#### 64OZ HAND SANITIZER GEL LEMONGRASS EVERCARE LABS- 64oz/1892.70ml gel lemongrass - 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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#### 64oz/1892.70ml Gel Lemongrass- 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)
E) Aloe Vera (0.01%v/v)

F) Lemongrass (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, Lemongrass, Sterile distilled water or boiled cold water.

#### Package Label - Principal Display Panel



## 1892.70 mL NDC: 75321-7064-5

## 64OZ HAND SANITIZER GEL LEMONGRASS EVERCARE LABS

64oz/1892.70ml gel lemongrass - evercare labs gel

Product Informa	ition						
Product Type		HUMAN OTC DRUG	Item Code	m Code (Source)		NDC:75321-7064	
Route of Administra	ation	TOPICAL					
Active Ingredier	nt/Active Moi	0 <b>t</b> x7					
Active Ingredient/Active Moiety Ingredient Name				sis of Str	angth	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)				Basis of Strength ALCOHOL 13		324.89 mL in 1892.7 mL	
					1		
Inactive Ingredi	nnte						
macuve ingreui		gredient Name				Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302)					18.93 mL in 1892.7 mL		
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)					5.68 mL in 1892.7 mL		
WATER (UNII: 059QF0KO0R)					539.99 mL in 1892.7 mL		
ALOE VERA LEAF (UNII: ZY81Z83H0X)					0.19 mL in 1892.7 mL		
TROLAMINE (UNII: 903K93S3TK)					2.84 mL in 1892.7 mL		
EAST INDIAN LEMO		0.19 mL in 1892.7 mL					
Packaging							
				36 1 .	ing Start		
# Item Code		Package Description		Market D	ate	Marketing End Dat	
		<b>Package Description</b> OTTLE; Type 0: Not a Combina	itio n		ate	Marketing End Dat	
1 NDC:75321-7064-	1892.7 mL in 1 B		tio n	D	ate	Marketing End Dat	
1 NDC:75321-7064-	1892.7 mL in 1 B		itio n	D	ate	Marketing End Dat	
1 NDC:75321-7064- 5	1892.7 mL in 1 B Product		itio n	D	ate	Marketing End Dat	
1 NDC:75321-7064-	1892.7 mL in 1 B Product			D	Date		

# Labeler - SunBeam Laboratories LLC (105139335)

Establishment									
Name	Address	ID/FEI	<b>Business Operations</b>						
SunBeam Laboratories LLC		105139335	manufacture(75321-7064)						

Revised: 11/2020

SunBeam Laboratories LLC