

## Hand Sanitizer Compounding during COVID-19

The FDA does NOT intend to take action against compounders that prepare alcohol-based hand sanitizers for consumer use and healthcare personnel for the duration of the public health emergency, provided the following circumstances are present:

1. The hand sanitizer is compounded using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation).
  - a. Alcohol (ethanol) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20; or Isopropyl Alcohol (75%, v/v) in an aqueous solution
  - b. Glycerol (1.45% v/v)
  - c. Hydrogen peroxide (0.125% v/v)
  - d. Sterile distilled water or boiled cold water

**The compounder does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.**

2. The compounder pays particular attention to ensure the ethanol or isopropyl alcohol active ingredient is correct and the correct amount of the active ingredient is used.
3. The hand sanitizer is prepared under conditions routinely used by the compounder to compound similar nonsterile drugs.
4. The hand sanitizer is labeled consistent with the [attached labeling](#) in Appendix A (Labeling for Ethyl Alcohol Formulation Consumer Use), Appendix B (Labeling for Isopropyl Alcohol Formulation Consumer Use), Appendix C (Labeling for Ethyl Alcohol Formulation Health Care Personnel Handrub Use), or Appendix D (Labeling for Isopropyl Alcohol Formulation Health Care Personnel Handrub Use).

**Packaging and Storage:** Package in suitable containers and store at room temperature.

**Labeling:** State for external use only, the percentage of ethanol, and the Beyond-Use Date.

**Beyond-Use Date:** NMT 30 days after the date on which it was compounded, when stored at room temperature.

NOTE: We've had reports that the rubbing alcohol can currently be hard to find. Some pharmacies are contacting their local liquor store and obtaining grain alcohol as an alternative.

For more information, click [here](#).