

# Not Effective and Not Safe: The FDA Must Regulate Dangerous Antimicrobials in Everyday Products

Consumers in the United States spend almost \$1 billion per year on “antibacterial” soaps and other products, often motivated by the notion that these products will protect their families from harmful germs and illnesses.



But in fact, these products are no more effective than regular soap and water for preventing illness, and they contain chemicals that can actually harm our health and the environment. Up to 75 percent of liquid soaps, as well as bar soaps, toothpaste, cosmetics, cleansing lotions, acne creams, and wipes contain triclosan or triclocarban—chemicals marketed as reducing the number of bacteria or “germs.” Even though triclosan and triclocarban may interfere with normal development and function in humans and animals, the Food and Drug Administration (FDA) has given these chemicals a pass for more than 30 years. The FDA needs to take action now to stop the continued sale of ineffective and potentially unsafe antimicrobial chemicals in household products.

### “Antibacterial” Products Interfere With Important Hormone Functions

Hormones are responsible for normal growth and development of body systems such as the brain, the immune system, and the reproductive organs. Interference with these hormones during critical periods of fetal development, infancy, or childhood can result in long-lasting impacts or even permanent changes in the structure and function of these systems.

When tested in laboratory animals, triclosan is known to interfere with thyroid hormone—a hormone critical for normal growth and brain development.<sup>1</sup> Both triclosan and triclocarban also interfere with male and female sex hormones, which are necessary for normal growth and function of the reproductive system.<sup>2</sup> One study in male rats reported that triclosan decreased sperm count, damaged the male reproductive system, and disrupted male hormone production.<sup>3</sup> Since humans have similar hormone systems as animals, these chemicals also may produce adverse effects in people.



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### Contaminating Our Bodies and the Environment

Triclosan is found in an alarmingly high percentage of Americans' bodies. Approximately three-quarters of Americans ages 6 to over 65 have triclosan in their urine. Triclosan has also been detected in human blood and breast milk. Preliminary studies found human blood levels of triclocarban spike after using bar soaps containing the chemical. People are exposed to these chemicals by applying antimicrobial products to their skin or using them in their mouth.

Most of these products get washed down the drain, where they enter our waterways and are then transported widely throughout the environment. Triclosan is one of the most frequently detected chemicals in streams across the U.S. It has even been found in the bodies of wild bottlenose dolphins. Both triclosan and triclocarban are found at high concentrations in treated sewage sludge (also known as biosolids) that is often applied to agricultural fields as fertilizer.<sup>4</sup> Because triclosan has been shown to accumulate in earthworms living in these biosolid-treated fields, there are concerns about these chemicals also moving into plants and wildlife.

In addition, when triclosan mixes with chlorine in tap water, it can form the hazardous gas chloroform. One study showed that, in some cases, the resulting chloroform levels could exceed federal

standards. Finally, triclosan can be transformed into highly toxic dioxin compounds under naturally occurring conditions in freshwater streams and rivers. Some dioxins are known human carcinogens and considered to be among the most toxic chemicals on earth.

### Undermining the Effectiveness of Needed Antibiotics

There are other troubling and unintended effects of antimicrobial chemicals. Laboratory studies suggest that these chemicals may be contributing to antibiotic resistance in bacteria known to cause human infections. The Centers for Disease Control and Prevention calls antibiotic resistance one of the most pressing health issues facing the United States. Infections caused by bacteria with resistance to at least one antibiotic have been estimated to kill more than 60,000 hospitalized patients each year. Many scientists are concerned that overuse of antimicrobials may in time lead to development and growth of antibiotic resistant bacteria.

### "Antibacterial" Soaps Are No Better than Regular Soap and Water

Washing hands with products containing triclosan and triclocarban is no more effective than using regular soap and water with proper hand-washing techniques.<sup>5</sup> People in households that use bar soap containing triclocarban have a similar risk of childhood diarrhea, respiratory infections, or a skin infection compared to those using regular soap.

### The FDA Should Take Long-Overdue Action to Ban Antimicrobials from Everyday Products

The FDA regulates antimicrobial soaps as part of the "over-the-counter topical antimicrobial products for human use." The regulation is currently in draft form. Although the FDA first proposed a regulation that would remove triclosan and triclocarban from this class of products in 1978, 32 years later the FDA has still not taken action. Until the FDA's draft regulation is finalized, these chemicals will continue to be marketed and sold legally across the United States—and we will all continue to be exposed to these hormone disrupting chemicals. Now is the time for the FDA to meet its obligation to protect our health by pulling these harmful chemicals off the shelves.

<sup>1</sup> Crofton KM et al. Short-term in vivo exposure to the water contaminant triclosan: Evidence for disruption of thyroxine. *Environ Toxicol Pharmacol* 24 (2007) 194-197.

<sup>2</sup> Chen, J. et al. Triclocarban Enhances Testosterone Action: A New Type of Endocrine Disruptor? *Endocrinology*. 149(2008) 1173-1179.

<sup>3</sup> Kumar, V. et al. Alteration of testicular steroidogenesis and histopathology of reproductive system in male rats treated with triclosan. *Reproductive Toxicology* 27 (2009) 177-185.

<sup>4</sup> McClellan, K. and R. U. Halden (2010). "Pharmaceuticals and personal care products in archived U.S. biosolids from the 2001 EPA national sewage sludge survey." *Water Research* 44(2): 658-668.

<sup>5</sup> Luby, S. P., M. Agboatwalla, et al. (2005). "Effect of handwashing on child health: a randomised controlled trial." *The Lancet* 366(9481): 225-233.