-3-nitrophenyl]imino]bisethanol	HC Blue No. 2	33229-34-4		2.8%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
30	1-[(2'-Methoxyethyl)amino]-2-nitro-4-[di-(2'-hydroxyethyl)amino]benzene	HC Blue No. 11	23920-15-2		2%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
31	1-(beta-Hydroxyethyl)amino-2-nitro-4-N-ethyl-N-(beta-hydroxyethyl)aminobenzene and its hydrochloride	HC Blue No. 12	104516-93-0/132885-85-9	0.75%(as hydrochloride)	1.5%(as hydrochloride)	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
32	4-[(2-Nitrophenyl)amino]phenol	HC Orange No. 1	54381-08-7		1%		
33	1-(beta-Aminoethyl)amino-4-(beta-hydroxyethyl)oxy-2-nitrobenzene and its salts	HC Orange No. 2	85765-48-6		1%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
34	2-Nitro-N1-phenyl-benzene-	HC Red No. 1	2784-89-6		1%		

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
	1,4-diamine						
35	1-Amino-2-nitro-4-(2',3'-dihydroxypropyl)amino-5-chloro-benzene+ 1,4-bis-(2',3'-dihydroxypropyl)amino-2-nitro-5-chlorobenzene	HC Red No. 10+ HC Red No. 11	95576-92-4+ 95576-89-9	1%	2%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
36	2,2'-[(4-Amino-3-nitrophenyl)imino]bisethanol hydrochloride and its salts	HC Red No. 13	29705-39-3/ 94158-13-1	1.25%(as hydrochloride)	2.5%(as hydrochloride)		
37	Ethanol, 2-[(4-amino-2-methyl-5-nitrophenyl)amino]- and its salts	HC Violet No. 1	82576-75-8	0.25%	0.28%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
38	1-Propanol, 3-[[4-[bis(2-hydroxyethyl)amino]-2-nitrophenyl]amino]	HC Violet No. 2	104226-19-9		2%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free	

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
						containers	
39	2-[(2-Nitrophenyl)amino]ethanol	HC Yellow No. 2	4926-55-0	0.75%	1%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
40	2-[bis(2-Hydroxyethyl)amino]-5-nitrophenol	HC Yellow No. 4	59820-43-8		1.5%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
41	1,5-Di-(beta-hydroxyethylamino)-2-nitro-4-chlorobenzene	HC Yellow No. 10	109023-83-8		0.1%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
42	3,4-Dihydro-2H-1,4-benzoxazin-6-ol	Hydroxybenzomorpholine	26021-57-8	1%		Do not use with nitrosating agents;	

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
						Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
43	2-(4-Methyl-2-nitroanilino)ethanol	Hydroxyethyl-2-nitro-p-toluidine	100418-33-5	1%	1%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
44	Hydroxyethyl-3,4-methylenedioxyaniline and its hydrochloride	Hydroxyethyl-3,4-methylenedioxyaniline HCl	94158-14-2	1.5%		Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
45	Hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine)and its tetrahydrochloride	Hydroxypropylbis(N-hydroxyethyl-p-phenylene-diamine) HCl	128729-30-6/ 128729-28-2	0.4%(as tetrahydrochloride)			
46	2-[(2-methoxy-4-	2-Hydroxyethylamino-5-	66095-81-6		0.2%	Do not use with	

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
	nitrophenyl)amino]ethanol and its salts	nitroanisole				nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
47	1-Hydroxy-2-beta-hydroxyethylamino-4,6-dinitrobenzene	2-Hydroxyethyl picramic acid	99610-72-7	1.5%	2%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
48	1-Hydroxy-3-nitro-4-(3-hydroxypropylamino)benzene	4-Hydroxypropylamino-3-nitrophenol	92952-81-3	2.6%	2.6%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
49	1,3-Benzenediol, 2-methyl	2-Methylresorcinol	608-25-3	1.8%	1.8%		
50	2-[3-(Methylamino)-4-nitrophenoxy]ethanol	3-Methylamino-4-nitrophenoxyethanol	59820-63-2		0.15%	Do not use with nitrosating agents; Maximum	

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
						nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
51	Naphthalene-2,7-diol	2,7-Naphthalenediol	582-17-2	1%	1%		
52	1-Naphthalenol	1-Naphthol	90-15-3	2%			
53	4-[(2-Hydroxyethyl)amino]-3-nitrophenol	3-Nitro-p-hydroxyethylaminophenol	65235-31-6	3%	1.85%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
54	1-(.beta.-Ureidoethyl)amino-4-nitrobenzene	4-Nitrophenyl aminoethylurea	27080-42-8	0.25%	0.5%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
55	3-Methyl-1-phenyl-5-pyrazolone	Phenyl methyl pyrazolone	89-25-8	0.25%			
56	1,3-Benzenediol	Resorcinol	108-46-3	1.25%			
57	3-Amino-2-chloro-6-	5-Amino-6-chloro-o-cresol/	84540-50-1/	1%	0.5%		

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
	methylphenol/ 3-Amino-4-chloro-6-methylphenol HCl	5-Amino-6-chloro-o-cresol HCl	80419-48-3				
58	2- Aminopyridin-3-ol	2-Amino-3-hydroxypyridine	16867-03-1	1%			
59	2-[(4-Aminophenyl)azo]-1,3-dimethyl-1H-imidazolium chloride	Basic Orange 31	97404-02-9	0.5%	1%		
60	2-[[4-(Dimethylamino)phenyl]azo]-1,3-dimethyl-1H-imidazolium chloride	Basic Red 51	77061-58-6	0.5%	1%		
61	[7-Hydroxy-8-[(2-methoxyphenyl)azo]-2-naphthyl]trimethylammonium chloride	Basic Red 76	68391-30-0		2%		
62	Pyridinium, 1-methyl-4-[(methylphenylhydrazono)methyl]-,methyl sulfate	Basic Yellow 87	68259-00-7	1%	1%		
63	1-Methyl-2,6-bis-(2-hydroxyethylamino)-benzene	2,6-Dihydroxyethylaminotoluene	149330-25-6	1%		Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
64	Ethanol, 2-((4-amino-2-nitrophenyl)amino)-	HC Red No. 3	2871-01-4	0.45%	3%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
65	3-(2-Hydroxyethyl)-p-phenylenediammonium sulphate	Hydroxyethyl-p-phenylenediamine sulfate	93841-25-9	2% (as sulfate)			
66	6-Methoxy-N2-methyl-2,3-pyridinediamine hydrochloride and dihydrochloride salt	6-Methoxy-2-methylamino-3-aminopyridine HCl	90817-34-8/ 83732-72-3	0.68%(as free base) 1%(as dihydrochlo-ride)	0.68%(as free base) 1%(as dihydrochlo-ride)	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
67	bis(N-phenylbenzene-p-diamine)sulphate	N-Phenyl-p-phenylenediamine sulfate	4698-29-7	3% (as free base)			
68	Trisodium 5-hydroxy-1-(4-sulphophenyl)-4-(4-sulphophenylazo)pyrazole-3-carboxylate and aluminium lake (CI19140)	Acid Yellow 23/ Acid Yellow 23 Aluminum lake	1934-21-0/ 12225-21-7		0.5%		
69	Benzenemethanaminium, N-	Acid Blue 9/	3844-45-9/		0.5%		

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
	ethyl-N-[4-[[4-[ethyl-[(3-sulfophenyl)-methyl]-amino]-phenyl](2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfo, inner salts, disodium salt and its ammonium and aluminium salts (CI 42090)	Acid Blue 9 Ammonium salt/ Acid Blue 9 Aluminum lake	2650-18-2/ 68921-42-6				
70	Disodium 6-hydroxy-5-[(2-methoxy-4-sulphonato-m-tolyl)azo]naphthalene-2-sulphonate (CI 16035)	Curry Red	25956-17-6		0.4%		
71	Trisodium 1-(1-naphthylazo)-2-hydroxynaphthalene-4',6,8-trisulphonate and aluminium lake (CI 16255)	Acid Red 18/ Acid Red 18 Aluminum lake	2611-82-7/ 12227-64-4		0.5%		
72	Hydrogen 3,6-bis(diethylamino)-9-(2,4-disulphona-tophenyl)xanthylium, sodium salt (CI 45100)	Acid Red 52	3520-42-1	1.5%	0.6%		
73	Sodium 1-amino-4-(cyclohexylamino)-9,10-dihydro-9,10-dioxoanthracene-2-sulphonate (CI 62045)	Acid Blue 62	4368-56-3		0.5%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb);	

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
						Keep in nitrite-free containers	
74	2,3-Dihydro-1H-indole-5,6-diol and its hydrobromide salt	Dihydroxyindoline/ Dihydroxyindoline HBr	29539-03-5/ 138937-28-7		2%		
75	Disodium 5-amino-4-hydroxy-3-(phenylazo)naphathlene-2,7-disulphonate (CI 17200)	Acid Red 33	3567-66-6		0.5%		
76	2,4,5,6-Tetraaminopyrimidine sulphate	Tetraaminopyrimidine sulfate	5392-28-9	3.4%(as sulfate)	3.4%(as sulfate)		
77	1H-Indole-5,6-diol	Dihydroxyindole	3131-52-0	0.5%	0.5%		
78	5-Amino-4-chloro-2-methylphenol hydrochloride	5-Amino-4-Chloro-o-Cresol HCl	110102-85-7	1.5% (as hydrochloride)			
79	1H-indole-2,3-dione	Isatin	91-56-5		1.6%		
80	2-Methyl-1-naphthyl acetate	1-Acetoxy-2-methylnaphthalene	5697-02-9	2%			
81	1-Hydroxy-2-methylnaphthalene	2-Methyl-1-naphthol	7469-77-4	2%			
82	Disodium 5,7-dinitro-8-oxido-2- naphthalene-sulfonate (CI 10316)	Acid Yellow 1	846-70-8	1%	0.2%		
83	1-Methoxy-3-(β-aminoethyl)amino-4-nitrobenzene, hydrochloride	HC Yellow No. 9	86419-69-4		0.5(as hydrochloride)	Do not use with nitrosating agents; Maximum nitrosamine content：50	

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
						microgram/kg(ppb); Keep in nitrite-free containers	
84	1-(4'-Aminophenylazo)-2-methyl- 4-(bis-2-hy-droxyethyl) aminobenzene	HC Yellow No. 7	104226-21-3		0.25%		
85	Benzenaminium, 3-[(4,5-dihydro- 3-methyl-5-oxo-1-phenyl-1H- pyrazol-4-yl)azo]-N,N,Ntrime-thyl-, chloride	Basic Yellow 57	68391-31-1		2%		
86	9,10-Anthracenedione, 1,4-bis[(2,3-dihydroxy-propyl) amino]-	HC Blue No. 14	99788-75-7		0.3%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
87	4,5-Diamino-1-(2-hydroxyethyl)-1H-pyrazole sulfate (1:1)	1-Hydroxyethyl-4,5-diamino pyrazole sulfate	155601-30-2	3%			
88	Quinolinium, 4-formyl-1-methyl-, salt with 4-methylbenzenesulfonic acid (1:1)	4-Formyl-1-methylquinolinium-p-toluenesulfonate	223398-02-5	2.5%			
89	2,6-Pyridinediamine, 3-(3-	2,6-Diamino-3-((pyridine-3-	28365-08-4	0.25%	0.25%		

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
	pyridinylazo)	yl)azo)pyridine					
90	4-((4-Amino-3-methylphenyl)(4-imino-3-methyl-2,5-cyclohexadien-1-ylidene)methyl)-2-methylphenylamine monohydrochloride (CI 42520)	Basic Violet 2	3248-91-7	1%	0.5%		
91	2,3-Diamino-6,7-dihydro-1H,5H-pyrazolo[1,2-a] Pyrazol-1-one dimethanesulfonate	2,3-Diaminopyrazolopyrazone dimethosulfonate	857035-95-1	2%			
92	1-Methylamino-2-nitro-5-(2,3-dihydroxy-propyl-oxy)-benzene	2-Nitro-5-glycerylmethylaniline	80062-31-3	0.8%	1%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free containers	
93	1-Propanaminium, 3-[[9,10-dihydro-4-(methylamino)-9,10-dioxo-1-anthracenyl]amino]-N,N-di-methyl-N-propyl-, bromide	HC Blue No. 16	502453-61-4		3%	Do not use with nitrosating agents; Maximum nitrosamine content：50 microgram/kg(ppb); Keep in nitrite-free	

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
						containers	
94	Phenol, 2,2'- methylenebis[4-amino-], dihydro-chloride	2,2'- Methylenebis-4-aminophenol HCl	27311-52-0/ 63969-46-0	1%	1%		
95	Fluorescein, 2',4',5',7'-tetrabromo-4,5,6,7-tetra-chloro-, disodium salt (CI 45410)	Acid Red 92	18472-87-2	2%	0.4%		
96	Mixture of (1), (2)& (3) in dispersing agent (lignosulphate): (1)9,10-Anthracenedione-1,4-bis[(2-Hydroxy ethyl)amino] (2)9,10-Anthracenedione-1-[(2-Hydroxyethyl) amino]-4-[(3-Hydroxypropyl)amino] (3)9,10-anthracenedione-1,4-bis[(3-hydroxylpropyl)amino	Disperse Blue 377 is a mixture of three dyes: (1)1,4-Bis[(2-hydroxyethyl)amino]anthra-9,10-quinone/ (2)1-[(2-hydroxyethyl)amino]-4-[(3-hydroxypropyl) amino]anthra-9,10-quinone/ (3)1,4-bis[(3-hydroxypropyl)amino]anthra-9,10- quinone	4471-41-4/ 67674-26-4/ 67701-36-4		2%		
97	Sodium,4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]toluene-3-sulphonate	Acid Violet 43	4430-18-6		0.5%		
98	2-(4-Amino-3-nitroanilino)ethanol	HC Red No. 7	24905-87-1		1%	Do not use with nitrosating agents; Maximum nitrosamine	

No.	Chemical name	INCI name	CAS No.	Maximum concentration		Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				Oxidative hair dye products	Non-oxidative hair dye products		
						content：50 microgram/kg(ppb); Keep in nitrite-free containers	
99	Phosphoric acid compound with 4-[(2,6-di-chlorophenyl)(4-imino-3,5-dimethyl-2,5-cyclo-hexadien-1-ylidene)methyl]-2,6-dimethylaniline (1:1)	HC Blue No. 15	74578-10-2	0.2%	0.2%		
100	Diammonium peroxodisulphate	Ammonium Persulfate	7727-54-0	61.3%		For professional use only (Decolorizer)	
101	Dipotassium peroxodisulphate	Potassium Persulfate	7727-21-1	70%		For professional use only (Decolorizer)	
102	Disodium peroxodisulphate	Sodium Persulfate	7775-27-1	47%		For professional use only (Decolorizer)	
103	Ammonia	Ammonia	7664-41-7/ 1336-21-6	6% (as NH_3)		To be printed on the label if ammonia above 2% : Contains ammonia above 2%	
104	Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide	Hydrogen peroxide	7722-84-1	12% (40 volumes) (present or released)		Second agent	
※Maximum concentration：means allowed to maximum concentration in ready for use preparation of finished hair dye product. ※For hair dye products only, unless the substance regulated elsewhere in others regulation							

Permanent Wave Agents

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
1	Thioglycolic acid and its salts(1)	Thioglycolic acid	68-11-1		(a) 8% (as thioglycollic acid)	(a) pH：7-9.5	(a) Contains Thioglycolate
					(b) 11% (as thioglycollic acid)	(b) pH：7-9.5; For professional use only	(b) Contains thioglycolate
2	Thioglycolic acid esters	-	-		(a) 8% (as thioglycollic acid)	(a) pH：6-9.5	(a) Contains Thioglycolate
					(b) 11% (as thioglycollic acid)	(b) pH：6-9.5; For professional use only	(b) Contains thioglycolate
3	L-Cysteine/ DL-Cysteine/ L-Cysteine hydrochloride/ DL-Cysteine hydrochloride/ L-Cysteine monohydrochloride/ N-Acetyl-L-Cysteine	L-Cysteine/ DL-Cysteine/ L-Cysteine hydrochloride/ DL-Cysteine hydrochloride/ L-Cysteine monohydrochloride/ N-Acetyl-L-Cysteine	52-90-4/ 3374-22-9/ 52-89-1/ 10318-18-0/ 7048-04-6/ 616-91-1	(a) Cold	(a) 3~7.5% (as cysteine)	(a) pH：8-9.5；Alkalinity: The amount of the 0.1 N hydrochloric acid volumetric solution consumed is not more than 12mL per mL of the sample.	
				(a) Tepid	(b) 1.5~5.5% (as cysteine)	(b) pH：4-9.5；Alkalinity: The amount of the 0.1 N hydrochloric	

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
						acid volumetric solution consumed is not more than 9 mL per mL of the sample.	
4	Sodium sulfite	Sodium sulfite	7757-83-7		6.7% (as free SO_2)		
5	Potassium or sodium hydroxide(1)	Potassium hydroxide/ Sodium hydroxide	1310-58-3/ 1310-73-2		(a) 2%		(a) Contains alkali; Can cause blindness
					(b) 4.5%	(b) For professional use only	(b) Contains alkali; Can cause blindness
6	Lithium hydroxide(1)	Lithium hydroxide	1310-65-2		(a) 2%		(a) Contains alkali; Can cause blindness
					(b) 4.5%	(b) For professional use only	(b) Contains alkali; Can cause blindness
7	Calcium hydroxide(1)	Calcium hydroxide	1305-62-0	Permanent wave agents contains calcium hydroxide and guanidine salt	7% (as calcium hydroxide)		Contains alkali; Can cause blindness
8	Sodium bromate	Sodium bromate	7789-38-0	Second agent	11.5%	pH：4.0-9.5	

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
9	Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide	Hydrogen peroxide	7722-84-1	Second agent	12% (40 volumes) (present or released)		Contains hydrogen peroxide
(1) For use other than as a permanent wave agents, see “List of Ingredients Restricted in Cosmetic Products” ※The concentration of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In case of mixtures, the sum should not exceed the limits.							

Antiperspirant and deodorant

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
1	Aluminum Chlorohydrate	-	12042-91-0		25%(as anhydride)	Function: Antiperspirant and deodorant	
2	Aluminum Zirconium salts	-	-		20%(as anhydride)	Function: Antiperspirant and deodorant Not to be used in spray products	
3	Aluminum Chloride	-	7446-70-0		15%(as aqueous solution)	Function: Antiperspirant and deodorant	
4	Aluminum sesquichlorohydrate and its derivatives	-	11089-92-2		25%	Function: Antiperspirant and deodorant	
5	Ammonium Silver Zinc Aluminum Silicate	-	-		5~10%	Function: Antibacterial, deodorant	Do not use on damaged skin or wounds.

Other

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
1	Ascorbyl Tetraisopalmitate	Ascorbyl Tetraisopalmitate	-		3.0%(Limit concentration used)	Function: Inhibit melanin production	
2	Sulfur	Sulfur	-		2%	Function: Prevent acne(For face cream and lotion products)	
3	Salicylic acid(1)	Salicylic acid	69-72-7		0.2~2%	Function: Soften Horniness, prevent acne Not to be used in products for children under 3 years of age, except in bath shampoo	Precautions (other than shampoo): Not to be used for children under 3 years of age.
4	Allantoin	Allantoin	97-59-6	Leave-on products	0.2 up to 0.5%	Function: Moisturising	
5	Hydrogen peroxide	Hydrogen peroxide	7722-84-1	Teeth whitening products for home use	6%	Function: Teeth whitening	1. If there is any discomfort of the gums or oral cavity (such as redness, swelling, pain, etc.), stop using the product immediately and consult a dentist.
6	Carbamide peroxide	Carbamide peroxide	124-43-6	Teeth whitening products for home use	18%	Function: Teeth whitening	

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
							2. If sensitization of teeth occurs, stop using the product and consult a dentist. 3. It is not advised for children under 12 years of age, pregnant women, or lactating women to use this product. 4. Do not use the product if there is any disease of the gums or oral cavity, or allergy to any ingredients of this product. 5. Avoid accidental swallowing. 6. Avoid contact of this product with eyes while using. If accidental eye contact occurs,

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
							rinse immediately with clean water. 7. Smoking or chewing betel nut is not advised while using teeth whitening agents. 8. Avoid direct contact of this product with gums while using. 9. If used continuously for 14 days or longer, use must follow dentist's instructions. 10. This product must be stored out of reach of children and away from direct exposure to sunlight.
7	Hydrogen peroxide	Hydrogen peroxide	7722-84-1	Teeth whitening products for home	1.5%~6%	Function: Teeth whitening	1. If there is any discomfort of the

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				use			gums or oral cavity (such as redness, swelling, pain, etc.), stop using the product immediately and consult a dentist. 2. If sensitization of teeth occurs, stop using the product and consult a dentist. 3. It is not advised for children under 12 years of age, pregnant women, or lactating women to use this product. 4. Do not use the product if there is any disease of the gums or oral cavity, or allergy to any ingredients of this product.

