

STREAM2SEA HAND SANITIZER- alcohol liquid

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.

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)

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)

Package Label - Principal Display Panel

0.3 fl. oz / 10 mL NDC: 69555-062-10

Hand-Sanitizer-10ml.pdf 1 5/8/2020 1:35:42 AM

Drug Facts

Active Ingredient(s) Purpose
Ethanol 62% v/v.....Antiseptic

Use(s) ■ Hand sanitizer to help reduce bacteria that potentially can cause disease 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.

Directions ■ Shake well before use. ■ Place enough product on hands to cover all surfaces. Rub hands together until dry. ■ Supervise children under 6 yrs.

EcoConscious & Biodegradable

STREAM2SEA[®] essentials

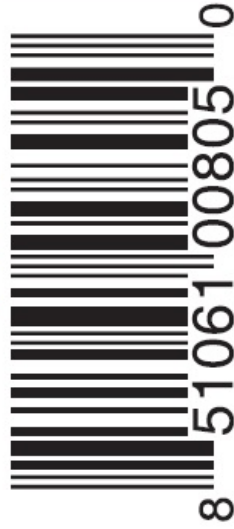
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ing Green, FL 33834 Questions? 866-960-9513 | Stream2Sea.com

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Inactive ingredients
 Deionized Water, Glycerin,
 Eucalyptus Globulus Leaf Oil,
 Camphor, Mixed Tocopherols
 (Vitamin E)



Mfd. in the USA by: Stream2Sea | Bowllir

HAND SANITIZER

Alcohol Antiseptic 62%
 Eucalyptus & Camphor
 Infused with Vitamin E



0.3 FL OZ (10 mL)



128 fl. oz / 1 Gal. / 3785 mL NDC: 69555-062-12



EcoConscious & Biodegradable

Stream2Sea® Essentials



STREAM2SEA®
essentials

REFILL SIZE
HAND
SANITIZER

Alcohol Antiseptic 62%
Eucalyptus & Camphor
Infused with Vitamin E

1 Gal. (3785 mL)



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



Please recycle.

Formulated to be safe for the planet without using carbomers, synthetic fragrances or triclosan,

Drug Facts

Active Ingredient(s)	Purpose
Ethanol 62% v/v.....	Antiseptic

Use(s) ■ 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.

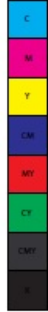
Directions ■ Shake well before use, ■ Place enough product on hands to cover all surfaces. Rub hands together until dry. ■ Supervise children under 6yrs.

Other Info
■ Store between 15-30C (59-86F)
■ Avoid freezing and excessive heat

Inactive ingredients
Deionized Water, Glycerin, Eucalyptus Globulus Leaf Oil, Camphor, Mixed Tocopherols (Vitamin E)



Manufactured in the USA by: Stream2Sea | Bowling Green, FL 33834
Questions or Comments: 866-960-9513 Share our Journey @ Stream2Sea.com



2 fl. oz / 60 mL NDC: 69555-062-02



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



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



Questions or Comments: 866-968-9513 Share our Journey @ Stream2Sea.com



16 fl. oz / 473 mL NDC: 69555-062-16

Stream2Sea® Hand Sanitizer

Formulated to be safe for the planet without using carbomers, synthetic fragrances or triclosan.

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

Drug Facts

Active Ingredient(s)	Purpose
Ethanol 62% v/v	Antiseptic
Use(s) ■ 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	
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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 ■ 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 Info ■ 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 (Vitamin E)	

Feel good using Stream2Sea, knowing that we never use any ingredients that will harm you or the planet. Try our full line of reef safe sunscreen and body care products at stream2sea.com



Please recycle this bottle after use.



Questions or Comments: 866-968-9513 Share our Journey @ Stream2Sea.com



STREAM2SEA®

— Reef-friendly • Biodegradable —

Refill Size Hand Sanitizer

Alcohol Antiseptic 62%
Eucalyptus & Camphor
Infused with Vitamin E

16 FL OZ (473 mL)

32 fl. oz / 946 mL NDC: 69555-062-32

STREAM2SEA®

— Reef-friendly • Biodegradable —

Refill Size Hand Sanitizer

Alcohol Antiseptic 62%
Eucalyptus & Camphor
Infused with Vitamin E

32 FL OZ (946 mL)

Stream2Sea® Hand Sanitizer

Formulated to be safe for the planet without using carbomers, synthetic fragrances or triclosan.

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

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STREAM2SEA HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69555-062
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: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
CAMPHOR, (-)- (UNII: 213N3S8275)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69555-062-02	1 in 1 BOX	04/09/2020	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69555-062-16	1 in 1 BOX	04/09/2020	
2		473 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69555-062-32	1 in 1 BOX	04/09/2020	
3		946 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69555-062-10	1 in 1 BOX	04/13/2020	
4		10 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:69555-062-12	1 in 1 BOX	04/13/2020	
5		3785 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	04/09/2020	

Labeler - Stream2Sea, LLC (052920828)

Registrant - Stream2Sea, LLC (052920828)

Establishment

Name	Address	ID/FEI	Business Operations
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