

Comparison of the Liquid alcohol-based hand antiseptic products with alcohol-based hand gels

Alcohols possess the best bactericidal and fungicidal activity of all agents used for hand disinfection. They act rapidly and are also capable to inactivate number of enveloped viruses. Alcohols evaporate rapidly from the skin and exhibit no sustained antimicrobial activity. Because alcohols possess very high antibacterial activity, which includes excellent activity against the resident skin flora, the lack of the sustained effect is generally not important. This is due to the fact that it takes several hours to regrow the resident flora, even after a 3 minute treatment with either 1-Propanol or Iso-Propanol.

It is important to note, that the bactericidal efficacy of different alcohols is not identical.

The bactericidal efficacy decreases in the order:

1-Propanol > Iso-Propanol > Ethanol

From the available data ¹ it can be shown that identical bactericidal activity can be expected for the following concentrations (V/V):

42% 1-Propanol = 60% Iso-Propanol = 77% Ethanol

Hand antiseptics are used for what is generally referred to as the waterless hand rub and also for surgical use. Alcohols are extensively used in both areas of hand antiseptics.

Due to the fact, that there are no standardized methods for the testing of antiseptics in Canada or USA, we have to rely on "state of the art" protocols developed in Europe and referred to as the European norms (EN)².

The EN 1500 standard is used to determine the efficacy of waterless hand rub products such as hand rinses or gels.

Products are tested under practical conditions by the comparing them with the reference disinfectant - 60 % Iso-Propanol on artificially contaminated hands. The bacteria used in this test are Escherichia coli K 12 (NTCC 10538)³ and time of application is 30 or 60 seconds as per manufacturer's instructions.

The tested product should not be significantly less effective, than the reference standard. (Statistical comparison)

The EN 12791 standard is used to determine the efficacy of the products intended for surgical use.

In this method the products are tested by comparing them with the reference disinfectant 60 % 1-Propanol and following a manufacturer's specified time of application of 3 or 5 minutes. The performance of the tested product should not be significantly less effective than the reference standard. (Statistical comparison)

These two standardized methods of testing allow the user to select the most effective antiseptic product for a specific use and facilitate comparison of various products available on the market, under reproducible conditions of testing.

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Therefore, the killing effects indicated in the test reports (log reductions) are generally higher, than those reached under practical conditions of use(shorter time of application).

Most studies clearly show, that the products are applied for much shorter time, (7- 15 sec.). Obviously, if the hypothetical product reaches 2-3 log reduction in 30 sec. testing, it will reach only about 1 log reduction under practical conditions of use (7-15 sec.).

This level of reduction is not likely adequate to prevent the transmission of the organism, since approximately 10% of the organism will remain on hands and there is a good chance that the organism will cause a disease.

On the other hand, a hypothetical product that reaches 5 log reduction under ideal test conditions (30 sec.) will likely reach about 3 log reduction under practical conditions of use, killing 99.9% of the organisms. This can probably prevent transfer of a large enough number of organisms to cause a disease.

In conclusion, due to the above reasons it is justifiable to set the level of efficacy (log reduction) relatively high, making it unlikely, that the amount of the organism remaining on hands after disinfection can cause a disease.

At present time, claims on the labels of antiseptic hand products usually contain non-specific information such as : "Kills 99.9% of most common germs in as little as 15 seconds". This kind of information is not only misleading, but creates a false sense of security, especially for health care workers, who depend on these products to protect themselves and their patients from infection diseases.

The tests that support these claims are not performed under practical conditions of use and if at all available, are carried out on some bacteria using non-standardized in-vitro suspension tests, which differ from manufacturer to manufacturer making any meaningful comparison of results impossible. This situation prevents the user to evaluate activities of the product against specific organism and compare relative activity (kill rate) against each organisms.

The most important step we can do to prevent the spread of infectious diseases is to introduce rational Guidelines for testing and approval of antiseptic drugs, based on Standardized test methods which include specific criteria of efficacy, pertaining to bactericidal, fungicidal and virucidal claims.

The new Guidelines for antiseptic drugs will allow the user to compare efficacy and the spectrum of activity of products in a transparent manner and consequently allow each user to select product based on specific criteria of activity/efficacy determined by tests performed under identical test conditions.

In conclusion: The new Canadian Guidelines are based on the longstanding European experience in testing of antiseptic products. The Canadian Guidelines incorporate specific test method from ASTM, recommended by the FDA for ascertaining virucidal activity of products under practical conditions of use. The entire content of the Standard test methods reflects current state of the art in the area of testing and approval of antiseptic disinfectants.