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
							5. Avoid accidental swallowing. 6. Avoid contact of this product with eyes while using. If accidental eye contact occurs, rinse immediately with clean water. 7. Smoking or chewing betel nut is not advised while using teeth whitening agents. 8. If used continuously for 14 days or longer, use must follow dentist's instructions. 9. This product must be stored out of reach of children and away from direct exposure to

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
							sunlight.
8	1-(4-Chlorophenyl)-3-(3,4-dichlorophenyl)urea(1)	Triclocarban	101-20-2	Rinse-off products	0.5 up to 1.5%	Function: Antibacterial	
(1)For use as a preservative, see “List of Preservatives in Cosmetic Products.							

※ Active ingredients of Specific Purpose Cosmetics shall conform to this annex. Regarding active ingredients of Specific Purpose Cosmetics not listed within this annex, if a jurisdiction such as the European Union, the United States or Japan has already announced permission of use and have applicable regulations, the active ingredients can also be used in accordance to respective standards, after providing such announcement, the permit to be issued per Regulations for Issuance of Permit License of Specific Purpose Cosmetics may be approved after applying for registration.

※ The outer packaging or containers of Specific Purpose Cosmetics shall conspicuously label the Precautions. If it cannot be labeled due to the surface area of outer packaging or container being too small or other special circumstances, said information shall be stated on the label, in the leaflet, or by other means.

19 Ingredients Limitation and Hygiene Standards of Cosmetic Products

19.2 List of Ingredients Prohibited in Cosmetic Products

List of Ingredients Prohibited in Cosmetic Products

Effective Date：2021-07-01

Category：Ministry of Health and Welfare

This rule has been translated into English according to the original Chinese version.
If there is any inconsistency or ambiguity between these two versions, the Chinese version shall prevail.

No.	Chemical name	CAS No.
1	Mercury and its compounds (with the exception of the substance listed in the "List of Preservatives in Cosmetic Products") Due to the raw material or other technically unavoidable reasons, the trace amounts of Mercury shall not exceed 1 ppm.	7439-97-6
2	4-Benzyloxyphenol and 4-ethoxyphenol	103-16-2/ 622-62-8
3	Bithionol	97-18-7
4	Pilocarpine and its salts	92-13-7
5	Halogeno-salicylanilide	-
6	Boric acid	10043-35-3/ 11113-50-1
7	Sodium perborate	7632-04-4
8	Sodium borate except for sodium borate used to emulsify beeswax or bleached beeswax, which content should not exceed 0.76%	1330-43-4
9	Chlorofluorocarbons	-
10	3'-Ethyl-5',6',7',8'-tetrahydro-5',5',8',8'-tetramethyl-2'- acetonaphthone or 7-acetyl-6-ethyl-1,1,4,4-tetramethyl-1,2,3,4-tetrahydronaphtalen (AETT; Versalide)	88-29-9
11	Cells, tissues or products of human origin	-
12	Hydroxy-8-quinoline and its sulphate For use as stabilizer of hydrogen peroxide in hair dyes and perming products, the content should not exceed 0.03% (calc. as base)	148-24-3/ 134-31-6
13	Dichloromethane	75-09-2

No.	Chemical name	CAS No.
14	4-*tert*-Butyl-3-methoxy-2,6-dinitrotoluene (Musk ambrette)	83-66-9
15	6-Methylcoumarin (Non-medical toothpaste and mouthwash are otherwise specified by law)	92-48-8
16	Vinyl chloride monomer	75-01-4
17	2,2'-Dihydroxy-3,3',5,5',6,6'-hexachlorodiphenylmethane (Hexachlorophene (INN))	70-30-4
18	Tretinoin (INN) (retinoic acid and its salts)	302-79-4
19	4-Amino-2-nitrophenol	119-34-6
20	Antimony and its compounds	7440-36-0
21	Arsenic and its compounds Due to the raw material or other technically unavoidable reasons, the trace amounts of Arsenic shall not exceed 3 ppm.	7440-38-2
22	Cadmium and its compounds Due to the raw material or other technically unavoidable reasons, the trace amounts of Cadmium shall not exceed 5 ppm.	7440-43-9
23	Cantharidine	56-25-7
24	Chloroacetamide	79-07-2
25	Chloroform	67-66-3
26	Chromium; Chromic acid and its salts (with the exception of the substance listed in the “List of Colorants in Cosmetic Products”)	7440-47-3
27	Dibutyl phthalate Due to the raw material or other technically unavoidable reasons, the trace amounts of Dibutyl phthalate shall not exceed 100 ppm.	84-74-2
28	Dichlorophen	97-23-4
29	2,6-Dimethyl-1,3-dioxan-4-yl acetate (Dimethoxane)	828-00-2
30	Dioxane Due to the raw material or other technically unavoidable reasons, the trace amounts of Dioxane shall not exceed 100 ppm.	123-91-1
31	2-Ethoxyethanol and its acetate (2-Ethoxyethyl acetate)	110-80-5/ 111-15-9
32	4-Ethoxy-m-phenylenediamine and its salts	67801-06-3/ 5862-77-1/ 68015-98-5/ 6219-69-8

No.	Chemical name	CAS No.
33	Fluorine compounds (as Inorganic compounds) (Non-medical toothpaste and mouthwash are otherwise specified by law)	
34	Formaldehyde (Formalin) (1)When used as preservatives in cosmetic products, the total amount of released free formaldehyde should not exceed 1000 ppm: DMDM Hydrantoin、Imidazolidinyl urea、Quaterium 15、Benzylhemiformal、5-Bromo-5-nitro-1,3-dioxane、Bronopol、Methenamine、Sodium hydroxymethylglycinate、Diazolidinyl urea. (2) Due to the raw material or other technically unavoidable reasons, the trace amounts of Formaldehyde shall not exceed 75 ppm.	50-00-0
35	HC Blue No.1 (2,2'-([4-(Methylamino)-3-nitrophenyl]imino)bis(ethanol))	2784-94-3
36	Hydrogen peroxide except when used as oxidizer in hair dyes, perming agents, and teeth whitening products	7722-84-1
37	*p*-Hydroxyanisole (4-Methoxyphenol；Hydroquinone monomethyl ether；Monobenzone)	150-76-5
38	Lead and its compounds Due to the raw material or other technically unavoidable reasons, the trace amounts of Lead shall not exceed 10 ppm.	7439-92-1
39	Local anesthetics (e.g.Lidocaine、Procaine)	-
40	1-Methoxy-2,4-diaminobenzene (2,4-Diaminoanisole; CI 76050) and its salts	615-05-4
41	1-Methoxy-2,5-diaminobenzene (2,5-Diaminoanisole) and its salts	5307-02-8
42	4-Methyl-*m*-phenylenediamine (Toluene-2,4-diamine) and its salts	95-80-7
43	Methyl methacrylate	80-62-6
44	Nitrofurantoin (INN)	67-20-9
45	Nitrosamines e.g. Dimethylnitrosoamine; Nitrosodipropylamine; 2,2'-Nitrosoimino)bisethanol; Nitrosamine diethyl (Diethylamine, N-nitroso-)	62-75-9/ 621-64-7/ 1116-54-7/ 55-18-5
46	Oestrogens	-
47	*o*-Phenylenediamine and its salts	95-54-5
48	*p*-Phenylenediamine except for use in hair dye products	106-50-3
49	Potassium bromate	7758-01-2

No.	Chemical name	CAS No.
50	Pregnanediol	80-92-2
51	Pregnenolone acetate	1778-02-5
52	Pyrocatechol (Catechol)	120-80-9
53	Pyrogallol	87-66-1
54	Selenium and its compounds except for selenium disulfide used in hair-related products。	7782-49-2
55	Strontium compounds (Non-medical toothpaste and mouthwash are otherwise specified by law)	7440-24-6
56	Sulphonamides (sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the -NH_2 groups) and their salts	-
57	2-Methyl-*m*-phenylenediamine (Toluene-2,6-diamine)	823-40-5
58	Trichloroacetic acid	76-03-9
59	3-Imidazol-4-ylacrylic acid (Urocanic acid) and its ethyl ester	104-98-3/ 27538-35-8
60	Zirconium and its compounds are prohibited to be used in aerosol products (except for zirconium lakes and salts used as colorants)	7440-67-7
61	*Aconitum napellus* L. (leaves, roots and galenical preparations)	84603-50-9
62	*Adonis vernalis* L. and its preparations	84649-73-0
63	*Ammi majus* L. and its galenical preparations	90320-46-0
64	*Anamirta cocculus* L. (fruit)	-
65	*Apocynum cannabinum* L. and its preparations	84603-51-0
66	Aristolochic acid and its salts; *Aristolochia* spp. and their preparations	475-80-9/ 313-67-7/ 15918-62-4
67	*Atropa belladonna* L. and its preparations	8007-93-0
68	Cantharides, *Cantharis vesicatoria* except for cantharides tincture used in hair products.	92457-17-5
69	*Chenopodium ambrosioides* L. (essential oil)	8006-99-3
70	*Claviceps purpurea* Tul., its alkaloids and galenical preparations	84775-56-4
71	*Colchicum autumnale* L. and its galenical preparations	84696-03-7

No.	Chemical name	CAS No.
72	*Conium maculatum* L. (fruit, powder, galenical preparations)	85116-75-2
73	*Croton tiglium* L. (oil)	8001-28-3
74	*Datura stramonium* L. and its galenical preparations	84696-08-2
75	Digitaline and all heterosides of *Digitalis purpurea* L.	752-61-4
76	*Hyoscyamus niger* L. (leaves, seeds, powder and galenical preparations)	84603-65-6
77	Ipecacuanha (*Cephaelis ipecacuanha* Brot. and related species) (roots, powder and galenical preparations)	8012-96-2
78	*Juniperus sabina* L. (leaves, essential oil and galenical preparations)	90046-04-1
79	Oil from the seeds of *Laurus nobilis* L.	84603-73-6
80	*Lobelia inflata* L. and its galenical preparations	84696-23-1
81	*Physostigma venenosum* Balf.	89958-15-6
82	*Phytolacca* spp. and their preparations	60820-94-2/ 65497-07-6
83	*Pilocarpus jaborandi* Holmes and its galenical preparations	84696-42-4
84	*Prunus laurocerasus* L. (cherry laurel water)	89997-54-6
85	*Pyrethrum album* L. and its galenical preparations	-
86	*Schoenocaulon officinale* Lind (seeds and galenical preparations)	84604-18-2
87	*Solanum nigrum* L. and its galenical preparations	84929-77-1
88	*Strophanthus* species and their galenical preparations	-
89	*Strychnos* species and their galenical preparations	-
90	*Thevetia neriifolia* Juss., glycoside extract	90147-54-9
91	*Urginea scilla* Steinh. and its galenical preparations	84650-62-4
92	*Veratrum* spp. and their preparations	90131-91-2
93	Arsenolite	-
94	*Daphnis Genkwa* Flos	-
95	Daturae Flos	-
96	*Euphorbiae Pallasii* Radix	-
97	*Euphorbiae Kansui* Radix	-
98	Hirudo	-

No.	Chemical name	CAS No.
99	Hyoscyami Semen	-
100	Impatientis Semen	-
101	Knoxiae Radix	-
102	Pharbitidis Semen	-
103	Tabanus	-
104	Acrolein	107-02-8
105	Acrylamide If raw material contain Polyacrylamides and related polymer, the trace amounts of Acrylamide shall not exceed 0.1 ppm; for rinse off product shall not exceed 0.5 ppm.	79-06-1
106	Acrylonitrile	107-13-1
107	Aldrin (ISO)	309-00-2
108	Allyl alcohol	107-18-6
109	Biphenyl-4-ylamine (4-Aminobiphenyl) and its salts	92-67-1
110	Aniline, its salts and its halogenated and sulphonated derivatives	62-53-3
111	Asbestos Follow the international testing standard, the cosmetic products and raw material talc shall not be detected the asbestos.	12001-28-4
112	Benzidine/ Benzidine acetate/ Benzidine sulfate/ Benzidine dihydrochloride/ Benzidine dihydrofluoride/ Benzidine perchlorate/ Benzidine perchlorate/ Benzidine diperchlorate	92-87-5/ 36341-27-2/ 531-86-2/ 531-85-1/ 41766-73-8/ 29806-76-6/ 38668-12-1/ 41195-21-5
113	Benzene	71-43-2
114	Beryllium and its compounds	7440-41-7
115	Oxybis[chloromethane], bis (Chloromethyl) ether	542-88-1
116	α-Bromobenzyl cyanide	5798-79-8
117	1,3-Butadiene	106-99-0

No.	Chemical name	CAS No.
118	Captafol	2425-06-1
119	*N*-(Trichloromethylthio)-4-cyclohexene-1,2-dicarboximide(Captan(ISO))	133-06-2
120	Chlordane, pur	57-74-9
121	Chlorine	7782-50-5
122	α-Chloroacetophenone (w-Chloroacetophenone)	532-27-4
123	Chlorobenzilate	510-15-6
124	Chloromethyl methyl ether	107-30-2
125	*p*-Chloro-*o*-toluidine	95-69-2
126	Cyanazine	21725-46-2
127	Sodium cyanide/ Potassium cyanide/ Silver cyanide/ Copper(I) cyanide/ Copper(I) potassium cyanide/ Cadmium cyanide/ Zinc cyanide/ Copper(II) cyanide/ Copper Sodium cyanide	143-33-9/ 151-50-8/ 506-64-9/ 544-92-3/ 13682-73-0/ 542-83-6/ 557-21-1/ 14763-77-0/ 14264-31-4
128	Cyhexatin	13121-70-5
129	1,2-Dibromo-3-chloropropane	96-12-8
130	3,3’-Dichlorobenzidine	91-94-1
131	Clofenotane (INN); DDT (ISO)	50-29-3
132	Dieldrin	60-57-1
133	Dimethylcarbamoyl chloride	79-44-7
134	Dimethylformamide (*N*,*N*-Dimethylformamide)	68-12-2
135	Dimethyl sulfate	77-78-1
136	4,6-Dinitro-o-cresol (DNOC(ISO))	534-52-1
137	Dinitrophenol isomers	51-28-5/ 329-71-5/

No.	Chemical name	CAS No.
		573-56-8/ 25550-58-7
138	Dinoseb, its salts and esters	88-85-7
139	1,2-Diphenylhydrazine	122-66-7
140	(1*R*,4*S*,5*R*,8*S*)-1,2,3,4,10,10-Hexachloro-6,7-epoxy1,4,4a,5,6,7,8,8a-octahydro-1,4:5,8-dimethano-naphthalene (endrin(ISO))	72-20-8
141	1-Chloro-2,3-epoxypropane (Epichlorohydrin)	106-89-8
142	1,2-Dibromoethane	106-93-4
143	Aziridine	151-56-4
144	2-Methoxyethanol and its acetate (2-Methoxyethyl acetate)	109-86-4/ 110-49-6
145	Ethylene oxide	75-21-8
146	Diethyl sulfate	64-67-5
147	*N*-(Trichloromethylthio)phthalimide (Folpet(ISO))	133-07-3
148	Heptachlor	76-44-8
149	Hexachlorocyclohexane	319-84-6/ 319-85-7/ 319-86-8 6108-10-7
150	Hexamethylphosphoric triamide	680-31-9
151	Hydrogen cyanide and its salts	74-90-8
152	Leptophos	21609-90-5
153	1,2,3,4,5,6-Hexachlorocyclohexane (BHC(ISO))	58-89-9
154	4,4'-Methylene-bis(2-chloroaniline)	101-14-4
155	Methyl hydrazine	60-34-4
156	Methyl isocyanate	624-83-9
157	Monofluoroacetamide	640-19-7
158	1-and 2-Naphthylamines and their salts	91-59-8/ 134-32-7

No.	Chemical name	CAS No.
159	Tetracarbonylnickel	13463-39-3
160	4-Nitrobiphenyl	92-93-3
161	Nitrofen	1836-75-5
162	*N*-Nitroso-*N*-methylurea	684-93-5
163	Pentachlorophenol and its alkali salts	87-86-5/ 131-52-2/ 7778- 73-6
164	Phosgene	75-44-5
165	Phosphine	7803-51-2
166	Phosphorus trichloride	7719-12-2
167	Phthalic anhydride	85-44-9
168	Polychlorinated biphenyls	1336-36-3
169	Propargyl alcohol	107-19-7
170	2-Methylaziridine	75-55-8
171	(Epoxyethyl)benzene (Styrene oxide)	96-09-3
172	Tetrachloroethylene	127-18-4
173	Thiosemicarbazide (1-amino-2-thiourea)	79-19-6
174	*m*-Tolylidene diisocyanate (Toluene diisocyanate)	26471-62-5
175	4-Methyl-*m*-phenylene diisocyanate (Toluene 2,4- diisocyanate)	584-84-9
176	Trichloroethylene	79-01-6
177	α,α,α-Trichlorotoluene	98-07-7
178	2,4,5-Trichlorophenol	95-95-4
179	2,4,6-Trichlorophenol	88-06-2
180	1,2,3-Trichloropropane	96-18-4
181	Trinickel disulfide	12035-72-2
182	Tris(2,3-dibromopropyl)phosphate	126-72-7
183	Bromoethylene (Vinyl bromide)	593-60-2
184	Acetonitrile	75-05-8

No.	Chemical name	CAS No.
185	Anthracene oil	120-12-7
186	Benzyl butyl phthalate (BBP) Due to the raw material or other technically unavoidable reasons, the trace amounts of group of phthalate acid esters shall not exceed 100 ppm.	85-68-7
187	Bis-(2-chloro-1-methylethyl) ether	108-60-1
188	bis(2-Ethylhexyl) phthalate (Diethylhexyl phthalate) Due to the raw material or other technically unavoidable reasons, the trace amounts of group of phthalate acid esters shall not exceed 100 ppm.	117-81-7
189	Bis(2-methoxyethyl) phthalate (Dimethoxyethyl phthalate) Due to the raw material or other technically unavoidable reasons, the trace amounts of group of phthalate acid esters shall not exceed 100 ppm.	117-82-8
190	Bromoform (Tribromomethane)	75-25-2
191	Carbon disulfide	75-15-0
192	Carbon tetrachloride	56-23-5
193	Chlorobenzene	108-90-7
194	Chloroethane (Ethyl chloride)	75-00-3
195	Chloromethane (Methyl chloride)	74-87-3
196	Crotonaldehyde	4170-30-3
197	Daminozide	1596-84-5
198	Dibenzofuran	132-64-9
199	Dibromomethane (Methylenebromide)	74-95-3
200	1,2-Dichloropropane	78-87-5
201	1,3-Dichlorobenzene	541-73-1
202	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear; n-Pentyl-isopentylphthalate; di-n-Pentyl phthalate; Diisopentylphthalate Due to the raw material or other technically unavoidable reasons, the trace amounts of group of phthalate acid esters shall not exceed 100 ppm.	605-50-5/ 84777-06-0/ 131-18-0
203	3,3′-Dimethoxybenzidine (*ortho*-Dianisidine) and its salts	119-90-4
204	4,4′-Bi-o-toluidine (*ortho*-Tolidine)	119-93-7

No.	Chemical name	CAS No.
205	Diphenylamine	122-39-4
206	Fenchlorphos	299-84-3
207	Hexachloro-1,3-butadiene	87-68-3
208	Hexachlorobenzene	118-74-1
209	Hexachloroethane	67-72-1
210	Hexachloronaphthalene	1335-87-1
211	2,4-Hexadienal	142-83-6
212	Hydrazine, its derivatives and their salts	302-01-2
213	4,4′-Methylenedianiline	101-77-9
214	Iodomethane (Methyl iodide)	74-88-4
215	Naphthalene	91-20-3
216	Nitrobenzene	98-95-3
217	*o*-Aminotoluene/ *m*-Aminotoluene/ *p*-Aminotoluene	95-53-4/ 108-44-1/ 106-49-0
218	Octachloronaphthalene	2234-13-1
219	*o*-Dichlorobenzene (1,2-Dichloro benzene)	95-50-1
220	Pentachloronitrobenzene	82-68-8
221	Propiolactone	57-57-8
222	Pyridine	110-86-1
223	Thiourea (Thiocarbamide)	62-56-6
224	Toxaphene	8001-35-2
225	Tributyltin oxide (Bis(tributyltin)oxide)	56-35-9
226	1,2,4-Trichlorobenzene	120-82-1
227	Fentin hydroxide	76-87-9
228	*Areca catechu* L.	-
229	*Asarum blumei* Duch.	-
230	*Brucea javanica* (L.) Merr.	-

