# GW LABS ADVANCED LIQUID 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.

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#### **GW Labs Advanced Liquid Hand Sanitizer**

### **Active Ingredient**

Alcohol 80% v/v

#### **Purpose**

Antiseptic

For 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 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.

#### Uses

- 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 until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

#### Other information

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

Inactive ingredients Glycerin, Hydrogen Peroxide, Purified Water USP

#### Do not use

- In 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.



### GW LABS ADVANCED LIQUID HAND SANITIZER

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57702-108
Route of Administration	TOPICAL		
Active Ingredient/Active Mojety			

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

nactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)		

l	Packaging				
l	#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
l	1 N	NDC:57702-108-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	12/31/2021

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/14/2020	12/31/2021	

## Labeler - Bocchi Laboratories (013579387)

## Registrant - Bocchi Laboratories (013579387)

Revised: 5/2020 Bocchi Laboratories