#### 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% 1000 mL

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.

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# 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)

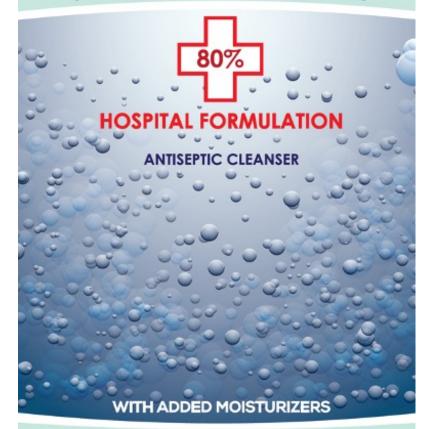
# Inactive ingredients

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

# Package Label - Principal Display Panel



# HAND SANITIZER GEL



Kills harmful bacteria and germs

33.8 FL OZ (1000 ml)



DRUG FACTS: Active Ingredient(s) Ethyl Alcohol 80% v/v	Purpose Antiseptic
USE(S): Hand Sanitizer to help reduce ge cause disease. For use when wate	rms and bacteria that potentially can er and soap are not available.
WARNINGS: For external use only. Flammable Do not use:	. Keep away from heat, flame and fire
<ul> <li>In children less than 2 mo</li> </ul>	onths of age
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together until dry.	hands to cover all surfaces. Rub hands en under 6 years of age when using lowing.
OTHER INFORMATION:	27 Mar 10
<ul> <li>Store between 15- 35C (5)</li> </ul>	
<ul> <li>Avoid freezing and excess</li> </ul>	ive heat above 40C(104F)
INACTIVE INGREDIENTS: Water(Aqua), Glycerin, PEG 75 L Triethanolamine.	anolin, Carbomer, Fragrance,
Distributed by / Distribué par	
ALPHA PACK LTD. 1357 Jessop Street	
Windsor, ON	
N8W 5P4	
Lot#	
Mfg Date:	
Exp:	
	B 682022 656612

# 1000 mL NDC: 78649-011-01

HAND SANITIZER alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78649-011
Route of Administration	TOPICAL		
Active Ingredient/Active Moi	ety		
Ingredient Name		Basis of Strengt	h Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	800 mL in 1000 mL
Inactive Ingredients			
In	gredient Name		Strength

2.54 mL in 1000 mL
3 mL in 1000 mL
13.1 mL in 1000 mL
179.7 mL in 1000 mL
1.18 mL in 1000 mL

# Fitem Code Marketing Start Date Marketing Start Date 1 NDC:78649-011- 000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product 06/05/2020 Of the sector o

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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	<b>Business Operations</b>
SEKTOR KIMYA DETERJAN SANAYI VE TICARET ANONIM SIRKETI		533132559	manufacture(78649-011)

Revised: 12/2020

Alpha Pack Ltd