No.	Chemical name	CAS No.
231	*Bufo melanostictus*	-
232	*Clematis chinensis* Osbeck	-
233	*Convallaria majalis* L. (*Convallaria keiskei* Miq.)	-
234	*Coriaria sinica* Maxim.	-
235	*Derris trifoliata* Lour.	-
236	*Ephedra* Tourn. ex L, (Ephedraceae).	-
237	*Euphorbia lathyris* L.	-
238	*Illicium lanceolatum* A.C. Smith	-
239	*Lycoris radiata* Herb.	-
240	*Nerium indicum* Mill.	-
241	*Phytolacca acinosa* Roxb.	-
242	*Pinellia ternata* (Thunb.) Breit.	-
243	*Rhododendron molle* G. Don	-
244	*Sinapis alba* L.	-
245	Lead acetate, it trihydrate and derivatives	6080-56-4
246	Acid Orange 24 (CI 20170) cannot be used in hair dye products.	1320-07-6
247	Acid Red 73 (CI 27290) cannot be used in hair dye products.	5413-75-2
248	4-Aminoazobenzene	60-09-3
249	4-*o*-Tolylazo-*o*-toluidine	97-56-3
250	5-Amino-4-fluoro-2-methylphenol sulfate cannot be used in hair dye products.	163183-01-5
251	2-Aminomethyl-*p*-aminophenol and its HCl salt cannot be used in hair dye products.	79352-72-0
252	*o*-Anisidine	90-04-0
253	2,6-Bis(2-Hydroxyethoxy)-3,5-pyridinediamine and its HCl salt cannot be used in hair dye products.	117907-42-3
254	Bis(2-Methoxyethyl) ether (Dimethoxydiglycol)	111-96-6
255	4-Chloro-2-aminophenol cannot be used in hair dye products.	95-85-2
256	4-Chloroaniline	106-47-8
257	Chromated Copper Arsenate	37337-13-6
258	Cobalt dichloride	7646-79-9

No.	Chemical name	CAS No.
259	*N*-Cyclopentyl-m-aminophenol cannot be used in hair dye products.	104903-49-3
260	3,4-Diaminobenzoic acid cannot be used in hair dye products.	619-05-6
261	2,4-Diaminodiphenylamine cannot be used in hair dye products.	136-17-4
262	4,5-Diamino-1-((4-chlorophenyl)methyl)-1H-pyrazole sulfate cannot be used in hair dye products.	163183-00-4
263	2,4-Diamino-5-methylphenetol and its HCl salt cannot be used in hair dye products.	113715-25-6
264	4,5-Diamino-1-methylpyrazole and its HCl salt cannot be used in hair dye products.	20055-01-0/ 21616-59-1
265	*N*,*N*-Diethyl-*m*-aminophenol cannot be used in hair dye products.	91-68-9/ 68239-84-9
266	*N*,*N*-Dimethyl-2,6-pyridinediamine and its HCl salt cannot be used in hair dye products..	-
267	4-Hydroxyindole cannot be used in hair dye products.	2380-94-1
268	2-Methoxymethyl-*p*-aminophenol and its HCl salt cannot be used in hair dye products.	29785-47-5/ 135043-65-1
269	6-Methoxy-2,3-pyridinediamine and its HCl salt cannot be used in hair dye products.	94166-62-8
270	4-Methoxytoluene-2,5-diamine and its HCl salt cannot be used in hair dye products.	56496-88-9
271	6-Methoxy-*m*-toluidine (*p*-Cresidine)	120-71-8
272	*N*-Methylacetamide	79-16-3
273	4,4'-Methylenedi-*o*-toluidine	838-88-0
274	*N*-(2-Methoxyethyl)-*p*-phenylenediamine and its HCl salt cannot be used in hair dye products.	72584-59-9/ 66566-48-1
275	1,7-Naphthalenediol cannot be used in hair dye products.	575-38-2
276	2,3-Naphthalenediol cannot be used in hair dye products.	92-44-4
277	5-Nitro-*o*-toluidine/ 5-Nitro-*o*-toluidine hydrochloride	99-55-8/ 51085-52-0
278	Diphenylether; octabromo derivate	32536-52-0
279	4,4′-Oxydianiline (*p*-Aminophenyl ether) and its salts	101-80-4
280	Pentabromodiphenyl ether	32534-81-9
281	Solvent Red 1 (CI 12150) cannot be used in hair dye products.	1229-55-6

No.	Chemical name	CAS No.
282	4,4′-Thiodianiline and its salts	139-65-1
283	2,4,5-Trimethylaniline/ 2,4,5-Trimethylaniline hydrochloride	137-17-7/ 21436-97-5
284	Di-n-octyl phthalate Due to the raw material or other technically unavoidable reasons, the trace amounts of group of phthalate acid esters shall not exceed 100 ppm.	117-84-0
285	6-Amino-*o*-cresol and its salts cannot be used in hair dye products.	17672-22-9
286	2-Amino-3-nitrophenol and its salts cannot be used in hair dye products.	603-85-0
287	[4-[[4-Anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (Basic Blue 26; CI 44045) cannot be used in hair dye products.	2580-56-5
288	4-[(4-Aminophenyl)(4-iminocyclohexa-2,5-dien-1-ylidene)methyl]-*o*-toluidine and its hydrochloride salt (Basic Violet 14; CI 42510) cannot be used in hair dye products.	632-99-5/ 3248-93-9
289	2-Chloro-5-nitro-*N*-hydroxyethyl-*p*-phenylenediamine and its salts cannot be used in hair dye products.	50610-28-1
290	4,4'-Diaminodiphenylamine and its salts cannot be used in hair dye products.	537-65-5
291	2,4-Diamino-5-methylphenoxyethanol and its salts cannot be used in hair dye products.	141614-05-3/ 113715-27-8
292	*N*,*N*-Diethyl-*p*-phenylenediamine and its salts cannot be used in hair dye products.	6065-27-6/ 6283-63-2/ 93-05-0
293	*N*,*N*-Dimethyl-*p*-phenylenediamine and its salts cannot be used in hair dye products.	99-98-9/ 6219-73-4
294	3-[(2-nitro-4-(trifluoromethyl)phenyl)amino]propane1,2-diol (HC Yellow No. 6) and its salts cannot be used in hair dye products.	104333-00-8
295	2-[(4-chloro-2-nitrophenyl)amino]ethanol (HC Yellow No. 12) and its salts cannot be used in hair dye products.	59320-13-7
296	Hydroxyethyl-2,6-dinitro-*p*-anisidine and its salts cannot be used in hair dye products.	122252-11-3
297	Hydroxyethylaminomethyl-*p*-aminophenol and its salts cannot be used in hair dye products.	110952-46-0/ 135043-63-9

No.	Chemical name	CAS No.
298	6-Nitro-2,5-pyridinediamine and its salts cannot be used in hair dye products.	69825-83-8
299	diethylene glycol Due to the raw material or other technically unavoidable reasons, the trace amounts of diethylene glycol shall not exceed 1000 ppm.	111-46-6
300	*m*-Phenylenediamine and its salts	108-45-2/ 541-69-5/ 541-70-8
301	Travamide	-
302	Methyl alcohol Due to the raw material or other technically unavoidable reasons, the trace amounts of methyl alcohol shall not exceed 2000 ppm.	67-56-1
303	Rhododendrol	69617-84-1
304	Coal tars	8007-45-2
305	Estradiol	50-28-2
306	Estrone	53-16-7
307	Ethinyl estradiol	57-63-6
308	Antihistamine	-
309	Safrole (Shikimol) Except for ingredients from the Lauraceae family and other botanical sources, and their residue limit of Safrole in the final product must not exceed 100 ppm.	94-59-7
310	Verbena essential oils (*Lippia citriodora* Kunth.) (except Verbena absolute (*Lippia citriodora* Kunth.))	8024-12-2
311	Costus root oil (*Saussurea lappa* Clarke)	8023-88-9
312	Fig leaf absolute (*Ficus carica* L.)	68916-52-9
313	*Alocasia cucullata* (Lour.) Schott	-
314	Amorphophallus rivieri Durieu (*Amorphophallus konjac*) The plant listed in this table is prohibited for use in cosmetic products (except for the edible konjac made by the process of refinement and detoxification).	-
315	*Alocasia macrorrhiza*（L.）Schott (*Alocasia odora* (Roxb.) K. Koch)	-

No.	Chemical name	CAS No.
316	*Catharanthus roseus* (L.) G. Don	-
317	*Cerbera manghas* L.	-
318	*Ranunculus* L.,(Ranunculaceae)	84929-74-8
319	*Crotalaria sessiliflora* L.	-
320	*Dioscorea hispida* Dennst.	-
321	*Gelsemium elegans* Benth.	-
322	*Stellera chamaejasme* L.	-
323	*Anemone hupehensis* Lemoine	-
324	Barium salts with the exception of barium sulfate and insoluble salts, lakes and pigments prepared from the colorants.	-
325	Tetrahydrocannabinols Due to the raw material (*Cannabis sativa* seed oil (Hemp seed oil)), the total residual limit of tetrahydrocannabinols in the final product is 10 ppm	1972-08-3
326	Nonylphenol and Nonylphenol polyethylene glycol ether Due to the raw material or other technically unavoidable reasons, the trace amounts of Nonylphenol and Nonylphenol polyethylene glycol ether shall not exceed 1000 ppm.	25154-52-3
327	Substances with androgenic effect	-
328	2,2,2 -Trichloroethane-1,1-diol	302-17-0
329	*N*,*N*-bis(2-Chloroethyl)methylamine *N*-oxide and its salts	126-85-2
330	Chlormethine (INN) and its salts	51-75-2
331	Cyclophosphamide (INN) and its salts	50-18-0
332	Cobalt benzenesulphonate	23384-69-2
333	Dichloroethanes (ethylene chlorides) e.g. 1,2-Dichloroethane	107-06-2
334	*O*,*O*' -Diethyl-*O*-4-nitrophenyl phosphorothioate	56-38-2
335	Barbiturates	-
336	Metaldehyde	9002-91-9
337	Triamterene (INN) and its salts	396-01-0
338	Thiotepa (INN)	52-24-4

No.	Chemical name	CAS No.
339	Trichlormethine (INN) and its salts	555-77-1/ 817-09-4/ 6138-32-5
340	Furocoumarines (e.g. trioxysalen (INN), 8 -methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used. In sun protection and in bronzing products, furocoumarines shall be below 1 mg/kg	298-81-7/ 484-20-8/ 3902-71-4
341	2,3,7,8-Tetrachlorodibenzo-*p*-dioxin (TCDD)	1746-01-6
342	1,2-Epoxybutane	106-88-7
343	3,3-Bis(4-hydroxyphenyl)phthalide (Phenolphthalein (INN))	77-09-8
344	Ethyl acrylate, when used as a fragrance ingredient	140-88-5
345	Cobalt sulphate	10124-43-3
346	Nickel monoxide; nickel oxide; bunsenite	1313-99-1/ 11099-02-8/ 34492-97-2
347	Nickel dioxide	12035-36-8
348	Nickel sulfide	16812-54-7
349	Hydrocarbons, C4, 1,3 -butadiene- and isobutene-free, if they contain > 0.1% w/w Butadiene	95465-89-7
350	Benzo[def]chrysene; (=benzo[a]pyrene)	50-32-8
351	Pitch, coal tar, high -temp., heat-treated, if it contains > 0.005% w/w benzo[a]pyrene	121575-60-8
352	Dibenz[a,h]anthracene	53-70-3
353	Benz[a]anthracene	56-55-3
354	Benzo[j]fluoranthene	205-82-3
355	Benz[e]acephenanthrylene	205-99-2
356	Benzo[k]fluoranthene	207-08-9
357	Chrysene	218-01-9
358	2,3-Dibromopropan-1-ol	96-13-9
359	1,3-Dichloropropan-2-ol	96-23-1
360	alpha-Chlorotoluene (Benzyl chloride)	100-44-7
361	Methyloxirane (Propylene oxide)	75-56-9

No.	Chemical name	CAS No.
362	1,2-Epoxy-3-phenoxypropane (Phenylglycidyl ether)	122-60-1
363	2,3-Epoxypropan-1-ol (Glycidol)	556-52-5
364	Urethane (Ethyl carbamate)	51-79-6
365	2-Nitropropane	79-46-9
366	2-Nitroanisole	91-23-6
367	2,4-Dinitrotoluene; Dinitrotoluene, technical grade	121-14-2/ 25321-14-6
368	5-Nitroacenaphthene	602-87-9
369	2,6-Dinitrotoluene	606-20-2
370	1-Methyl-3-nitro-1-nitrosoguanidine	70-25-7
371	4,4'-(4-Iminocyclohexa-2,5-dienylidenemethylene) dianiline hydrochloride	569-61-9/ 479-73-2
372	*o*-Toluidine based dyes	-
373	(Methyl-ONN-azoxy)methyl acetate	592-62-1
374	Furan	110-00-9
375	1,3-Propanesultone	1120-71-4
376	Sulfallate	95-06-7
377	Erionite	12510-42-8
378	Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo] [1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate	1937-37-7
379	Disodium[5-[[4'-[[2,6-dihydroxy-3-[(2-hydroxy-5-sulphophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]salicylato(4-)]cuprate(2-)	16071-86-6
380	Resorcinol diglycidyl ether	101-90-6
381	Divanadium pentaoxide	1314-62-1
382	Chlordecone	143-50-0
383	Chlorothalonil	1897-45-6
384	Dodecachloropentacyclo[5.2.1.02,6.03,9.05,8]decane (Mirex)	2385-85-5
385	4,4'-Carbonimidoylbis[*N*,*N*-dimethylaniline] and its salts	492-80-8

No.	Chemical name	CAS No.
386	Acetamide	60-35-5
387	1-Vinyl-2-pyrrolidone	88-12-0
388	α, α-Dichlorotoluene	98-87-3
389	Isoprene (stabilized); (2 -Methyl-1,3-butadiene)	78-79-5
390	1-Bromopropane; n-Propyl bromide	106-94-5
391	Chloroprene (stabilized); (2 -Chlorobuta-1,3-diene)	126-99-8
392	4,4'-Bis(dimethylamino)benzophenone; (Michler's ketone)	90-94-8
393	1,4-Dichlorobenzene (*p*-Dichlorobenzene)	106-46-7
394	Creosote, if it contains > 0.005 % w/w benzo[a]pyrene	8001-58-9
395	*Drosera peltata* Sm. var. *Multisepala* Y. Z. Ruan	-
396	*Skimmia reevesiana* Fortune	-
397	*Typhonium giganteum* Engl.	-
398	*Sapium sebiferum* (L.) Roxb.	-
399	Colchicin, its salts and derivatives	64-86-8
400	Hyoscyamine, its salts and derivatives	101-31-5
401	Hyoscine, its salts and derivatives	51-34-3
402	Deanol aceglumate (INN)	3342-61-8
403	Spironolactone (INN)	52-01-7
404	[4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl]acetic acid (Tiratricol (INN)) and its salts	51-24-1
405	Methotrexate (INN)	59-05-2
406	Cinchophen (INN), its salts, derivatives and salts of these derivatives	132-60-5/ 5949-18-8
407	Thyropropic acid (INN) and its salts	51-26-3
408	Epinephrine (INN)	51-43-4
409	Isoprenaline (INN)	7683-59-2
410	Alloclamide (INN) and its salts	5486-77-1
411	Nalorphine (INN), its salts and ethers	62-67-9
412	Betoxycaine (INN) and its salts	3818-62-0

No.	Chemical name	CAS No.
413	Zoxazolamine (INN)	61-80-3
414	Procainamide (INN), its salts and derivatives	51-06-9
415	Tuaminoheptane (INN), its isomers and salts	123-82-0
416	Octodrine (INN) and its salts	543-82-8
417	Isocarboxazid (INN)	59-63-2
418	Bendroflumethiazide (INN) and its derivatives	73-48-3
419	Bretylium tosilate (INN)	61-75-6
420	Carbromal (INN)	77-65-6
421	Bromisoval (INN)	496-67-3
422	Brompheniramine (INN) and its salts	86-22-6
423	Benzilonium bromide (INN)	1050-48-2
424	Tetrylammonium bromide (INN)	71-91-0
425	Tetracaine (INN) and its salts	94-24-6
426	Mofebutazone (INN)	2210-63-1
427	Tolbutamide (INN)	64-77-7
428	Carbutamide (INN)	339-43-5
429	Phenylbutazone (INN)	50-33-9
430	Phenprobamate (INN)	673-31-4
431	Chlorpropamide (INN)	94-20-2
432	Chlorzoxazone (INN)	95-25-0
433	Chlorprothixene (INN) and its salts	113-59-7
434	Clofenamide (INN)	671-95-4
435	Mannomustine (INN) and its salts	576-68-1
436	Butanilicaine (INN) and its salts	3785-21-5
437	Chlormezanone (INN)	80-77-3
438	Triparanol (INN)	78-41-1
439	Chlorphenoxamine (INN)	77-38-3
440	Phenaglycodol (INN)	79-93-6

No.	Chemical name	CAS No.
441	Glycyclamide (INN)	664-95-9
442	Feclemine (INN); 2-(alpha-Cyclohexylbenzyl)-*N,N,N′,N′*-tetraethyl-1,3-propanediamine	3590-16-7
443	Cyclomenol (INN) and its salts	5591-47-9
444	Sodium hexacyclonate (INN)	7009-49-6
445	Hexapropymate (INN)	358-52-1
446	Pipazetate (INN) and its salts	2167-85-3
447	*N,N′*-Pentamethylenebis(trimethylammonium) salts, e. g. pentamethonium bromide (INN)	541-20-8
448	*N,N′*-[(Methylimino)diethylene]bis(ethyldimethylammonium) salts, e. g. azamethonium bromide (INN)	306-53-6
449	Cyclarbamate (INN)	5779-54-4
450	*N,N′*-Hexamethylenebis(trimethylammonium) salts, e. g. hexamethonium bromide (INN)	55-97-0
451	Lysergide (INN) (LSD) and its salts	50-37-3
452	Cinchocaine (INN) and its salts	85-79-0
453	3-Diethylaminopropyl cinnamate	538-66-9
454	[Oxalylbis(iminoethylene)]bis[(*o*-chlorobenzyl)diethylammonium] salts, e. g. ambenonium chloride (INN)	115-79-7
455	Methyprylon (INN) and its salts	125-64-4
456	Dioxethedrin (INN) and its salts	497-75-6
457	Piprocurarium iodide (INN)	3562-55-8
458	Propyphenazone (INN)	479-92-5
459	Tetrabenazine (INN) and its salts	58-46-8
460	Captodiame (INN)	486-17-9
461	Mefeclorazine (INN) and its salts	1243-33-0
462	Methapyrilene (INN) and its salts	91-80-5
463	Metamfepramone (INN) and its salts	15351-09-4
464	Amitriptyline (INN) and its salts	50-48-6
465	Metformin (INN) and its salts	657-24-9
466	Isosorbide dinitrate (INN)	87-33-2
467	Inproquone (INN)	436-40-8
468	Dimevamide (INN) and its salts	60-46-8

No.	Chemical name	CAS No.
469	Diphenylpyraline (INN) and its salts	147-20-6
470	Sulfinpyrazone (INN)	57-96-5
471	*N*-(3-Carbamoyl-3,3-diphenylpropyl)-*N,N*-diisopropylmethyl-ammonium salts, e. g. isopropamide iodide (INN)	71-81-8
472	Benactyzine (INN)	302-40-9
473	Benzatropine (INN) and its salts	86-13-5
474	Cyclizine (INN) and its salts	82-92-8
475	5,5-Diphenyl-4-imidazolidone (Doxenitoin (INN))	3254-93-1
476	Probenecid (INN)	57-66-9
477	Disulfiram (INN); thiram (INN)	97-77-8/ 137-26-8
478	Oxanamide (INN) and its derivatives	126-93-2
479	Choline salts and their esters, e. g. choline chloride (INN)	67-48-1
480	Caramiphen (INN) and its salts	77-22-5
481	Metethoheptazine (INN) and its salts	509-84-2
482	Oxpheneridine (INN) and its salts	546-32-7
483	Ethoheptazine (INN) and its salts	77-15-6
484	Metheptazine (INN) and its salts	469-78-3
485	Methylphenidate (INN) and its salts	113-45-1
486	Doxylamine (INN) and its salts	469-21-6
487	Tolboxane (INN)	2430-46-8
488	Parethoxycaine (INN) and its salts	94-23-5
489	Fenozolone (INN)	15302-16-6
490	Glutethimide (INN) and its salts	77-21-4
491	Bemegride (INN) and its salts	64-65-3
492	Valnoctamide (INN)	4171-13-5
493	Haloperidol (INN)	52-86-8
494	Paramethasone (INN)	53-33-8
495	Fluanisone (INN)	1480-19-9

