#### BIOSAFE HAND SANITIZER- alcohol liquid BioSafe Distributors, 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.

-----

### **BioSafe Hand Sanitizer**

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:

- 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.

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.

## 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.

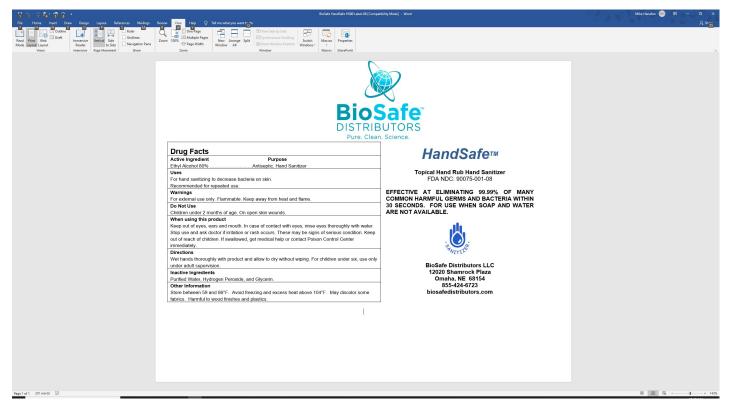
#### Other information

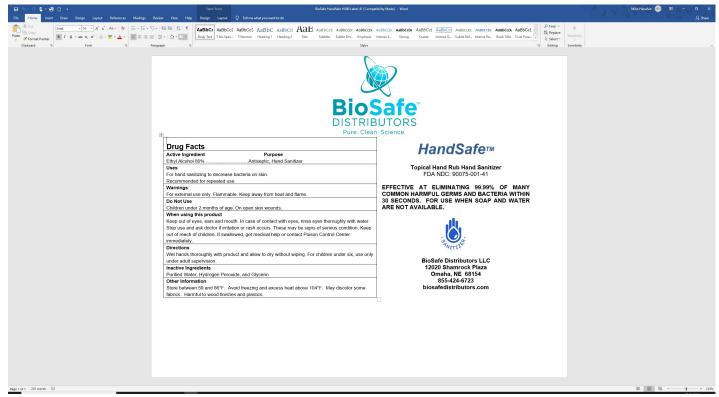
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

#### Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

## **BioSafe Hand Sanitizer**





4 ml in 1 Box NDC: 90075-001-41

BIOSAFE H	AND SAN	ITIZER					
alcohol liquid							
Product Info	rmation						
Product Type		HUMAN OTC DRUG	Item Code (Source)			NDC:90075-001	
Route of Admir	nistration	TOPICAL					
Active Ingred	lient/Active	Moiety					
Ingredient Name			<b>Basis of Strength</b>		Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)				ALCOHOL		80 mL in 100 mL	
Inactive Ingr	odionto						
mactive mgr		ngredient Name			Strength		
GLYCERIN (UNII: PDC6A3C00X)					1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)					0.125 mL in 100 mL		
WATER (UNII: 059QF0K00R)							
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)							
Packaging							
# Item Code	Pa	ackage Description		Marketing S Date	tart	Marketing End Date	
<b>1</b> NDC:90075- 001-08	237 mL in 1 BO Combination Pr	TTLE, SPRAY; Type 0: Not a oduct		08/19/2020			

OTC monograph no final	part333A	08/19/2020					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
Marketing Information							
2 NDC:90075- 001-41	mL in 1 BOX; Type 0: Not a Combination Product 08/19/2020						

# Labeler - BioSafe Distributors, LLC (117558126)

Establishment							
Name	Address	ID/FEI	<b>Business Operations</b>				
Span-World LLC		102758400	manufacture(90075-001)				

Revised: 1/2022

BioSafe Distributors, LLC