

**WAC 246-215-02320 Hands and arms—Hand antiseptics (FDA Food Code 2-301.16).** (1) A hand antiseptic used as a topical application, hand antiseptic solution used as a hand dip, or a hand antiseptic soap must:

(a) Comply with one of the following:

(i) 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; or

(ii) Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash; and

(b) Consist only of components which the intended use of each complies with one of the following:

(i) A threshold of regulation exemption under 21 C.F.R. 170.39 - Threshold of Regulation for Substances Used in Food Contact Articles; or

(ii) 21 C.F.R. 178 - Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers as regulated for use as a FOOD ADDITIVE with conditions of safe use; or

(iii) A determination of generally recognized as safe (GRAS). Partial listings of substances with FOOD uses that are GRAS may be found in 21 C.F.R. 182 - Substances Generally Recognized as Safe, 21 C.F.R. 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 C.F.R. 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with FOOD, and in FDA's Inventory of GRAS Notices; or

(iv) A prior sanction listed under 21 C.F.R. 181 - Prior Sanctioned Food ingredients; or

(v) A FOOD Contact Notification that is effective; and

(c) Be applied only to hands that are cleaned as specified under WAC 246-215-02305.

(2) If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the requirements specified under subsection (1)(b) of this section, use must be:

(a) Followed by thorough hand rinsing in clean water before hand contact with FOOD or by the use of gloves; or

(b) Limited to situations that involve no direct contact with FOOD by the bare hands.

(3) A hand antiseptic solution used as a hand dip must be maintained clean and at a strength equivalent to at least 100 MG/L chlorine.

[Statutory Authority: RCW 43.20.050 and 43.20.145. WSR 21-01-122, § 246-215-02320, filed 12/15/20, effective 3/1/22; WSR 13-03-109, § 246-215-02320, filed 1/17/13, effective 5/1/13.]