No.	Chemical name	CAS No.
496	Trifluperidol (INN)	749-13-3
497	Fluoresone (INN)	2924-67-6
498	Fluorouracil (INN)	51-21-8
499	Furfuryltrimethylammonium salts, e. g. furtrethonium iodide (INN)	541-64-0
500	Galantamine (INN)	357-70-0
501	Hydrazides and their salts e.g. Isoniazid (INN)	54-85-3
502	Octamoxin (INN) and its salts	4684-87-1
503	Warfarin (INN) and its salts	81-81-2
504	Methocarbamol (INN)	532-03-6
505	Propatylnitrate (INN)	2921-92-8
506	Fenadiazole (INN)	1008-65-7
507	Nitroxoline (INN) and its salts	4008-48-4
508	Pemoline (INN) and its salts	2152-34-3
509	Decamethylenebis(trimethylammonium) salts, e. g. decamethonium bromide (INN)	541-22-0
510	Lobeline (INN) and its salts	90-69-7
511	Coumetarol (INN)	4366-18-1
512	Dextromethorphan (INN) and its salts	125-71-3
513	Isometheptene (INN) and its salts	503-01-5
514	Mecamylamine (INN)	60-40-2
515	Guaifenesin (INN)	93-14-1
516	Dicoumarol (INN)	66-76-2
517	Phenmetrazine (INN), its derivatives and salts	134-49-6
518	Thiamazole (INN)	60-56-0
519	Carisoprodol (INN)	78-44-4
520	Meprobamate (INN)	57-53-4
521	Tefazoline (INN) and its salts	1082-56-0
522	Poldine metilsulfate (INN)	545-80-2
523	Hydroxyzine (INN)	68-88-2

No.	Chemical name	CAS No.
524	Naphazoline (INN) and its salts	835-31-4
525	Neostigmine and its salts e. g. neostigmine bromide (INN)	114-80-7
526	Furazolidone (INN)	67-45-8
527	Acenocoumarol (INN)	152-72-7
528	Noscapine (INN) and its salts	128-62-1
529	Guanethidine (INN) and its salts	55-65-2
530	Chlortalidone (INN)	77-36-1
531	Pentaerithrityl tetranitrate (INN)	78-11-5
532	Petrichloral (INN)	78-12-6
533	Octamylamine (INN) and its salts	502-59-0
534	Phenacemide (INN)	63-98-9
535	Difencloxazine (INN)	5617-26-5
536	2-Phenylindan-1,3-dione (phenindione (INN))	83-12-5
537	Ethylphenacemide (pheneturide (INN))	90-49-3
538	Phenprocoumon (INN)	435-97-2
539	Fenyramidol (INN)	553-69-5
540	Psilocybine (INN)	520-52-5
541	Thalidomide (INN) and its salts	50-35-1
542	α-Piperidin-2-ylbenzyl acetate, laevorotatory threoform (levofacetoperane (INN)) and its salts	24558-01-8
543	Pipradrol (INN) and its salts	467-60-7
544	Azacyclonol (INN) and its salts	115-46-8
545	Bietamiverine (INN)	479-81-2
546	Butopiprine (INN) and its salts	55837-15-5
547	Metyrapone (INN)	54-36-4
548	Sparteine (INN) and its salts	90-39-1
549	Sultiame (INN)	61-56-3
550	Xylometazoline (INN) and its salts	526-36-3
551	Ethionamide (INN)	536-33-4

No.	Chemical name	CAS No.
552	Phenothiazine (INN) and its compounds	92-84-2
553	Mephenesin (INN) and its esters	59-47-2
554	Tranylcypromine (INN) and its salts	155-09-9
555	Tretamine (INN)	51-18-3
556	Gallamine triethiodide (INN)	65-29-2
557	Ergocalciferol (INN) and cholecalciferol (vitamins D2 and D3)	50-14-6/ 67-97-0
558	Dimethyl sulfoxide (INN)	67-68-5
559	Diphenhydramine (INN) and its salts	58-73-1
560	Dihydrotachysterol (INN)	67-96-9
561	Tripelennamine (INN)	91-81-6
562	Bithionol (INN)	97-18-7
563	Pyrithione sodium (INNM)	3811-73-2
564	6-(Piperidinyl)-2,4-pyrimidinediamine 3-oxide (Minoxidil (INN)) and its salts	38304-91-5
565	3,4',5-Tribromosalicylanilide (Tribromsalan (INN))	87-10-5
566	Amyl 4-dimethylaminobenzoate, mixed isomers (Padimate A (INN))	14779-78-3
567	Tetrahydrozoline (Tetryzoline (INN)) and its salts	84-22-0
568	Lidocaine (INN)	137-58-6
569	Pramocaine (INN)	140-65-8
570	Phytonadione [INCI] / phytomenadione [INN]	84-80-0/ 81818-54-4
571	Thallium and its compounds	7440-28-0
572	Beryllium and its compounds	7440-41-7
573	Neodymium and its salts	7440-00-8
574	Tellurium and its compounds	13494-80-9
575	1-Methyl-2,4,5-trihydroxybenzene and its salts cannot be used in hair dye products.	1124-09-0
576	2,6-Dihydroxy-4-methylpyridine and its salts cannot be used in hair dye products.	4664-16-8
577	5-Hydroxy-1,4-benzodioxane and its salts cannot be used in hair dye products.	10288-36-5

No.	Chemical name	CAS No.
578	3,4-Methylenedioxyphenol and its salts cannot be used in hair dye products.	533-31-3
579	3,4-Methylenedioxyaniline and its salts cannot be used in hair dye products.	14268-66-7
580	Hydroxypyridinone and its salts cannot be used in hair dye products.	822-89-9
581	3-Nitro-4-aminophenoxyethanol and its salts cannot be used in hair dye products.	50982-74-6
582	2-Methoxy-4-nitrophenol (4-Nitroguaiacol) and its salts cannot be used in hair dye products.	3251-56-7
583	CI Acid Black 131 and its salts cannot be used in hair dye products.	12219-01-1
584	1,3,5-Trihydroxybenzene (Phloroglucinol) and its salts cannot be used in hair dye products.	108-73-6
585	1,2,4-Benzenetriacetate and its salts cannot be used in hair dye products.	613-03-6
586	Ethanol, 2,2' -iminobis-, reaction products with epichlorohydrin and 2-nitro-1,4-benzenediamine (HC Blue No 5) and its salts cannot be used in hair dye products.	68478-64-8/ 158571-58-5
587	*N*-Methyl-1,4-diaminoanthraquinone, reaction products with epichlorohydrin and monoethanolamine (HC Blue No 4) and its salts cannot be used in hair dye products.	158571-57-4
588	4-Aminobenzenesulfonic acid (Sulfanilic acid) and its salts cannot be used in hair dye products.	121-57-3/ 515-74-2
589	3,3'-(Sulfonylbis(2-nitro-4,1-phenylene)imino) bis(6-(phenylamino))benzenesulfonic acid and its salts cannot be used in hair dye products.	6373-79-1
590	3(or5)-((4-(Benzylmethylamino)phenyl)azo)-1,2-(or1,4)-dimethyl-1H-1,2,4-triazolium and its salts cannot be used in hair dye products.	89959-98-8/12221-69-1
591	2,2'-((3-Chloro-4-((2,6-dichloro-4-nitrophenyl) azo)phenyl)imino)bisethanol (Disperse Brown 1) and its salts cannot be used in hair dye products.	23355-64-8
592	Benzothiazolium, 2-[[4-[ethyl(2-hydroxyethyl)amino]phenyl]azo]-6-methoxy-3-methyl- and its salts cannot be used in hair dye products.	12270-13-2
593	2-[(4-Chloro-2-nitrophenyl)azo)-*N*-(2-methoxyphenyl)-3-oxobutanamide (Pigment Yellow 73) and its salts cannot be used in hair dye products.	13515-40-7
594	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-*N*-phenylbutanamide] (Pigment Yellow 12) and its salts cannot be used in hair dye products.	6358-85-6
595	2,2'-(1,2-Ethenediyl)bis[5-((4-ethoxyphenyl)azo]benzenesulfonic acid) and its salts cannot be used in hair dye products.	2870-32-8

No.	Chemical name	CAS No.
596	2,3-Dihydro-2,2-dimethyl-6-[(4-(phenylazo)-1-naphthelenyl)azo]-1H-pyrimidine (Solvent Black 3) and its salts cannot be used in hair dye products.	4197-25-5
597	3(or5)-[[4-[(7-amino-1-hydroxy-3-sulphonato-2-naphthyl)azo]-1-naphthyl]azo]salicylic acid and its salts cannot be used in hair dye products.	3442-21-5/ 34977-63-4
598	2-Naphthalenesulfonic acid, 7-(benzoylamino)-4-hydroxy-3-[[4-[(4-sulfophenyl)azo]phenyl]azo]- and its salts cannot be used in hair dye products.	2610-11-9
599	(μ-((7,7'-Iminobis(4-hydroxy-3-((2-hydroxy-5-(N-methylsulphamoyl)phenyl)azo)naphthalene-2-sulphonato))(6-)))dicuprate(2-) and its salts cannot be used in hair dye products.	37279-54-2
600	3-[(4-(Acetylamino)phenyl)azo]-4-hydroxy-7-[[[[5-hydroxy-6-(phenylazo)-7-sulfo-2-naphthalenyl]amino]carbonyl]amino]-2-naphthalenesulfonic acid and its salts cannot be used in hair dye products.	3441-14-3
601	2-Naphthalenesulfonic acid, 7,7'-(carbonyldiimino)bis(4-hydroxy-3-[[2-sulfo-4-[(4-sulfophenyl)azo]phenyl]azo]-, and its salts cannot be used in hair dye products.	2610-10-8/ 25188-41-4
602	Ethanaminium, *N*-(4-[bis[4-(diethylamino)phenyl]methylene]-2,5-cyclohexadien-1-ylidine)-*N*-ethyl- and its salts cannot be used in hair dye products.	2390-59-2
603	3H-Indolium, 2-[[(4-methoxyphenyl)methylhydrazono]methyl]-1,3,3-trimethyl- and its salts cannot be used in hair dye products.	54060-92-3
604	3H-Indolium, 2-(2-((2,4-dimethoxyphenyl)amino)ethenyl]-1,3,3-trimethyl- and its salts cannot be used in hair dye products.	4208-80-4
605	Nigrosine spirit soluble (Solvent Black 5) and its salts cannot be used in hair dye products.	11099-03-9
606	Phenoxazin-5-ium, 3,7-bis(diethylamino)-, and its salts cannot be used in hair dye products.	47367-75-9/ 33203-82-6
607	Benzo[a]phenoxazin -7-ium, 9-(dimethylamino)-, and its salts cannot be used in hair dye products.	7057-57-0/ 966-62-1
608	6-Amino-2-((2,4-dimethylphenyl)-1H-benz[de]isoquinoline-1,3(2H)-dione (Solvent Yellow 44) and its salts cannot be used in hair dye products.	2478-20-8
609	1-Amino-4-[[4-[(dimethylamino)methyl]phenyl]amino]anthraquinone and its salts cannot be used in hair dye products.	67905-56-0/ 12217-43-5
610	Laccaic acid (CI Natural Red 25) and its salts cannot be used in hair dye products.	60687-93-6
611	Benzenesulfonic acid, 5 -[(2,4-dinitrophenyl]amino]-2-(phenylamino)-, and its salts cannot be used in hair dye products.	6373-74-6/

No.	Chemical name	CAS No.
		15347-52-1
612	4-[(4-Nitrophenyl)azo]aniline (Disperse Orange 3) and its salts cannot be used in hair dye products.	730-40-5/ 70170-61-5
613	4-Nitro-*m*-phenylenediamine and its salts cannot be used in hair dye products.	5131-58-8
614	1-Amino-4-(methylamino)-9,10-anthracenedione (Disperse Violet 4) and its salt cannot be used in hair dye products.	1220-94-6
615	*N*-Methyl-3-nitro-*p*-phenylenediamine and its salts cannot be used in hair dye products.	2973-21-9
616	N1-(2-Hydroxyethyl)-4-nitro-*o*-phenylenediamine (HC Yellow No 5) and its salts cannot be used in hair dye products.	56932-44-6
617	N1-(Tris(hydroxymethyl))methyl-4-nitro-1,2-phenylenediamine (HC Yellow No 3) and its salts cannot be used in hair dye products.	56932-45-7
618	2-Nitro-*N*-hydroxyethyl-*p*-anisidine and its salts cannot be used in hair dye products.	57524-53-5
619	*N,N'*-Dimethyl-*N*-hydroxyethyl-3-nitro-*p*-phenylenediamine and its salts cannot be used in hair dye products.	10228-03-2
620	3-(*N*-Methyl-*N*-(4-methylamino-3-nitrophenyl)amino)propane-1,2-diol and its salts cannot be used in hair dye products.	93633-79-5
621	4-Ethylamino-3-nitrobenzoic acid (*N*-Ethyl-3-Nitro PABA) and its salts cannot be used in hair dye products.	2788-74-1
622	(8-[(4-Amino-2-nitrophenyl)azo]-7-hydroxy-2-naphthyl)trimethylammonium and its salts, (except Basic Red 118 as impurity in Basic brown 17) cannot be used in hair dye products.	71134-97-9
623	5-((4-(Dimethylamino)phenyl)azo)-1,4-dimethyl-1H-1,2,4-triazolium and its salts cannot be used in hair dye products.	12221-52-2
624	*m*-Phenylenediamine, 4-(phenylazo)-, and its salts cannot be used in hair dye products.	495-54-5
625	1,3 -Benzenediamine, 4-methyl-6-(phenylazo)- and its salts cannot be used in hair dye products.	4438-16-8
626	2,7 -Naphthalenedisulfonic acid, 5-(acetylamino)-4-hydroxy-3-((2-methylphenyl)azo)- and its salts cannot be used in hair dye products.	6441-93-6
627	4,4'-[(4-Methyl-1,3-phenylene)bis(azo)]bis[6-methyl-1,3-benzenediamine] (Basic Brown 4) and its salts cannot be used in hair dye products.	4482-25-1
628	Benzenaminium, 3-[[(4-[[diamino(phenylazo)phenyl]azo]-2-methylphenyl]azo]-*N,N,N*-trimethyl- and its salts cannot be used in hair dye products.	83803-99-0
629	Benzenaminium, 3-[[(4-[[diamino(phenylazo)phenyl]azo]-1-naphthalenyl]azo]-*N,N,N*-trimethyl- and its salts cannot be used in hair dye products.	83803-98-9
630	Ethanaminium, *N*-(4-[(4-(diethylamino)phenyl)phenylmethylene]-2,5-cyclohexadien-1-ylidine)-*N*-ethyl- and its salts cannot be used in hair dye products.	633-03-4
631	9,10-Anthracenedione, 1-[(2-hydroxyethyl)amino]-4-(methylamino)-, and its derivatives and salts cannot be used in	2475-46-9/

No.	Chemical name	CAS No.
	hair dye products.	86722-66-9
632	1,4 -Diamino-2-methoxy-9,10-anthracenedione (Disperse Red 11) and its salts cannot be used in hair dye products.	2872-48-2
633	1,4-Dihydroxy-5,8-bis[(2-hydroxyethyl)amino]anthraquinone (Disperse Blue 7) and its salts cannot be used in hair dye products.	3179-90-6
634	1-[(3-Aminopropyl)amino]-4-(methylamino)anthraquinone and its salts cannot be used in hair dye products.	22366-99-0
635	*N*-[6-[(2-Chloro-4-hydroxyphenyl)imino]-4-methoxy-3-oxo-1,4-cyclohexadien-1-yl]acetamide (HC Yellow No 8) and its salts cannot be used in hair dye products.	66612-11-1
636	[6-[[3-Chloro-4-(methylamino)phenyl]imino]-4-methyl-3-oxocyclohexa-1,4-dien-1-yl]urea (HC Red No 9) and its salts cannot be used in hair dye products.	56330-88-2
637	Phenothiazin-5-ium, 3,7-bis(dimethylamino)- and its salts cannot be used in hair dye products.	61-73-4
638	4,6-Bis(2-hydroxyethoxy)-*m*-phenylenediamine and its salts cannot be used in hair dye products.	94082-85-6
639	5-Amino-2,6-dimethoxy-3-hydroxypyridine and its salts cannot be used in hair dye products.	104333-03-1
640	4-Diethylamino-*o*-toluidine and its salts cannot be used in hair dye products.	148-71-0/ 24828-38-4/ 2051-79-8
641	Toluene-3,4-Diamine and its salts cannot be used in hair dye products.	496-72-0
642	2-Nitro-*p*-phenylenediamine and its salts cannot be used in hair dye products.	5307-14-2/ 18266-52-9
643	Phenazinium, 3,7-diamino-2,8-dimethyl-5-phenyl- and its salts cannot be used in hair dye products.	477-73-6
644	3-Hydroxy-4-[(2-hydroxynaphthyl)azo]-7-nitronaphthalene-1-sulphonic acid and its salts cannot be used in hair dye products.	16279-54-2/ 5610-64-0
645	3-[[4-[(2-Hydroxyethyl)methylamino]-2-nitrophenyl]amino]-1,2-propanediol and its salts cannot be used in hair dye products.	173994-75-7/ 102767-27-1
646	3-[[4-[(2-Hydroxyethyl)amino]-2-nitrophenyl]amino]-1,2-propanediol and its salts cannot be used in hair dye products.	114087-41-1/ 114087-42-2
647	Ethanaminium, *N*-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidine]-*N*-ethyl-, and its salts cannot be used in hair dye products.	2390-60-5

No.	Chemical name	CAS No.
648	Raw material made from bovine and sheep tissues in countries where Bovine Spongiform Encephalopathy occurs. (Except for lanolin and gelatin through alkali treatment other than from England, milk and milk product other than from England, and tallow derivatives such as fatty acid, amino acid and glycerin. The manufacturing process of tallow derivatives should process viruses or other antigens with deactivation methods.) (1) The countries where Bovine Spongiform Encephalopathy occurs is as determined by the List of Infectious Animal Diseases-free and Disease Infected Countries (Zones) announced by Council of Agriculture, Executive Yuan. (2) Tissues including Brain, Spinal cord, Eye, Ileum, Lymph nodes, Proximal Colon, Spleen, Tonsil, Dura mater, Pineal gland, Placenta, Cerebrospinal fluid, Pituitary gland, Adrenal gland, Distal colon, Nasal mucosa, Peripheral nerves, Bone marrow, Liver, Lung, Pancreas, and Thymus gland.	-
※Pharmaceutical ingredients (including controlled drugs) without public announcement of or approval of the central competent authority are prohibited in cosmetics.		

19 Ingredients Limitation and Hygiene Standards of Cosmetic Products

19.3 List of Preservatives in Cosmetic Products

List of Preservatives in Cosmetic Products

Effective Date：2020-07-01

Category：Ministry of Health and Welfare

This rule has been translated into English according to the original Chinese version. If there is any inconsistency or ambiguity between these two versions, the Chinese version shall prevail.

