



Antibacterial Triclosan Banned by FDA for Medical Use

Remains in toothpaste and consumer products, despite lack of efficacy and contributing to crisis in bacterial resistance to antibiotics

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Antibacterial products with triclosan are being banned for medical use by the Food and Drug Administration (FDA). The pesticide has long been identified as a highly toxic, ineffective, and unnecessary antibacterial pesticide that contributes to the escalating international crisis of bacterial resistance to antibiotics and antimicrobials, especially when sold in soap, toothpaste, or in plastics and textiles in consumer goods. The FDA in December announced it was removing from the market 24 over-the-counter (OTC) disinfectants or antimicrobial ingredients, including triclosan, used by health care providers primarily in medical settings, such as hospitals, health care clinics, and doctors' offices. Despite banning its use in liquid soaps in 2016, FDA allows the pesticide in toothpaste, while wide use continues in products under the jurisdiction of the U.S. Environmental Protection Agency (EPA).

FDA ACTS AFTER FOUR DECADES OF CONCERN

FDA took this action after the chemical industry did not respond to a 2015 request for data to support a finding of "generally recognized as safe and effective (GRASE)." The decision, which follows a 2016 FDA decision to remove OTC consumer soap products with triclosan for the same reason, leaves toothpaste and numerous EPA-regulated consumer products (fabrics and textiles, sponges, undergarments, cutting boards, hair brushes, toys, prophylactics, computer keyboards, other plastics, etc.) on the market with triclosan (often labeled as or produced by Microban®). The December

decision leaves in commerce six antiseptic compounds widely used in the hospital and medical setting, in response to industry requests for more time to develop safety and efficacy data.

In what appears to contradict FDA's finding that it does not have sufficient data to make a GRASE determination for virtually all antiseptic products used in the health care and medical settings, the agency, under chemical industry pressure, is not restricting the mostly widely used compounds. There is heightened concern that health care providers and hospitals are using fraudulently labeled products for patient and staff protection from pathogenic bacteria, leading to potentially deadly infections. In its press release, FDA states,

In response to requests from industry, the FDA has deferred final rulemaking for one year, subject to renewal, on six specific active ingredients that are the most commonly used in currently marketed OTC health care antiseptic products—alcohol (ethanol), isopropyl alcohol, povidone-iodine, benzalkonium chloride, benzalkonium chloride, benzethonium chloride, and chloroxylenol (PCMX—to provide manufacturers with more time to complete the scientific studies necessary to fill the data gaps identified so that the agency can make a safety and efficacy determination about these ingredients. In addition, the final rule does not affect health care antiseptics that are currently marketed under new drug applications and abbreviated new drug applications.



Examples of products infused with Microban®.

For public health advocates, the speed of the federal government's progress on regulating toxic chemicals is alarmingly slow. FDA's narrow 2016 ban of triclosan and triclocarban—its chemical cousin—in consumer soap products, promulgated after persistent scientific arguments over the course of the past few decades, is a case in point.

CAPITALIZING ON CONSUMER FEARS OF GERMS

The common and rapid adoption of soaps with triclosan or triclocarban was based largely on a public perception that the antibacterial compounds are effective tools for safeguarding health from harmful bacteria. For years, studies have challenged the utility of the chemicals, and found that, in fact, OTC antibacterial soaps show no health benefits compared to soap and water washing. The chemical was originally introduced as a surgical scrub in 1972 and exploded on to the consumer market over the next decade. With widespread exposure, the Centers for Disease Control and Prevention (CDC) has found that 75% of U.S. residents contains triclosan in their bodies. Triclosan enters the food chain through contaminated water or soil in which crops are grown.

After years of public health advocacy to ban triclosan from consumer products, FDA's 2016 ruling banned 19 specific ingredients in soap products, including triclosan and triclocarban, saying they were no longer "recognized as safe and effective," and citing risks to health and contributions to the problem of bacterial resistance. Manufacturers had until September 6, 2017 to reformulate their products and remove existing triclosan products from the market. That ban did not apply to products used in health care and food service settings.

