Content

Title: Establishment Standards for Cosmetics Manufactory Ch Date: 2008.04.30 Legislative: 1.Full text jointly formulated and promulgated by Ministry of Economic Affairs and Department of Health, Executive Yuan on January 11, 1974 2. Full text including 13 articles jointly amended and promulgated by Ministry of Economic Affairs and Department of Health, Executive Yuan on September 20, 1997 3. Text of Article 2 and 11 jointly amended and promulgated by Ministry of Economic Affairs and Department of Health, Executive Yuan on April 30, 2008

Content: 1 This set of standards is formulated in accordance with regulations of Paragraph 5, 15 of the Statute for Control of Cosmetic Hygiene.

> 2 Cosmetics manufactories shall comply with the following basic requirements and be provided with common equipment:

Manufactories shall be separated from residential or public area and may not interfere with public health or safety.

Manufactory buildings shall be solid and clean, and designed to prevent rodents, insects and dust; interior ceilings, walls and floors shall be smooth and free of cracks and crevices, easy to clean, and non-conducive to the collection of dust (e.g. utilizing materials such as epoxy resins that are easily disinfected and cleaned); Interior pipelines shall utilize materials with smooth surfaces and minimize the visibility; drainage systems shall have outlets with sewage reflux prevention functions.

Operation areas shall be clearly delineated (e.g. the liquid form preparation manufacturing room, the powder form preparation manufacturing room, the packaging room, the warehouse and other relevant areas).

Storage areas of raw materials, supplies, semi-finished products and finished products may be appropriately separated according to manufacturers' need.

There shall be container-washing equipment.

All containers and manufacturing equipment in manufactories shall utilize stainless steel, anodized aluminum, non-toxic plastic or other water-tolerant materials where necessary; lead, iron, copper, and other toxic chemical materials are forbidden to be utilized.

There shall be weighing equipment complying with regulations and being calibrated regularly. There shall be locker rooms and hand-washing facilities for employers, and facilities for washing or sterilization of work clothes, caps, face masks, gloves and shoes.

Boilers, water pumps, vacuum pumps, compressors, general-use-water treatment systems, equipment for water distillation or purification, equipment for dust removal, air ventilating or air cleaning and sterilization, or air, temperature and moisture control facilities shall be installed as needed.

Operations, such as production, processing, or packaging, shall be conducted by relevant facilities in manufactories in an integrated closed system from the inlet to the outlet of materials, in principle. 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.

There shall be Bates numbering machines for direct printing of batch numbers and manufacture date of products.

3 Cosmetics manufactories producing powder form products shall install the following equipment: Powder milling or ultra-fine powder milling equipment.

Screening and dust collecting equipment.

Mixing equipment.

Quantitative filling (packaging) equipment.

Manufactories in the preceding Paragraph may, as needed, install drying machines or drying ovens.

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

Liquid blending containers, settling tanks or ceramic vats.

Stirring equipment.

Filtrating equipment.

Quantitative filling (packaging) equipment.

Manufactories in the preceding Paragraph may, as needed, install the following equipment:

Heat compression (pressure-reduction) equipment.

Autoclave sterilization equipment.

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

Stirring emulsion equipment.

Blending equipment.

Quantitative filling (packaging) equipment.

Manufactories in the preceding Paragraph may, as needed, install the following equipment:

Heating equipment.

Filtrating equipment.

Cooling equipment.

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

Oil blending containers.

Stirring equipment.

Quantitative filling (packaging) equipment.

Manufactories in the preceding Paragraph may, as needed, install filtrating equipment.

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

Powder milling or ultra-fine powder milling equipment.

Screening and dust collecting equipment.

Blending equipment.

Quantitative filling (packaging) equipment.

Manufactories in the preceding Paragraph may, as needed, install the following equipment:

Double heating kettles: shall be installed for preparations required to be heated.

Ointment tube sealing equipment: shall be installed for ointment preparations.

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

Powder milling or ultra-fine powder milling equipment.

Screening and dust collecting equipment.

Blending equipment.

Mixing equipment.

Molding equipment.

Drying or cooling equipment.

Quantitative packaging equipment.

9 Cosmetics manufactories producing eyebrow pencils shall install the following equipment:

Raw material blending equipment.

Equipment for producing pencil core.

Equipment for producing pencil barrel.

Equipment for painting pencil barrel.

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

Blending containers.

Pressure filling equipment.

Leak testing equipment.

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

Stainless steel storage tanks.

Saponification equipment.

Drying equipment.

Equipment for adding fragrances or colorants.

Pressing machines.

Molding machines.

Cutting machines.

Manufactories in the preceding Paragraph may, as needed, install the following equipment:

Salting-out equipment.

Conveying machines.

Manufactories producing handmade soaps shall install the following equipment:

Electronic scales.

Stainless steel vats.

Gas stoves, electronic stoves or other heating equipment.

Mixers.

Graduated cylinders.

Thermometers.

Rubber scrapers.

Molds.

Soap cutting machines.

12 Cosmetics manufactories producing cosmetic colorants may install equipment as needed.

13 This set of standards shall be implemented on the date of promulgation.

Data Source: Ministry of Economic Affairs R.O.C.(Taiwan) Laws and Regulations Retrieving System