

§ 347.3

21 CFR Ch. I (4–1–13 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.

(4) The ingredients identified in § 347.10(f) and (l) may be combined provided the combination is labeled according to § 347.50(b)(7) and provided each ingredient in the combination is within the concentration specified in § 347.10.

(b) *Combination of ingredients to prepare an aluminum acetate solution.* Aluminum sulfate tetradecahydrate may be combined with calcium acetate monohydrate in powder or tablet form to provide a 0.13 to 0.5 percent aluminum acetate solution when the powder or tablet is dissolved in the volume of water specified in “Directions.”

(c) *Combinations of skin protectant and external analgesic active ingredients.* Any one (two when required to be in combination) or more of the active ingredients identified in § 347.10(a), (d), (e), (i), (k), (l), (m), and (r) may be combined with any of the following generally recognized as safe and effective external analgesic active ingredients: Single amine and “caine”-type local anesthetics, alcohols and ketones, antihistamines, or any permitted combination of these ingredients, but not with hydrocortisone, provided the product is labeled according to § 347.60(b)(1).

(d) *Combinations of skin protectant and first aid antiseptic active ingredients.* Any one (two when required to be in combination) or more of the active ingredients identified in § 347.10(a), (d), (e), (i), (k), (l), (m), and (r) may be combined with any generally recognized as safe and effective single first aid antiseptic active ingredient, or any permitted combination of these ingredients, provided the product is labeled according to § 347.60(b)(2).

(e) *Combinations of skin protectant and sunscreen active ingredients.* Any one (two when required to be in combination) or more of the skin protectant active ingredients identified in § 347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r) may be combined with any generally recognized as safe and effective single sunscreen active ingredient, or any permitted combination of these ingredients, provided the product meets the conditions in § 352.20(b) of this chapter and is labeled according to

§§ 347.60(b)(3) and 352.60(b) of this chapter.

[68 FR 33377, June 4, 2003, as amended at 74 FR 9765, Mar. 6, 2009]

EFFECTIVE DATE NOTE: At 68 FR 33377, June 4, 2003, in § 347.20 paragraph (d) was stayed until further notice, effective June 4, 2004. At 74 FR 9765, Mar. 6, 2009, in § 347.20, paragraph (d) was redesignated as paragraph (e).

Subpart C—Labeling

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

§ 347.50 Labeling of skin protectant drug products.

A skin protectant drug product may have more than one labeled use and labeling appropriate to different uses may be combined to eliminate duplicative words or phrases as long as the labeling is clear and understandable. When the labeling of the product contains more than one labeled use, the appropriate statement(s) of identity, indications, warnings, and directions must be stated in the labeling.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product with one or more of the following:

(1) *For any product.* “Skin protectant” (optional, may add dosage form, e.g., “cream,” “gel,” “lotion,” or “ointment”).

(2) *For any product formulated as a lip protectant.* “Skin protectant,” “lip protectant,” or “lip balm” (optional, may add dosage form, e.g., “cream,” “gel,” “lotion,” or “ointment”).

(3) *For products containing any ingredient in § 347.10(b), (c), (j), (s), (t), and (u).* “Poison ivy, oak, sumac drying” (optional, may add dosage form, e.g., “cream,” “gel,” “lotion,” or “ointment”).

(4) *For products containing any ingredient in § 347.10(b), (c), (f), (j), (o), (s), (t), and (u).* “Poison ivy, oak, sumac protectant.”

(b) *Indications.* The labeling of the product states, under the heading “Uses,” one or more of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements, describing only the uses that have been established and listed in