NURTUREFLO GEL HAND SANITIZER OCEAN BREEZE- is opropyl 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:

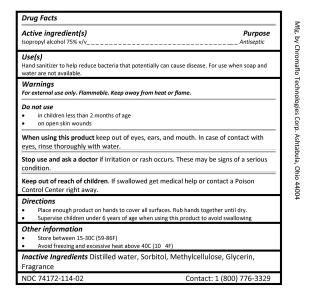
- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

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)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

74172-114-02



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

473 ml NDC: 74172-114-02





Isopropyl Alcohol Antiseptic 75% Topical Solution Non-sterile Solution

NURTUREFLO GEL HAND SANITIZER OCEAN BREEZE

isopropyl alcohol liquid

ъ	1 .	T (. •
Pro	าสมเต	Infor	mation

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

-	•			
Panta	Λŧ	Δ	minic	tration

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			
SORBITOL (UNII: 506T60A25R)	0.7125 mL in 100 mL			
METHYLCELLULO SE, UNSPECIFIED (UNII: Z944H5SN0 H)	0.62 mL in 100 mL			
GLYCERIN (UNII: PDC6A3C0OX)	0.2375 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				
FRAGRANCE CLEAN ORC0600327 (UNII: 329 LCV5BTF)	0.63 mL in 100 mL			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:74172-114- 02	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/12/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	11/12/2020		

Labeler - Chromaflo Technologies Corp (054127519)

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

Revised: 11/2020 Chromaflo Technologies Corp