

## **HAND SANITIZER- alcohol gel**

### **HS HomeWorx LLC**

*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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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:

- a. 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.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. 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.

### **Active Ingredient(s)**

Alcohol 75% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic

### **Use**

to help reduce bacteria on skin

### **Warnings**

For external use only. Flammable. Keep away from fire, flame and high heat.

When using this product avoid contact with eyes, If contact occurs, rinse eyes thoroughly with water.

Do not inhale or ingest. Avoid contact with broken skin.

Stop use and ask a doctor if irritation or redness occurs.

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

Center right away.

## Directions

- Dispense into hands, rub thoroughly until dry

## Other information

- Do not store above 110 F (43 C)
- May discolor certain fabrics or surfaces

## Inactive ingredients

Aqua (Water), Glycerin, Butylene Glycol, Fragrance (Parfum), Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine  
Aloe Barbadensis Leaf Extract, Artemisia Argyi Leaf Extract, Cnidium Monnieri Fruit Extract, Sargassum Fusiforme Extract

## Package Label - Principal Display Panel

236 mL NDC: 81282-046-01



## HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81282-046
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	1 mL in 100 mL
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	1 mL in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	1 mL in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81282-046-01	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/01/2021	

**Labeler** - HS HomeWorx LLC (080653110)

Establishment			
Name	Address	ID/FEI	Business Operations
Cosbe Laboratory Inc		543033650	manufacture(81282-046)

Revised: 5/2021

HS HomeWorx LLC