

TABLE 1.—ANTIPERSPIRANT ACTIVE INGREDIENTS

Name in Tentative Final Monograph	Current Name
Aluminum chloride	Same
Aluminum chlorohydrate	Same
Aluminum chlorohydrate polyethylene glycol complex	Aluminum chlorohydrate polyethylene glycol
Aluminum chlorohydrate propylene glycol complex.	Aluminum chlorohydrate propylene glycol
Aluminum dichlorohydrate	Same
Aluminum dichlorohydrate polyethylene glycol complex	Aluminum dichlorohydrate polyethylene glycol
Aluminum dichlorohydrate propylene glycol complex.	Aluminum dichlorohydrate propylene glycol
Aluminum sesquichlorohydrate	Same
Aluminum sesquichlorohydrate polyethylene glycol complex	Aluminum sesquichlorohydrate polyethylene glycol
Aluminum sesquichlorohydrate propylene glycol complex	Aluminum sesquichlorohydrate propylene glycol
Aluminum sulfate buffered <sup>1</sup>	Same
Aluminum zirconium octachlorohydrate	Same
Aluminum zirconium octachlorohydrate glycine complex	Aluminum zirconium octachlorohydrate gly
Aluminum zirconium pentachlorohydrate	Same
Aluminum zirconium pentachlorohydrate glycine complex	Aluminum zirconium pentachlorohydrate gly
Aluminum zirconium tetrachlorohydrate	Same
Aluminum zirconium tetrachlorohydrate glycine complex	Aluminum zirconium tetrachlorohydrate gly
Aluminum zirconium trichlorohydrate	Same
Aluminum zirconium trichlorohydrate glycine complex	Aluminum zirconium trichlorohydrate gly

<sup>1</sup> Aluminum sulfate buffered with sodium aluminum lactate.

The agency is including in § 350.10 of this final monograph those antiperspirant active ingredients that currently have a compendial monograph. Only one active ingredient, aluminum sulfate buffered, does not have a current or proposed compendial monograph. While aluminum sulfate does have a compendial monograph, the buffer component, sodium aluminum lactate, does not. This buffer ingredient must also have a compendial monograph or there must be a compendial monograph for aluminum sulfate buffered in order for aluminum sulfate buffered to be included in the antiperspirant final monograph. At the present time, this ingredient is being included in § 310.545(a)(4)(ii) as a nonmonograph ingredient because the agency is not aware of any pending compendial monograph being developed. Should a compendial monograph eventually be developed, the agency will move this ingredient from § 310.545(a)(4)(ii) to § 350.10.

2. The agency is revising the format for active ingredients in § 350.10 for consistency with recent monographs:

The proposed chart format is now a paragraph format listing ingredients in alphabetical order. The amount of active ingredient is stated as “up to \_\_\_\_\_ percent” instead of as “\_\_\_\_\_ percent or less concentration.” The information about calculating the concentration on an anhydrous basis is moved to the preamble of § 350.10. The preamble statement about aluminum to chloride and/or aluminum to zirconium ratios is revised to state: “Where applicable, the ingredient must meet the aluminum to chloride, aluminum to zirconium, and aluminum plus zirconium to chloride atomic ratios described in the United States Pharmacopeia-National Formulary.” The proposed ratio range table is not included in the final monograph because this information is now included in the USP–NF monographs for each active ingredient in § 350.10, where applicable.

3. The agency is expanding the indications proposed in § 350.50(b) of the TFM to provide additional uses based on new effectiveness data. The

agency is also revising the uses format to make it more concise.

Because the indications proposed in § 350.50(b)(1), (b)(2), and (b)(3) of the TFM are very similar, the agency is combining them as a single indication with choices under § 350.50(b)(1): [Select one of the following: “decreases,” “lessens,” or “reduces”] “underarm” [select one of the following: “dampness,” “perspiration,” “sweat,” “sweating,” or “wetness”]. (See section II.B, comment 6 of this document.) The agency is adding a new additional indication in § 350.50(b)(2): “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”. (See section II.B, comment 6 and section II.C, comment 13 of this document.) The agency is adding a new additional indication in § 350.50(b)(3): Select one of the following: [“all day protection,” “lasts all day,” “lasts 24 hours,” or “24 hour protection”]. (See section II.C, comment 12 of this document.) The agency is adding a new additional