ENVIRO SPECIALTY CHEMICALS INC
ENVIRONMENTALLY RESPONSIBLE CHEMICALS

ESC BRANDS

Brief Technical Summary

My-shield® Hand Sanitizer Foam with Aloe Vera:

+1 (888) 331-8332 | 664 Old Hargrave Road - Suite B | Lexington, NC 27295 | info@escbrands.com | www.escbrands.com

A. Introduction:

The "ESC" My-shield® Hand Sanitizer Foam with Aloe Vera is a unique antimicrobial technology that not only kills microorganisms on contact, but also has persistent activity designed to help prevent infections in a wide variety of venues from healthcare to food service and everywhere in between. The following is a brief summary of testing and qualifications.

B. Efficacy Testing:

1. **Rapid Broad Spectrum Kill –** In testing with both hand sanitizer products they were effective at killing more than 99.99% (>99.99%) of FDA (25 specified) test organisms in 15 seconds, using Quantitative Suspension Test methods. A total of 45 different bacteria, fungi and viruses* have been effectively killed in testing by "ESC" hand sanitizer products (for active ingredients the kill list is even longer.

2. **Burkholderia Cepacia_Assessment Of Time Kil Activity Using ASTM E2315-16 -** Burkholderia cepacia is a bacterial species that has been found by the FDA to contaminate health care products during the manufacturing process. Burkholderia cepacia showed growth to 57,000 cfu in 2.0% Chlorhexidine gluconate Hand Sanitizer wipes. Testing My-shield® Hand Sanitizer Foam in a Time Kill Study using ASTM E 2315 showed a steady decrease in activity over time negating any threat of growth.

3. **Healthcare Hand Rub Efficacy Testing (EN 1500) -** The FDA requires hand sanitizers to be tested on actual hands to prove real world performance. EN 1500 testing was chosen, as it is the European standard method for qualifying hand rubs used in healthcare facilities employing 20 test subjects. To be EN 1500 compliant a test product must exceed efficacy of a reference alcohol. My-shield® Hand Sanitizer Foam has passed the testing exceeding efficacy of reference alcohol qualifying for use in healthcare institutions in Europe and Australia.

4. **Long Term Sustained Activity –** The World Health Organization (WHO) and the CDC recommends "persistent" antiseptics for hand sanitizers. Persistent activity is defined as the prolonged or extended antimicrobial activity that prevents or inhibits the proliferation or survival of microorganisms after application of the product.

    A. **Extended Protection >24 hours** - In an ex-vivo test using a pigskin model (using ASTM E2897-12 & ASTM WK36911), My-shield® Hand Sanitizers (Foam) was applied to the skin. After the specified amount of time, the skin samples were challenged with S. aureus. Testing was performed at 2 minutes with >99.9% kill and sustained kill of 99.9% was shown at 1 hr., 98.3% at 2 hrs, 96.9% at 4 hrs, 84.9 at 8 hrs, 79.5 % at 16 hours and 54% at 24 hours.

    B. **Extended Protection Against Antibiotic Resistant Strains*** - In using the same ex-vivo test method utilizing the pigskin model, persistent activity was shown against all three antibiotic resistant strains MRSA, VRE and CRE for up to 4 hours. Mean reduction between all 3 strains was over 99.9% at 2 minutes, 98.9% at 1 hour, 96.1% at 2 hours and 91.3% at 4 hours.

    C. **Sustained Activity When Gloves are Utilized > 12 Hours -** To access persistent activity on hands when used in clinical settings ASTM Test method E1115-11 was used with 20 human volunteers. Immediate activity results demonstrated that bacterial reduction of hand flora after using the product was greater than a 5.8 Log10 reduction factor. Persistent activity suppressing regrowth of skin bacteria was shown to be in the same order of magnitude (5.8 Log10) at 3 hours, 6 hours and even at 12 hours after product application 99.99 % (4.0 Log10) with hands kept occluded within surgical gloves.

5. Challenge Testing as Further Proof of Wide Spectrum - Challenge testing of products regulated by FDA as over-the-counter antimicrobial drugs is the ultimate test of effectiveness of individual formulations as here instead of just killing germs on hands or in suspension tests, multiple high count inoculation and long term incubation is used. In a double 28 day challenge inoculated with over a million bacteria each challenge both the Gel and Foam formulation killed off the following bacteria and fungi: Escherichia coli, Klebsiella pneumonia, Pseudomonas aeruginosa, Staphylococcus aureus, Burkholderia cepacia, Bacillus subtilis, Candida albicans, Aspergillus niger and Penicillium luteum Antiviral Activity- My-shield® Hand Sanitizer Foam with Aloe Vera has been shown to have antiviral activity against Norovirus (Murine Norovirus Type 1), Rhinovirus cause of the common cold (ATCC VR-482), Influenza virus (ATCC VR-1741), MERS, Feline Infectious Peritonitis Virus (FIPV) and Enterovirus 71 (Hand, Foot & Mouth Disease Virus).*

C. Mode of Action:

My-shield® Hand Sanitizer products are known as a "PolyQuats" (a mixture of quaternary ammonium chloride compounds). They consist of a sophisticated polymer backbone formula employing multifaceted modes of activity. It is a 3-component system working in unison to deliver a safe but powerful antimicrobial punch. By building onto the well-proven safety of the 3-TSP polymer a chemo-electro-mechanical mode of action can be demonstrated. Skin drying is prevented by the polymer and Aloe Vera present to pro-actively improve skin health. This highly effective formula goes beyond any other family of antimicrobial products available today.

D. Dermal Compatibility:

At time of formula creation every precaution was taken to develop a product that did not irritate the skin with repeated use. Qualified skin care product experts reviewed every aspect of the formulation. Now with several years successfully manufacturing and distributing these products in the US, Australia and New Zealand, and a brief trial in a healthcare facility, low irritation potential of My-shield® alcohol-free Hand Sanitizer with Aloe Vera is well established for foam liquid products. The "ESC" hospital trial also demonstrated skin compatibility in a well-monitored population of healthcare professionals. Numerous school trials of similar hand sanitizer formulated with the same active ingredient Benzalkonium Chloride have shown skin compatibility where hand and skin monitoring clearly demonstrated this to be a positive endpoint. The various production runs of the product represent positive experiences by close to 100,000 individuals using these products in a wide variety of settings from households, schools and healthcare to prisons.

E. Regulatory Status:

The active ingredient of My-shield® Hand Sanitizer Foam with Aloe Vera, Benzalkonium Chloride is a mixture of alkyl benzyl dimethyl ammonium chlorides with the following chain lengths 50% C12, 30% C14, 17% C16, 3% C18 18. Benzalkonium chloride at the concentrations used in the "ESC" formula is generally recognized as safe (GRAS) and effective by the US FDA for use in topically applied anti-bacterial products such as hand sanitizers. My-shield® Hand Sanitizers utilize an active ingredient that has been safely used in health care for over sixty years (see FDA Federal Register/Vol 56, No. 140 confirming Benzalkonium chloride 0.1 to 0.13 percent in addition to alcohol as an FDA acceptable antimicrobial active ingredient). The CDC does not require an alcohol hand sanitizer but only recommends its use. The FDA does not have an approval process in place for instant hand sanitizers but instead has published a Tentative Final Monograph (TFM) that is used as a guideline to ensure instant hand sanitizers conform to the guidelines set by the FDA. "ESC" My-shield® formulas meet and exceed these guidelines.

*Please note that the FDA has taken a very restrictive position regarding making labeling, advertising or Internet claims of efficacy against antibiotic resistant strains of bacteria (MRSA, VRE, CRE) and viruses in general.