HAND SANITIZERS

Chemical compliance insights for the EU and US markets

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*:

Formulation 1	Formulation 2
Final concentrations: • Ethanol 80% (v/v), • Glycerol 1.45% (v/v), • Hydrogen peroxide 0.125% (v/v)	**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.

The Biocidal Products Regulation (BPR, Regulation (EU) No. 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials, or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product.

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 expert 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

https://www.fda.gov/drugs/information-drug-class/qa-consumers-hand-sanitizers-and-covid-19

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**.

Empowering Trust®