

### § 347.3

### 21 CFR Ch. I (4–1–10 Edition)

#### § 347.3 Definitions.

As used in this part:

*Astringent drug product.* A drug product applied to the skin or mucous membranes for a local and limited protein coagulant effect.

*Lip protectant drug product.* A drug product that temporarily prevents dryness and helps relieve chapping of the exposed surfaces of the lips; traditionally called “lip balm.”

*Poison ivy, oak, sumac dermatitis.* An allergic contact dermatitis due to exposure to plants of the genus *Rhus* (poison ivy, poison oak, poison sumac), which contain urushiol, a potent skin-sensitizer.

*Skin protectant drug product.* A drug product that temporarily protects injured or exposed skin or mucous membrane surfaces from harmful or annoying stimuli, and may help provide relief to such surfaces.

[68 FR 33376, June 4, 2003]

#### Subpart B—Active Ingredients

SOURCE: 68 FR 33377, June 4, 2003, unless otherwise noted.

#### § 347.10 Skin protectant active ingredients.

The active ingredients of the product consist of any of the following, within the concentration specified for each ingredient:

- (a) Allantoin, 0.5 to 2 percent.
- (b) Aluminum hydroxide gel, 0.15 to 5 percent.
- (c) Calamine, 1 to 25 percent.
- (d) Cocoa butter, 50 to 100 percent.
- (e) Cod liver oil, 5 to 13.56 percent, in accordance with § 347.20(a)(1) or (a)(2), provided the product is labeled so that the quantity used in a 24-hour period does not exceed 10,000 U.S.P. Units vitamin A and 400 U.S.P. Units cholecalciferol.
- (f) Colloidal oatmeal, 0.007 percent minimum; 0.003 percent minimum in combination with mineral oil in accordance with § 347.20(a)(4).
- (g) Dimethicone, 1 to 30 percent.
- (h) Glycerin, 20 to 45 percent.
- (i) Hard fat, 50 to 100 percent.
- (j) Kaolin, 4 to 20 percent.
- (k) Lanolin, 12.5 to 50 percent.

(l) Mineral oil, 50 to 100 percent; 30 to 35 percent in combination with colloidal oatmeal in accordance with § 347.20(a)(4).

- (m) Petrolatum, 30 to 100 percent.
- (n) [Reserved]
- (o) Sodium bicarbonate.
- (p) [Reserved]
- (q) Topical starch, 10 to 98 percent.
- (r) White petrolatum, 30 to 100 percent.
- (s) Zinc acetate, 0.1 to 2 percent.
- (t) Zinc carbonate, 0.2 to 2 percent.
- (u) Zinc oxide, 1 to 25 percent.

#### § 347.12 Astringent active ingredients.

The active ingredient of the product consists of any one of the following within the specified concentration established for each ingredient:

- (a) Aluminum acetate, 0.13 to 0.5 percent (depending on the formulation and concentration of the marketed product, the manufacturer must provide adequate directions so that the resulting solution to be used by the consumer contains 0.13 to 0.5 percent aluminum acetate).
- (b) Aluminum sulfate, 46 to 63 percent (the concentration is based on the anhydrous equivalent).
- (c) Witch hazel.

#### § 347.20 Permitted combinations of active ingredients.

(a) *Combinations of skin protectant active ingredients.* (1) Any two or more of the ingredients identified in § 347.10(a), (d), (e), (i), (k), (l), (m), and (r) may be combined provided the combination is labeled according to § 347.50(b)(1) and provided each ingredient in the combination is within the concentration specified in § 347.10.

(2) Any two or more of the ingredients identified in § 347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r) may be combined provided the combination is labeled according to § 347.50(b)(2) and provided each ingredient in the combination is within the concentration specified in § 347.10.

(3) Any two or more of the ingredients identified in § 347.10(b), (c), (j), (s), (t), and (u) may be combined provided the combination is labeled according to § 347.50(b)(3) and provided each ingredient in the combination is within the concentration specified in § 347.10.