

ULTRA HAND SANITIZER- alcohol liquid

Bocchi Laboratories

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Omega Industrial Supply Inc. Ultra Hand Sanitizer

Active Ingredient

Alcohol 80% v/v

Purpose

Antiseptic

External use only. Flammable. Keep away from heat or flame.

When using this product keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Use - Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Directions

- Place enough product on hands to cover all surfaces.
- Rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product to avoid swallowing.

Other information

- Store between 15°-30°C (59°-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients Glycerin, Hydrogen Peroxide, Purified Water USP

Do not use

- On children less than 2 months of age.
- On open skin wounds.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (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.

Glycerol (1.45% v/v).

Hydrogen peroxide (0.125% v/v).

Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may

impact the quality and potency of the product.

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DIRECTIONS FOR USE
Place enough product in your palm to thoroughly cover your hands. Rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product. Store between 59-86 degrees F (15-30 degrees C). May discolor certain fabrics or surfaces.

WARNING
Flammable. Keep away from fire or flame. For external use only. When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash appears and lasts. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

KEEP OUT OF REACH OF CHILDREN
For Emergencies, Call 24hr
ChemTel: 800-255-3924

REORDER FROM:



Omega Industrial Supply, Inc.
101 Grobick Court #1
Fairfield, CA 94534
800-571-7347
Fax: 707-864-8134
www.onlyomega.com

ONLY OMEGA.COM

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57702-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57702-102-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2020	12/31/2021
2	NDC:57702-102-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2020	12/31/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/21/2020	12/31/2021

Labeler - Bocchi Laboratories (013579387)

Revised: 4/2020

Bocchi Laboratories