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
1	Alkyl (C12-22) trimethyl ammonium bromide and chloride	Behentrimonium chloride(1)/ Cetrimonium bromide/ Cetrimonium chloride(1)/ Laurtrimonium bromide/ Laurtrimonium chloroide/ Steartrimonium bromide/ Steartrimonium chloride(1)	17301-53-0/ 57-09-0/ 112-02-7/ 1119-94-4/ 112-00-5/ 1120-02-1/ 112-03-8		0.1%		
2	Benzalkonium chloride, bromide and saccharinate(1)	Benzalkonium chloride/ Benzalkonium bromide/ Benzalkonium	8001-54-5/ 91080-29-4/ 61789-71-7/ 63449-41-2/ 68391-01-5/		0.1% (as benzalkonium chloride)		Avoid contact with eyes

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
		saccharinate	68424-85-1/ 68989-01-5/ 85409-22-9				
3	Benzenemethanaminium, N,N-dimethyl-N-[2-[2-[4-(1,1,3,3,-tetramethylbutyl)phen o-xy]ethoxy] ethyl]-, chloride	Benzethonium chloride	121-54-0	(a)Rinse off products (b)Leave on products other than oral products	0.1%		
4	Salts of benzoic acid and esters of benzoic acid	Ammonium benzoate/ Butyl benzoate/ Calcium benzoate/ Ethyl benzoate/ Isobutyl benzoate/ Isopropyl benzoate/ Magnesium benzoate/ MEA-benzoate/ Methyl benzoate/ Phenyl benzoate/ Potassium benzoate/ Propyl benzoate/	1863-63-4/ 2090-05-3/ 582-25-2/ 553-70-8/ 4337-66-0/ 93-58-3/ 93-89-0/ 2315-68-6/ 136-60-7/ 1205-50-3/ 939-48-0/ 93-99-2/		0.5% (as acid)		

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
5	Benzoic acid and its sodium salt	Benzoic acid/ Sodium benzoate	65-85-0/ 532-32-1	(a)Leave-on products other than oral products (b)Leave on products (c)Oral products	(a)2.5% (as acid) (b)0.5% (as acid) (c)1.7% (as acid)		
6	Benzyl alcohol	Benzyl alcohol	100-51-6		1%		
7	2-Benzyl-4-chlorophenol	Chlorophene	120-32-1		0.2%		
8	Tosylchloramide sodium	Chloramine T	127-65-1		0.2%		
9	N,N'-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazat-etradecanediamidine and its digluconate, diacetate and dihydrochloride	Chlorhexidine/ Chlorhexidine digluconate/ Chlorhexidine dihydrochloride/ Chlorhexidine diacetate	55-56-1/ 18472-51-0/ 3697-42-5 56-95-1/		0.3% (as chlorhexidine)		
10	Chlorobutanol	Chlorobutanol	57-15-8		0.5%	Not to be used in aerosol products	Contains Chlorobutanol
11	Chlorocresol	p-Chloro-m-cresol	59-50-7		0.2%	Not to be used in products	

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
						applied on mucous mem- branes	
12	Chloroxylenol	Chloroxylenol	88-04-0/ 1321-23-9		0.5%		
13	1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate and 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, silver(1+) salt, monohydrate	Citric acid (and) Silver citrate	-		0.2% (Corresponding to 0.0024% of silver)	Not to be used in oral products and eye products	
14	1-(4-Chlorophenoxy)-1-(imi-dazol-1-yl)-3,3-dimethylbutan-2-one	Climbazole	38083-17-9		0.5%		
15	3-Acetyl-6-methylpyran-2,4 (3H)-dione and its salts	Dehydroacetic acid/ Sodium dehydroacetate	520-45-6/ 16807-48-0/ 4418-26-2		0.6% (as acid)	Not to be used in aerosol products	
16	4,4-Dimethyl-1,3-oxazolidine	Dimethyl oxazolidine	51200-87-4		0.1%	pH>6	
17	2,2'-Methylenebis(6-bromo-4-	Bromochlorophene	15435-29-7		0.1%		

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
	chlorophenol)						
18	3,3'-Dibromo-4,4'-hexameth-ylene dioxydibenzamidine and its salts (including isethionate)	Dibromohexamidine isethionate	93856-83-8		0.1%		
19	2,4-Dichlorobenzyl alcohol	Dichlorobenzyl alcohol	1777-82-8		0.15%		
20	Ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride(1)	Ethyl lauroyl arginate HCl	60372-77-2	(a)Mouthwashes (b)Other products	(a)0.15% (b)0.4%	(a)Not to be used in prep-arations for children under 10 years of age (b)Not to be used in lip, oral products (other than mouthwashes), and spray products.	(a)Not to be used for children under 10 years of age.
21	5-Ethyl-3,7-dioxa-1-azabicyc-lo [3.3.0] octane	7-Ethylbicyclooxazolidine	7747-35-5		0.3%	Not to be used in oral products and in products applied on mucous mem-branes	
22	Formic acid and its	Formic acid/	64-18-6/		0.5% (as acid)		

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
	sodium salt	Sodium formate	141-53-7				
23	Glutaraldehyde (Pentane-1,5-dial)	Glutaral	111-30-8		0.1%	Not to be used in spray products	If the concentration ex- ceeds 0.05%: Contains glutaral
24	Benzenecarboximidamide, 4,4'-(1,6-hexanediylbis (oxy))bis- and its salts (including isethionate and p-hydroxybenzoate)	Hexamidine/ Hexamidine diisethionate/ Hexamidine paraben	3811-75-4/ 659-40-5/ 93841-83-9		0.1%		
25	5-Pyrimidinamine, 1,3-bis (2-ethylhexyl) hexahydro-5-methyl	Hexetidine	141-94-6		0.1%		
26	Inorganic sulphites and hydrogensulphites(1)	Sodium sulfite(3)/ Sodium bisulfite/ Sodium metabisulfite/ Potassium sulfite/ Potassium metabisulfite/ Ammonium sulfite/ Ammonium bisulfite	7757-83-7/ 7631-90-5/ 7681-57-4/ 10117-38-1/ 16731-55-8/ 10196-04-0/ 10192-30-0/ 7773-03-7		0.2% (as free SO_2)		

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
27	3-Iodo-2-propynylbutylcarba-mate ([2])	Iodopropynyl butylcarbamate	55406-53-6	(a)Rinse off products (b)Leave on products (c)Deodorants and an- ti-perspirants	(a)0.02% (b)0.01% (c)0.0075%	Not to be used in oral and lip products (a)Not to be used in prod- ucts for children under 3 years of age, except in bath products/ shower gels and shampoo (b)Not to be used in body lotion and body cream (b)&(c)Not to be used in products for children un- der 3 years of age	(a)Precautions (other than bath products and sham-poo): Not to be used for children under 3 years of age. (b)&(c): Not to be used in products for children un- der 3 years of age.
28	4-Isopropyl-m-cresol	o-Cymen-5-ol	3228-02-2		0.1%		
29	2-Methyl-2H-isothiazol-3-one	Methylisothiazolinone	2682-20-4	Rinse off products	0.0015%		
30	Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-Methylisothiazol-	Methylchloroisothiazol inone and Methylisothiazolinone	55965-84-9, 26172-55-4, 2682-20-4	Rinse off products	0.0015%	Mixture in the ratio 3:1 of 5-Chloro-2-methyl-isothia zol-3(2H)-one and 2-	

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
	3(2H)-one with magnesium chloride and magnesium nitrate					Methylisothiazol-3(2H)-one	
31	Biphenyl-2-ol, and its salts	o-Phenylphenol/ Sodium o-phenylphenate/ MEA o-phenylphenate/ Potassium o-phenylphenate	90-43-7/ 132-27-4/ 84145-04-0/ 13707-65-8		0.2% (as phenol)		
32	Butyl 4-hydroxybenzoate and its salts Propyl 4-hydroxybenzoate and its salts(2)	Butylparaben/ Propylparaben/ Sodium propylparaben/ Sodium butylparaben/ Potassium butylparaben/ Potassium propylparaben	94-26-8/ 94-13-3/ 35285-69-9/ 36457-20-2/ 38566-94-8/ 84930-16-5		(a)0.14% (as acid), for the sum of the individual concentrations (b)0.8% (as acid), for mixtures of No.32 and 33, where the sum of the individual concentrations of butylparaben and propylparaben and their salts does not exceed 0.14 %	Not to be used in leave-on products for application on the nappy area of children under 3 years of age.	Precautions for leave-on products: Not to be used in leave-on products for application on the nappy area of children under 3 years of age.
33	4-Hydroxybenzoic	Methylparaben/	99-76-3/		(a)0.4% (as acid),		

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
	acid and its Methyl- and Ethyl- esters, and their salts	Ethylparaben/ 4-Hydroxybenzoic acid/ Potassium ethylparaben/ Potassium paraben/ Sodium methylparaben/ Sodium ethylparaben/ Sodium paraben/ Potassium methylparaben/ Calcium paraben	120-47-8/ 99-96-7/ 36457-19-9/ 16782-08-4/ 5026-62-0/ 35285-68-8/ 114-63-6/ 26112-07-2/ 69959-44-0		single ester (b)0.8% (as acid), mixtures of esters		
34	3-(p-chlorophenoxy)-propane-1,2-diol	Chlorphenesin	104-29-0		0.3%		
35	2-Phenoxyethanol	Phenoxyethanol	122-99-6		1%		
36	1-Phenoxypropan-2-ol(1)	Phenoxyisopropanol	770-35-4	Rinse-off products	1%		
37	Phenylmercuric salts (including borate)	Phenyl mercuric acetate/ Phenyl mercuric benzoate	62-38-4/ 94-43-9	Eye products	0.007% (as Hg)	When mixed with other mercurial compounds authorised by Regulation, the maximum	Contains Phenylmercuric compounds

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
						concentration of Hg remains fixed at 0.007%	
38	1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2 pyridon and its monoethanolamine salt	1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-pyridon/ Piroctone olamine	50650-76-5/ 68890-66-4	(a)Rinse-off products (b)Other products	(a)1% (b)0.5%		
39	Poly(methylene),.alpha.,.ome-ga.-bis[[[(aminoiminomethyl)amino]iminomethyl]amino]-, dihydrochloride	Polyaminopropyl biguanide	32289-58-0/ 133029-32-0/ 28757-47-3/ 27083-27-8		0.3%		
40	Propionic acid and its salts	Propionic acid/ Sodium propionate/ Ammonium propionate/ Calcium propionate/ Magnesium propionate/ Potassium propionate	79-09-4/ 137-40-6/ 17496-08-1/ 4075-81-4/ 557-27-7/ 327-62-8		2% (as acid)		
41	Salicylic acid and its	Salicylic acid(3) /	69-72-7/		0.5% (as acid)	Not to be used in	Precautions (other

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
	salts	Calcium salicylate/ Magnesium salicylate/ MEA-salicylate/ Sodium salicylate/ Potassium salicylate/ TEA-salicylate	824-35-1/ 18917-89-0/ 59866-70-5/ 54-21-7/ 578-36-9/ 2174-16-5			products for children under 3 years of age, except for shampoos	than shampoos): Not to be used for children under 3 years of age.
42	Silver Chloride deposited on titanium dioxide	Silver chloride	7783-90-6		0.004% (as AgCl)	20% AgCl (w/w) on TiO_2; Not to be used in products for children under 3 years of age, in oral products and in eye and lip products	
43	Hexa-2,4-dienoic acid and its salts	Sorbic acid/ Potassium sorbate/ Calcium sorbate/ Sodium sorbate	110-44-1/ 24634-61-5/ 7492-55-9/ 7757-81-5		0.6% (as acid)		
44	Thiomersal	Thimerosal	54-64-8	Eye products	0.007% (as Hg)	When mixed with other mercurial compounds authorised by Regulation, the maximum concentration of Hg	Contains Thiomersal

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
						remains fixed at 0.007%	
45	5-Chloro-2- (2,4-dichlorophenoxy) phenol	Triclosan	3380-34-5	(a)Toothpastes, Hand soaps, Body soaps/ Shower gels, Deodorants (other than spray products), Face powders, Foundation, Nail products for cleaning the finger-nails and toenails before the application of artificial nail systems (b)Mouthwashes	(a)0.3% (b)0.2%		
46	1-(4-Chlorophenyl)-3-(3,4-di-chlorophenyl) urea(3)	Triclocarban	101-20-2		0.2%	Purity criteria: 3,3',4,4'-Tetrachloroazobenzene <1 ppm; 3,3',4,4'-	

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
						Tetrachloroazoxybenzene <1 ppm	
47	Undec-10-enoic acid and its salts	Undecylenic acid/ Potassium undecylenate/ Calcium undecylenate/ Sodium undecylenate/ MEA-undecylenate/ TEA-undecylenate	112-38-9/ 6159-41-7/ 1322-14-1/ 3398-33-2/ 56532-40-2/84471-25-0		0.2% (as acid)		
48	Pyrithione zinc(1)	Zinc pyrithione	13463-41-7	(a)Hair products (b)Other products	(a)1% (b)0.5%	Only rinse-off products; Not to be used in oral products	
49	5-Bromo-5-nitro-1,3-dioxane	5-Bromo-5-nitro-1,3-dioxane	30007-47-7	Rinse-off products	0.1%	Avoid formation of nitrosamines; When used as preservatives in cosmetic products, the total amount of released free formaldehyde should not exceed 1000 ppm	
50	Bronopol	2-Bromo-2-	52-51-7		0.1%	Avoid formation of	

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
		nitropropane-1,3-diol				nitrosamines; When used as preservatives in cosmetic products, the total amount of released free formaldehyde should not exceed 1000 ppm	
51	Methanol, (phenylmethoxy-)	Benzylhemiformal	14548-60-8	Rinse-off products	0.15%	When used as preservatives in cosmetic products, the total amount of released free formaldehyde should not exceed 1000 ppm	
52	1,3-Bis (hydroxymethyl)-5,5-dimethylimidazolid-ine-2,4-dione	DMDM hydantoin	6440-58-0		0.6%	When used as preservatives in cosmetic products, the total amount of released free formaldehyde should not exceed	

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
						1000 ppm	
53	N-(Hydroxymethyl)-N- (dihydroxymethyl-1,3-dioxo-2,5-imidazolidinyl-4)-N'-(hydroxymethyl) urea	Diazolidinyl urea	78491-02-8		0.5%	When used as preservatives in cosmetic products, the total amount of released free formaldehyde should not exceed 1000 ppm	
54	N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	Imidazolidinyl urea	39236-46-9		0.6%	When used as preservatives in cosmetic products, the total amount of released free formaldehyde should not exceed 1000 ppm	
55	Methenamine	Methenamine	100-97-0		0.15%	When used as preservatives in cosmetic products, the total amount of released free formaldehyde should not exceed	

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
						1000 ppm	
56	Methenamine 3-chloroallylochloride	Quaternium-15	4080-31-3		0.2%	When used as preservatives in cosmetic products, the total amount of released free formaldehyde should not exceed 1000 ppm	
57	Sodium hydroxymethylamino acetate	Sodium hydroxymethylglycinate	70161-44-3		0.5%	When used as preservatives in cosmetic products, the total amount of released free formaldehyde should not exceed 1000 ppm	

(1) For use other than as a preservative, see “List of Ingredients Restricted in Cosmetic Products”
(2) If the product is indeed not involved in the use of children under the age of three, the business may determine whether it is necessary to print the precautions based on the attributes of the product. However, if the product endangers consumers’ bodies and health because of not printing the precautions, the business shall assume related responsibility for its own.
(3) For use other than as a preservative, see “List of Specific Purpose Ingredients in Cosmetic”
※ Regarding preservatives not listed within this table, if a jurisdiction such as the European Union, the United States or Japan has already announced permission of use and have applicable regulations,

No.	Chemical name	INCI name	CAS No.	Product type/ Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
the preservative can also be used in accordance to respective standards. If there's a difference between the above jurisdictions, the safest limitation should be applied. ※ The “oral products” in the list means non-pharmaceutical toothpaste and mouthwash, and teeth whitening products.							

19 Ingredients Limitation and Hygiene Standards of Cosmetic Products

19.4 List of Colorants in Cosmetic Products

List of Colorants in Cosmetic Products

Effective Date：2021-07-01

Category：Ministry of Health and Welfare

This rule has been translated into English according to the original Chinese version. If there is any inconsistency or ambiguity between these two versions, the Chinese version shall prevail.

Explanation of Colorants Classification：
Class 1：Colorants allowed in all cosmetic products
Class 2：Colorants allowed in all cosmetic products except those intended to be applied in the vicinity of the eyes
Class 3：Colorants allowed exclusively in cosmetic products intended not to come into contact with the mucous membranes
Class 4：Colorants allowed exclusively in cosmetic products intended to come into contact only briefly with the skin

Number	Colour Index Number/ Ingredient Name	Alias Name	Scope of Application	Restriction
1	CI 10006	Pigment Green 8	4	
2	CI 10020	Acid Green 1 Ext. D&C Green No. 1 Naphthol Green B	3	Using in hair dye products is forbidden.
3	CI 10316	Acid Yellow 1 Ext. D&C Yellow No. 7 Naphthol Yellow S	2	
4	CI 11680	Pigment Yellow 1 Ext. D&C Yellow No. 5 Hansa Yellow G	3	
5	CI 11710	Pigment Yellow 3	3	
6	CI 11725	Pigment Orange 1 Hansa Yellow 3R	4	
7	CI 11920	Food Orange 3	1	Using in hair dye products is forbidden.
8	CI 12010	Solvent Red 3	3	Using in hair dye products is forbidden.
9	CI 12085	Pigment Red 4 D&C Red No. 36 Permanent Red	1	1. Limited content: 3% 2. Using in hair dye products is

Number	Colour Index Number/ Ingredient Name	Alias Name	Scope of Application	Restriction
				forbidden.
10	CI 12120	Pigment Red 3 D&C Red No. 35 Toluidine Red	4	
11	CI 12370	Pigment Red 112	4	Using in hair dye products is forbidden.
12	CI 12420	Pigment Red 7	4	
13	CI 12480	Pigment Brown 1	4	
14	CI 12490	Pigment Red 5	1	Using in hair dye products is forbidden.
15	CI 12700	Disperse Yellow 16	4	
16	CI 13015	Acid Yellow 9 Food Yellow 2 Fast Yellow	1	
17	CI 14270	Acid Orange 6	1	Using in hair dye products is forbidden.
18	CI 14700	Food Red 1 FD&C Red No. 4 Ponceau SX	1	Using in hair dye products is forbidden.
19	CI 14720	Acid Red 14 Food Red 3 Azorubin	1	
20	CI 14815	Food Red 2	1	
21	CI 15510	Acid Orange 7 D&C Orange No. 4 Orange II	2	
22	CI 15525	Pigment Red 68	1	
23	CI 15580	Pigment Red 51	1	
24	CI 15620	Acid Red 88 Ext. D&C Red No. 8 Fast Red S	4	

Number	Colour Index Number/ Ingredient Name	Alias Name	Scope of Application	Restriction
25	CI 15630	Pigment Red 49 D&C Red No. 10 Lithol Red Na Pigment Red 49:1 D&C Red No. 12 Lithol Red Ba Pigment Red 49:2 D&C Red No. 11 Lithol Red Ca Pigment Red 49:3 D&C Red No. 13 Lithol Red Sr	1	Limited content: 3%
26	CI 15800	Pigment Red 64 Pigment Red 64:1 D&C Red No. 31 Brilliant Lake Red R	3	Using in hair dye products is forbidden.
27	CI 15850	Pigment Red 57 D&C Red No. 6 Lithol Rubine B Pigment Red 57:1 D&C Red No. 7 Lithol Rubine B Ca	1	
28	CI 15865	Pigment Red 48 Permanent Red F5R	1	Using in hair dye products is forbidden.
29	CI 15880	Pigment Red 63 Pigment Red 63:1 D&C Red No. 34 Deep Maroon	1	Using in hair dye products is forbidden.
30	CI 15980	Food Orange 2	1	
31	CI 15985	Food Yellow 3 FD&C Yellow No. 6 Sunset Yellow FCF	1	
32	CI 16035	Food Red 17 FD&C Red No. 40 Allura Red Ac	1	
33	CI 16185	Food Red 9 Acid Red 27	1	Using in hair dye products is forbidden.
34	CI 16230	Acid Orange 10	3	
35	CI 16255	Acid Red 18 Food Red 7	1	

Number	Colour Index Number/ Ingredient Name	Alias Name	Scope of Application	Restriction
		New Coccine		
36	CI 16290	Food Red 8	1	
37	CI 17200	Acid Red 33 D&C Red No. 33 Fast Acid Magenta Food Red 12	1	
38	CI 18050	Acid Red 1 Food Red 10 Fast Crimson 1	3	
39	CI 18130	Acid Red 155	4	
40	CI 18690	Acid Yellow 121	4	
41	CI 18736	Acid Red 180	4	
42	CI 18820	Acid Yellow 11 Ext. D&C Yellow No. 3 Fast Light Yellow 3G	4	
43	CI 18965	Food Yellow 5	1	
44	CI 19140	Acid Yellow 23 FD&C Yellow No. 5 Tartrazine Food Yellow 4	1	
45	CI 20040	Pigment Yellow 16	4	
46	CI 20470	Acid Black 1 Solvent Brown 12 Naphthol Blue Black	4	
47	CI 21100	Pigment Yellow 13	4	Using in hair dye products is forbidden.
48	CI 21108	Pigment Yellow 83	4	
49	CI 21230	Solvent Yellow 29	3	Using in hair dye products is forbidden.
50	CI 24790	Acid Red 163	4	
51	CI 26100	Solvent Red 23 D&C Red No. 17 Sudan III	3	Using in hair dye products is forbidden.

