Introduction and Overview

The American Cleaning Institute (ACI) is the trade association representing the $30 billion U.S. cleaning products market. Our members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. ACI and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. ACI’s mission is to support the sustainability of the cleaning products industry through research, education, outreach and science-based advocacy. Since 1926, ACI has promoted health through personal hygiene and effective cleaning. More information about ACI can be found at www.cleaninginstitute.org.

Human health and environmental safety are significant priorities for ACI members, and throughout its history, the Institute’s sound, technical, risk-based research has demonstrated the safe, beneficial, and proper use of cleaning products and their ingredients.

ACI Comments on Senate File 1166

ACI opposes Senate File 1166. This measure would, among other things, virtually ban all cleaning products from sale in Minnesota. In targeting “cleaning products containing triclosan, triclocarban, or similar antibacterial compounds,” the bill disregards all federal regulatory authority and scores of scientific studies that show that products that use these ingredients are safe and effective ways to protect human health. The language in this bill would ban hundreds of beneficial and recognized cleaning and hand hygiene products that consumers rely on to clean their homes and keep their families safe from harmful disease causing bacteria.

As a result of this legislation, Minnesota consumers would have very limited product options and may go to other states for their cleaning products. Hard surface cleaners that also disinfect, which have multiple household and institutional applications, would be especially impacted. These products may use a range of ingredients that provide antibacterial action against harmful bacteria.
Hand Washing is the Single Most Important Means of Preventing the Spread of Infection

- Minnesota Department of Health

The 2006 Minnesota Handwashing Tool Kit illustrates the need for strong and positive handwashing messages to be conveyed to all Minnesotans. In three observational studies, the American Society of Microbiology and Minnesota Department of Health (MDH) studies showed that Minnesotans, in large populated events such as the Minnesota State Fair, are not washing their hands enough.¹

2003 Back to 50’s Car Show Event—64% females washed and 30% males
2003 State fair—65% females washed and 39% males
2004 State fair—75% females washed and 51% males

This public health concern should not be taken lightly. A ban on soaps containing triclosan or triclocarban or similar antibacterial compounds sends a mixed message to Minnesotans and increases their vulnerability to certain diseases. Removing these products from the marketplace works against the public policy goal of increasing the frequency and duration spent washing one’s hands.

The Centers for Disease Control² and MDH³ agree – to effectively clean your hands, you must scrub them with soap and water for 20 seconds or sing “Happy Birthday” twice. Studied in 15 and 30 second intervals, soaps containing triclosan were proved to be more effective than regular soap at killing harmful bacteria.⁴ People do not always have the time to sing “Happy Birthday” while washing their hands. **Antibacterial soaps clean hands faster and more completely even in the event someone does not take the time needed to effectively wash.** Removing an effective alternative for cleaning your hands is inconstant with the clean hands message and the ultimate goal of preventing the spread of disease.

Soap Restrictions Harm Public Health and Hygiene

Hand soaps are present and applied in a variety of settings in the home and in public settings. Schools, for instance, are not just a modern learning environment. They may serve as a venue for a wide variety of community events and meetings throughout the course of a day. It may also provide food and health care services. From cafeteria meals to after school activities that may include “dirtying your hands,” these facilities need the flexibility and availability of a wide range of products to promote and protect public health. And in each circumstance, proper hand hygiene can help prevent disease transmission.

¹ [http://www.health.state.mn.us/handhygiene/stats/statistics.html](http://www.health.state.mn.us/handhygiene/stats/statistics.html)
² [http://www.cdc.gov/handwashing/](http://www.cdc.gov/handwashing/)
³ [http://www.health.state.mn.us/handhygiene/wash/hwfactsheet.html](http://www.health.state.mn.us/handhygiene/wash/hwfactsheet.html)
The “clean hands” concept is about health: it is essential to breaking the chain of infection in schools as well as other public and shared environments. ACI has partnered with the CDC to improve hand hygiene among middle school students. This program has the option of utilizing all kinds of tools to increase the awareness and stress the importance of hand hygiene for middle school students. To that end, and as but one example, a state statutory limitation on hand soap products could negatively impact effective message delivery about hand hygiene in school communities.

