

U.S. Food and Drug Administration

**Over-the-Counter (OTC) Monograph M019:
Antiperspirant Drug Products for Over-the-Counter Human Use
(Posted November 23, 2021)¹**

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

Part A—General Provisions

§ M019.1 Scope

An over-the-counter (OTC) 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 OTC monograph and each general condition established in 21 CFR 330.1.

§ M019.1.3 Definition

As used in this OTC monograph:

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

¹ Final Administrative Order (OTC000015), effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

Part B—Active Ingredients

§ M019.10 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 (USP)-National Formulary (NF). The concentration of ingredients in §§ M019.10(b) through (j) 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 §§ M019.10(k) through (r) 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 chlorohydrate polyethylene glycol up to 25 percent.
- (d) Aluminum chlorohydrate propylene glycol up to 25 percent.
- (e) Aluminum dichlorohydrate up to 25 percent.
- (f) Aluminum dichlorohydrate polyethylene glycol up to 25 percent.
- (g) Aluminum dichlorohydrate propylene glycol up to 25 percent.
- (h) Aluminum sesquichlorohydrate up to 25 percent.
- (i) Aluminum sesquichlorohydrate polyethylene glycol up to 25 percent.
- (j) Aluminum sesquichlorohydrate propylene glycol up to 25 percent.
- (k) Aluminum zirconium octachlorohydrate up to 20 percent.
- (l) Aluminum zirconium octachlorohydrate gly up to 20 percent.
- (m) Aluminum zirconium pentachlorohydrate up to 20 percent.
- (n) Aluminum zirconium pentachlorohydrate gly up to 20 percent.
- (o) Aluminum zirconium tetrachlorohydrate up to 20 percent.

(p) Aluminum zirconium tetrachlorohydrate up to 20 percent.

(q) Aluminum zirconium trichlorohydrate up to 20 percent.

(r) Aluminum zirconium trichlorohydrate up to 20 percent.

Part C—Labeling

§ M019.50 Labeling of antiperspirant drug products

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an “antiperspirant.”

(b) Indications. The labeling of the product states, under the heading “Uses,” the phrase listed in § M019.50(b)(1) and may contain any additional phrases listed in §§ M019.50(b)(2) through (b)(5), as appropriate. Other truthful and nonmisleading statements, describing only the uses that have been established and listed in §§ M019.50(b)(1) through (b)(5), may also be used, as provided in 21 CFR 330.1(c)(2), subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352) relating to misbranding and the prohibition in section 301(d) of the FD&C Act (21 U.S.C. 331(d)) against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the FD&C Act (21 U.S.C. 355(a)).

(1) For any product, the labeling states [select one of the following: “decreases,” “lessens,” or “reduces”] “underarm” [select one of the following: “dampness,” “perspiration,” “sweat,” “sweating,” or “wetness”].

(2) The labeling may state “also [select one of the following: ‘decreases,’ ‘lessens,’ or ‘reduces’] underarm [select one of the following: ‘dampness,’ ‘perspiration,’ ‘sweat,’ ‘sweating,’ or ‘wetness’] due to stress”.

(3) For products that demonstrate standard effectiveness (20 percent sweat reduction) over a 24-hour period, the labeling may state [select one of the following: “all day protection,” “lasts all day,” “lasts 24 hours,” or “24 hour protection”].

(4) For products that demonstrate extra effectiveness (30 percent sweat reduction), the labeling may state “extra effective”.

(5) Products that demonstrate extra effectiveness (30 percent sweat reduction) sustained over a 24-hour period may state the claims in §§ M019.50(b)(3) and (b)(4) either individually or combined, e.g., “24 hour extra effective protection,” “all day extra effective protection,” “extra effective protection lasts 24 hours,” or “extra effective protection lasts all day”.

(c) Warnings. The labeling of the product contains the following statements under the heading “Warnings”:

- (1) “Do not use on broken skin”.
- (2) “Stop use if rash or irritation occurs”.
- (3) “Ask a doctor before use if you have kidney disease”.
- (4) For products in an aerosolized dosage form.
 - (i) “When using this product [bullet]² keep away from face and mouth to avoid breathing it”.
 - (ii) The warning required by 21 CFR 369.21 for drugs in dispensers pressurized by gaseous propellants.

(d) Directions. The labeling of the product contains the following statement under the heading “Directions”: “apply to underarms only”.

Part D—Guidelines for Effectiveness Testing

§ M019.60 Guidelines for effectiveness testing of antiperspirant drug products

An antiperspirant in finished dosage form may vary in degree of effectiveness because of minor variations in formulation. To assure the effectiveness of an antiperspirant, the Food and Drug Administration is providing guidelines that manufacturers may use in testing for effectiveness. These guidelines are available in the OTC Monographs@FDA portal at <https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm>.

[68 FR 34291, June 9, 2003, as amended at 76 FR 31470, June 1, 2011; 79 FR 68115, Nov. 14, 2014]

² See 21 CFR 201.66(b)(4) for definition of bullet.