

STEAM2SEA ESSENTIAL HAND SANITIZER GEL- alcohol gel

Stream2Sea, 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.

Steam2Sea Essential Hand Sanitizer Gel

This is a hand sanitizer manufactured according to the Part 333: Topical Antimicrobial Drug Products for Over The Counter Human Use.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (60+%, 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 (1.30% v/v).
- c. Deionized Water
- d. Eucalyptus Globulus Leaf Oil
- e. Camphor
- f. Mixed Tocopherols (Vitamine E)
- g. Hydroxypropyl Guar (1% v/v)
- h. Citric Acid (less than 0.5% v/v)

The firm does not add other active ingredients.

Active Ingredient(s)

Alcohol 62% 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

- Shake well before use.
- 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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

Deionized Water, Glycerin, Eucalyptus Globulus Leaf Oil, Camphor, Mixed Tocopherols (Vitamine E), Hydroxypropyl Guar, Citric Acid

Package Label - Principal Display Panel

2 fl. oz / 60 mL NDC: 69555-062-01

Hand-Sanitizer-Gel-Label2oz.pdf 1 5/2/2020 3:42:31 AM

EcoConscious & Biodegradable

STREAM2SEA® essentials

HAND SANITIZER GEL

Alcohol Antiseptic 62%
Eucalyptus & Camphor
Infused with Vitamin E

2 FL OZ (60 mL)

Drug Facts

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Hand Sanitizer Gel

Formulated with non-toxic ingredients to be safe for the planet without using carbomers, synthetic fragrances or triclosan.

Try our full line of reef safe sunscreen and body care products at stream2sea.com

Manufactured in the USA by: Stream2Sea | Bowling Green, FL 33834

Questions or Comments: 866-960-9513 Share our Journey @ Stream2Sea.com

Fresh Florida
MADE IN USA

Vegan

Please recycle.

4 fl. oz / 118 mL NDC: 69555-062-04

EcoConscious &
Biodegradable

Stream2Sea® Essentials



STREAM2SEA®
essentials

HAND
SANITIZER
GEL

Alcohol Antiseptic 62%
Eucalyptus & Camphor
Infused with Vitamin E

4 fl oz (118 mL)



Hand Sanitizer Gel

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Manufactured in the USA by:
Stream2Sea | Bowling Green, FL 33834



STEAM2SEA ESSENTIAL HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69555-063
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	620 mL in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
WATER (UNII: 059QF0K00R)	

GLYCERIN (UNII: PDC6A3C0OX)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
CAMPHOR, (-)- (UNII: 213N3S8275)	
GUARAPROLOSE (1300 MPAS AT 1%) (UNII: 1530WMS90S)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69555-063-01	1 in 1 BOX	05/12/2020	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69555-063-04	1 in 1 BOX	05/12/2020	
2		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/12/2020	

Labeler - Stream2Sea, LLC (052920828)

Registrant - Stream2Sea, LLC (052920828)

Establishment

Name	Address	ID/FEI	Business Operations
Stream2Sea, LLC		052920828	manufacture(69555-063)

Revised: 5/2020

Stream2Sea, LLC