

## **Establishment Standards for Cosmetics Manufactory**

Announced Date: Jan 11<sup>th</sup>, 1974

Amended Date: Aug 29<sup>th</sup>, 2019

### 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.

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 kettles shall 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 producing non-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 1<sup>st</sup>, 2019.