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.

Prudence Hand Sanitizer 72%

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.

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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

DRUG FACTS:

Active Ingredient(s)	***Purpose***
Ethyl Alcohol 72% v/v	Antiseptic

USE(S):
Hand Sanitizer to help reduce germs and bacteria that potentially can cause disease. For use when water and soap are not available.

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

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 maybe sign of a serious condition.

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

DIRECTIONS:
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children children under 6 years of age when using this product to avoid swallowing.

OTHER INFORMATION:
- Store between 15- 35C (59- 95F)
- Avoid freezing and excessive heat above 40C(104F)

INACTIVE INGREDIENTS:
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:

8 68202 65612

236 mL NDC: 78649-000-01

HAND SANITIZER
alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78649-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	169.92 mL in 236 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER 940 (UNII: 4Q93RCW27E)	0.71 mL in 236 mL
PEG-75 LANOLIN (UNII: 09179OX7TB)	1.18 mL in 236 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	2.36 mL in 236 mL
WATER (UNII: 059QF0KO0R)	61.75 mL in 236 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.071 mL in 236 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:78649-000-01	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(78649-000)

Revised: 12/2020 Alpha Pack Ltd