Antibacterial Soaps: Are they Necessary?

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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)
- Povidone-iodine, 5-10% (I)

- Hexachlorophene (II)
- Chloroxylenol (PCMX) (III)
- Quaternary ammonium compounds
  - Benzalkonium chloride (III)
  - Benzethonium chloride (III)
- Triclosan, <1% (III)

- *Chlorhexidine gluconate, 2 or 4% (ns)
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)
The topical antiseptic monograph at FDA has remained in draft form for over 35 years.

Through a loophole in the existing law, until the monograph is finalized, chemicals in category III (including triclosan and triclocarban) can be legally sold for consumer and health care use.
“At this time, FDA does not have evidence that triclosan added to antibacterial soaps and body washes provides extra health benefits over soap and water.”

“It is FDA’s opinion that existing data raise valid concerns about the effects of repetitive daily human exposure to these antiseptic agents.”
Antibacterials - Triclosan and Triclocarban

- Triclosan – 75% liquid hand soaps + other products.
- Triclocarban - >25% of bar soaps
Triclosan in health care

Drug Facts
Active ingredient
Triclosan, 0.30%

Uses: For hand washing to reduce bacteria.

Warnings: Read the label carefully before use.

TRICLONEX T2
Surgical brush/spoon with nailcleaner - TRICLOSAN 0.5 %

Drug Facts
Active Ingredients: Triclosan
Uses: For surgical instruments, brushes, spoons, and nails.

Other Information: Do not use on the face or eyes.

Manufactured by: Nex Medical s.a.s., via Nieve 3, 20023 Corso Maggiore (MI) - ITALY
Product of Italy

Sponge impregnated with 0.7 fl oz (20 ml) of Antiseptic Solution
More than 1 million pounds produced annually

Absorbed across the skin, mucosa with a half life 11-12 hours.

Found in >75% Americans surveyed by the CDC, exposure levels are increasing (Calafat, EHP, 2008)

Volunteers brushing with triclosan toothpaste for 14 days, had dramatic rise in blood levels (average 450x). (Allymr, 2009)
Concerns about triclosan – unnecessary exposure

• No more effective than plain soap and water.
  • Community intervention studies, no significant reduction in viral or bacterial disease
  • No reduction of bacterial levels found on hands (Aiello, 2007)

• some Gram(-) bacteria have intrinsic resistance
  • Fatal hospital outbreak *Pseudomonas* due to contamination of triclosan soap dispenser (Lanini, 2006)
  • Associated with outbreak of *S. marsecens* in SICU (Barry, 1984)
Concerns about triclosan - antibiotic resistance

- Potential to promote drug-resistant bacteria

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

\[ E. coli, Salmonella enterica, Staph. aureus \]
\[ Amp, Chl, Cipro, Ery, INH, Tet \]
Concerns about triclosan – endocrine disruption

- 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)
Concerns about triclosan - muscle activity

- TCS weakens heart muscle – impairing contractions, 25% reduction in heart function
- TCS weakens skeletal muscle – impairing contractions, 18% reduction in grip strength
- TCS disturbs ability of fathead minnows to swim

(Cherednichenko, et al. 2012)
Concerns about triclosan - altered immune function

- Triclosan exposure – associated with allergy or hay fever diagnosis < 18 y.o. (Clayton, 2011)

- Triclosan exposure – associated with allergies to common airborne triggers and food (peanuts, shrimp, dairy) (Savage, 2012)
Concern about “antibacterials”
triclocarban

- 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)
Antimicrobials in environmental media

- Triclosan and Triclocarban have been found in surface water, waste water and sewage sludge/biosolids.

- WWTPs are efficient in removing triclosan from wastewater (secondary treatment)

- Less well studied, triclocarban may be less efficiently removed in WWTPs
Antimicrobials in environmental media

- Together 2/3 of the pharmaceuticals and personal care products mass. (McClellan, 2010).

- TCC concentrations 3x > triclosan in biosolids.

- Triclosan has been described as “the most abundant polychlorinated phenol ever found in wastewater sludge”
Triclosan in wildlife

- Triclosan has acute aquatic toxicity
- Interferes with survival and reproduction in crustaceans and may interfere with the action of natural thyroid hormone in amphibians
- Bioaccumulates in fish
- Found in the bodies of wild bottlenose dolphins
- Triclosan has been shown to accumulate in earthworms living in biosolid-treated fields,
Antimicrobials in food?

Wu, et al. 2010

Aryal, et al. 2011

Antimicrobials in food?

![Triclocarban dose, mg/kg-bw/day](image)

Ayral, 2011
Antibacterial soaps: Are they necessary?
“Despite their recent proliferation in consumer products, the use of antibacterial agents such as triclosan in consumer products has not been studied extensively. No data exist to support their efficacy when used in such products or any need for them, but increasing data now suggest growing acquired resistance to these commonly used antimicrobial agents.”

“The use of common antimicrobials for which acquired resistance has been demonstrated in bacteria as ingredients in consumer products should be discontinued, unless data emerge to conclusively show that such resistance has no impact on public health and that such products are effective at preventing infection.”
RESOLVED: That CMA recognize the toxicity and potential adverse health and environmental effects of Triclosan-containing products and endorse efforts to eliminate this chemical from consumer and health care products; and be it further

RESOLVED: That CMA encourage the Food and Drug Administration to finalize the antimicrobial monograph first drafted in 1978 and updated in 1994 which found evidence for the safety and effectiveness of only alcohol and iodine-based topical products in health care use; and be it further

RESOLVED: That CMA encourage the education of members on the issue of the importance of proper hand hygiene and the preferential use of plain soap and water or alcohol-based hand sanitizers in health care settings, consistent with the recommendations of the Centers for Disease Control; and be it further
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.
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?
Discontinued purchasing of antibacterial (triclosan) soaps

- Palo Alto, CA (2006)
- East Bay Municipal Utility District (2007)
- San Jose, CA (2008)
- UT-Austin campus ban on triclosan soaps
Canada declared triclosan “toxic to the environment” - March 30, 2012

EU limits allowed in personal care products and ban on use in food contact products.

Norway, Denmark, Sweden, Finland – issued consumer advisories.

Norway instituted a ban “No necessary function in most products”

Germany - “use should be restricted to the absolutely necessary minimum”

Japan – restricted amount allowed in consumer products
NRDC fact sheet on triclosan
Available for download at:

www.nrdc.org/health/files/antimicrobials.pdf