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|  |  | **2-301.16 Hand Antiseptics.**   1. A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall: |
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|  |  | (1) Comply with one of the following: |

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|  |  | (a) Be an approved drug that is listed in the FDA publication **Approved Drug Products with Therapeutic Equivalence Evaluations** as an approved drug based on safety and effectiveness; Pf or |
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|  |  | (b) Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash, Pf and |
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|  |  | (2) Comply with one of the following: |
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|  |  | (a) Have components that are exempted from the requirement of being listed in federal food additive regulations as specified in 21 CFR 170.39 - Threshold of regulation for substances used in food-contact articles;Pf or |
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|  |  | (b) Comply with and be listed in: |
|  |  |  |
|  |  | (i) 21 CFR 178 - Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers as regulated for use as a food additive with conditions of safe use, Pf or |
|  |  |  |
|  |  | (ii) 21 CFR 182 - Substances Generally Recognized as Safe, 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with food, Pf and |
|  |  |  |
|  |  | (3) Be applied only to hands that are cleaned as specified under § 2‑301.12. Pf |
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|  |  | (B) If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the criteria specified under Subparagraph (A)(2) of this section, use shall be: |
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|  |  | (1) Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; Pf or |
|  |  |  |
|  |  | (2) Limited to situations that involve no direct contact with food by the bare hands. Pf |
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|  |  | (C) A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 mg/L chlorine. Pf |