

## **HAND SANITIZER- alcohol gel**

### **Alpha Pack Ltd**

*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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### **Prudence Hand Sanitizer 80 %**

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 80% v/v. 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.

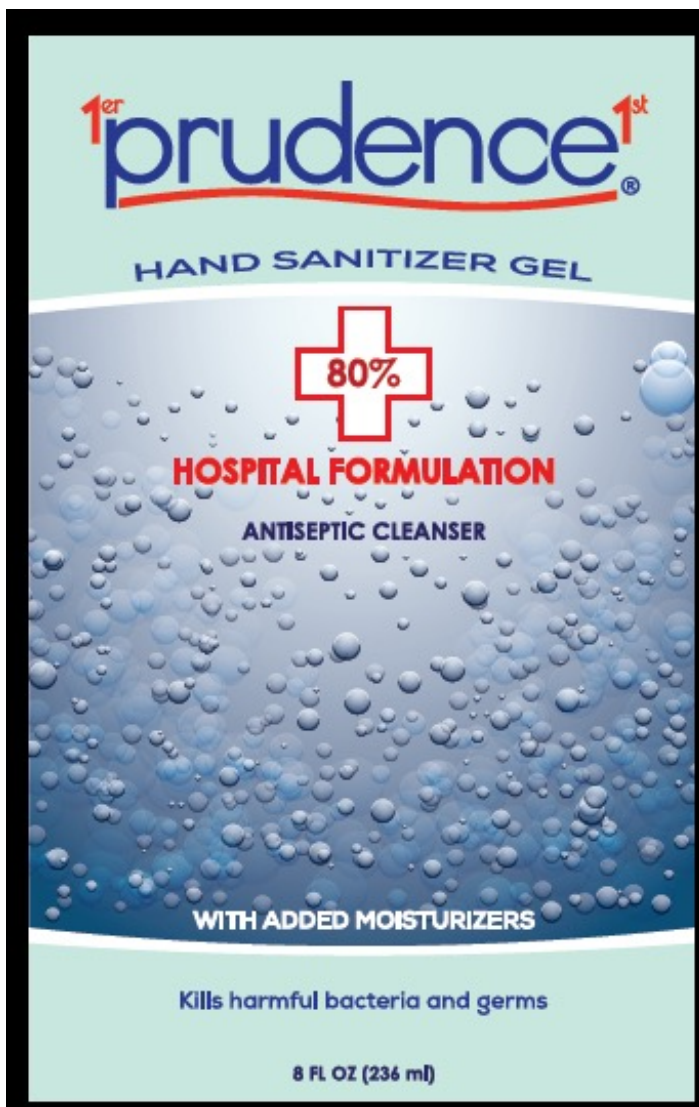
### Other information

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

### Inactive ingredients

glycerine, purified water USP, Hydrogen Peroxide, Aminomethyl Propanol, Carbomer

### Package Label - Principal Display Panel





<b>DRUG FACTS:</b>	
<b>Active Ingredient(s)</b>	<b>Purpose</b>
Ethyl Alcohol 80% v/v.....	Antiseptic
<b>USE(S):</b>	
Hand Sanitizer to help reduce germs and bacteria that potentially can cause disease. For use when water and soap are not available.	
<b>WARNINGS:</b>	
For external use only. Flammable. Keep away from heat, flame and fire.	
<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 sign of a serious condition.	
<b>Keep out of reach of children</b> If swallowed, get medical help or contact a Poison Control Center immediately.	
<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- 35C (59- 95F)</li> <li>Avoid freezing and excessive heat above 40C(104F)</li> </ul>	
<b>INACTIVE INGREDIENTS:</b>	
Water(Aqua), Glycerin, PEG 75 Lanolin, Carbomer, Fragrance, Triethanolamine.	

Distributed by / Distribué par  
 ALPHA PACK LTD.  
 1357 Jessop Street  
 Windsor, ON  
 N8W 5P4

Lot#  
 Mfg Date:  
 Exp:



236 mL NDC: 78649-001-01

## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78649-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	188.8 mL in 236 mL

### Inactive Ingredients

Ingredient Name	Strength
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<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	0.59 mL in 236 mL
<b>AMINOMETHYLPROPANOL</b> (UNII: LU49E6626Q)	0.71 mL in 236 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	3.1 mL in 236 mL
<b>WATER</b> (UNII: 059QF0KO0R)	42.5 mL in 236 mL
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	0.28 mL in 236 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78649-001-01	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/05/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/05/2020	

**Labeler** - Alpha Pack Ltd (204135164)

**Registrant** - Alpha Pack Ltd (204135164)

### Establishment

Name	Address	ID/FEI	Business Operations
SEKTOR KIMYA DETERJAN SANAYI VE TICARET ANONIM SIRKETI		533132559	manufacture(78649-001)

Revised: 12/2020

Alpha Pack Ltd