

## **Benzalkonium Chloride Hand Sanitizer with modified preservative.**

### **Regulatory Agencies; FDA, CDC and USDA and Hand Sanitizing**

The FDA Code specifies strict hand sanitizer guidelines that must be met by manufacturers including that products must "Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic hand wash." mPulse Hand Sanitizer's FDA approved active ingredient meets all FDA guidelines. 1, 8, 9

In September 2009, the CDC severed its 13 year exclusive recommendation of alcohol hand sanitizer by also accepting alcohol free alternatives that met FDA guidelines. 2, 8, 9

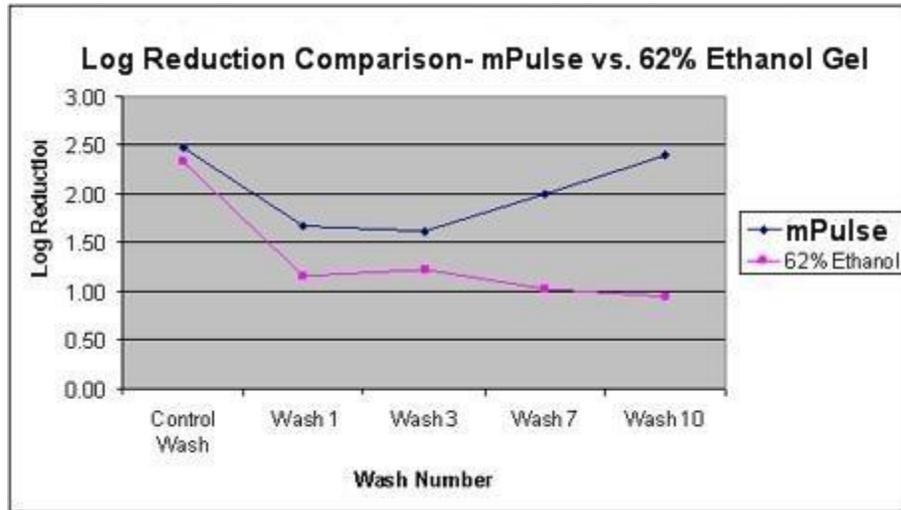
MPulse Hand Sanitizer's unscented products are approved by the USDA (now NSF) as an E2 rated product that is safe to use in the handling of food. It is important to note that the FDA requires that if alcohol is applied to hands, hands must be rinsed under water before they come into contact with food (since mPale's is non-toxic, this additional event of rinsing hands post use is unnecessary). 3,4

MPulse Hand Sanitizer, a proprietary product formulated by Doctors and leading scientists and extensively tested on human subjects in a major university and microbiological labs is the first soothing alternative to the drying effects of alcohol that also offers *proven* germ killing (including MRSA, VRE and C. diff) efficacy greater than alcohol. MPulse also has an added benefit of providing extended protection between hand washings. Alcohol kills germs by stripping away the skin's natural oils and with repetitive use leaves hands dry and cracked. mPulse's extensive testing proved that the benefit of alcohol based hand sanitizers drops off significantly after repeated use because germs get trapped in the dry skin and increase the potential risk for cross contamination. All mPulse products are "green", non-toxic, non-drying, non-flammable, skin soothing and smoothing and its metered foamer and sprayers provide twice as many uses per ounce than alcohol gels. mPulse Hand Sanitizer has followed the FDA monograph concerning allowable concentrations of the BAC formula and added an organofunctional silane molecule as a preservative that gives the BAC active ingredient the ability to last throughout several handwashing per day. Testing has show that the added organosilane molecule allows persistent functioning of up to 16 hours on skin, and the graph below conveys an increase in effectiveness over time.

The active ingredient in the organosilane molecule has been used extensively in many markets for over thirty years. Extensive testing has been performed on toxicity and patented uses of the base product has included many products including eye drops, oral products, skincare additives, and textile coatings. FDA 510K alterations to medical goods have been obtained with addition of the silane molecule.

mPulse Hand Sanitizer is manufactured in an EPA, FDA and USDA approved facility following strict guidelines concerning both batch control and product integrity. Samples are collected of every lot manufactured and held as retains for any future testing necessary.