Number	Colour Index Number/ Ingredient Name	Alias Name	Scope of Application	Restriction
52	CI 27755	Food Black 2	1	Using in hair dye products is forbidden.
53	CI 28440	Food Black 1	1	
54	CI 40215	Direct Orange 39	4	
55	CI 40800	beta, beta-Carotene Food Orange 5	1	
56	CI 40820	Food Orange 6	1	
57	CI 40825	Food Orange 7	1	
58	CI 40850	Food Orange 8	1	
59	CI 42045	Acid Blue 1	3	Using in hair dye products is forbidden.
60	CI 42051	Food Blue 5	1	Using in hair dye products is forbidden.
61	CI 42053	Food Green 3 FD&C Green No. 3 Fast Green FCF	1	Using in hair dye products is forbidden.
62	CI 42080	Acid Blue 7	4	
63	CI 42090	Food Blue 2 FD&C Blue No. 1 Brilliant Blue FCF Acid Blue 9 D&C Blue No. 4 Alphazurine FG	1	
64	CI 42100	Acid Green 9	4	
65	CI 42170	Acid Green 22	4	
66	CI 42520	Basic Violet 2	4	Limited content: 5 ppm
67	CI 42735	Acid Blue 104	3	
68	CI 44090	Food Green 4	1	
69	CI 45100	Acid Red 52 Acid Red	4	
70	CI 45190	Acid Violet 9 Ext. D&C Red No. 3	4	Using in hair dye products is

Number	Colour Index Number/ Ingredient Name	Alias Name	Scope of Application	Restriction
		Violamine R		forbidden.
71	CI 45220	Acid Red 50	4	
72	CI 45350	Acid Yellow 73 D&C Yellow No. 8 Uranine D&C Yellow No. 9 Uranine K D&C Yellow No. 7 Fluorescein	1	1. Limited content: 6% 2. Using in hair dye products is forbidden.
73	CI 45370	Acid Orange 11 Solvent Red 72 D&C Orange No. 5 Dibromofluorescein	1	Using in hair dye products is forbidden.
74	CI 45380	Acid Red 87 D&C Red No. 22 Eosine YS Acid Red 87 D&C Red No. 23 Eosine YSK Solvent Red 43 D&C Red No. 21 Tetrabromo Fluorescein	1	Using in hair dye products is forbidden.
75	CI 45396	Solvent Orange 16	1	Using in lip products: the limited content is 1%, and shall be used in free acid form.
76	CI 45405	Acid Red 98	2	
77	CI 45410	Acid Red 92 D&C Red No. 28 Phloxine BK Phloxine B Solvent Red 48 D&C Red No. 27 Tetrachloro tetrabromofluorecein	1	
78	CI 45430	Acid Red 51 FD&C Red No. 3 Erythrosine Food Red 14	1	Using in hair dye products is forbidden.
79	CI 47000	Solvent Yellow 33	3	Using in hair dye

Number	Colour Index Number/ Ingredient Name	Alias Name	Scope of Application	Restriction
		D&C Yellow No. 11 Quinoline Yellow SS		products is forbidden.
80	CI 47005	Acid Yellow 3 D&C Yellow No. 10 Quinoline Yellow WS	1	
81	CI 50325	Acid Violet 50	4	
82	CI 50420	Acid Black 2	3	Using in hair dye products is forbidden.
83	CI 51319	Pigment Violet 23	4	Using in hair dye products is forbidden.
84	CI 58000	Pigment Red 83	1	Using in hair dye products is forbidden.
85	CI 59040	Solvent Green 7 D&C Green No. 8 Pyranin Conc	3	Using in hair dye products is forbidden.
86	CI 60724	Disperse Violet 27	4	
87	CI 60725	Solvent Violet 13 D&C Violet No. 2 Alizarine Purple SS	1	Using in hair dye products is forbidden.
88	CI 60730	Acid Violet 43 Ext. D&C Violet No. 2 Alizarine Violet NR	3	
89	CI 61565	Solvent Green 3 D&C Green No. 6 Quinizarine Green SS	1	Using in hair dye products is forbidden.
90	CI 61570	Acid Green 25 D&C Green No. 5 Alizarine Cyanine Green	1	
91	CI 61585	Acid Blue 80	4	
92	CI 62045	Acid Blue 62	4	
93	CI 69800	Food Blue 4	1	
94	CI 69825	Pigment Blue 64 D&C Blue No. 9 Carbanthrene Blue	1	
95	CI 71105	Vat Orange 7	3	

Number	Colour Index Number/ Ingredient Name	Alias Name	Scope of Application	Restriction
96	CI 73000	Pigment Blue 66 D&C Blue No. 6 Indigo	1	
97	CI 73015	Acid Blue 74 FD&C Blue No. 2 Indigo Carmine	1	
98	CI 73360	D&C Red No. 30 Vat Red 1 Helindone Pink CN	1	Using in hair dye products is forbidden.
99	CI 73385	Vat Violet 2	1	
100	CI 73900	Pigment Violet 19	4	Using in hair dye products is forbidden.
101	CI 73915	Pigment Red 122	4	
102	CI 74100	Pigment Blue 16	4	
103	CI 74160	Pigment Blue 15 Phthalocyanine Blue	1	Using in hair dye products is forbidden.
104	CI 74180	Direct Blue 86	4	Using in hair dye products is forbidden.
105	CI 74260	Pigment Green 7 Phthalocyanine Green	2	Using in hair dye products is forbidden.
106	CI 75100	Natural Yellow 6 Crocetine	1	
107	CI 75120	Natural Orange 4 Annatto	1	
108	CI 75125	Natural Yellow 27 Lycopene	1	
109	CI 75130	Natural Yellow 26 Beta-Carotene	1	
110	CI 75135	Rubixanthin	1	
111	CI 75170	Natural White 1 Guanine	1	
112	CI 75300	Natural Yellow 3 Curcumin	1	
113	CI 75470	Natural Red 4 Carmine	1	
114	CI 75810	Natural Green 3	1	

Number	Colour Index Number/ Ingredient Name	Alias Name	Scope of Application	Restriction
		Sodium Copper Chlorophyllin Chlorophyllin-Copper Complex		
115	CI 77000	Aluminum Powder Pigment Metal 1	1	
116	CI 77002	Pigment White	1	
117	CI 77004	Pigment White 19 Kaolin Bentonite	1	
118	CI 77007	Pigment Blue 29 Ultramarine Blue	1	
119	CI 77015	Pigment Red 101 Pigment Red 102 Aluminum silicate coloured with ferric oxide	1	
120	CI 77019	Pigment White 20 Mica	1	
121	CI 77120	Pigment White 21	1	
122	CI 77163	Pigment White 14 Bismuth Oxychloride	1	
123	CI 77220	Pigment White 18 Calcium Carbonate	1	
124	CI 77231	Pigment White 25 Calcium Sulfate	1	
125	CI 77266	Pigment Black 6 Carbon Black	1	Using in CI 77266 (nano): 1. Particle size ≧ 20 nm 2. Limited content: 10% 3. Using in a product that may be inhaled into the lungs is forbidden.
126	CI 77267	Pigment Black 9 Charcoal, bone	1	
127	CI 77268:1	Food Black 3 Coke Black	1	

Number	Colour Index Number/ Ingredient Name	Alias Name	Scope of Application	Restriction
128	CI 77288	Pigment Green 17 Chromium Oxide	1	
129	CI 77289	Pigment Green 18 Chromium Hydroxide	1	
130	CI 77346	Pigment Blue 28 Cobalt Aluminum Oxide	1	
131	CI 77400	Pigment Metal 2 Bronze Powder Copper Powder	1	
132	CI 77480	Pigment Metal 3 Gold Leaf	1	
133	CI 77489	Ferrous Oxide Iron Oxides	1	
134	CI 77491	Pigment Red 101 Red Iron Oxide	1	
135	CI 77492	Pigment Yellow 11 Yellow Iron Oxide	1	
136	CI 77499	Pigment Black 11 Black Iron Oxide	1	
137	CI 77510	Pigment Blue 27 Ferric Ferrocyanide	1	
138	CI 77713	Pigment White 18 Magnesium Carbonate	1	
139	CI 77742	Pigment Violet 16 Manganese Violet	1	
140	CI 77745	Manganese Phosphate	1	
141	CI 77820	Silver	1	
142	CI 77891[(3)]	Pigment White 6 Titanium dioxide	1	
143	CI 77947[(4)]	Zinc oxide	1	Using in a product that may be inhaled into the lungs is forbidden.
144	Lactoflavin	Riboflavin	1	
145	Caramel	Natural Brown 10	1	
146	Capsanthin, capsorubin		1	
147	Beetroot red		1	

Number	Colour Index Number/ Ingredient Name	Alias Name	Scope of Application	Restriction
148	Anthocyanins		1	
149	Aluminum stearate/ Zinc stearate / Magnesium stearate / Calcium stearate		1	
150	Bromothymol blue		4	
151	Bromocresol green		4	
152	Acid red 195		3	

※ Notes:

1. The lakes and salts formed by the listed colorants and non-prohibitive ingredients may also be used.
2. If any country or region in European Union, the United States or Japan has announced usage standard of the ingredient which is not listed in this chart (based on the effective date), this ingredient is permitted to use per the respective standard (excepted for CI11380 and 19 ingredients listed in the following chart). However, the standard of usage permission as a proven document should be attached when applying for registration.
3. The ingredient is used as non-colorants, it shall refer to the “Ingredients Restricted in Cosmetic Products.”
4. The ingredient is used as non-colorants, it shall refer to the “List of Specific Purpose Ingredients in Cosmetic Products.”

Number	Ingredient Name
1	CI 11380 (Solvent Yellow 5) (Ext. D& C Yellow No.9) (Oil Yellow AB)
2	CI 11390 (Solvent Yellow 6) (Ext. D& C Yellow No.10) (Oil Yellow OB)
3	CI 12100 (Solvent Orange 2) (Ext. D&C Orange No.4) (Orange SS)
4	CI 12140 (Solvent Orange 7) (Ext. D&C Red No.14) (Oil Red XO)
5	CI 12315 (Pigment Red 22) (Brilliant Fast Scarlet)
6	CI 13065 (Acid Yellow 36) (Ext. D& C Yellow No.1) (Metanil Yellow)
7	CI 14600 (Acid Orange 20) (Ext. D&C Orange No.3) (Orange Ⅰ)
8	CI 16150 (Acid Red 26) (D&C Red No. 5) (Poncear 2R)
9	CI 16155 (Food Red 6) (Ext. D&C Red No.15) (Poncear 3R)
10	CI 18950 (Acid Yellow 40) (Ext. D&C Yellow No.4) (Polar Yellow 5G)
11	CI 21090 (Pigment Yellow 12) (Benzidine Yellow G)
12	CI 26105 (Solvent Red 24) (Scarlet Red N.F.)
13	CI 42052 (Na Salt) (Acid Blue 5) (D&C Blue No.7) (Patent Blue Na)
14	CI 42052:1 (Ca Salt) (Acid Blue 5) (D&C Blue No.8) (Patent Blue Ca)
15	CI 42085 (Acid Green 3) (FD&C Green No.1) (Guinea Green B)
16	CI 42095 (Acid Green 5) (D&C Green No.4) (Light Green SF)
17	CI 45440 (Na Salt) (Acid Red 94) (Rose Bengale)
18	CI 45440 (K-Salt) (Acid Red 94) (Rose Bengale k)
19	CI 61520 (Solvent Blue 63) (Suden Blue B)

19 Ingredients Limitation and Hygiene Standards of Cosmetic Products

19.5 List of Ingredients Restricted in Cosmetic Products

List of Ingredients Restricted in Cosmetic Products

Effective Date：2020-01-01

Category：Ministry of Health and Welfare

This rule has been translated into English according to the original Chinese version. If there is any inconsistency or ambiguity between these two versions, the Chinese version shall prevail.

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
1	Allantoin(1)	Allantoin	97-59-6	(a)Leave-on products (b)Rinse-off products	(a)0.2% (b)0.5%		
2	Aluminum potassium bis(sulfate)	Potassium Alum	10043-67-1/ 7784-24-9		1%		
3	Alcloxa	Alcloxa	1317-25-5		1%		
4	Bismuth nitrate, basic	Bismuth subnitrate	1304-85-4		3%		
5	Urea	Urea	57-13-6	(a)Hair dye products (b)Other products	10% 5%		
6	Zinc 4-hydroxybenzene sulphonate	Zinc phenolsulfonate	127-82-2		2%		
7	Cantharides tincture/ Capsicum tincture/ Ginger tincture	-	-	Hair products	1%(total)		
8	Ascorbic acid, monoester with phosphoric acid, magnesium salt (2:3)	Magnesium Ascorbyl Phosphate	114040-31-2/ 113170-55-1		3%		
9	5-Hydroxy-2-	Kojic Acid	501-30-4		2%		

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
	hydroxymethyl-4-pyrone						
10	2-O-alpha-D-Glucopyranosyl-L-ascorbic acid	Ascorbyl Glucoside	129499-78-1		2%		
11	4-Hydroxyphenyl-beta-D-glucopyranoside	Arbutin	497-76-7		7%	Impurity Hydroquinone≦ 20ppm	
12	Sodium Ascorbyl Phosphate	Sodium Ascorbyl Phosphate	66170-10-3		3%		
13	2,3,7,8-Tetrahydroxy-[1]-benzopyrano[5,4,3,-cde]-[1]-benzopyran-5,10-dione	Ellagic Acid	476-66-4		0.5%		
14	Chamomile ET	-	-		0.5%		
15	1,7,7-Trimethylbicyclo[2.2.1]-2-heptanone; Bornan-2-one	Camphor	464-49-3/ 76-22-2		3%		Products which might be used for children under 2 years of age(exception of rinse off products): “consult physician or pharmacist before uses to children under age 2 years of age.”
16	Menthol	Menthol	-				Products which might be used for children under 2 years of age(exception of rinse off products): “consult physician

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
							or pharmacist before uses to children under age 2 years of age.”
17	Methyl Salicylate	Methyl Salicylate	119-36-8		1%		Precautions （exception of rinse off products）： 1. Products which might be used for children under 2 years of age: “consult physician or pharmacist before uses to children under age 2 years of age.” 2. Methyl Salicylate shall does not exceed 1.8gm per day to prevent cause salicylate intoxications (such as dyspnea and other central nervous system poisoning; Consult physician or pharmacist before use with aspirin or salicylate idiosyncrasy
18	Arylsulfonamide–formaldehyde resin	Arylsulfonamide–formaldehyde resin	-	Nail products	25%		
19	Benzene, methyl-	Toluene	108-88-3	Nail products	25%		Keep out of reach

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
							of children.
20	Titanium dioxide(2)	Titanium dioxide	13463-67-7/ 1317-70-0/ 1317-80-2		25%	1. Titanium dioxide at a maximum concentration below 25% in cosmetic product (other than nano and spray form) will be regulated as general cosmetic 2. Cosmetic combined use of titanium dioxide and titanium dioxide (nano), the sum of concentration shall not exceed 25%. 3. If the ingredient is used as sunscreen agent and the product is claimed or labeled with sun protection factor, the data of sun protection efficacy should be kept by cosmetic businesses as reference for competent authorities.	

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
21	3-O-Ethyl Ascorbic Acid	3-O-Ethyl Ascorbic Acid	86404-04-8		2%		
22	Cyclohexanecarboxylic acid, 4-(aminomethyl)-, trans-	Tranexamic acid	1197-18-8		3%		
23	Benzoic acid, 2-hydroxy-4-methoxy-, monopotassium salt	Potassium Methoxysalicylate	152312-71-5		3%		
24	5,5'-Dipropyl-Biphenyl-2,2'-diol	Tetrahydromagnolol	20601-85-8		0.5%		
25	Cyclohexanecarboxylic Acid, 4-(Aminomethyl)-, Hexadecyl Ester, Hydrochloride, Trans-	Cetyl Tranexamate HCl	913541-96-5		3%		
26	α-Hydroxy acids(AHA)	-	-		pH≧3.5; Rinse off products(shampoos or hair conditioner): when AHA concentration less than or equal to 3%, a pH as low as 3.2 to 3.5.	The Chinese National Standard 「Methods of Hygienic Test for Cosmetics - pH Value, Acidity and Alkalinity」 CNS number: 9036, Category Number: S2073.	1. Alpha hydroxy acids are prone to cause skin irritation, consumers shall pay attention to the following matters during use: (1) A consumer whose skin is sensitive, please take a skin sensitization test before use.

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
							(2) A consumer whose skin is damaged, wounded or inflamed shall not use the product. (3) Infants and children are inappropriate for using the product. (4) A consumer whose skin has abnormalities during use, please stop using it. (5) A consumer whose skin is persistently inflamed or occur adverse reactions after use, please consult a doctor immediately. (6) The product contains alpha hydroxy acids may increase the sensitivity of skin to sunlight and

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
							the possibility of sunburn. (7) A consumer shall use sunscreen, wear clothing which has protection function and shall keep away from sunlight within a week. 2. Cosmetics contain alpha hydroxy acids and related ingredients, the content is not more than 10%, and the pH value of the product is not less than 3.5, the labels, leaflets or packaging may exempt from printing the preceding precautions for use when using these as pH adjuster.
27	1-Phenoxypropan-2-ol([3])	Phenoxyisopropanol	770-35-4	Rinse-off products (Not to be used in	2%		

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				oral products)			
28	Benzalkonium chloride, bromide and saccharinate(3)	Benzalkonium bromide/ Benzalkonium chloride/ Benzalkonium saccharinate	91080-29-4/ 63449-41-2/ 68391-01-5/ 68424-85-1/ 85409-22-9/ 68989-01-5	Rinse-off hair products	3% (as benzalkonium chloride) In the final products the concentrations of benzalkonium chloride, bromide and saccharinate with an alkyl chain of C 14, or less must not exceed 0.1 % (as benzalkonium chloride)		Avoid contact with eyes
29	Inorganic sulfites and bisulfites(3)			Oxidative hair dye products	0.67%(as free SO_2)		
30	Pyrithione zinc(3)	Zinc pyrithione	13463-41-7	Leave-on hair products	0.1%		
31	Ethyl-N-alphadodecanoyl-Larginate hydrochloride(3)	Ethyl Lauroyl Arginate HCl	60372-77-2	(a)Soap (b)Anti-dandruff shampoos (c)Deodorants(not in form of spray)	0.8%		
32	C16-alkyltrimethylammonium chloride(3)/ C18-alkyltrimethylammonium chloride(3)	Cetrimonium chlorid/ Steartrimonium chloride	112-02-7/ 112-03-8	(a) Rinse-off hair products (b) Leave-on hair products (c) Leave-on face products	(a)2.5 % for the individual concentrations or the sum of the individual concentrations of cetrimonium chloride and steartrimonium chloride.		