The U.S. Environmental Protection Agency regulates antibacterial ingredients

Triclosan was registered with the U.S. Environmental Protection Agency (EPA) in 1969 and has been used safely as an antimicrobial ingredient since then. Millions of consumers throughout the United States and the world use products that contain triclosan daily as part of common sense hygiene routines in homes, hospitals, doctors’ offices, day care centers, nursing homes, and countless other office and institutional settings.

EPA completed a very thorough review of the safety of the ingredient in a 2008 regulatory decision that formally re-registered triclosan for its use as a material preservative and has confirmed the wide margins of safety since then. EPA considered triclosan for all sources in determining the human and environmental exposure levels to be assessed.

The safety of triclosan extends to infants and children. The EPA calculated exposure to infants and children using accepted practices and did not find an increased risk. When combining this methodology with the known metabolic pathways available to infants and children (glucuronidation and/or sulfation), which are also used by the body to safely handle triclosan, the risk likelihood from everyday exposure, planned or not, becomes even more minute. The Agency considered these exposures in its decision to re-register triclosan. The concept of triclosan potentially presenting an increased risk to infants and children due to their greater vulnerability does not hold true when the principles of sound science are applied.

The U.S. Food and Drug Administration regulates antibacterial ingredients

Antibacterial ingredients, including triclosan and triclocarban, used in over-the-counter products like antibacterial soap are regulated for safety and efficacy under the Food and Drug Administration’s (FDA) Tentative Final Monograph for Over-the-Counter Healthcare Antiseptic Drug Products, which was issued in 1994. Claims that triclosan or triclocarban is unregulated or its safety is in question are simply false. Furthermore, triclosan used in Over-the-Counter antibacterial wash products must conform to the extremely rigid purity and impurity standards set by the United States Pharmacopeia (USP).

---

6 Ibid.
Antibacterial wash products with triclosan provide a key public health benefit by reducing or eliminating pathogenic bacteria on the skin to a significantly greater degree than plain soap and water. When consumers use products with antibacterial ingredients, including triclosan, they receive an extra measure of protection when handling food, changing diapers, or caring for a sick family member. These products can kill or inhibit the growth of bacteria that cause skin infections and intestinal illnesses such as *E. coli* and Salmonella.

The FDA has found no basis for consumers to stop using products containing this ingredient. Triclosan and triclocarban containing products have a long track record of human and environmental safety that is supported by a multitude of scientific, transparent, and risk-based analysis.

**Safety reviews by other governments**

The European Union has assessed the safety of triclosan and found no basis for consumers to stop using products containing it. A 2012 preliminary screening assessment of triclosan by Health Canada and Environment Canada reiterated that triclosan-containing products are safe for consumers to use.

**Consumers have the information they need to choose the product they want**

Under FDA regulations, consumers know if a soap product contains triclosan, triclocarban, or other antibacterial ingredients because they are listed on the drug facts label on the product container.

---


Triclosan and triclocarban-containing products do not contribute to antibiotic resistance

Scientific research, such as reported in a 2011 scientific paper in the International Journal of Microbiology Research,\(^\text{11}\) repeatedly affirms that the use of antibacterial wash products in the home setting does not contribute to antibiotic resistance. In the most recent review by a government authority specific to triclosan, the European Commission Scientific Committee on Consumer Safety indicated in their 2010 report on triclosan and antimicrobial resistance that to date there are no epidemiological data linking outbreaks of antimicrobial resistant human and zoonotic pathogens to exposure to triclosan and triclocarban.\(^\text{12}\)

Antibacterial products and their ingredients have stood the test of time through extensive research and testing.

**Triclosan, triclocarban and other antibacterial-containing wash products benefit human health**

The effectiveness of antibacterial hand wash products for infection control in both clinical and non-clinical settings has been documented in a number of studies. A summary of several pertinent studies and reports follows.

