



CDC and FDA Requirements for Hand Hygiene

The CDC's goal is to improve hand hygiene practices of health care workers and to reduce transmission of pathogenic microorganisms to patients and personnel in the healthcare environment.

The CDC does not have an approval process in place for instant hand sanitisers, but instead has published guidelines for instant hand sanitisers to ensure they conform to the requirements set by the FDA.

EcoHydra's Antimicrobial Instant Hand Sanitiser formula meets and exceeds these guidelines.

The CDC recommends the use of alcohol based instant hand sanitisers when hand washing facilities are not readily available. It should be noted that in 2002, when the CDC issued the Hand Hygiene Guidelines, representatives from alcohol gel manufacturers participated as consultants in drafting the guidelines.

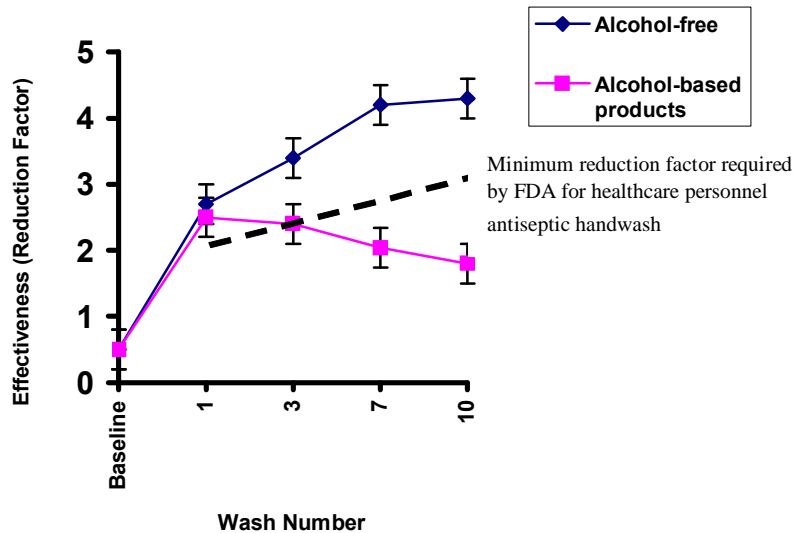
EcoHydra's Antimicrobial Instant Hand Sanitiser was not available at that time. Clinical data now substantiates that our new generation products have been proven to be superior to alcohol in being non skin drying, non-toxic, non-flammable and they have a more persistent fill rate than alcohol. These are all features required by the FDA.

Alcohol kills germs by stripping away the natural oils of the skin. These oils do not regenerate if alcohol is continuously used throughout the day. When the skin dries, bacteria gets trapped in the skin, therefore making the hands more contaminated with each use of alcohol. People who have skin susceptible to the drying effects of alcohol require an option to meet the CDC's recommendation of hand hygiene compliance.

It is important to note that alcohol based instant hand sanitisers fail to meet the FDA criteria after multiple uses. The graph and research noted below demonstrate that alcohol based products fail to reach FDA minimum requirements after the third application.

Alcohol-free* vs. Alcohol-based Gels Antimicrobial Effectiveness with Repeated Use

(* active ingredient Benzalkonium Chloride)



Alcohol-based gels fall below FDA minimum requirements after 3rd application

FDA testing protocol listed in Federal Register, Vol. 59(116), June 17, 1994, 21 CFR 333.470.
Effectiveness testing of an antiseptic Handwash or healthcare antiseptic Handwash.+

EcoHydra's Antimicrobial Instant Hand Sanitiser utilizes an active ingredient that has been safely used in health care for over sixty years (see FDA Federal Register/Vol 56, No. 140 approving Benzalkonium chloride 0.1 to 0.13 percent as an FDA acceptable antimicrobial active ingredient).

Recent testing has also established that the EcoHydra Antimicrobial Instant Hand Sanitiser is effective against *Clostridium difficile* and Norovirus at 30 seconds. Alcohol based products are not effective against either of these pathogens. Many hospitals require that alcohol based products are not used during *C. diff* outbreaks. This is because alcohol breaks down the cell wall of the *C. diff* spores, causing them to become active. Using EcoHydra's Antimicrobial Instant Hand Sanitiser, hospital wards can continue using an instant hand sanitising agent and maintain effective hand hygiene protocols at all times.

The CDC's opinion on alcohol based hand sanitisers was based on data available in 2002. **It is a recommendation and NOT A REQUIREMENT.**

The CDC's ultimate goal is to have more hands sanitized more often throughout the day.

By providing EcoHydra's Antimicrobial Instant Hand Sanitiser, especially for those individuals who cannot or will not use alcohol based hand sanitizing products, healthcare organisations will meet acceptable health and safety practice levels and address the CDC's requirements.