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
					(b)1% for the individual concentrations or the sum of the individual concentrations of cetrimonium chloride and steartrimonium chloride. (c)0.5% for the individual concentrations or the sum of the individual concentrations of cetrimonium chloride and steartrimonium chloride.		
33	C22-alkyltrimethylammonium chloride([3])	Behentrimonium chloride	17301-53-0	(a)Rinse-off hair products (b)Leave-on hair products (c)Leave-on face products	(a)5% for the individual concentration of behentrimonium chloride or the sum of the individual concentrations of cetrimonium chloride, steartrimonium chloride and behentrimonium chloride, while at the same time respecting the		

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
					relevant maximum concentration for the sum of cetrimonium chloride and steartrimonium chloride set out in entry 32. (b)3% for the individual concentration of behentrimonium chloride or the sum of the individual concentrations of cetrimonium chloride, steartrimonium chloride and behentrimonium chloride, while at the same time respecting the relevant maximum concentration for the sum of cetrimonium chloride and steartrimonium chloride set out in entry 32. (c)3% for the individual concentration of behentrimonium		

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
					chloride or the sum of the individual concentrations of cetrimonium chloride, steartrimonium chloride and behentrimonium chloride, while at the same time respecting the relevant maximum concentration for the sum of cetrimonium chloride and steartrimonium chloride set out in entry 32.		
34	Thioglycolic acid and its salts(4)	Thioglycolic acid	68-11-1	Rinse-off hair products	2%(as thioglycollic acid)	pH:7-9.5	Contains thioglycolate; Read and follow the instructions; Keep out of reach of children
35	Potassium or sodium hydroxide(4)	Potassium hydroxide/ Sodium hydroxide	1310-58-3/ 1310-73-2	(a)Nail cuticle solvent (b)Other use as pH adjuster	(a)5%	(b)pH<11	(a) Contains alkali; Avoid contact with eyes; Can cause blindness; Keep out of reach of children
36	Lithium hydroxide(4)	Lithium hydroxide	1310-65-2	Other uses as pH adjuster (rinse-off products only)		pH<11	
37	Calcium hydroxide(4)	Calcium hydroxide	1305-62-0	Other uses as pH adjuster,		pH<11	

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				processing aid)			
38	1,3-benzenediol(5)	Resorcinol	108-46-3	Hair lotions and shampoos	0.5%		Contains resorcinol
39	Water-soluble zinc salts with the exception of zinc 4-hydroxy-benzenesulphonate and zinc pyrithione	Zinc acetate/ Zinc chloride/ Zinc gluconate/ Zinc glutamate	-		1%(as zinc)		
40	Verbena absolute (*Lippia citriodora* Kunth.)	-	8024-12-2		0.2%		
41	Ammonium monofluorophosphate	Ammonium monofluorophosphate	20859-38-5/ 66115-19-3	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)	When mixed with other fluorine compounds, total fluorine concentration not exceed 0.15%	1. Non-pharmaceutical toothpaste with containing fluorine in a concentration of 0.1 to 0.15 % unless it is labelled as precautions for children (e.g. 'for adult use only') the following labelling is obligatory: 'Children of 6 years and younger: use a pea-sized amount for supervised brushing to minimize swallowing. In
42	Disodium fluorophosphate	Sodium monofluorophosphate	10163-15-2/ 7631-97-2	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
43	Dipotassium fluorophosphate	Potassium monofluorophosphate	14104-28-0	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
44	Calcium fluorophosphate	Calcium monofluorophosphate	7789-74-4	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
45	Calcium fluoride	Calcium fluoride	7789-75-5	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
46	Sodium fluoride	Sodium fluoride	7681-49-4	Non-pharmaceutical toothpaste and	0.15%(calculated as F)		

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				mouthwash			case of intake of fluoride from other sources consult a dentist or doctor.'
47	Potassium fluoride	Potassium fluoride	7789-23-3	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		2. The amount of fluoride contained in non-pharmaceutical toothpaste should be indicated on the toothpaste tube.
48	Ammonium fluoride	Ammonium fluoride	12125-01-8	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
49	Aluminium fluoride	Aluminium fluoride	7784-18-1	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
50	Tin difluoride	Stannous fluoride	7783-47-3	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
51	Hexadecyl ammonium fluoride	Cetylamine hydrofluoride	3151-59-5	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
52	9-Octadecen-1-amine hydrofluoride	Octadecenyl-ammonium fluoride	36505-83-6	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
53	Disodium hexafluorosilicate	Sodium fluorosilicate	16893-85-9	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
54	Dipotassium hexafluorosilicate	Potassium fluorosilicate	16871-90-2	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
55	Ammonium hexafluorosilicate	Ammonium fluorosilicate	16919-19-0	Non-pharmaceutical	0.15%(calculated as F)		

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
				toothpaste and mouthwash			
56	Magnesium hexafluorosilicate	Magnesium fluorosilicate	16949-65-8	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
57	Magnesium fluoride	Magnesium fluoride	7783-40-6	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
58	3-Pyridinemethanol hydrofluoride	Nicomethanol Hydrofluoride	62756-44-9	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
59	3-(N-Hexadecyl-N-2-hydroxyethylammonio)propylbis(2-hydroxyethyl)ammoniumdifluoride			Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
60	N,N',N'-Tris(polyoxyethylene)-N-hexadecylpropylene diamine dihydrofluoride			Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
61	Magnesium fluoride	Magnesium fluoride	7783-40-6	Non-pharmaceutical toothpaste and mouthwash	0.15%(calculated as F)		
62	Strontium chloride hexahydrate	Strontium chloride	10476-85-4	Non-pharmaceutical toothpaste and mouthwash	3.5%(as strontium)	When mixed with other strontium compounds, total strontium content	1. Contains strontium chloride 2. Frequent use by children is not
63	Strontium acetate	Strontium acetate	543-94-2	Non-	3.5%(as strontium)		

No.	Chemical name	INCI name	CAS No.	Product type/Limit for the use	Maximum concentration	Restriction	Precautions (The precautions to be labeled as specified shall be provided in Chinese)
	hemihydrate			pharmaceutical toothpaste and mouthwash		must not exceed 3.5 %	advisable
64	Boric acid, borates and tetraborates with the exception of substance N,N-Dimethylanilinium tetrakis(pentafluorophenyl)borate	Boric acid	10043-35-3/ 11113-50-1	Non-pharmaceutical toothpaste and mouthwash	0.1%(as boric acid)	Not to be used in products for children under 3 years of age	1. Not to be swallowed 2. Not to be used for children under 3 years of age
65	6-Methylcoumarin	6-Methylcoumarin	92-48-8	Non-pharmaceutical toothpaste and mouthwash	0.003%		
66	Chlorates of alkali metals	Sodium chlorate/ Potassium chlorate	7775-09-9/ 3811-04-9	Non-pharmaceutical toothpaste	5%		

(1) Allantoin: Shall be applied for registration when allantoin concentration over 0.2% up to 0.5% in leave-on products.

(2) Contains titanium dioxide in cosmetic product shall applied for registration if one of the following conditions applies:
1. In case of use of titanium dioxide and titanium dioxide (nano), the sum concentration exceeds 25%. 2. Contains titanium dioxide and used in sprays.

(3) For use as a preservatives, see 「List of Preservatives in Cosmetic Products」. If the purposes other than preservatives in the product, the business may determine whether it is necessary to print the purpose based on the attributes of the product. However, if the product endangers consumers' bodies and health because of not printing the purpose, the business shall assume related responsibility for its own.

(4) For use as a permanent wave agents, see 「List of Specific Purpose Ingredients in Cosmetic Products」.

(5) For use as a hair dye, see 「List of Specific Purpose Ingredients in Cosmetic Products」.

※ The outer packaging or containers of cosmetics shall conspicuously label the Precautions. If it cannot be labeled due to the surface area of outer packaging or container being too small or other special circumstances, said information shall be stated on the label, in the leaflet, or by other means.

※The "oral products" in the list means non-pharmaceutical toothpaste and mouthwash, and teeth whitening products.

※ The claimed effect of products shall follow "Regulations Governing of Criteria for the Label, Promotion and Advertisement of Cosmetic Products Identify False, Exaggerated or Having Medical Efficacy".

19 Ingredients Limitation and Hygiene Standards of Cosmetic Products

19.6 List of Microorganisms Limits in Cosmetic Products

List of Microorganisms Limits in Cosmetic Products

Effective Date：2022-01-01

Category：Ministry of Health and Welfare

This rule has been translated into English according to the original Chinese version.

If there is any inconsistency or ambiguity between these two versions, the Chinese version shall prevail.

No.	Product type	Total plate count	Others
1	For children under 3 years of age, eye, mucosa prod-ucts	Below 100 CFU/g or CFU/mL	*Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus or Candida albicans* shall not be detected.
2	Other products	Below 1000 CFU/g or CFU/mL	

Effective Date：2020-01-01

Category：Ministry of Health and Welfare

No.	Product type	Total plate count	Others
1	For infant, eye, mucosa prod- ucts	Below 100 CFU/g or CFU/mL	Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus shall not be detected
2	Other products	Below 1000 CFU/g or CFU/mL	

20 Standards of Administrative Fees for Cosmetics

Standards of Administrative Fees for Cosmetics

Amended Date：2019-05-28

Category：Ministry of Health and Welfare

Article 1

These Standards are adopted pursuant to the provisions of Article 30 of the Cosmetic Hygiene and Safety Act (the Act) and Article 10 of the Charges and Fees Act.

Article 2

The standards for charging the review fees, certificate fees, and inspection fees for cosmetics notification, applications for registration, applications for inspection of compliance with the cosmetic Good Manufacturing Practice Regulations are as follows:

1. Cosmetics notification
   (1) The review fee charged for cosmetics notification shall be NT$600 per application.
   (2) The review fee charged for modification of cosmetics notification shall be NT$600 per application.
   (3) The review fee charged for extension of cosmetics notification shall be NT$600 per application.
2. Applications of animal testing for the safety assessment of cosmetics or cosmetic ingredients
   (1) The review fee charged for animal testing for the safety assessment of cosmetics or cosmetic ingredients, NT$40,000 shall be charged per application.
   (2) For reissuing or renewing approved documents of animal testing for the safety assessment of cosmetics or cosmetic ingredients, NT$4,000 shall be charged per application.
3. Applications for registration of specific purposes cosmetics
   (1) The review fee charged for registering new specific purposes cosmetics shall be NT$36,000 per application.
   (2) The review fee charged for registering specific purposes cosmetics shall be NT$12,000 per application.
   (3) The review fee to register changes of specific purposes cosmetics (product name, packaging, usage, business applicant, or manufacturer) shall be NT$3,500 per application.
   (4) The review fee to register modification of specific purposes cosmetics (ingredient or item) shall be NT$5,000 per application.
   (5) The review fee charged for registering license extension of specific purposes cosmetics shall be

NT$3,500 per application.

(6) For reissuing lost licenses, approved documents of label or package insert for specific purposes cosmetics, NT$3,500 shall be charged per application.

(7) The review fee charged for regulatory determination of the property of cosmetic products shall be NT$2,500 per application.

(8) The review fee charged for importing cosmetics for specific purposes and related products for registration or research, NT$3,000 shall be charged per application.

(9) The fee charged for authorizing a license of specific purposes cosmetics shall be NT$4,000 each.

(10) The fee charged for a license shall be NT$1,500 each.

4. Applications for inspection of compliance with the cosmetic Good Manufacturing Practice Regulations

(1) For inspections or subsequent inspections of establishment, relocation, or expansion of manufacturing facilities for domestic cosmetics, new forms of cosmetics, or processed items, NT$60,000 shall be charged per application.

(2) For on-site inspections or subsequent inspections of manufacturing facilities for foreign cosmetics, NT$600,000 shall be charged per application, including document review of NT$60,000 and on-site inspection of NT$540,000.

(3) For changes of approved documents of cosmetic Good Manufacturing Practice, NT$6,000 shall be charged per application.

5. Cosmetics certificates and approval letters

(1) The document review fee charged for cosmetics manufacturing and sale certificates, imported cosmetics sale certificates, and cosmetics manufacturing certificates shall be NT$2,000 per application.

(2) For Chinese cosmetics manufacturing and sale certificates, imported cosmetics sale certificates or cosmetics manufacturing certificates, NT$1,500 shall be charged for an original, and NT$200 shall be charged for a copy.

(3) For English cosmetics manufacturing and sale certificates, imported cosmetics sale certificates or cosmetics manufacturing certificates, NT$1,500 shall be charged for an original, and NT$200 shall be charged for a copy.

(4) NT$1,500 shall be charged for a Chinese cosmetics GMP compliance certificate.

(5) NT$1,500 shall be charged for an English cosmetics GMP compliance certificate.

(6) For reissuing lost approved documents of cosmetics GMP compliance, NT$1,800 shall be charged per

application.

Article 3

The on-site inspection fee for auditors and experts set forth in Item 2, Subparagraph 4 of the preceding article shall apply mutatis mutandis to the Directions for the Overseas Travel Allowance Disbursement, and shall be charged from the audited unit by the central competent authority.

Article 4

The Standards shall be effect on July 1, 2019.

21 Regulations for Issuance and Management of the Cosmetics Certificates

Regulations for Issuance and Management of the Cosmetics Certificates

Announced Date：2019-05-22

Category：Ministry of Health and Welfare

Article 1

The Regulations are enacted under Paragraph 2 of Article 29 of the Cosmetics Hygiene and Safety Act (the "Act").

Article 2

The certificates stipulated under the Regulations are classified into the following five categories:

1. Type A Cosmetics Manufacturing and Sale Certificate: the certificate could prove that domestic cosmetics may be produced and sold domestically.
2. Type B Cosmetics Manufacturing and Sale Certificate: the certificate could prove that domestic cosmetics have been produced and sold domestically.
3. Cosmetics Manufacturing Certificate: the certificate could prove that domestic cosmetics produced at a domestic manufacturing facility.
4. Imported Cosmetics Sale Certificate: the certificate could prove that imported cosmetics sold domestically.
5. Cosmetic Good Manufacturing Practice Certificate: the certificate could prove that cosmetics manufacturing facility complies with Cosmetic Good Manufacturing Practice.

Article 3

Applying for the Type A Cosmetics Manufacturing and Sale Certificate, the applicant shall file an application and attach the following documents and information:

1. The certificate of completed product notification or the copy of the license.
2. The copy of the company or business registration.
3. Except for the factory exempt from the registration, the copy of the factory registration.
4. For the contract manufacturer, the OEM agreement.
5. Necessary documents and information required by the central competent authority.

Article 4

Applying for the Type B Cosmetics Manufacturing and Sale Certificate, the applicant shall file an application and attach the following documents and information:

1. The certificate of completed product notification or the copy of the license.
2. The copy of the company or business registration.
3. Except for the factory exempt from the registration, the copy of the factory registration.
4. For the contract manufacturer, the OEM agreement.
5. The proof could prove that cosmetics have been sold.
6. Necessary documents and information required by the central competent authority.

Article 5

Applying for the Cosmetics Manufacturing Certificate, the applicant shall file an application and attach the following documents and information:

1. The certificate of completed product notification or the copy of the license.
2. The copy of the company or business registration.
3. Except for the factory exempt from the registration, the copy of the factory registration.
4. For the contract manufacturer, the OEM agreement.
5. Necessary documents and information required by the central competent authority.

Article 6

Applying for the Imported Cosmetics Sale Certificate, the applicant shall file an application and attach the following documents and information:

1. The certificate of completed product notification or the copy of the license.
2. The copy of the company or business registration.
3. The authorization document of the original manufacturer.
4. Necessary documents and information required by the central competent authority.

Article 7

Cosmetics business apply for Cosmetic Good Manufacturing Practice Certificate shall file an application and attach the following documents and information:

1. The copy of the company or business registration of the applicant.

2. The copy of the factory registration.

The central competent authority shall execute an on-site inspection after receiving the application of the preceding Paragraph. It issues document and certificate of conformity after determining the cosmetics business comply with the Cosmetic Good Manufacturing Practice Regulations.

Cosmetics business may apply mutatis mutandis the preceding two Paragraph and apply for the inspection of Cosmetic Good Manufacturing Practice Regulations compliance to the central competent authority. After determining the compliance, the authority issues the document of conformity.

Cosmetics business may attach the document of conformity and apply the certificate per Paragraph 1 of this Article. The validity term of the certificate is determined by the validity term of the document of conformity.

Cosmetics business shall apply to the Ministry of Economic Affairs for the inspection of Paragraph 2 and Paragraph 3 before January 1, 2021. After determining the compliance, the Ministry of Economic Affairs issues the document of conformity.

Article 8

If the attached document or information of the application per the Regulations is incomplete, the central competent authority shall request for the correction within the time limit. Fail to correct within the time limit, and the application shall be refused.

Article 9

The application of the certificate stipulated under the Regulations shall not be granted if the attached document or information meets one of the following conditions:

1. Attached document or information is inconsistent with the content of the application.

2. Attached document or information is deceptive or false.

Article 10

The certificate stipulated under the Regulations may be rescinded if one of the following conditions met:

1. The certificate of cosmetics notification or the license has been revoked or rescinded.

2. The registration of the company, business, or factory has been revoked or rescinded.

The cosmetics manufacturing facility is inspected under Paragraph 2 of Article 8 of the Act and the result is non-conformance, after the request of correction within the time limit per Sub-paragraph 3 of Paragraph 1 of Article 22 of the Act, the cosmetic Good Manufacturing Practice certificate shall be rescinded if the failure of correction within the time limit.

Article 11

If the certificate stipulated under the Regulations has been revoked or rescinded, the central competent authority shall request cosmetics business return the certificate within the time limit. Fail to return the certificate within the time limit, and it shall be canceled.

Article 12

The Regulations shall take effect on July 1, 2019.

22 Regulations Governing Criteria for the Label, Promotion, Advertisement with Deception, Exaggeration, or Medical efficacy of Cosmetic Products

Regulations Governing Criteria for the Label, Promotion, Advertisement with Deception, Exaggeration, or Medical efficacy of Cosmetic Products

Announced Date：2019-06-04

Category：Ministry of Health and Welfare

Article 1

The Regulations are prescribed in accordance with the provisions of Paragraph 4, Article 10 of the Cosmetic Hygiene and Safety Act (hereinafter referred to as “the Act”).

Article 2

The determining standards of the false, exaggerated labeling, promotion or advertisement referred to in Article 10 Paragraph 1 and medical efficacy referred to in Article 10 Paragraph 2 in the Act shall be comprehensively judged by the overall presentation and relation of the name, text, picture, symbol, image, sound or other messages conveyed to consumers of the product.

Article 3

The labeling, promotion or advertisement of cosmetic products referred to in Article 10 Paragraph 1 of the Act is identified as false or exaggerated if involving any of the following conditions:

1.The content description does not conform to facts.

2.The content description has no evidence, or the evidence is insufficient to support such description.

3.The content description does not comply with the definition, categories and scope referred to in Article 3 of the Act.

4.The content description involves phrases of affecting physiological functions or changing appearance of human body as in Appendix 1.

Article 4

The commonly used phrases exemplified in Appendix 2 or the phrases of ingredients’ physiological functions exemplified in Appendix 3 may be used in the labeling, promotion or advertisement of cosmetic products based on the category, subcategory, scope and ingredient of the products respectively, and shall not be identified as false or exaggerated.

Article 5

The labeling, promotion or advertisement of the cosmetic products referred to in Article 10 Paragraph 2 in the Act shall be identified as having medical efficacy if involving any of the following conditions:

1. The content description relates to prevention, mitigation, diagnosis or treatment of any disease, disease syndrome or symptom, or uses other phrases of having medical efficacy as in Appendix 4.
2. The content description relates to having efficacy of any drug or medical equipment, or uses the phrases with similar meanings.

Article 6

The Regulations shall be implemented on 1st July, 2019.

23 Regulations for the Inspection and Examination of Imported Cosmetics

Regulations for the Inspection and Examination of Imported Cosmetics

Announced Date：2019-06-27

Category：Ministry of Health and Welfare

Article 1

These regulations have been established according to Paragraph 2 of Article 14 of the Cosmetic Hygiene and Safety Act (the “Act”).

Article 2

Definition: terms used in these regulations:

1. Inspections: This refers to border checks or examination before permitting the importation of cosmetics.
2. Examination: This refers to conducting sensory, physical, chemical, or biological tests and experiments in a laboratory.
3. Inspection authorities: This refers to inspection enforcement by the central competent authority or its appointed agencies (organizations), orporations, or groups.
4. Obligatory inspection applicants: This refers to cosmetics importers.

Article 3

For cosmetics required for inspection as promulgated by the competent authority in accordance with Paragraph 1 of Article 14 of the Act, the obligatory inspection applicants shall file an application for inspection and submit the following documents and information to the inspection authority at the port of entry within fifteen (15) days prior to the date of import:

1. A copy of the application for import declaration.
2. Necessary documents required by the inspection authority.

The application of the preceding Paragraph can be submitted electronically.

If the representative files the application of Paragraph 1, a letter of Power of Attorney and the identification documents for the representative, corporation, or business shall be submitted.

Article 4

Cosmetics pursuant to Paragraph 1 of the preceding Article that conform to one of the following situations

may be exempted from inspection:

1. Products to be imported are issued with a certificate of examination by the government of the country of origin who has signed an examination waiver reciprocity agreement with the government of the Republic of China.
2. Others with the special permit of the central competent authority.

Article 5

The central competent authority shall inspect the compliance of imported cosmetics; the inspection shall not include the situations mentioned in Article 7 and Paragraph 1 of Article 10 of the Act.

Obligatory inspection applicant shall legalize the items of the preceding Paragraph before the products were supplied, sold, gifted, publicly displayed, or offered for consumer trial.

Article 6

In addition to documentation review (as prescribed in Paragraph 1 and Paragraph 3 of Article 3), inspection authority may carry out the inspection of imported cosmetics in one or some of the following measures:

1. On-site inspection: check items, inspect the appearance of the packaging, labels, and other related items on site.
2. Randomly-selected batch examination: perform based on a 2%-50% inspection rate.
3. Batch-by-batch examination: carry out for each submitted batch of imported cosmetics.

Article 7

The samples required for inspection shall be taken free-of-charge. The maximum number (amount) of sampling shall be limited to what is required for inspection purpose. After collecting the samples, the authority shall issue a receipt to the obligatory inspection applicant.

For the sampling mentioned in the preceding Paragraph, the obligatory inspection applicant shall not designate the sample.

Article 8

The inspection and sampling shall be conducted at the storage site of products. If the products shipped in full container load, the inspection and sampling shall be conducted at the centralized inspection area or the

specified zone approved by Taiwan Food and Drug Administration of the Ministry of Health and Welfare (TFDA).

Article 9

The examination of imported cosmetics shall be conducted in the order of sampling. However, the original examination laboratory shall prioritize inspection on products applying for re-examination according to Paragraph 2 of Article 12.

Article 10

Due to the difficulty of sampling in a container yard, requiring five or more days for examination, or deterioration or lack of stability of cosmetics, the inspection authority may issue a notice of prior release for import for customs clearance after the obligatory inspection applicant signs an affidavit of custodial responsibility.

If the pledged storage location does not conform to the actual storage location, or for anyone who intentionally uses, moves, provides, sells or gifts cosmetics before issuing the import permit, the inspection authority may suspend the acceptance of an application for prior release of import by the obligatory inspection applicant within 180 days from the day of discovery.

Article 11

After imported cosmetics applied for inspection are found to conform to the regulations, the inspection authority shall issue an import permit to the obligatory inspection applicant. The obligatory inspection applicant may apply to the inspection authority for a written permit.

The obligatory inspection applicant shall claim the remaining samples by presenting the sampling receipt within 15 days after receiving the permission. However, if the sample is not claimed within the statutory period or has a short shelf life, the inspection authority may dispose of the samples directly.