When the 2016 ruling was announced, Beyond Pesticides executive director Jay Feldman noted, "FDA's decision to remove the antibacterial triclosan, found in liquid soaps (its use in toothpaste went unaddressed), is a long time coming.

The agency's failure to regulate triclosan for nearly two decades . . . put millions of people and the environment at unnecessary risk [of] toxic effects and elevated risk [of] other bacterial diseases. Now, FDA should remove it from toothpaste and EPA should immediately ban it in common household products, from plastics to textiles." During the past few years, with pressure from consumer groups and media, major manufacturers, such as Procter & Gamble and Johnson & Johnson, have quietly reformulated their consumer products without triclosan; Colgate-Palmolive removed it from liquid soaps, but continues to include it in its Total® toothpaste.

CHALLENGING FEDERAL REGULATORS

Triclosan and triclocarban compounds have been the subject of a ban campaign and petitions by a coalition of health and environmental groups, led by Beyond Pesticides and Food and Water Watch (and targeted litigation by the Natural Resources Defense Council). In 2009, Beyond Pesticides, in partnership with Food and Water Watch and 80 other groups, submitted a petition to FDA calling for a ban on the non-medical uses of triclosan. (A companion petition was filed with EPA.) The agency announced plans in 2010 to address the use of triclosan in cosmetics and other products, saying in a response letter to U.S. Senator Ed Markey, D-MA (then a U.S. Representative), who had repeatedly requested that FDA write regulations for antibacterial products in hand soap and EPA on other products, that recent studies "raise valid concerns about the effect of repetitive daily human exposure to these antiseptic ingredients." FDA initiated triclosan's registration review in 2013, announcing that it would require manufacturers to prove that their antibacterial soaps were safe and more effective than soap and water (including providing the agency with data from clinical studies to demonstrate their findings). Manufacturers failed to do so. The state of Minnesota enacted a ban on triclosan in personal care cleaning products in 2014, and the European Union banned its uses altogether in 2015.

EXTRAORDINARY HAZARDS

Following the accumulated body of scientific literature developed over the past decade, in 2016, 200 scientists, medical doctors, and public health professionals released *The Florence Statement on Triclosan and Triclocarban* (Environmental Health Perspectives, 2017), which reads,

The Florence Statement on Triclosan and Triclocarban documents a consensus of more than 200 scientists and medical professionals on the hazards of and lack of demonstrated benefit from common uses of triclosan and triclocarban. These chemicals may be used in thousands of personal care and consumer products, as well as in building materials. Based on extensive peer-reviewed research, this statement concludes that triclosan and triclocarban are environmentally persistent endocrine disruptors that bioaccumulate in and are toxic to aquatic and other organisms. Evidence of other hazards to humans and ecosystems from triclosan and triclocarban is presented, along with recommendations intended to prevent future harm from triclosan, triclocarban, and antimicrobial substances with similar properties and effects. Because antimicrobials can have unintended adverse health and environmental impacts, they should only be used when they provide an evidence-based health benefit. Greater transparency is needed in product formulations, and before an antimicrobial is incorporated into a product, the long-term health and ecological impacts should be evaluated.

