#### 32OZ HAND SANITIZER GEL PEPPERMINT EVERCARE LABS- 32oz/946.35ml gel peppermint - evercare labs gel SunBeam Laboratories 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.

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#### 32oz/946.35ml Gel Peppermint- EverCare Labs

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) (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) Isopropyl Alcohol (1.00% v/v).C) Carbomer (0.30% v/v).D) Triethanolamine (0.15% v/v)

- D) I fieulanoiannie (0.15% V)
- E) Aloe Vera (0.01%v/v)
- F) Peppermint (0.01%v/v)

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 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**

Isopropyl Alcohol, Carbomer, Triethanolamine, Aloe Vera, Peppermint, Sterile distilled water or boiled cold water.

#### Package Label - Principal Display Panel



946.35 mL NDC: 75321-3032-6

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Product Type		HUMAN OTC DRUG	Ite m Co	Item Code (Source)			NDC:75321-3032	
Route of Administr	ation	TOPICAL						
Active Ingredie	nt/Activ	ve Moiety						
Ingredient Name					Basis of Strength		Strength	
ALCOHOL (UNII: 3K	I	ALCOHOL 66		662	.45 mL in 946.35 mL			
Inactivo Ingradi	onte							
Inactive Ingredients Ingredient Name					Strength			
ISOPROPYL ALCOHOL (UNII: ND2M416302)					9.46 mL in 946.35 mL			
CARBOMER 940 (UNII: 4Q93RCW27E)					2.84 mL in 946.35 mL			
WATER (UNII: 059QF0KO0R)					269.99 mL in 946.35 mL			
TROLAMINE (UNII: 903K93S3TK)					1.42 mL in 946.35 mL			
PEPPERMINT (UNII: V95R5KMY2B)					0.09 mL in 946.35 mL			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)					0.09 mL in 946.35 mL			
Packaging								
# Item Code		Package Description			Marketing Sta Date	rt	Marketing End Dat	
1 NDC:75321-3032- 6	946.35 1 Product	mL in 1 BOTTLE; Type 0: Not a Comb	inatio n	03/30/2020				
Marketing In	forma	ition						
Marketing Categ	ory A	Application Number or Monograp	h Citation	Ma	rketing Start D	ate	Marketing End Date	
	inal pa	rt333A		03/30/2020				

# Labeler - SunBeam Laboratories LLC (105139335)

Establishment										
Name	Address	ID/FEI	<b>Business Operations</b>							
SunBeam Laboratories LLC		105139335	manufacture(75321-3032)							

Revised: 11/2020

SunBeam Laboratories LLC