



ALCOHOL-BASED HAND SANITISERS – ETHANOL AND ISOPROPYL ALCOHOL (IPA)

Due to the worldwide pandemic of Coronavirus (COVID-19) the use and demand for alcohol-based hand sanitisers has increased substantially. Market research by Neilson shows an increase in sales of 300% and 470% in the last week of February and the first week of March compared to the same period last year. ⁽²⁾

The World Health Organisation (WHO) define alcohol-based hand rubs or ABHRs as alcohol containing preparations (liquid, gel or foam) designed for application to the hands to inactivate micro-organisms and /or temporarily suppress their growth. ⁽²⁾

According to WHO guidelines when an alcohol hand sanitiser is available it should be used as the preferred means for routine hand hygiene in healthcare. A training programme is important to ensure the correct dose, contact time and technique is used. ⁽¹²⁾ The correct technique is shown on Evans hand hygiene posters, which is taken from these guidelines.

Hands need to be washed with soap and water when visibly dirty or soiled, a hand rub should be used once hands are visibly clean or where there is a lack of water or sinks. The aim of a hand rub is to reduce the number of micro-organisms on hands with a short contact time and without the use of water. For these practical reasons, alcohols like Ethanol and Isopropyl alcohol (IPA) or combinations of both are the most appropriate and are used in many formulations of alcohol hand sanitisers available on the market. ⁽⁶⁾ Formulations including emollients are better for skin, causing less irritation. ^(7,9)

EFFICACY

There have been numerous papers published assessing and reviewing the antimicrobial activity of alcohol when used in hand sanitisers. ^(1, 3, 4, 5, 8, 10)

When the EN 1500 method was used for assessing a range of hand gels and rinses with a 30 second contact time, it was found that formulations should contain >80% ethanol or >60% IPA. ⁽⁶⁾

WHO developed 2 formulations for alcohol hand sanitisers using 80% v/v Ethanol and 75% v/v IPA. These were developed to help with the Ebola outbreak in Africa as they were considered easier and cheaper to manufacture due to the urgent need. ⁽¹¹⁾ Both formulations were tested using EN 1500 and were effective. ⁽¹³⁾

The effectiveness of alcohol formulations depends on the type of alcohol, the concentration, quantity applied to hands and the exposure time. ⁽¹¹⁾ There is an optimal percentage range for effectiveness, typically 60 to 90%, with <60% or >95% not as effective. ⁽⁸⁾

A product label with water as the first ingredient and/or less than 50% alcohol can be considered ineffective. ⁽²⁾ Products with a low-viscosity, liquid formulation, may be difficult to use, spill easily, potentially leading to a decrease in efficacy. ⁽²⁾ Gel formulations with a higher viscosity are more portable, conveniently dispensed, with a low risk of spillage. They also reduce the evaporation rate helping the alcohol to penetrate through the contaminating organisms. ⁽²⁾

Alcohols mode of action is to denature and coagulate proteins causing cells to lyse and then disrupt cellular metabolism. ⁽⁵⁾ Proteins are not denatured easily in the absence of water so >95% is not as effective. ⁽⁸⁾

Ethanol and IPA

Both Ethanol and IPA are effective against bacteria, mycobacteria and enveloped viruses, but not effective against bacterial spores.

Their virucidal activity only differs in respect to non-enveloped viruses where Ethanol has better activity. ^(2, 5) They are both effective against Coronavirus (COVID-19), which is an enveloped virus.

REGULATIONS

IPA is approved as an active ingredient in Europe via the Biocidal Products Regulation (BPR) [no. 528/2012]. There are also authorised products based on the IPA available in the marketplace, including the Evans Vanodine product **Handsan** [UK-2019-1195-0001].

Ethanol is not yet approved as an active under this system so existing local regulations apply. e.g. in the UK, as most disinfectant use is unregulated, products can be on the market without authorisation.

Product efficacy testing is an essential component of the authorisation process and products like **Handsan** are supported with a full suite of test results to match their label claims. Bactericidal, yeasticidal and virucidal EN test methods have been used, including EN 1500, a practical in-use test where volunteers hands are inoculated with bacteria. After the hand sanitiser is used the numbers of surviving bacteria are compared to an IPA preparation used as a control. ⁽¹⁾

Many of the Ethanol products on the market at present are not supported by any efficacy and rely on the WHO formulation data and temporary derogation from regulation to be supplied. The derogation will end on 25/09/20.

Her Majesty's Revenue and Customs (HMRC) have temporary measures in place for formulations using industrial denatured alcohol (ethanol). Records need to be kept for the amounts of denatured ethanol and the method used to produce the formulation. (GOV.UK)

Very few of the new products will be Halal or kosher approved and their role would be to supply general public demand rather than professional or specific use where authorisation or approval is required.

CONCLUSION

It is considered acceptable to use either Ethanol or IPA in hand sanitiser formulations. WHO have recommended formulations using either alcohol.

At present some Ethanol formulations are on the market based on these WHO guidelines and do not require testing or need to meet any regulations apart from HMRC. The derogation is only temporary and will end in September 2020.

There needs to be an awareness that some of the new products on the market are making unsubstantiated claims and they are not presently regulated.

The efficacy of both Ethanol or IPA is very similar i.e. both are effective against a range of bacteria, and viruses.

When the Coronavirus pandemic is at an end we would expect the new Ethanol formulations, manufactured to help with the spread of the virus, to either be removed from the market or the manufacturers will have to ensure their products are tested against the relevant test methods to meet all applicable regulations to be continued to be sold.

Evans **Handsan** has been tested with all the appropriate EN test methods to support all the claims for the BPR. **Handsan** is recommended wherever food is handled, prepared or served, and is ideal for in between patient contact in non-surgical, medical care establishments.

Handsan is a quick acting, highly effective alcohol-based hand sanitiser containing emollients to help with skin protection.

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