#### SEA-WASH HAND SANITIZER- alcohol gel 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

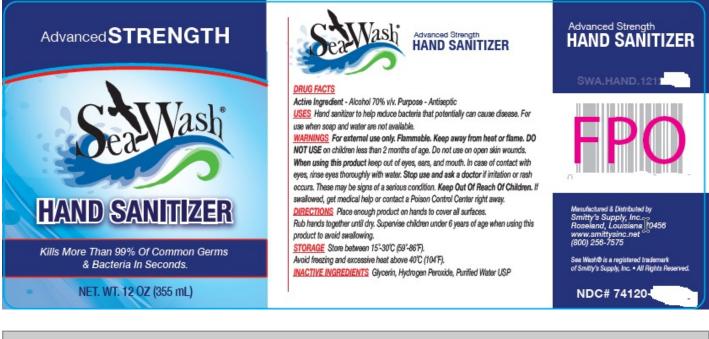
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

#### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

### Package Label - Principal Display Panel

355 mL NDC: 74120-056-12



## SEA-WASH HAND SANITIZER

alcohol gel

Product Information								
HUMAN OTC DRUG	Item Code	(Source)	NDC:74120-056					
TOPICAL								
Active Ingredient/Active Moiety								
lient Name		Basis of Strength	Strength					
	TOPICAL	TOPICAL ety	TOPICAL ety					

Ir	Inactive Ingredients							
Ingredient Name								
GLYCERIN (UNII: PDC6A3C0OX)								
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)								
W	WATER (UNII: 059QF0KO0R)							
PI	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)							
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)								
	Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:74120-056-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2020					
N	Marketing Information							
	Marketing Catego	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
0	TC monograph not fi	al part333A	05/22/2020					

Labeler - Smitty's Supply Inc (081113611)

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Smitty's Supply Inc		081113611	manufacture(74120-056)

Revised: 5/2020

Smitty's Supply Inc