Dietary Supplements and COVID-19 Pandemic

USP Support to Public Health Response

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USP’s 3-part response to the COVID-19 pandemic

1. Ensuring safety and security of staff
2. Adapting our operations
3. Delivering on our public health mission
USP’s Commitment to Tackling Supply Chain Vulnerability

**Goal:** Reduced challenges to the supply of new and existing quality medical products required for, and impacted by, the Covid-19 pandemic

- Maintain and strengthen production of quality medical products required for, and impacted by, the Covid19 pandemic
- Maintain and strengthen support to regulators and public health stakeholders to ensure quality medical products in response to the Covid19 pandemic
- Increase prioritization of supply chain resiliency and quality of medical products on balance with current public health challenges
Addressing shortage risks in a three-prong approach

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Hand sanitizer toolkit

- Consolidated guidelines for compounders, OTC drug manufacturers, and other facilities (e.g. distilleries): https://www.usp.org/covid-19/hand-sanitizer-information
  - Tool kit for hand sanitizers (formulae, ingredients sources, USP standards for ingredients etc.)

- Sourcing from WHO, FDA, USP, NASPA, TTB
Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic

Demand for alcohol-based hand sanitizers has surpassed its supply due to the rapidly evolving COVID-19 pandemic. In response, the U.S. Pharmacopeia has provided an informational resource document on compounding hand sanitizer to help address the shortages. Please visit usp.org/compounding for more info.*

Formulation 1

Ethanol¹ 96% 8333 mL
Hydrogen peroxide 3% 417 mL
Glycerol² 98% 145 mL
Water ¹ a sufficient quantity to make 10,000 mL

Formulation 2

Isopropyl Alcohol¹ 99% 7576 mL
Hydrogen peroxide 3% 417 mL
Glycerol³ 98% 75 mL
Water ¹ a sufficient quantity to make 10,000 mL

Formulation 3

Isopropyl Alcohol¹ 91% 8242 mL
Hydrogen peroxide 3% 417 mL
Glycerol² 98% 75 mL
Water ¹ a sufficient quantity to make 10,000 mL

¹ When the concentration of alcohol in the starting ingredient is not exact, follow the calculation on the USP hand sanitizer resource document to ensure a final concentration of at least 60% ethanol or 75% isopropyl alcohol.
² It is recommended to use denatured ethanol instead of nondenatured ethanol because there have been reports of adverse events, including deaths, from unintentional ingestion of hand sanitizer, particularly in young children. If it is not denatured, package in a child-resistant container.
³ Glycerin and glycerol are synonymous and may be interchanged. Glycerin and glycerol are added as humectants.
⁴ Water may be distilled, cold boiled potable, reverse osmosis, or filtered.

Packaging and Storage: Package in well-closed, suitable containers and store at controlled room temperature.

Labeling: Label it to state for external use only, the percentage of active ingredient (i.e., ethanol, isopropyl alcohol), and the Beyond-Use Date.

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

* This infographic is for informational purposes for healthcare practitioners and scientific professionals, and is intended to help address shortages of alcohol-based hand sanitizers associated with the COVID-19 pandemic; it is not intended to provide advice or guidance on the use of alcohol-based hand sanitizers or any other medical product. It is not a substitute for professional medical advice, diagnosis, or treatment. This infographic is based on the USP hand sanitizer resource document and is subject to change. Always consult with a healthcare professional before using any alcohol-based hand sanitizer to ensure it is appropriate for your situation.

For more information on compounding hand sanitizer, please visit usp.org/compounding.
Goal: Providing support to DS manufacturers to help ensure the quality of dietary supplements

- Additional Information available at the:

- USP DSHM website at

- USP Verification Services website at
  - https://www.usp.org/services/verification-services
Thank You