

## **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 72% 3.78 L**

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 72% 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**

Propylene glycol, purified water USP, Triethanolamine, PEG-75 Lanolin, Fragrance

**Package Label - Principal Display Panel**

<sup>1<sup>er</sup></sup>prudence<sup>1<sup>st</sup></sup>®

HAND SANITIZER GEL

WITH ADDED MOISTURIZERS

ANTISEPTIC CLEANSER

72% vol.

Kills harmful bacteria and germs

128 FL OZ (3.78 L)



<b>DRUG FACTS:</b>	
<b>Active Ingredient(s)</b>	<b>Purpose</b>
Ethyl Alcohol 72% 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 maybe 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:

3.78L NDC: 78649-007-01

<b>HAND SANITIZER</b>			
alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78649-007
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	2.72 L in 3.78 L

## Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	0.01 L in 3.78 L
PEG-75 LANOLIN (UNII: 09179OX7TB)	0.019 L in 3.78 L
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.004 L in 3.78 L
WATER (UNII: 059QF0K00R)	0.99 L in 3.78 L
TROLAMINE (UNII: 9O3K93S3TK)	0.001 L in 3.78 L

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78649-007-01	3.78 L 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(78649-007)

Revised: 12/2020

Alpha Pack Ltd