

4626.0085 HAND ANTISEPTICS. 2-301.16

A. A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap must:

(1) comply with 1 of the following requirements:

(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. This publication is incorporated by reference, is subject to frequent change, and can be found at www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm;p₂or

(b) have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash;p₂

(2) consist only of components that the intended use of each complies with one of the following:

(a) a threshold of regulation exemption under Code of Federal Regulations, title 21, section 170.39;p₂

(b) Code of Federal Regulations, title 21, section 178, as regulated for use as a food additive with conditions of safe use;p₂

(c) a determination of generally recognized as safe (GRAS). Partial listings of substances with food uses that are GRAS may be found in Code of Federal Regulations, title 21, sections 182, 184, and 186, and in the FDA's inventory of GRAS notices;p₂

(d) a prior sanction listed under Code of Federal Regulations, title 21, section 181;p₂
or

(e) a food-contact notification that is effective;p₂ and

(3) be applied only to hands that are cleaned as specified in part 4626.0070.p₂

B. If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the criteria under item A, subitem (2), use must be:

(1) followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves;p₂ or

(2) limited to situations that involve no direct contact with food by the bare hands.p₂

C. A hand antiseptic solution used as a hand dip must be maintained clean and at a strength equivalent to at least 100 mg/L of chlorine.p₂

Statutory Authority: *MS s 31.101; 31.11; 144.05; 144.07; 144.08; 144.12; 157.011*

History: *23 SR 519; 43 SR 295*

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