



Frequently Asked Questions: Alcohol-Based Hand Sanitizer During COVID-19 Pandemic

April 28, 2020

1. Why are the hand sanitizer formulations important?

The [CDC](#) recommends hand washing with soap and water or using hand sanitizer to help people avoid getting sick and spreading germs to others. Laboratory data demonstrates that 60% ethanol or 70% isopropyl alcohol inactivates viruses that are genetically related to, and with similar physical properties as, the SARS-CoV-2. Alcohol-based hand sanitizers must be properly formulated in order to protect the health of the skin, reduce bacteria on the hands, and avoid inadvertent exposure to organisms not killed by alcohol (e.g., spores).

2. How were the formulations in the USP compounding hand sanitizer resource document developed?

The formulas in the USP compounding resource document were developed by the Compounding Expert Committee based on their scientific and professional expertise, and with input from regulatory agencies at the federal and state level and compounders. The formulations were based on [WHO-recommended Handrub Formulations](#).

3. Can I extend the beyond-use date (BUD) of compounded hand sanitizers beyond those specified in USP's compounding hand sanitizer resource document?

The 35-day BUD is assigned based on USP General Chapter <795> *Pharmaceutical Compounding – Nonsterile Preparations* defaults for *Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations*.

4. Can I use isopropyl alcohol 70% to compound the hand sanitizer formulations in the USP compounding resource document?

[CDC](#) recommends a hand sanitizer formulation with a final concentration of greater than 70% isopropyl alcohol to inactivate viruses that are genetically related to, and with similar physical properties as, the SARS-CoV-2. Formulations in the USP compounding resource document specifies a higher concentration of 75% isopropyl alcohol to account for the potential for sub-potent ingredients, evaporative loss, and margin of error. Compounding with 70% isopropyl alcohol as a starting ingredient would not be sufficient to achieve a final concentration of at least 70% isopropyl alcohol because the addition of other required ingredients would dilute it below this minimum concentration.

5. Why do the USP hand sanitizer formulas have 80% ethanol and 75% isopropyl alcohol final concentrations where the CDC recommendations are at least 60% ethanol and 70% isopropyl alcohol?

The final concentration of 80% ethanol or 75% isopropyl alcohol recommended in the USP compounding hand sanitizer resource document is aligned with recommendations from the FDA, WHO, and CDC. The higher concentrations help ensure the final concentration of the preparation will exceed those needed to inactivate viruses. These formulas with higher final alcohol concentrations account for the potential for sub-potent ingredients, evaporative loss, and margin of error.



6. Can I substitute ingredients recommended in the USP compounding hand sanitizer resource document?

The USP resource [document](#) includes recommended substitutions. Other substitutions are not recommended by the USP Compounding Expert Committee at this time.

USP is aware of ingredient shortages and is working with the Expert Committee on an ongoing basis to discuss alternative ingredients and formulas to meet public health needs.

7. How can I ensure my ingredient meets USP standards?

USP, NF, or FCC grade ingredients must comply with the requirements specified in the applicable monograph. Relevant USP standards for ingredients used to prepare hand sanitizers are included within the [toolkit](#), accessible free of charge.

8. What is the recommended packaging for alcohol-based hand sanitizers?

The formulations in the USP hand sanitizer compounding resource document are solutions. They should be packaged in tightly closed containers that minimize evaporative loss but allow for easy dispensing and use. If denatured ethanol is not used, it is recommended to package in child-resistant containers to minimize the risk of accidental ingestion by children. Denatured ethanol is preferred because its bitter taste may deter accidental ingestion by children.

9. Who can I contact for questions about hand sanitizers, including questions about specific ingredients?

For any questions, please contact CompoundingSL@usp.org.