



Technical Bulletin

March 16, 2020

To: All Distributors

Understanding Efficacy for Hand Hygiene Products

Antimicrobial hand hygiene products are regulated by The Food and Drug Administration (FDA). The FDA monograph (the FDA's set of rules and regulations) specifies the acceptable active ingredients and their use level. The two most popular on the market today are Ethanol (Alcohol) and Benzalkonium Chloride.

Unlike EPA registered disinfectants, FDA regulated products, such as antimicrobial handwashes or antibacterial hand sanitizers, do not undergo viral efficacy testing at the agency. The monograph assumes the active ingredients have antimicrobial activity, and responsible manufacturers self-verify their formulas efficacy against a list of 26 organisms including bacteria, yeast, and mold. This list of organisms is recommended by the FDA.

Making anti-viral claims or reduction in illness claims are considered false and misleading under the monograph. Making these claims could cause the FDA to issue a warning letter and a request (an order) to cease and desist making the claims.

Many customers may inquire about antimicrobial efficacy against specific organisms. Example: "What hand sanitizer kills COVID-19". This request may seem reasonable; however, the FDA considers making specific antimicrobial claims as a claim of preventing infection by the organism in humans and making these claims is prohibited. In special cases, infection control nurses or environmental services personnel may request efficacy data, but companies are never permitted to market efficacy data associated with a product.

Active Ingredients and Hand Sanitizers

Hand sanitizers are an important part of any hand hygiene program. They are especially important when soap and running water are not available. These products are widely available and are especially prevalent in healthcare settings.

Ethanol (Alcohol) and Benzalkonium Chloride have different modes of efficacy. Alcohol has high kill but evaporates in 15 seconds or so and has no continued efficacy. Benzalkonium Chloride formulas such as Spartan's Lemon Blossom Hand Sanitizer have increasing efficacy over time. Our efficacy data demonstrates that the log kill goes up significantly from 15 seconds to 30 seconds. Both are effective at reducing the number of bacterial on the hands.

Approximately 15 years ago, the CDC began recommending greater than 60% alcohol hand sanitizers based on both limited available data and lobbying from the largest alcohol hand sanitizer manufacturer. In the past 15 years, many studies have been done on Benzalkonium chloride that contradict the CDC's statements. Interestingly, many of the claims made by the CDC would be considered FALSE and MISLEADING by the FDA If Spartan or other manufacturers made the claims because there simply is not enough evidence that they are true. The CDC recommending alcohol is a recommendation only. The CDC has done no testing or studies of hand sanitizer's effectiveness. It is the CDC's opinion and nothing more.

Spartan Chemical FDA Registered Products:

- foamyiQ™ Lemon Blossom Hand Sanitizer (4604)
- foamyiQ™ Eucalyptus Mint Sanitizing Handwash (4603)
- foamyiQ™ Healthcare Personnel Handwash (4605)
- foamyiQ™ E2 Sanitizing Handwash (4606)
- Lite'n Foamy® Lemon Blossom Hand Sanitizer (3338)
- Lite'n Foamy® Eucalyptus Mint Sanitizing Handwash (3337)
- Lite'n Foamy® Healthcare Personnel Handwash (3341)
- Lite'n Foamy® E2 Sanitizing Handwash (3339)
- Lite'n Foamy® E3 Hand Sanitizer (3340)

Spartan Chemical Company takes regulatory compliance very seriously. We make effective, quality products that function well for their intended purpose. We also make a good faith effort to comply with all regulations and take a conservative stance on making claims.

Yours truly,

Ron Barnhart

Personal Care and Antimicrobial Formulation Specialist
Spartan Chemical Company