The graph below demonstrates how alcohol-based germ-kill rates actually decrease over time as bacteria gets trapped in the skin leaving hands more contaminated with each use. In contrast, the germ



killing benefits of mPulse increases with repeated use. The active ingredient in mPulse Hand Sanitizer is Benzalkonium Chloride, which is an approved and widely distributed compound that has been used in the health care industry for more than sixty years.

**mPulse vs. Alcohol Germ Kill Rates Using the FDA Recommended Glove Juice Test**

### Solution to Combat Rise of Infection Rates

The mPulse alcohol free alternative to alcohol mirrors the 1980's unprecedented growth when latex-free gloves were introduced for those who could not don latex gloves. Twenty-years later compliance with hand hygiene protocol due to the painful and drying effects, toxicity and flammability of alcohol hand sanitizers has been made possible by the availability and regulatory acceptance of alcohol free hand sanitizers such as mPulse Hand Sanitizer. In fact, alcohol hand sanitizers are now being banned in some school districts, prisons, day care and nursing homes due to the flammability of alcohol, as well as its properties as an intoxicant. In 2008, poison control centers reported over 12,000 cases of alcohol hand sanitizer related poisoning in children under the age of six. Alcohol hand sanitizers contain a potentially fatal amount of 60-90% alcohol which is equivalent to four shots of vodka.

Children with under-developed immune systems and the elderly who are immuno-compromised are particularly sensitive to alcohol's drying effects. Since it is non-toxic and non-flammable with a pleasant fragrance, mPulse is safe to use in ALL markets from schools, day care, health care, nursing homes, hospitals, food service, health clubs, homes, and travel to virtually any environment where hand sinks are inaccessible.

1 Benzalkonium Chloride is listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic hand wash as a Topical Antimicrobial Ingredient category III SE for use as an accepted “Antiseptic hand wash or health-care personnel hand wash”.

2 This category rating indicates that mPulse BAC active ingredient is considered to be safe and effective (SE). The monograph also indicates an acceptable concentration range of 0.1 – 0.13% for the Benzalkonium Chloride (BAC)

**3 The Benzalkonium Chloride is also listed in the Code of Federal Regulations,** Volume 21 (21CFR) as being an accepted active ingredient in a sanitizing solution which “may be safely used on food- processing equipment and utensils, and on other food-contact articles as specified ....” (21CFR178.1010).

4 The other ingredients which make up this formulation are listed as GRAS substances by the FDA in

21CFR. MPulse meets all of the necessary criteria for what would have previously been designated by the USDA as an E2 hand soap and can be used as a replacement for those products which were previously classified as such.

5 “Infection Control Today,” mPulse Points to Dangers of Alcohol Based Sanitizers,” Feb. 2009.

6 Human Subject Tested at Major U.S. University, “the active ingredient in mPulse Alcohol-Free Hand Sanitizer Comparison to Purell® Using Glove Juice Method”, University of California Fresno’s Research and Development Laboratories, Studies Report, June, 2006. NE Labs, Microbiological Testing, AOAC 960.09: Germicidal & Detergent Sanitizing Action of Disinfectant, January, 2009.

7 Published in Leading Journals, Testing a New Alcohol-Free Hand Sanitizer to Combat Infection,” AORN Journal, August 1998, VOL 68, NO 2. “Promoting Health in School through Hand Hygiene,” American School Health Association, November, 2001.

8 FDA Compliant, FDA Registered and CDC Compliant. FDA Federal Register/Vol. 56, NO 140 approved mPulse active ingredient Benzalkonium Chloride (BAC) in concentrations of 0.1 to 0.13 percent.

9 See <http://www.cdc.gov/h1n1flu/qa.htm>: Sept 10, 2009, the CDC released a report stating “What if soap and water are not available and alcohol-based products are not allowed in a facility?” ... other hand sanitizers that do not contain alcohol may be useful for killing flu germ on hands.