

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% 473 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 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





| | |
|--|----------------|
| 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: | |
| <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 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: | |
| 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:

473 mL NDC: 78649-003-01

| HAND SANITIZER | | | |
|--|-------------------|--------------------|---------------|
| alcohol gel | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78649-003 |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 340.6 mL in 473 mL | |

Inactive Ingredients

| Ingredient Name | Strength |
|-------------------------------------|--------------------|
| CARBOMER 940 (UNII: 4Q93RCW27E) | 1.42 mL in 473 mL |
| PEG-75 LANOLIN (UNII: 09179OX7TB) | 2.36 mL in 473 mL |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | 4.72 mL in 473 mL |
| WATER (UNII: 059QF0K00R) | 123.5 mL in 473 mL |
| TROLAMINE (UNII: 9O3K93S3TK) | 0.142 mL in 473 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:78649-003-01 | 473 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(78649-003) |

Revised: 12/2020

Alpha Pack Ltd