A hand sanitizer is a preparation applied to the hands for the purpose of removing common pathogens (disease-causing organisms) that is typically sold in the form of foam, gel, or liquid.

A hand sanitizer can be alcohol based or alcohol-free depending on the used active ingredient.

The World Health Organization formulation recommendations:

**Hand Sanitizers**

**Chemical compliance insights for the EU and US markets**

- **Formulation 1**
  - Final concentrations:
    - Ethanol 80% (v/v),
    - Glycerol 1.45% (v/v),
    - Hydrogen peroxide 0.125% (v/v)

- **Formulation 2**
  - Final concentrations:
    - Isopropyl alcohol 75% (v/v),
    - Glycerol 1.45% (v/v),
    - Hydrogen peroxide 0.125% (v/v)
**Chemical compliance requirements for the EU and US markets**

**Europe**

In the EU, all products containing an active substance and supplied with a primary biocidal purpose, i.e. intended to control harmful organisms, fall within the scope of the biocides Regulation (EU) No. 528/2012**.

Several European countries have implemented derogations to help manufacturers and importers to satisfy the increasing demand for hand sanitizers.

**United States**

Hand sanitizers are regulated by the U.S. FDA as over-the-counter (OTC) rubs and washes.

The FDA requirements are:

- U.S. FDA registration - Register the manufacturing establishment with the FDA
- NDC labeler code - Request a labeler code for the establishment or company
- Hand sanitizer listing with FDA - Assign a unique 10-digit NDC number and list each hand sanitizer with the FDA
- Label compliance - Antiseptic hand sanitizer must have “Drug Facts” labeling and all other required information
- Comply with GMP requirements as per 21 CFR 211
- Comply with OTC monograph - The eligible active ingredients in the OTC monograph are:
  - Benzalkonium chloride
  - Ethyl alcohol or Ethanol (60% to 95%)
  - Isopropyl alcohol (70% to 91.3%)
- Recently, a “Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency” applicable to the production of hand sanitizers formulated as per WHO suggestions.

UL’s experts are able to provide companies with a complete regulatory scenario based on their needs and target markets.

**SOURCES and NOTES**

* https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf
* https://ec.europa.eu/docsroom/documents/40523

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To learn more about chemical insights on EU and U.S. markets for your hand sanitizers, visit **CRS.UL.com** or write us by clicking here.