

| Chemical name or description | Chemical formula | Established label name |
|---|------------------|---|
| 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

Sec.

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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, 5100 Paint Branch Pkwy., College Park, MD 20740,

or at any Food and Drug Administration district office. The completed form should be mailed to Cosmetic Product Establishment Registration, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

[39 FR 10059, Mar. 15, 1974, as amended at 68 FR 15355, Mar. 31, 2003]

§ 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

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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, 5100 Paint Branch Pkwy., College Park, MD 20740.

[39 FR 10059, Mar. 15, 1974, as amended at 68 FR 15355, Mar. 31, 2003]

§ 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 COMPOSITION STATEMENTS

Sec.

720.1 Who should file.

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720.2 Times for filing.

720.3 How and where to file.

720.4 Information requested about cosmetic products.

720.5 [Reserved]

720.6 Amendments to statement.

720.7 Notification of person submitting cosmetic product ingredient statement.

720.8 Confidentiality of statements.

720.9 Misbranding by reference to filing or to statement number.

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

SOURCE: 39 FR 10060, Mar. 15, 1974, unless otherwise noted.

§ 720.1 Who should file.

Either the manufacturer, packer, or distributor of a cosmetic product is requested to file Form FDA 2512 (“Cosmetic Product Ingredient Statement”), whether or not the cosmetic product enters interstate commerce. This request extends to any foreign manufacturer, packer, or distributor of a cosmetic product exported for sale in any State as defined in section 201(a)(1) of the Federal Food, Drug, and Cosmetic Act. No filing fee is required.

[57 FR 3129, Jan. 28, 1992]

§ 720.2 Times for filing.

Within 180 days after forms are made available to the industry, Form FDA 2512 should be filed for each cosmetic product being commercially distributed as of the effective date of this part. Form FDA 2512 should be filed within 60 days after the beginning of commercial distribution of any product not covered within the 180-day period.

[57 FR 3129, Jan. 28, 1992]

§ 720.3 How and where to file.

Forms FDA 2512 and FDA 2514 (“Discontinuance of Commercial Distribution of Cosmetic Product Formulation”) are obtainable on request from the Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at any Food and Drug Administration district office. The completed form should be mailed or delivered to: Cosmetic Product Statement, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD