

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:

- 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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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

BioSafe
DISTRIBUTORS
Pure. Clean. Science.

HandSafe™
Topical Hand Rub Hand Sanitizer
FDA NDC: 90075-001-08

EFFECTIVE AT ELIMINATING 99.99% OF MANY COMMON HARMFUL GERMS AND BACTERIA WITHIN 30 SECONDS. FOR USE WHEN SOAP AND WATER ARE NOT AVAILABLE.

Sanitizer

BioSafe Distributors LLC
12020 Shamrock Plaza
Omaha, NE 68154
855-424-6723
biosafedistributors.com

Drug Facts				
<table><tr><td>Active Ingredient</td><td>Purpose</td></tr><tr><td>Ethyl Alcohol 80%</td><td>Antiseptic, Hand Sanitizer</td></tr></table>	Active Ingredient	Purpose	Ethyl Alcohol 80%	Antiseptic, Hand Sanitizer
Active Ingredient	Purpose			
Ethyl Alcohol 80%	Antiseptic, Hand Sanitizer			
Uses For hand sanitizing to decrease bacteria on skin. Recommended for repeated use.				
Warnings For external use only. Flammable. Keep away from heat and flame.				
Do Not Use Children under 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 doctor if irritation or rash occurs. These may be signs of serious condition. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center immediately.				
Directions Wet hands thoroughly with product and allow to dry without wiping. For children under six, use only under adult supervision.				
Inactive Ingredients Purified Water, Hydrogen Peroxide, and Glycerin.				
Other Information Store between 59 and 86°F. Avoid freezing and excess heat above 104°F. May discolor some fabrics. Harmful to wood finishes and plastics.				

BioSafe
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Pure. Clean. Science.

HandSafe™
Topical Hand Rub Hand Sanitizer
FDA NDC: 90075-001-41

EFFECTIVE AT ELIMINATING 99.99% OF MANY COMMON HARMFUL GERMS AND BACTERIA WITHIN 30 SECONDS. FOR USE WHEN SOAP AND WATER ARE NOT AVAILABLE.

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

BIOSAFE HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:90075-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:90075-001-08	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/19/2020	

2	NDC:90075-001-41	4 mL in 1 BOX; Type 0: Not a Combination Product	08/19/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part333A		08/19/2020	

Labeler - BioSafe Distributors, LLC (117558126)

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

Revised: 1/2022

BioSafe Distributors, LLC