

## **HAND SANITIZER- alcohol gel**

### **Consolidated Chemicals, 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.*

-----

## **80% Alcohol Gel Sanitizer**

### **Hand Sanitizer Alcohol Gel**

This hand sanitizer is manufactured using the following ingredients in the preparation of the product (wt% in final product formulation) consistent with 21 CFR Part 310:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80 wt%) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol USP Grade (2 wt%).
- c. Hydrogen peroxide (0.14 wt%).
- d. Hydroxypropyl methylcellulose USP (0.75 wt%)
- e. Distilled water

The firm does not add other active or inactive ingredients.

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

Alcohol 80%. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

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

### **Warnings**

For external use only. Flammable. Keep away from heat or flame

### **Do not use**

- in children less than 2 months of age
- on open skin wounds

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.

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.

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

### Inactive ingredients

glycerin, hydrogen peroxide, hydroxypropyl methylcellulose, purified water USP

### Package Label - Principal Display Panel

## Instant Hand Sanitizer Gel


80% Alcohol

*Contains Glycerin  
Fragrance Free*

Kills 99.9% of most  
common germs that may  
cause illness.

**DANGER: FLAMMABLE**  
KEEP OUT OF REACH OF CHILDREN.  
KEEP AWAY FROM FIRE OR FLAME. FOR  
EXTERNAL USE ONLY.  
See other cautions on opposite panel of  
label.

1 Gal (3.8 L)

Drug Facts	
Active Ingredient	Purpose
Alcohol 80%	Antiseptic
<b>Use[s]</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame.</b>	
<b>Do not use</b> <ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul>	
<b>Other information</b> <ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, hydroxypropyl methylcellulose, purified water USP	
 <b>Consolidated Chemicals, LLC,</b> 3191 West Tharpe St., Tallahassee FL 32303 Ph: (850) 575-0321	

3784 mL NDC: 75632-210-40

## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75632-210
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C00X)	2 g in 100 g
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.14 g in 100 g
WATER (UNII: 059QF0KO0R)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	0.75 g in 100 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75632-210-40	3175 g in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/16/2020	

**Labeler** - Consolidated Chemicals, LLC (117478303)

**Registrant** - Consolidated Chemicals, LLC (117478303)

### Establishment

Name	Address	ID/FEI	Business Operations
Consolidated Chemicals, LLC		117478303	manufacture(75632-210)