

Antibacterial Soap Live Q&A with Kerri Mixon

HSCG Member's Discussion Group on Facebook
<https://www.facebook.com/groups/HSCGMembers/>
Wednesday, March 31, 2021, at 7 PM EST (4 PM PDT)

This Q&A discussion and handouts are for HSCG members. Join the HSCG:
<https://www.soapguild.org/cart/memberships.php>

In our new pandemic world of masks and hand sanitizers, handmade antibacterial soap is on the rise. What makes soap antibacterial? Is it any soap or a specific ingredient? Is it hard to make? If antibacterial soap is intended to prevent disease, then is it a drug and regulated by the government? Can it be sold by handcrafters?

Learn the answers to these questions during the HSCG's Live Facebook Q&A with master soapmaker and cosmetic formulator Kerri Mixon. This 1-time event will cover how to make antibacterial soap, simple steps to formulating antibacterial bars, an easy recipe to follow, a short live demo, and regulatory information.

What is Antibacterial Soap?

Antibacterial soap is intended to kill and remove harmful bacteria from human skin in order to prevent microbial infection. Because antibacterial soap is meant to prevent infection, it is deemed an over-the-counter (OTC) drug by the FDA; in 1978, the FDA placed the product into the category of OTC consumer antiseptic washes (US FDA, 2020, "Is it a Cosmetic"). The sale of OTC drugs requires the manufacturer register with the FDA, follow good manufacturing practices, and either comply with an existing OTC drug monograph or submit a new drug application (NDA) (US FDA, 2020, "Over-the-Counter OTC"). In 2020, the FDA registration process was simplified and the fee was eliminated. More information about the new registration process is provided at the end of this handout and, time permitting, will be discussed at the end of the presentation.

Effectiveness of Antibacterial Soap

According to the CDC and the FDA, antibacterial soap is not necessary because plain soap does a good enough job of removing bacteria (US FDA, 2019, "Antibacterial Soap"). In contrast, the American Cleaning Institute (formerly the Soap and Detergent Association) has cited a barrage of information (including clinical trials, research papers, and an expert panel report from the American Journal of Infection Control) finding antibacterial soap is more effective at both killing and removing virulent microorganisms from human skin (Boyce, et al., 2012).

Active Ingredient: Benzalkonium Chloride

The main active ingredient for antibacterial soap used to be triclosan. After tests of large concentrations of triclosan on animal subjects resulted in thyroid hormone issues, triclosan and 2 similar ingredients were banned from antibacterial soap through a 2016 FDA final rule, which banned 19 total ingredients from OTC consumer antiseptic products (US FDA, 2016, "Safety and Effectiveness"). When the media released the final rule, U.S. sales of antibacterial soap increased 400%. During the coronavirus outbreak of 2019, antibacterial soap sold out of stock at the same rate as hand sanitizer and toilet paper.

Antibacterial Soap Live Q&A with Kerri Mixon

The current active ingredient in antibacterial soap is benzalkonium chloride, an ammonium mineral salt. To remember this term, compare the 3 terms below.

sodium chloride, sodium mineral salt consumed as table salt
potassium chloride, potassium mineral salt consumed as low-sodium table salt
benzalkonium chloride, ammonium mineral salt used as cationic surfactant & biocide

Benzalkonium chloride must not be consumed. It is found in several commercial brands of antibacterial soaps in the following percentages.

All Dial antibacterial bar soap 0.10%

All Dial antibacterial liquid soap 0.13%

All SoftSoap antibacterial liquid soap .. 0.13%

The Cosmetic Ingredient Review panel and Personal Care Products Council have both deem benzalkonium chloride generally regarded as safe and effective (GRAS/E) in soap from 0.10% to 1.00% (Johnson, Jr., 1989).

The antibacterial soap recipe follows on page 3.

Antibacterial Soap Live Q&A with Kerri Mixon

Recipe for Antibacterial Soap

Coconut oil (40% of oils).....	235 grams	}	Total weight of oil is 590 g
Cocoa butter (15% of oils)	90 grams		
Olive oil (45% of oils).....	265 grams		
Sodium hydroxide	85 grams		
Water	200 grams		
Fragrance*	24 grams		
Colorant*	1 gram		
Total weight	900 grams		

*The fragrance used is Soapmaking Studio eucalyptus lemon (*Eucalyptus citriodora*) essential oil. The colorant is Crafter's Choice Baby Grasshopper Green Mica Powder and contains mica, titanium dioxide, and chromium oxide green.

Calculate the Benzalkonium Chloride (BAC) at 0.10%

weight of soap ingredients without BAC $\div$ 0.999 = weight of soap with BAC

weight of soap with BAC – weight of soap ingredients without BAC = weight of BAC

weight of BAC $\times$ 2 = weight of 50% BAC solution (mine is 50% BAC and 50% glycerin)

900 g soap only $\div$ 0.999 = 900.9009 g soap with BAC

900.9009 g soap with BAC – 900 g soap only = 0.9009 g BAC

0.9009 g BAC $\times$ 2 = 1.8018 g BAC solution

So, add 1.8 grams benzalkonium chloride solution to the 900-gram soap recipe above to achieve a true 0.10%. If your scale will not weigh grams in decimals (i.e., tenth of a gram), then round up and use 2 grams of the benzalkonium chloride solution and the total BAC will be 0.11%.

