NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH RE: RULES, PROCEDURES AND CONDITIONS ON REQUIREMENTS FOR PERSONS MANUFACTURING FOR SALE, PERSONS IMPORTING FOR SALE OR CONTRACT MANUFACTURERS TO COLLECT INFORMATION PERTAINING TO COSMETICS FOR INSPECTION,

B.E. 2560 (2017)*

By virtue of the provisions of section 5 paragraph one, section 6 (8) of the Cosmetics Act, B.E. 2558 (2015), in the interest of protecting safety and health of persons, the Minister of Public Health, upon recommendation of the Cosmetics Committee, hereby issues the Notification prescribing rules, procedures and conditions on requirements for persons manufacturing for sale, persons importing for sale or contract manufacturers to collect information pertaining to cosmetics for inspection as follows.

Clause 1. A person manufacturing for sale, a person importing for sale or a contract manufacturer of a cosmetic shall prepare information pertaining to the cosmetic, and maintain the information on the cosmetic for inspection.

Clause 2. The collection of information pertaining to a cosmetic for inspection can be made in the form of documents or electronic documents and in Thai language or English language. Such information shall be stored at the manufacturing facility or import facility.

Clause 3. A person manufacturing a cosmetic for sale, a person importing a cosmetic for sale or a contract manufacturer of a cosmetic shall deliver information pertaining to the cosmetic to a competent official for inspection. In the case where further documents are requested, they shall be delivered within thirty days. In an urgent case or a potentially life-threatening case, they shall be delivered within forty-eight hours.

Clause 4. In the case where a cosmetic has no longer been distributed in the market, information pertaining to such cosmetic shall be maintained for at least three years.

^{*} Published in the Government Gazette, Vol. 134, Special Issue, Part 288d, page 7, dated 23rd November B.E. 2560 (2017)

Clause 5. Information pertaining to a cosmetic shall have the details in accordance with the annex to this Notification.

Clause 6. This Notification shall come into force after the expiration of one hundred and eighty days from the date of its publication in the Government Gazette.

Announced on the 12th day of October B.E. 2560 (2017)

Piyasakol Sakolsatayadorn

Minister of Public Health

Annex to

the Notification of the Ministry of Public Health

Re: Rules, Procedures and Conditions on Requirements for Persons Manufacturing for Sale,
Persons Importing for Sale or Contract Manufacturers
to Collect Data Pertaining to Cosmetics for Inspection, B.E. 2561 (2018)

Information on Cosmetic

Information pertaining to cosmetic consists of 3 parts as follows.

Part 1 Summary of Cosmetic

- 1.1 General Information
 - 1.1.1 Copy of the notification receipt;
- 1.1.2 In case of manufacturing, evidence to verify the ownership of the cosmetic or other relevant evidence, e.g. hiring contract;
- 1.1.3 In case of importation, evidence to verify the ownership of the cosmetic or other relevant evidence, i.e.:
 - Letter of authorization from trademark owner or manufacturer;
- Document containing information on formulation of the imported cosmetic under 1.2 issued by the manufacturer or owner of the cosmetic abroad.
 - 1.2 Formulation of Ingredients of Cosmetic
 - 1.2.1 Name of cosmetic (trade name and name of cosmetic):
- 1.2.2 Names of raw materials identified in accordance with the International Nomenclature of Cosmetic Ingredients (INCI name), except for chemicals used as color in which case they shall be identified by their Color Index Number (CI No.), or for natural raw materials in which case their scientific name as well as the part and form of raw materials being used shall be identified;
 - 1.2.3 Purpose of use;
- 1.2.4 Quantity used for each item of raw materials (their concentration shall be numbered in %w/w).
 - 1.3 Label of Cosmetic
- 1.3.1 Label of container. In case of a cosmetic sold in Thailand, a label in Thailanguage containing statements which are complete and correct as prescribed by law shall be provided;

- 1.3.2 Package insert and/or instruction for use which forms an integral part of the cosmetic (if any).
 - 1.4 Information on Manufacture
- 1.4.1 In case of manufacturer of cosmetic, steps of manufacturing process and a system to determine lot number shall be shown.

In case of an imported cosmetic, evidence to prove the manufacturing steps and process and a system to determine lot number from the manufacturer shall be provided. In the case where additional information is needed, the competent official may request manufacturing details from the importer. In this regard, the owner of the cosmetic may send such information directly to the competent official.

- 1.5 A report summarizing adverse effects from the use of the cosmetic as prescribed by the Notification of the Ministry of Public Health (if any).
- 1.6 The evaluation of the verifiability of the claims on properties of the cosmetic based on its raw materials, ingredients and tests on the cosmetic.

Part 2 Information on Raw Materials

- 2.1 A manufacturer and contract manufacturer of a cosmetic must prepare details on specific properties of the raw materials and ingredients by preparing specification of each type of raw materials and ingredients, including water used for the manufacture.
 - 2.2 Safety Data Sheet (SDS) for each item of raw materials.

Part 3 Information on Finished Product

- 3.1 Master formula:
- 3.2 Product specification;
- 3.3 Product testing method.