

Subpart C—Labeling of Specific Ingredients

§ 701.20 Detergent substances, other than soap, intended for use in cleansing the body.

(a) In its definition of the term *cosmetic*, the Federal Food, Drug, and Cosmetic Act specifically excludes soap. The term *soap* is nowhere defined in the act. In administering the act, the Food and Drug Administration interprets the term “soap” to apply only to articles that meet the following conditions:

- (1) The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the detergent properties of the article are due to the alkali-fatty acid compounds; and
- (2) The product is labeled, sold, and represented only as soap.

(b) Products intended for cleansing the human body and which are not “soap” as set out in paragraph (a) of this section are “cosmetics,” and accordingly they are subject to the requirements of the act and the regulations thereunder. For example, such a product in bar form is subject to the requirement, among others, that it shall bear a label containing an accurate statement of the weight of the bar in avoirdupois pounds and ounces, this statement to be prominently and conspicuously displayed so as to be likely to be read under the customary conditions of purchase and use.

§ 701.30 Ingredient names established for cosmetic ingredient labeling.

The Commissioner establishes the following names for the purpose of cosmetic ingredient labeling pursuant to paragraph (e) of § 701.3:

Chemical name or description	Chemical formula	Established label name
Trichlorofluoromethane	CCl ₃ F	Chlorofluorocarbon 11.
Trichlorofluoromethane and 0.3 pct nitromethane	CCl ₃ F+CH ₃ NO ₂ ..	Chlorofluorocarbon 11 S.
Dichlorodifluoromethane	CCl ₂ F ₂	Chlorofluorocarbon 12.
Chlorodifluoromethane	CHClF ₂	Hydrochlorofluorocarbon 22.
1, 2-dichloro-1, 1, 2, 2-tetrafluoroethane	CClF ₂ CClF ₂	Chlorofluorocarbon 114.
1-Chloro-1, 1-difluoroethane	CH ₃ CClF ₂	Hydrochlorofluorocarbon 142 B.
1, 1-difluoroethane	CH ₃ CHF ₂	Hydrofluorocarbon 152 A.
Ethyl ester of hydrolyzed animal protein is the ester of ethyl alcohol and the hydrolysate of collagen or other animal protein, derived by acid, enzyme, or other form of hydrolysis.	Ethyl ester of hydrolyzed animal protein.

[42 FR 24255, May 13, 1977, as amended at 45 FR 3577, Jan. 18, 1980]

PART 710—VOLUNTARY REGISTRATION OF COSMETIC PRODUCT ESTABLISHMENTS

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AUTHORITY: 21 U.S.C. 321, 331, 361, 362, 371, 374.

SOURCE: 39 FR 10059, Mar. 15, 1974, unless otherwise noted.

§ 710.1 Who should register.

The owner or operator of a cosmetic product establishment which is not exempt under § 710.9 and engages in the manufacture or packaging of a cosmetic product is requested to register for each such establishment, whether or not the product enters interstate commerce. This request extends to any foreign cosmetic product establishment whose products are exported for sale in any State as defined in section 201(a)(1) of the act. No registration fee is required.

§ 710.2 Time for registration.

The owner or operator of an establishment entering into the manufacture or packaging of a cosmetic product should register his establishment

within 30 days after the operation begins.

§ 710.3 How and where to register.

Form FD-2511 (“Registration of Cosmetic Product Establishment”) is obtainable on request from the Food and Drug Administration, Department of Health and Human Services, Washington, DC 20204, or at any Food and Drug Administration district office. The completed form should be mailed to Cosmetic Product Establishment Registration, Food and Drug Administration, Department of Health and Human Services, Washington, DC 20204.

§ 710.4 Information requested.

Form FD-2511 requests information on the name and address of the cosmetic product establishment, including post office ZIP code; all business trading names used by the establishment; and the type of business (manufacturer and/or packer). The information requested should be given separately for each establishment as defined in § 700.3(j) of this chapter.

[39 FR 10059, Mar. 15, 1974, as amended at 46 FR 38073, July 24, 1981; 54 FR 39640, Sept. 27, 1989]

§ 710.5 Amendments to registration.

Within 30 days after a change in any of the information contained on a submitted Form FD-2511, a new Form FD-2511 should be submitted to amend the registration. This amendment is also necessary when a registration is to be canceled because an establishment has changed its name and no longer conducts business under the original name.

§ 710.6 Notification of registrant; cosmetic product establishment registration number.

The Commissioner of Food and Drugs will provide the registrant with a validated copy of Form FD-2511 as evidence of registration. This validated copy will be sent only to the location shown for the registering establishment. A permanent registration number will be assigned to each cosmetic product establishment registered in accordance with the regulations in this part.

§ 710.7 Inspection of registrations.

A copy of the Form FD-2511 filed by the registrant will be available for inspection at the Food and Drug Administration, Department of Health and Human Services, Washington, DC 20204.

§ 710.8 Misbranding by reference to registration or to registration number.

Registration of a cosmetic product establishment or assignment of a registration number does not in any way denote approval of the firm or its products by the Food and Drug Administration. Any representation in labeling or advertising that creates an impression of official approval because of registration or possession of a registration number will be considered misleading.

§ 710.9 Exemptions.

The following classes of persons are not requested to register in accordance with this part 710 because the Commissioner has found that such registration is not justified:

(a) Beauty shops, cosmetologists, retailers, pharmacies, and other persons and organizations that compound cosmetic products at a single location and administer, dispense, or distribute them at retail from that location and who do not otherwise manufacture or package cosmetic products at that location.

(b) Physicians, hospitals, clinics, and public health agencies.

(c) Persons who manufacture, prepare, compound, or process cosmetic products solely for use in research, pilot plant production, teaching, or chemical analysis, and who do not sell these products.

PART 720—VOLUNTARY FILING OF COSMETIC PRODUCT INGREDIENT AND COSMETIC RAW MATERIAL COMPOSITION STATEMENTS

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