

NURTUREFLO GEL HAND SANITIZER OCEAN BREEZE- isopropyl alcohol liquid
Chromaflo Technologies Corp

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 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:

- Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- Glycerol (1.45% v/v).
- Hydrogen peroxide (0.125% v/v).
- 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)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

Drug Facts	
Active ingredient(s)	Purpose
Isopropyl alcohol 75% 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	
<i>For external use only. Flammable. Keep away from heat or flame.</i>	
Do not use	
<ul style="list-style-type: none">in children less than 2 months of ageon open skin wounds	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse 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	
<ul style="list-style-type: none">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	
<ul style="list-style-type: none">Store between 15-30C (59-86F)Avoid freezing and excessive heat above 40C (104F)	
Inactive Ingredients Distilled water, Sorbitol, Methylcellulose, Glycerin, Fragrance	
Contact: 1 (800) 776-3329	

Purpose

Antiseptic, Hand Sanitizer

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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

1890 ml NDC: 74172-114-01



NURTUREFLO GEL HAND SANITIZER OCEAN BREEZE

isopropyl alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74172-114

Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)		ISOPROPYL ALCOHOL	75.17 mL in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)		0.63 mL in 100 mL		
SORBITOL (UNII: 506T60A25R)		0.7125 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)		0.2375 mL in 100 mL		
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)		0.62 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74172-114-01	1890 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/10/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	09/10/2020	

Labeler - Chromaflo Technologies Corp (054127519)

Establishment			
Name	Address	ID/FEI	Business Operations
Chromaflo Technologies Corp		054127519	manufacture(74172-114)