PART 350—ANTIPERSPIRANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Subpart B—Active Ingredients

Subpart C—Labeling

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AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 68 FR 34291, June 9, 2003, unless otherwise noted.

Subpart A—General Provisions

§ 350.1 Scope.

(a) An over-the-counter antiperspirant drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 350.3 Definition.

As used in this part:

Antiperspirant. A drug product applied topically that reduces the production of perspiration (sweat) at that site.

Subpart B—Active Ingredients

§ 350.10 Antiperspirant active ingredients.

The active ingredient of the product consists of any of the following within the established concentration and dosage formulation. Where applicable, the ingredient must meet the aluminum to chloride, aluminum to zirconium, and aluminum plus zirconium to chloride atomic ratios described in the U.S. Pharmacopeia-National Formulary. The concentration of ingredients in paragraphs (b) through (j) of this section is calculated on an anhydrous basis, omitting from the calculation any buffer component present in the compound, in an aerosol or nonaerosol dosage form. The concentration of ingredients in paragraphs (k) through (r) of this section is calculated on an anhydrous basis, omitting from the calculation any buffer component present in the compound, in a nonaerosol dosage form. The labeled declaration of the percentage of the active ingredient should exclude any water, buffer components, or propellant.

(a) Aluminum chloride up to 15 percent, calculated on the hexahydrate form, in an aqueous solution nonaerosol dosage form.

(b) Aluminum chlorohydrate up to 25 percent.

(c) Aluminum chlorohydrex polyethylene glycol up to 25 percent.

(d) Aluminum chlorohydrex propylene glycol up to 25 percent.

(e) Aluminum dichlorohydrate up to 25 percent.

(f) Aluminum dichlorohydrex polyethylene glycol up to 25 percent.

(g) Aluminum dichlorohydrex propylene glycol up to 25 percent.

(h) Aluminum sesquichlorohydrate up to 25 percent.

(i) Aluminum sesquichlorohydrex polyethylene glycol up to 25 percent.

(j) Aluminum sesquichlorohydrex propylene glycol up to 25 percent.

(k) Aluminum zirconium octachlorohydrate up to 20 percent.

(l) Aluminum zirconium octachlorohydrex gly up to 20 percent.

(m) Aluminum zirconium pentachlorohydrate up to 20 percent.

(n) Aluminum zirconium pentachlorohydrex gly up to 20 percent.

(o) Aluminum zirconium tetrachlorohydrate up to 20 percent.

(p) Aluminum zirconium tetrachlorohydrex gly up to 20 percent.

(q) Aluminum zirconium trichlorohydrate up to 20 percent.

(r) Aluminum zirconium trichlorohydrex gly up to 20 percent.