Article 12

In the event the imported cosmetics fail to conform to regulations, the inspection authority shall issue a notification of noncompliance for cosmetics to the obligatory inspection applicant.

The obligatory inspection applicant may apply for re-examination to the original inspection authority within

15 days after receiving the preceding notification, and the application is limited to one-time only. The original inspection authority performs re-examination by using the remaining samples.

Remaining samples of imported cosmetics that do not conform to regulations shall be destroyed after the end of the period of application for re-examination or receiving the notification of noncompliance by the obligatory inspection applicant unless otherwise stated by law.

Article 13

The imported cosmetics fail to conform to regulations; the inspection authority shall conduct the following measures followed by the result of randomly-selected examination or inspection unless otherwise stated by law:

1. Violation of Paragraph 2 of Article 10 of the Act, the obligatory inspection applicant may apply for a correction which improves within a given period. The correction may be made after the products were imported if the inspection authority approves.
2. Fail to apply for the correction per the preceding Subparagraph, the application was not approved or other noncompliance matters, the obligatory inspection applicant shall conduct a return or destruction.

The products of the preceding Paragraph were prior released per Paragraph 1 of Article 10 shall be conducted per preceding Paragraph.

Article 14

In the event the cosmetics applied for inspection correspond to one of the following situations, the inspection authority may require the obligatory inspection applicant to submit documents or information before a given date, to explain the reasons for non- compliance, and a proposed improvement plan with preventative measures. Before the approval is granted, the application of re-examination of products belong to the same cosmetics registration number or permit license shall not be accepted:

1. Products belong to the same registration number or cosmetics permit license of the same obligatory inspection applicant, and whose batch-by-batch examination results do not conform to regulations for two times.
2. Products belong to the same registration number or cosmetics permit license, and whose inspection results do not conform to regulations for three times within 180 days from the day of the failure of the inspection.

Article 15

In the event the cosmetics applied for inspection correspond to one of the following situations, the inspection authority may suspend the acceptance of an application for products inspection from the same manufacturer, same origin, or same exporting country:

1. Products mentioned in the preceding Article requiring documents and information are not provided before the given date.
2. Products mentioned in the preceding Article requiring documents and information provided are not approved upon review.

Article 16

The application fees for border checks and examination per Article 30 of the Act shall include the following:

1. Review fees: the fees for reviewing the application of inspection by inspection authority.
2. On-site inspection fees: the fees for sampling, checking items, examining the packaging, labels, and other related inspection measures by inspectors.
3. Extended operation fees: the fees for applying the extension of inspection by obligatory inspection applicant or representative.
4. Documentary operation fees: the fees for re-issuance, replacement, additional copy, or correction of the import permit.
5. Examination fees: the fees for products batch-by-batch examination or re-examination.

The fees in the Subparagraph 1 to Subparagraph 4 of the preceding Paragraph is described in Annex. The fees in Subparagraph 5 shall be collected based on Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics.

Article 17

When conducting inspections according to these regulations, inspectors shall present the identification documents about the performance of their duties.

Article 18

The Regulations shall take effect on July 1, 2019.

24 Regulations on Cosmetic Hygiene and Safety Violation Report and Reward

Regulations on Cosmetic Hygiene and Safety Violation Report and Reward

Announced Date：2019-06-27

Category：Ministry of Health and Welfare

Article 1

These Regulations are adopted pursuant to Paragraph 2 of Article 19 of the Cosmetic Hygiene and Safety Act ("the Act").

Article 2

In case of violation, reporters may file reports in oral or written statements, by email or others, specifying information below:

1. Reporter’s name, national identification number, phone number and address.
2. Violator’s name, address, company name (trade name), responsible person’s name, and company address.
3. Facts or circumstances of violation, location of violation, related information or evidence for further investigation.

The second and third items from previous paragraph are not compulsory if reporter is unable to identify.

When a report is filed orally, authorities accepting the reports shall produce documentation and verify report statement with reporter.

In cases where authorities accepting the report do not possess jurisdiction in the matter, it shall be transferred to the party with such jurisdiction within seven working days and reporter shall be informed.

Article 3

Authorities shall process reports effectively and inform reporter of case progress within 30 days from the day a report is filed.

Article 4

If reporting violations are confirmed, the municipal or county (city) authority shall provide at least 5% of fine as reward.

If reporter is or was the violator’s employee and the violation includes any of the following circumstances, reporter shall receive at least 10% of fine as reward:

1 The product contains mercury, lead, or other substances prohibited by the central competent authority, violating Article 6 of The Act.

2 The act violates Paragraph 3 of Article 6 of The Act.

3 The act violates Paragraph 4 or 5 of Article 6 of The Act.

4 The manufacturing facilities do not meet Establishment Standards for Cosmetics Manufactory, violating Article 8 of The Act, or the facilities are yet to finish registration legally.

5 Manufacturing facilities do not comply with cosmetic Good Manufacturing Practice Regulations, violating Paragraph 2 of Article 8 of The Act.

The municipal or county (city) authorities shall include the first two accounts of reward in the budgets.

Article 5

When reports are withdrawn or revoked, not owning to false report after the reward is issued, the municipal or county (city) authorities shall not demand the reporter for reward return.

Article 6

Reports of following circumstance are not granted with reward:

1. Anonymous or false personal information.

2. Without factual statement.

3. Violation has been reported to authorities accepting reports or other agencies.

Article 7

When there are multiple reporters in one case, reward is shared by all. When two separate reports involve same violation, reward is given to the first reporter. If authorities are unable to determine the order of reporting, reward is distributed evenly.

Article 8

Authorities accepting reports and other agencies shall keep confidential of reporter's name, age, address, writing, picture, information, appearance, personal information and other identifiable details of reporters. Any violations are subject to penalty of criminal law or other related regulations.

Reporters' application, written transcript or any other documents shall be kept confidential and forbidden to

be viewed or transcribed by any third party.

Article 9

Authorities accepting reports are obliged to ensure reporters' personal safety and must contact police authorities for protection when necessary.

If reporters are under threats, intimidations or any other abusive behaviors, the municipal or county (city) authorities shall contact local police authorities for law enforcement.

Article 10

The regulations are implemented since 1st July, 2019.

25 Regulations Governing Accreditation and Outsourced Accreditation Management of Cosmetic Testing Institutions

Regulations Governing Accreditation and Outsourced Accreditation Management of Cosmetic Testing Institutions

Announced Date：2019-08-05

Category：Ministry of Health and Welfare

Chapter 1 General Principles

Article 1

These regulations are promulgated pursuant to the Paragraph 3of Article 28 of the Cosmetic Hygiene and Safety Act.

Article 2

Definition of the terms herein employed are as follows:

1. Testing institution: It refers to a testing body (institution), corporation, or group possessing the capacity to implement cosmetics testing.
2. Accreditation: It refers to the procedure established under this set of regulations instituted to validate the testing competence of a testing institution for a particular testing item.

Chapter 2 Accreditation Requirements and Procedure for Testing Institutions

Article 3

Testing institutions applying for accreditation shall have their exclusive test laboratory that meets the following requirements:

1. Equipped with the essential test equipment, space, and quality management system, capable of performing tests independently.
2. Complete with a laboratory head, a report signatory, a technical manager, a quality control manager, and the pertinent test personnel possessing the following qualifications:
   (1) Education: graduates from medicine, chemistry, biology, or food science programs of a college, university or higher education institution, either a domestic one or a foreign one that meets the requirements in the Regulations Governing the Assessment and Recognition of Foreign Academic Records by Institutions of Higher Education;
   (2) Work Experience:

1. for the laboratory head, the report signatory, the technical manager, and the quality control manager, having completed quality management related professional training and at least 3 years of testing related work experience;
2. for test personnel, having completed testing work related training.

The work experience requirements inItem (2)-1 in Sub-paragraph 2 of the preceding paragraph may be offset by the education qualifications in Item (1) in the same sub-paragraph; the master's degree counts for one year, and the doctoral degree counts for two years. Only one degree can be used for offset in case the person holds several degrees on the same level, and only the highest degree can be used in a case.

Article 4

Testing institutions applying for accreditation shall submit an application form, togetherwith the following supporting documents and information to the central competent authority:

1. the certificates manifesting the compliance with the requirements stipulated in the preceding article;
2. documents certifying the testing capability;
3. documents prepared in accordance with the Basic Guidelines Governing the Quality System of Testing Institutions and Laboratories as provided by the central competent authority:
   (1) Quality Manual.
   (2) Standard operating procedures for methods of testing, including the measures for quality control of testing results.
   (3) Assessment report of uncertainty of measurements in case of an application filed for quantitative test item.
   (4) A method validation assessment report for a test item under accreditation application .
   (5) The template of test report of the accredited test items and the signature format of the report signatory in Chinese.
4. Laboratory location map and the configuration diagram of the test facilities.

Article 5

Where the documents and information stipulated in the foregoing article do not comply with regulations or is found incomplete, the central competent authority shall issue a supplementation request and deadline to the applicant; where requirement is not fulfilled within the prescribed deadline, application shall be denied.

Article 6

The central competent authority shall conduct a document review and on-site assessment on the applications of testing institutions.

Where the on-site assessment findsa deficiency, the testing institutions shall submit a corrective plan to the central competent authorityfor re-assessment after the end of on-site assessment within 60 days.

Article 7

Where the application passes the assessment stated in Article 4, the central competent authorityshall issue the accreditation certificate and make official announcement in acknowledgment thereof.

Article 8

The accreditation certificate shall contain the following information:

1. The title of the testing institution.
2. Thetitle and address of the laboratory, and the full name of the laboratory head.
3. Test items as accredited, test method, test scope, and the report signatory.
4. Year, month, day, and serial number of the accreditation certificate.
5. Validity period of the accreditation certificate.

The testing institution shall display the accreditation certificate in a highly visible place of the premises.

Article 9

The accreditation certificate has a validity period of three years. An application for extension, when necessary, shall be filed between six and eight months preceding the date of expiration. The maximum period of an extension is three years.

The provisions of Articles 4 to 6 shall apply mutatis mutandis to the document, information and procedures required for accreditation period extension application. The documents and information specified in all sections thereof, except for those listed in Paragraph 2 of Article 4, need not be included in the application provided that there is no change in the content since the previous application for accreditation or extension.

If the application for extension filed during the period as specified in Paragraph 1 does not receive a decision of approval or dismissal from the central competent authority within the original accreditation validity period,

the validity of the original accreditation is extended to the date of the decision.

Chapter 3 Management of Accredited Testing Institutions

Article 10

In the event of changes in any of the items enumerated under Subparagraphs 1 to 3 of Paragraph 1 of Article 8, the testing institution shall, within the following periods, submit an application for changes to the central competent authority:

1. Change of laboratory address: application shall be filed within 30 days of event.
2. Change of the basis of testing methods: application shall be filed within 90 days of event.
3. Change of test scope due to prohibited use, limited use or maximum level amendmentof the ingredients of specific-purpose cosmetics: application shall be filed within 90 days of the effective date.
4. Change of the title of the testing institution, the title of the laboratory, the name of the laboratory head or the report signatory: application shall be filed within 90 days of event.

For the applications specified above, the central competent authority, when necessary, may conduct on-site review.

Article 11

Relocation based on the Subparagraph 1 of Paragraph 1 of the preceding Article shall be reported to the central competent authority in a relocation plan 15 days prior to the relocation.

The plan mentioned in the preceding paragraph shall include the following items:

1. The time course of relocation.
2. The laboratory's new address and location map.
3. The test instrument list and the test facility configuration diagram.

Article 12

Upon failure to perform the test as specified in the accreditation, the exclusive laboratory of the testing institution shall notify the central competent authority of the event within seven days from the date of the event; and the same applies when the function is resumed.

Article 13

A testing institution shall perform testing based on the quality manual as specified in Item (1) in Subparagraph 3 of Article 4 and the standard operating procedures for methods of testing as specified in Item (2) and shall comply with the following provisions:

1. Sign a written contract of test entrustment with the client when entrusted with a test, indicating the entrusted test items, test methods, test scope, status of accreditation of the entrusted test items, and other matters. For any changes to the entrustment, the content of and the reasons for the changes shall be stated in the contract of test entrustment and verified and recorded by both parties.
2. Accurately record the detailed informationof the client and the use purpose of the test report.
3. Accurately record the condition of sample(s) received, including the name,batch number, manufacturing date or expiry date, source, packaging, and quantity of the sample(s). No space or column shall be left blank; moreover, photographs of the sample(s) submitted for testing shall be kept on file.
4. The test report shall indicate the sample information, test item, testing method, test scope, and test results. All information shall be true and accurate.
5. Make clear statements or remarks where the report also contains results beyond the scope of accreditation (including test item, testing method, and test scope)
6. Non-accredited testing methods shall not be used for performing tests on accredited test items; however, this limitation shall not apply where such is requested in a specifically signed contract with the client or in a written request of the client, and such is specified in the test report.
7. The test report shall clearly note the following:"The test report merely reflects the test results of the consigned matters of the client and is not a certification of the legitimacy of the related products."
8. The test report and records of quality control information and raw data shall be kept on file together for at least 3 years.
9. Test reports shall be designed to thwart forgery.
10. The entrusted matter shall not be sub-entrusted to another person without the consent of the client; in the case where consent is granted to sub-entrust the matter to another person, the other person shall be one that possesses the ability to perform the entrusted test items, and the test report shall include the serial number of the test report issued by the sub-entrusted organization or other traceable information.
11. Products of different names, raw material sources, or samples in minimum individual packages shall be tested separately and covered in separated test reports, with no mixture.

12. The results of all the entrusted test items of the same sample listed in the test entrustment contract shall be stated in the same test report.
13. For tests performed on accredited test items, the results shall be stated in a test report in the form recognized by the central competent authority.

Article 14

The central competent authorityshall regularly audit the equipment, personnel organization, quality management, operating procedures, testingcapacity, and test records of the accredited testing institutions and may require the testing institutions to submit reports of the testing procedures conducted within the accreditation scope. When necessary, the central competent authoritymay conductirregular audit.

The central competent authority may require the testing institutions to take, at their own expenses, proficiency testing activities organized by the central competent authority, or administered by other proficiency testing providers as entrusted or recognized by the central competent authority.

Testing institutions are not entitled to evade, obstruct, or refuse the audit procedure, report submission, and proficiency testing participation requirement prescribed in the foregoing two paragraphs.

Article 15

Where the testing institution undergoing the proficiency testing required in the second paragraph of the preceding article fails to pass the proficiency assessment, it shall be obliged to institute corrective actionswithin 15 days following the date of acceptance of the test assessment notice; moreover, a corrective action report shall be submitted to the central competent authority. The testing institution shall be required to receive the follow-up proficiency testing as per date scheduled by the central competent authority.

Article 16

In the event of a major unforeseen cosmetics related event,testing institutions receiving an emergency mobilization notification from the central competent authority shall be obliged to process the cosmetics testing within the prescribed deadline; thereafter, testing institutions shall submit complete sample information and testing results to the central competent authority.

Article 17

In any of the following circumstances of a testing institution, the central competent authority may suspend or abolish its accreditation. Where the accreditation is abolished, the testing institution is not allowed to apply for accreditation within one year.

1. Violation of the provisions of Paragraph 3 of Article 14 of no evading, obstructing, or refusing.
2. False information contained in test statistics, test reports or other documents and information submitted.
3. Other violations of the provisions of this set of regulations causing the central competent authority to deem the testing institution unsuitable for test administration.

Article 18

In any of the following circumstances of a testing institution, the central competent authority may suspend or abolish a part or all of the accredited test items:

1. After obtaining the accreditation according to this set of Regulations, the exclusive laboratory no longer exists or the laboratory does not meet the conditions set out in Article 3.
2. Violation of the provisions of Article 10, with no changes made or no changes made within the time limit.
3. Violation of the provisions of Article 11 or Article 12, with no report or notification submitted within the time limit.
4. Violation of the provisions of any one paragraph of Article 13.
5. Violation of the provisions of Article 15, by failing to submit a corrective action report within the time limit, failing to take the follow-up proficiency test, or failing to pass the test.
6. Closedown or discontinuation of the testing institution.

Chapter 4 Procedure for the Outsourcing of Accreditation Work

Article 19

The central competent authority intending to outsource the accreditation work to a related body (institution), corporation, or group(hereafter referred as independent provider) pursuant to the provisions of Paragraph 2 of Article 28 of the Cosmetic Hygiene and Safety Actshall process assignment through an open selection process.

Article 20

The independent provider shall meet the following requirements:

1. Possession of the experiences required for the accreditation of testing institutions and the necessary documents supporting said eligibility.
2. Employment of personnel meeting the following qualifications:
   (1) Graduates from food science, nutrition, medicine, chemistry, biology, or other related programs of a college, university or higher education institution, either a domestic one or a foreign one that meets the requirements in the Regulations Governing the Assessment and Recognition of Foreign Academic Records by Institutions of Higher Education, with previous employment experience in the testing institution's testing competence validation related work;
   (2) Having completed studies of at least 15 academic credits of legal subjects involving civil law, criminal law, and administrative laws and regulations in a domestic university, with a transcript of records reflecting said credits.
3. Fulfillment of all other requirements announced by the central competent authority.

Chapter 5 Management of Independent Providers

Article 21

An independent provider shall have an established management system and the related operating procedures established in coordination with its accreditation procedures and produce an information manual; the information manual shall contain at least the following information:

1. organization chart;
2. document control;
3. records;
4. nonconformities and corrective actions;
5. preventive actions;
6. internal audit;
7. management review;
8. complaints.

The aforementioned manual shall be reviewed regularly to ensure appropriateness with operations and updated or revised from time to time to suit actual operating conditions. The internal audit and management review procedures shall be conducted at least once a year.

Article 22

An independent provider shall ensure that the personnel implementing the accreditation procedures possess the necessary cosmetics testing related knowledge and proficiency; moreover, the independent provider shall keep a record of the initial and regular assessments conducted on said personnel.

The personnel stated in the preceding paragraph shall attend at least 12 hours of continued education and training course conducted by an institution (body) or civilian institution or group recognized by the central competent authority. Education or training curriculum shall include audit techniques, testing knowledge and skills, and related laws.

Article 23

Any information acquired by an independentproviderin the course of the accreditation process or any accreditation related information provided by the testing institution shall be retained on file for at least15 years; whereas records of accreditation work related documents and information shall be permanently retained on file.

Upon the conclusion of the independent provider's outsourcing service, the aforementioned documents and information retained on file shall be turned over to the central competent authority.

Article 24

An independent provider shall be obliged to maintain the confidentiality of all information acquired in the course of implementing accreditation work, and shall refrain from disclosing said information.

Article 25

An independent provider implementing an on-site assessment pursuant to Paragraph 1 of Article 6 shallsubmit the prepared assessment schedule to the central competent authority a week before the assessment date; on the other hand, the central competent authoritymay appoint a representative to attend the assessment. The independent providershall not evade, obstruct, or refuse such attendance.

Article 26

An independent providershall inform the central competent authority of the accreditation results of every case processed; moreover, related documents and information shall be attached.

Article 27

The central competent authoritymay notify the independent provider of its requirement to submit operation-related documents and information and may conduct irregular audit procedures on the venue of operations of the independent provider.

The independent provider shall not evade, obstruct, or refuse the foregoing notice, requirement or audit.

Article 28

All documents and information provided to the central competent authorityby the independent provider pursuant to the provisions of the Regulations shall be true and accurate.

Article 29

An independent provider and its personnel entrusted with the processing of accreditation work shall observe the “conflict of interest” regulations as dictated in the Administrative Procedure Law.

An independent provider processing the work in the preceding paragraph shall not be engaged in behaviors in violation of the criminal law. Upon any suspicion of violation, the central competent authority shall bring the case to the related law enforcement organizations.

Article 30

The central competent authority shall sign a work consignment contract with the independent provider. Contract shall clearly define matters and other details, related rights and obligations, breach of contract penalty and reasons, dispute processing, and factors for the revocation or temporary suspension of the consigned work and other information covered in the contract.

Article 31

In any of the following circumstances of the independent provider, the central competent authority may suspend or revoke the outsourcing eligibility of the independent provider. An independent provider shall not be qualified to accept any outsourcing appointment within one year if the outsourcing eligibility is revoked due to severe circumstances.

1. Violation of the provisions of Article 24.

2. Violation of the provisions of Article 25, by failing to notify the central competent authority within the time limit, or by evading, obstructing, or refusing the attendance in assessment by the central competent authority.
3. Violation of Paragraph 2 of Article 27.
4. Violation of the provisions of Article 28.
5. Violation of the provisions of Paragraph 1 of Article 29 on the “conflict of interest” regulations.
6. Any violation of the criminal law as provided in Paragraph 2 of Article 29.

Chapter 6 Supplementary Provisions

Article 32

These regulations shall be effective as of the date of promulgation.