

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 III-005

Council Recommendation:	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
Delegate Action:	Accepted _____	Rejected _____	

All information above the line is for conference use only.

Title:

HHC 3 - Definition for "Antiseptic Hand Rub"

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (using underlining for language additions):

1. Add a definition for "ANTISEPTIC HAND RUB."

"ANTISEPTIC HAND RUB" An antiseptic hand hygiene product applied to the hands and rubbed until dry, used to reduce the transient microorganisms on the hands.

2. Add reference to ANTISEPTIC HAND RUB to Section 2-301.16, Hand Antiseptics.

(A) A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, ANTISEPTIC HAND RUB, or a hand antiseptic soap shall:

(1) Comply with one of the following:

(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

(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

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

(a) **A threshold of regulation exemption under 21 CFR 170.39 - Threshold of regulation for substances used in FOOD-contact articles;** ^{Pf} or

(b) **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

(c) **A determination of generally recognized as safe (GRAS). Partial listings of substances with FOOD uses that are GRAS may be found in 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, and in FDA's Inventory of GRAS Notices,^{Pf} or

(d) A prior sanction listed under 21 CFR 181 – Prior Sanctioned FOOD Ingredients,^{Pf} or

(e) a FOOD Contact Notification that is effective,^{Pf} and

(3) Be applied only to hands that are cleaned as specified under § 2-301.12.^{Pf}

(B) If a hand antiseptic, ANTISEPTIC HAND RUB 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:

(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}

(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}

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

The original Issue contained referenced text from the 2009 Food Code; the CORRECT 2013 Food Code text is noted in red.