Antibacterial Soaps: Are they Necessary?

Sarah Janssen, M.D., Ph.D., M.P.H
Senior Scientist, Natural Resources Defense Council
sjanssen@nrdc.org

Health Care Research Collaborative
Safety and Sustainability in the Health Care Sector
April 6, 2011
Topical Antimicrobials

Regulated by the FDA through the Federal Food, Drug, and Cosmetic Act ("Food and Drug Act") prohibiting the marketing of drugs unless they are found to be safe and effective.
FDA monograph on topical antimicrobials

- **1974.** 1st Proposal To Establish a Monograph for OTC Topical Antimicrobial Products
- **1978** Tentative final order
- **1994** Amended Tentative final order
- **2010** Working on new amendments to proposed final rule
I. Conditions under which antimicrobial products are generally recognized as safe and effective and are not misbranded.

II. Conditions under which antimicrobial products are not generally recognized as safe and effective or are misbranded.

III. Conditions for which the available data are insufficient to permit final classification at this time.
Active Ingredients Used in Healthcare (FDA categorization)

- Isopropyl Alcohol, >70% (I)
- Chloroxylenol (PCMX) (III)
- Hexachlorophene (II)
- Quaternary ammonium compounds
  - Benzalkonium chloride (III)
  - Benzethonium chloride (III)
- Chlorhexidine gluconate, 2 or 4% (ns)
- Triclosan, <1% (III)
- Povidone-iodine, 5-10% (I)
Active Ingredients Used in Consumer Antiseptics (FDA categorization)

- Alcohol (I)
- Chloroxylenol (PCMX) (III)
- Quaternary ammonium compounds –
  - Benzalkonium chloride (III)
  - Benzethonium chloride (III)
- Triclocarban (III)
- Triclosan (III)
Emerging Endocrine Disruptors
Antibacterials - Triclosan and Triclocarban

- Triclosan – 75% liquid hand soaps.
- Triclocarban - >25% of bar soaps
Triclosan in health care
Concern about “antibacterials” – triclosan

- Absorbed across the skin, mucosa.
- Half life 11 hours.
- Found in >75% Americans surveyed by the CDC, exposure increasing (Calafat, EHP, 2008)
- Volunteers brushing with triclosan toothpaste for 14 days, had dramatic rise in blood levels (average 450X). (Allymr, 2009)
Concern about “antibacterials” triclosan

- No more effective than plain soap and water.
  - Community intervention studies, no significant reduction in viral or bacterial disease (Aiello, 2007)

- Potential to promote drug-resistant bacteria
  - Triclosan-resistant bacteria isolated from residential and feedlot soil (Welsch, 2011)
  - Studies show cross-resistance to ≥1 antibiotic for at least 1 bacteria species (Aiello, 2007)

- Not effective against Gram negative bacteria
  - Fatal hospital outbreak *Pseudomonas* contamination of triclosan soap dispenser, (Lanini, 2006)
Endocrine Disruption – triclosan

- Thyroid disruptor, decreases thyroxine levels (Crofton, 2007)
- Interferes with testosterone synthesis, decrease sperm counts (Kumar, 2009)
- Interferes with estrogen action, earlier onset of puberty (Stoker, 2010)
Concern about “antibacterials”

- Found primarily in bar soaps, some liquid
- Also rapidly absorbed across skin (Schebb, 2011)
- No more effective than plain soap and water (Aiello, 2007)
- Potential to promote drug-resistant bacteria
- Capable of entering the food chain
Endocrine Disruption – triclocarban

- Unique Endocrine disruptor
  - No activity alone
  - Amplifies activity of endogenous steroid hormones (Ahn, 2008)
  - Amplifies testosterone activity, increases male accessory sex organ weight (Chen, 2008)
Down the drain and into farm fields

(Wu, ES&T, 2010)
1. When hands are visibly dirty or contaminated with proteinaceous material or are visibly soiled with blood or other body fluids, wash hands with either a non-antimicrobial soap and water or an antimicrobial soap and water (IA) (66).

2. If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in all other clinical situations described in items 1C–J (IA) (66).

“Alcohol-based products are more effective for standard handwashing or hand antisepsis by HCWs than soap or antimicrobial soaps.”

3. Provide personnel with efficacious hand-hygiene products that have low irritancy potential, particularly when these products are used multiple times per shift (IB)

4. Provide HCWs with hand lotions or creams to minimize the occurrence of irritant contact dermatitis associated with hand antisepsis or handwashing (IA)
5. To maximize acceptance of hand-hygiene products by HCWs, solicit input from these employees regarding the feel, fragrance, and skin tolerance of any products under consideration. The cost of hand hygiene products should not be the primary factor influencing product selection (IB)

6. Do not add soap to a partially empty soap dispenser. This practice of “topping off” dispensers can lead to bacterial contamination of soap (IA)

Consumer advice on avoiding antimicrobials

- Use plain soap and water
- Alcohol–based hand sanitizers
- Avoid buying other products impregnated with antimicrobials

- Read labels
- Organic food?
Hospital initiatives on antibacterials

- Kaiser Permanente
  - Eliminated the use of triclosan hand soaps in all facilities, public and patient care areas.
  - Also doesn’t recommend the use of antimicrobial impregnated fabrics, paints, carpets or building materials because of unproven effectiveness and higher costs.
Resources

- Natural Resources Defense Council
  [www.nrdc.org](http://www.nrdc.org)

NRDC fact sheet on triclosan
Available for download at: