Food and Drug Administration, HHS

§ 346.20 Keratolytic active ingredients.

The active ingredient of the product consists of any of the following when used within the concentration range established for each ingredient:

(a) Alcloxa 0.2 to 2 percent.
(b) Resorcinol 1 to 3 percent.

§ 346.12 Vasoconstrictor active ingredients.

The active ingredient of the product consists of any of the following when used in the concentration or within the concentration range established for each ingredient.

(a) Ephedrine sulfate 0.1 to 1.25 percent.
(b) Ephedrine 0.005 to 0.01 percent.
(c) Ephedrine hydrochloride 0.005 to 0.01 percent.
(d) Phenylephrine hydrochloride 0.25 percent.

§ 346.14 Protectant active ingredients.

(a) The following active ingredients may be used as the sole protectant active ingredient in a product if the ingredient as identified constitutes 50 percent or more by weight of the final product. In addition, the following active ingredients may be used in concentrations of less than 50 percent by weight only when used in combinations in accordance with §346.22 (a), (b), (n), and (o) and with the following limitations:

(1) Camphor not to exceed 25 percent by weight per dosage unit.
(2) Juniper tar 1 to 5 percent.
(3) Menthol 0.1 to 1 percent.

§ 346.16 Analgesic, anesthetic, and antipruritic active ingredients.

The active ingredient of the product consists of any of the following when used within the concentration range established for each ingredient:

(a) Camphor 0.1 to 3 percent.
(b) Juniper tar 1 to 5 percent.
(c) Menthol 0.1 to 1 percent.

§ 346.18 Astringent active ingredients.

The active ingredient of the product consists of any of the following when used within the concentration range established for each ingredient:

(a) Calamine within a concentration range of 5 to 25 percent by weight per dosage unit (based on the zinc oxide content of calamine).
(b) Witch hazel, 10 to 50 percent.
(c) Zinc oxide, within a concentration range of 5 to 25 percent by weight per dosage unit.

§ 346.20 Keratolytic active ingredients.

The active ingredient of the product consists of any of the following when used within the concentration range established for each ingredient:

(a) Alcloxa 0.2 to 2 percent.
(b) Resorcinol 1 to 3 percent.