HAND SANITIZER- alcohol gel
Premier Essential Solutions, 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 April, 12, 2019 FDA Final Monograph 84FR14847.

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):

a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, 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. Sterile distilled water or boiled cold water.
c. Carbomer.
d. fragrance.
e. glycerin.
f. hydrogen peroxide.
g. sodium hydroxide.

Active Ingredient(s)

Alcohol 70% 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

carbomer, fragrance, glycerin, hydrogen peroxide, sodium hydroxide, purified water USP

Package Label - Principal Display Panel

473mL NDC: 80699-001-01

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80699-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER 1342 (UNII: 809Y72KV36)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	25 mL in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:80699-001-01	1 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/01/2020	

Labeler - Premier Essential Solutions, LLC (117635716)

Establishment

Name	Address	ID/FEI	Business Operations
Premier Essential Solutions, LLC		117635716	repack(80699-001) , manufacture(80699-001)

Revised: 10/2020 Premier Essential Solutions, LLC