

HAND SANITIZER- alcohol liquid
Stone Soap Co., Inc.

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.

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

1892mL NDC:62065-110-01

Hand sanitizer is used to decrease infectious agents on the hands. Since alcohol-based hand sanitizer works against a variety of microorganisms but not spores, a combination of washing with soap and water and hand sanitizer is advised. This product contains glycerol to prevent drying of the skin. Alcohol-based hand sanitizer has been commonly used since the 1980s and is on the World Health Organization's List of Essential Medicines, as one of the safest and most effective medicines needed in a health system.

Stone Soap has been a leader and innovator in cleaning and personal care products since 1932.



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Made in U.S.A.



HAND SANITIZER NON-STERILE SOLUTION

Alcohol Antiseptic 80% Topical Solution

WARNING
FLAMMABLE

Keep away from heat, spark,
electrical, fire or flame

Use only in a well-ventilated area; fumes may be harmful.
Read entire label before use.

Net Contents: 1/2 Gallon US (64 fl. oz./1.893 L)

Drug Facts	
Active Ingredients:	Purpose:
Alcohol 80% v/v	Antiseptic
Uses: 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 • on 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.	
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 59-86°F (15-30°C)	
• Avoid freezing and excessive heat above 104°F (40°C).	
Inactive Ingredients: Glycerin, hydrogen peroxide, purified water USP.	

HAND SANITIZER

alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:62065-110

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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62065-110-08	1 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:62065-110-06	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
3	NDC:62065-110-12	1893 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:62065-110-18	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
5	NDC:62065-110-15	56781 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Stone Soap Co., Inc. (005365119)

Establishment

Name	Address	ID/FEI	Business Operations
Stone Soap Co.		005365119	manufacture(62065-110)

Revised: 1/2022

Stone Soap Co., Inc.