

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 80% 946 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.

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.

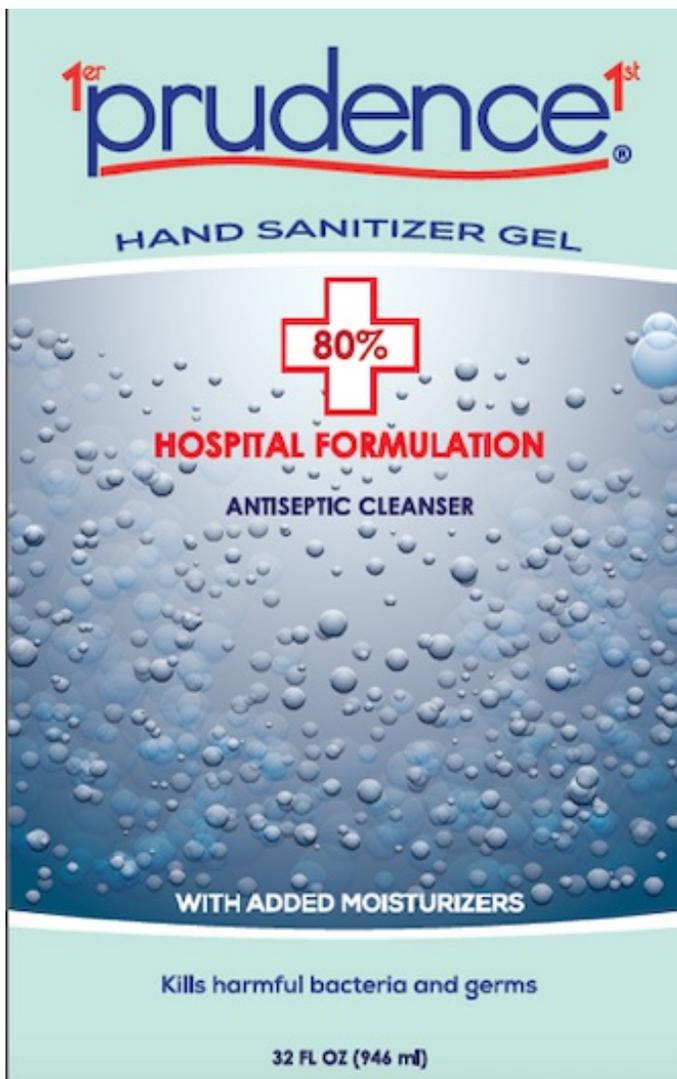
Other information

- 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





DRUG FACTS:	
Active Ingredient(s)	Purpose
Ethyl Alcohol 80% 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:	
<ul style="list-style-type: none"> 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:	
<ul style="list-style-type: none"> 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:	
<ul style="list-style-type: none"> Store between 15- 35C (59- 95F) Avoid freezing and excessive heat above 40C(104F) 	
INACTIVE INGREDIENTS:	
Aminomethyl Propanol, Glycerin, Hydrogen Peroxide, Carbomer, Water(Aqua)	

Distributed by:
ALPHA PACK LTD.
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Lot# U/2020-80001
Mfg Date: 06/04/2020
Exp Date: 06/04/2023

946 mL NDC: 78649-013-01

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78649-013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	756.8 mL in 946 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	2.4 mL in 946 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	2.84 mL in 946 mL
GLYCERIN (UNII: PDC6A3C0OX)	12.4 mL in 946 mL

WATER (UNII: 059QF0KO0R)	170 mL in 946 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	1.12 mL in 946 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78649-013-01	946 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/07/2020	

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(78649-013)

Revised: 12/2020

Alpha Pack Ltd