**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) Comply with one of the following:

(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

(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

(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

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.