

PRISM HEALTH LAB HAND SANITIZER- ethyl alcohol solution
Prism Holistic Care 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.

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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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

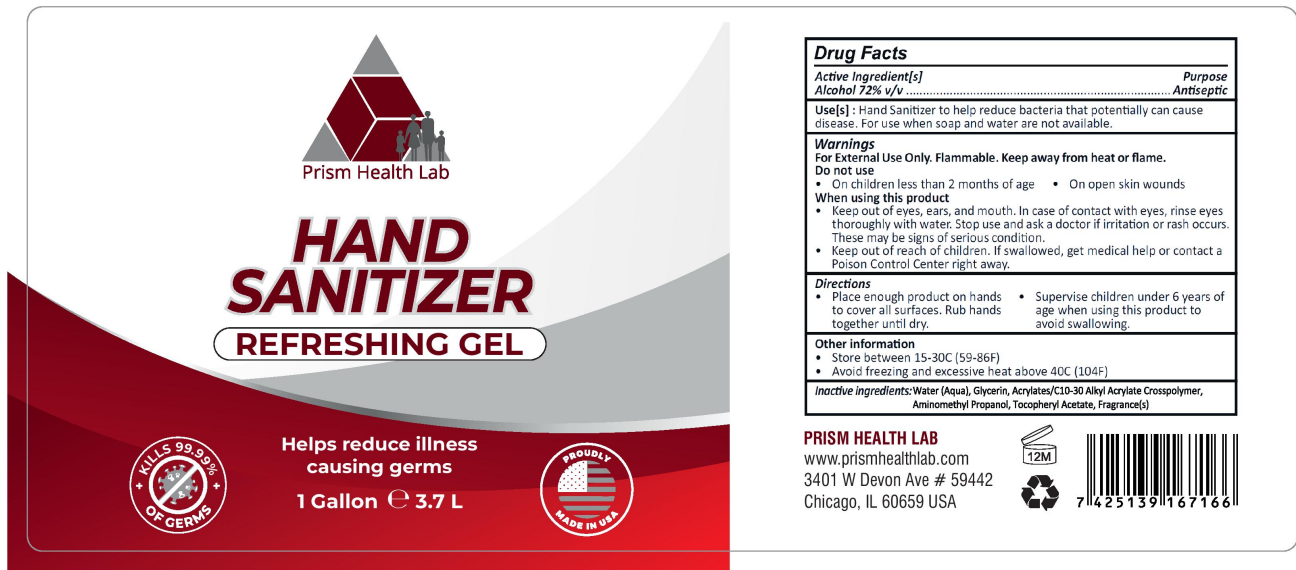
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, water, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Tocopherol Acetate, Fragrance(s)

Package Label - Principal Display Panel

000 mL NDC: 00000-000-00



The image shows the principal display panel of a hand sanitizer package. At the top center is the Prism Health Lab logo, a red and grey geometric shape with the text 'Prism Health Lab' below it. Below the logo, the words 'HAND SANITIZER' are written in large, bold, red letters, with 'REFRESHING GEL' in smaller white letters on a red background below that. The bottom section of the label is red and contains three circular icons: 'KILLS 99.99% OF GERMS', 'Helps reduce illness causing germs', and 'PROUDLY MADE IN USA'. Below these icons, it says '1 Gallon e 3.7 L'. On the right side of the label, there is a 'Drug Facts' panel with sections for Active Ingredient[s], Use[s], Warnings, Directions, and Other information. Below the Drug Facts panel, there is contact information for Prism Health Lab, including the website, address, and phone number, along with a barcode and a 12-month shelf life icon.

PRISM HEALTH LAB HAND SANITIZER
ethyl alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81064-792
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81064-792-04	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/01/2020	

Labeler - Prism Holistic Care Ltd. (055831868)

Revised: 1/2021

Prism Holistic Care Ltd.