- The single infection control measure of changing a hand wash and bathing product to a 0.3\% triclosan product was associated with the immediate termination of the acute phase of a Methicillin Resistant Staphylococcus Aureus (MRSA) outbreak.\(^\text{13}\)

- Following the introduction of a triclosan hand wash in a neonatal intensive care unit, there was a gradual elimination of MRSA in the unit, and lower antibiotic use and nosocomial infections were recorded.\(^\text{14}\)

- It has been demonstrated that there is a much greater potential to reduce the acquisition and transmission of disease resulting from the handling of food through the use of an antibacterial hand wash compared to plain soap.\(^\text{15}\)

---


\(^\text{13}\) Zafar AB et al., 1995. Use of 0.3 triclosan to eradicate an outbreak of MRSA in a neonatal nursery. Am. J. Infect. Control. 23:200–208.


\(^\text{15}\) Fischler GE, et al. 2007. Effect of hand wash agents on controlling the transmission of pathogenic bacteria from hands to food. J. Food Protect. 70:2873–2877.
Antimicrobial hand soaps have been shown to provide a significantly greater bacterial reduction on the hands compared to plain soap. In addition, the transfer of bacteria to objects following washing with antimicrobial hand soap was significantly reduced compared to plain soap.\textsuperscript{16}

A 2005 meeting of the Nonprescription Drugs Advisory Committee (NDAC) recommended to the FDA that antibacterial hand wash products should demonstrate a reduction in infection when compared with non-antibacterial hand wash products. A summary of a scientific model and expert panel review of the model developed to demonstrate the effectiveness of antibacterial hand wash products versus nonantibacterial hand wash products has been published since the 2005 NDAC meeting. The expert panel concluded that the model was a realistic test for the efficacy (demonstration of reduction in infection) of antibacterial hand wash products. Data from studies using this model to demonstrate the benefit of antibacterial wash products compared with plain soap were presented to FDA in November 2008 and formally submitted to the FDA under FDA docket number FDA-1980-N-0006.\textsuperscript{17}

Concerns with the recent University of Minnesota Study, published January 2013 in the Journal Environmental Science & Technology:

The University of Minnesota (U of MN) study detected triclosan at very low levels; also dioxins were also detected at very low levels. The authors did not investigate whether these levels have any impact on human or environmental health. The study’s authors raise concerns about triclosan in sediment but do not present an environmental risk assessment that supports a claim that overlying waters or aquatic life is adversely affected.

Triclosan does not bio-accumulate in food-chains because it is conjugated and excreted by animals via basic metabolism. If a constant inflow occurs, a steady concentration will be present in body fluids. These steady state concentrations cannot be interpreted as accumulation and there is no triclosan remaining some time after cessation of intake. It is known that triclosan does not concentrate in the edible parts of fish. Thus, even though triclosan has been detected in fish bile from animals exposed to sewage treatment outflows or river sediment, it does not build up in the food chain.

The levels of triclosan in Minnesota waters are safe

Waste Water Treatment Plants (WWTP) are increasingly efficient and in the case of triclosan, a removal rate of over 97\% is often reported for activated sludge (AS) plants.\textsuperscript{18} This efficient removal rate results in very small levels of triclosan in the effluent, which are further reduced by in-stream sorption, biodegradation, and photodegradation resulting in levels not considered an


environmental hazard. Furthermore, the environmental concentration of triclosan under even the highest likely exposures which could occur immediately downstream of the WWTP discharge point has been calculated to be less than the concentrations known not cause effects suggesting that risks to aquatic species are low.19

MDH has developed a health-based guidance value of 50 ppb for triclosan in drinking water. The U.S. Geological Survey (USGS) detected triclosan in samples collected from Minnesota wastewater and surface water at concentrations ranging from 0.088 to 4.3 parts per billion (ppb).20 The level of triclosan found in Minnesota wastewater and surface waters are more than 10 times lower that the level MDH has deemed to safe for drinking.

Conclusion

Thank you for your attention and consideration of these comments. ACI appreciates the opportunity to testify before the Committee. For future reference, my contact information is (202) 662-2514 or via electronic mail at jcassady@cleaninginstitute.org.
