HAND SANITIZER- alcohol liquid JLA Distillery LLC

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.

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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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.

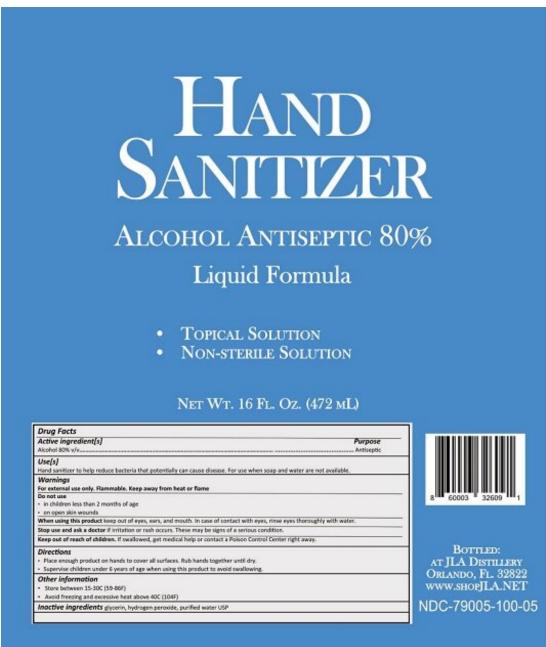
Other information

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



alcohol liquid					
Product Inform	ation				
Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:79005-100
Route of Administ	ration	TOPICAL			
Active Ingredie	nt/Active Moi	ety			
				Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL					80 mL in 472 mL
Inactive Ingred	ients	Ingredient Name			
	Strength				
GLYCERIN (UNII: PI HYDROGEN PERO X					
WATER (UNII: 059Q					
Packaging					
# Item Code		Package Description		Marketing Start Date	Marketing End Date
NDC:79005-100-	472 mL in 1 BOT Product	ГLE, PLASTIC; Туре 0: Not a Co	mbinatio n	07/06/2020	
05					
05					
05	formation				
Marketing In Marketing Categ		ion Number or Monograph C	Citation M	Aarketing Start Date	Marketing End Dat

Labeler - JLA Distillery LLC (116280457)

Establishment							
Name	Address	ID/FEI	Business Operations				
JLA Distillery LLC		116280457	manufacture(79005-100)				

Revised: 12/2020

JLA Distillery LLC