Soap from recipe above	900 grams
BAC from solution.....	1 gram
Glycerin from BAC solution	1 gram
Total weight	902 grams

Labels for “Hand and Body Soap”

Handcrafters may legally sell soap containing benzalkonium chloride without FDA registration as long as the antibacterial benefit is never mentioned. “In most cases, the determining factor is not the formulation, but what the consumer thinks is the intended use of the product, based on what you have said about it” (Gale, 2015, p. 26).

Antibacterial Soap Live Q&A with Kerri Mixon

Label Front

Hand and Body Soap



***This eucalyptus lemon-scented
soap smells like the fresh
outdoors and cleans great!***

3.0 ounces net weight

Label Back

Warning: For external use only. Do not ingest.
If irritation occurs, discontinue product.

Directions: Use with water as soap to clean
hands and body. Rinse lather thoroughly from
skin.

Ingredients: Olive oil, coconut oil, water, cocoa
butter, sodium hydroxide, fragrance, mono- and
di-glycerides, glycerin, benzalkonium chloride,
mica, titanium dioxide, chromium oxide green.

Manufactured by Soapmaking Studio 7301 Mount Vernon St Lemon Grove, CA 91945	This product is not intended to diagnose, treat, cure, or prevent any disease.
---	---

With the coronavirus pandemic, more and more people understand the use of benzalkonium chloride in antibacterial soap. Remember not to state or imply your soap is “antibacterial” if you have not had your company and product both approved by the FDA. It may be a good idea to include the disclaimer, “This product is not intended to diagnose, treat, cure, or prevent any disease” on the soap label and advertising.

Antibacterial Soap Live Q&A with Kerri Mixon

FDA Registration Process

FDA registration for making and selling OTC drugs used to be a lengthy and expensive process. In 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law and included the Over-the-Counter Monograph Safety, Innovation, and Reform Act, which eliminated FDA OTC drug registration fee. FDA registration is now free and the process has been simplified, in an effort to promote the production of coronavirus-relief products, such as antibacterial soap, hand sanitizer, and other OTC consumer antiseptic products (US FDA, 2021, “OTC Monograph Reform”).

The FDA registration process begins with applying for a D-U-N-S number from Dun and Bradstreet. If your business is an LLC, a corporation, in business for several years, then your business may have already been assigned a number. Visit <https://www.dnb.com/duns-number.html> to search for your number or request one—it's free. The remaining process is through the FDA website. You must submit information to register your business and then information to register your product. More information is available from the FDA website <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/electronic-drug-registration-and-listing-system-edrls>

References follow on page 6.

Antibacterial Soap Live Q&A with Kerri Mixon

References

Boyce, DuPont, Massaro, Sack, & Schaffner (2012). An expert panel report of a proposed scientific model demonstrating the effectiveness of antibacterial handwash products. Retrieved from American Journal of Infection Control website <https://doi.org/10.1016/j.ajic.2011.09.016>

Gale, Marie. (2015). *Soap & Cosmetic Labeling: How to Follow the Rules and Regs Explained in Plain English* (3rd ed.). Broadbent, OR: Cinnabar Press.

Johnson, Jr., Wilbur. (1989). Final Report on the Safety Assessment of Benzalkonium Chloride. Journal of the American College of Toxicology. Retrieved from the Personal Care Products Council website <https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr142.pdf>

U.S. Department of Food and Drug Administration. Antibacterial Soap? You Can Skip It, Use Plain Soap and Water. (2019). *Consumer Updates*. Retrieved from <https://www.fda.gov/consumers/consumer-updates/antibacterial-soap-you-can-skip-it-use-plain-soap-and-water>

U.S. Department of Food and Drug Administration. Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?). (2020). *Cosmetic Laws and Regulations*. Retrieved from <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap>

U.S. Department of Food and Drug Administration. Over-the-Counter OTC Nonprescription Drugs. (2020). *Development and Approval Process*. Retrieved from <https://www.fda.gov/drugs/how-drugs-are-developed-and-approved/over-counter-otc-nonprescription-drugs>

U.S. Department of Food and Drug Administration. Over-the-Counter OTC Nonprescription Drugs. (2021). *OTC Monograph Reform in the CARES Act*. Retrieved from <https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act>

U.S. Department of Food and Drug Administration. Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use. (2016). Retrieved from the Federal Register <https://www.federalregister.gov/documents/2016/09/06/2016-21337/safety-and-effectiveness-of-consumer-antiseptics-topical-antimicrobial-drug-products-for>