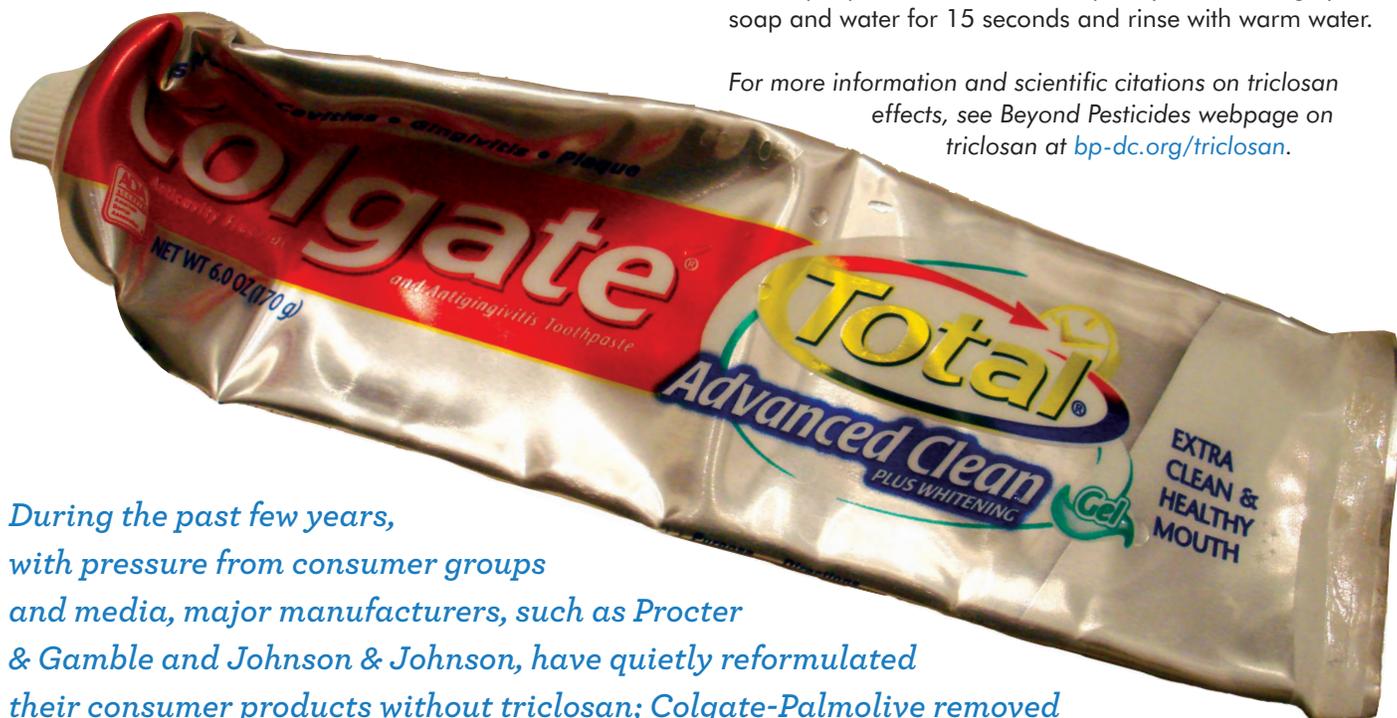
Scientific evidence has demonstrated a variety of adverse health effects of triclosan and its cousin, triclocarban: skin irritation; exacerbation of allergic response; endocrine disruption (e.g., triclocarban has been shown to amplify the activities of natural hormones, which can cause adverse reproductive and developmental effects); interference with production of the thyroid hormones thyroxine and triiodothyronine; and increased risk (for children) of developing asthma, eczema, and allergies. In addition, there is substantial evidence that broad use of these compounds promotes the emergence of bacteria that are resistant to antibiotic medications and antibacterial cleansers important in health care, thus, contributing to the extremely serious issue of antibiotic resistance in “superbug” bacteria. Many health impacts are likely still unknown.

Another cause for concern about the prevalence of triclosan in waterways is that, when exposed to sunlight, it is converted into a dioxin. Dioxins are highly toxic compounds that cause reproductive and developmental problems, damage immune systems, interfere with hormones, and cause cancer. If that were not sufficiently alarming, triclosan can also combine with chlorine in tap water to form chloroform (which is listed as a probable human carcinogen)—creating yet another toxic exposure.

CONSUMER BEWARE: PROTECT YOURSELF

Products with triclosan can be avoided in the market. Whether it is toothpaste or textile or plastic/synthetic products, triclosan or Microban® ingredients can be avoided. Health experts advise people to wash hands frequently and thoroughly with soap and water for 15 seconds and rinse with warm water.

For more information and scientific citations on triclosan effects, see *Beyond Pesticides* webpage on triclosan at bp-dc.org/triclosan.



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