

HAND SANITIZER- alcohol liquid
Smitty's Supply 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.

Sea Wash 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.

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

Package Label - Principal Display Panel

Advanced
STRENGTH

Sea Wash®

HAND SANITIZER

FRAGRANCE FREE

*Kills More Than 99% Of Common Germs
& Bacteria In Seconds.*

NET. WT. 32 OZ (946 mL)

Sea Wash®

Advanced Strength
HAND SANITIZER

DRUG FACTS
Active Ingredient - Alcohol 80% v/v. Purpose - 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.
Do not use 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.
STORAGE Store between 15°-30°C (59°-86°F).
Avoid freezing and excessive heat above 40°C (104°F).
INACTIVE INGREDIENTS Glycerin, Hydrogen Peroxide, Purified Water USP

Manufactured & Distributed by
Smitty's Supply, Inc.
Roseland, Louisiana 70456
www.smittysinc.net
(800) 256-7575 • **MADE IN U.S.A.**
Sea Wash® is a registered trademark
of Smitty's Supply, Inc.
All Rights Reserved.

SWA.HAND.1232.044

0 85051 80050 2

946mL NDC: 74120-502-32

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74120-502	
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: 059QF0K00R)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74120-502-32	946 mL in 1 BOTTLE; 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 - Smitty's Supply Inc (081113611)

Establishment

Name	Address	ID/FEI	Business Operations
Smitty's Supply Inc.		081113611	manufacture(74120-502)

Revised: 4/2020

Smitty's Supply Inc