FRESH WAVE HAND SANITIZER- alcohol solution OMI Industries

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. 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.

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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



Package Label - Principal Display Panel

	Drug Facts
	Active ingredient[s] Purpose Alcohol 80% v/vAntiseptic
resh vave	Use[s] Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
wuve	Warnings For external use only. Flammable. Keep away from heat or flame
Icohol Antiseptic 80%	Do not use • in children less than 2 months of age • on open skin wounds
Topical Solution	When using this product keep out of eyes, ears, 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.
AND SANITIZER	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
ON-STERILE SOLUTION	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)
fl. oz. (59 mL) DC: 75399-001-00	Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Product Information				
Product T ype	HUMAN OTC DRUG	Item Code (Sour	ce) I	NDC:75399-001
Route of Administration	TOPICAL			
Active Ingredient/Active	Moiety			
In	igredient Name	Bas	is of Strength	Strength
ALCOHOL (UNII: 3K9958V90M)	(ALCOHOL - UNII:3K9958V90M)	ALCO	HOL	80 mL in 100 mL
Inactive Ingredients				
Inactive Ingredients	Ingredient Name		S	trength
			S 1.45 mL in 100 m	0
Inactive Ingredients GLYCERIN (UNII: PDC6A3C0OX HYDROGEN PEROXIDE (UNII: B)			nL

# Item Code		Package Description		Mar	Date	магкенид ели Date
1 NDC:75399-001- 00	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination 04 Product			04/15/2	020	
Marketing In	formation					
Marketing Categ		ion Number or Monograph Cit	ation I	Marketi	ng Start Date	Marketing End Date
OTC monograph not		0 1		4/15/2020	-	
F RESH WAV Ilcohol solution	E HAND SA	NITIZER				
Product Inform	ation					
Product T ype		HUMAN OTC DRUG	tem Code	e (Sourc	2 e)	NDC:75399-003
Route of Administr	ration	TOPICAL				
Active Ingredie	nt/Active Moi	ety				
	•	lient Name		Basi	s of Strength	Strength
ALCOHOL (UNII: 3K	(ALC) (ALC) (9958V90M)	:OHOL - UNII:3K9958V90M)		ALCOH	IOL	80 mL in 100 mL
Inactive Ingredi	ients					
Inactive Ingredi		redient Name			S	strength
	Ing	redient Name			S 1.45 mL in 100 r	0
GLYCERIN (UNII: PD HYDRO GEN PERO X	Ing C6A3C0OX) IDE (UNII: BBX06				1.45 mL in 100 n 0.125 mL in 100	nL mL
GLYCERIN (UNII: PD HYDRO GEN PERO X	Ing C6A3C0OX) IDE (UNII: BBX06				1.45 mL in 100 i	nL mL
GLYCERIN (UNII: PD HYDROGEN PEROX WATER (UNII: 059Q)	Ing C6A3C0OX) IDE (UNII: BBX06				1.45 mL in 100 n 0.125 mL in 100	nL mL
GLYCERIN (UNII: PD HYDROGEN PEROX WATER (UNII: 059Q) Packaging	Ing C6A3C0OX) IDE (UNII: BBX06				1.45 mL in 100 n 0.125 mL in 100	nL mL
Inactive Ingredi	Ing 006 A3C0OX) 11DE (UNII: BBX06 F0KO0R)	0 AN9 V)	nation		1.45 mL in 100 n 0.125 mL in 100 18.425 mL in 10 *keting Start Date	nL nL 0 mL Marketing End
GLYCERIN (UNII: PD HYDROGEN PEROX WATER (UNII: 059Q) Packaging # Item Code 1 NDC:75399-003- 00	Ing C6A3C0OX) CIDE (UNII: BBX06 F0KO0R) 236 mL in 1 BOT Product	0AN9V) Package Description	nation	Mai	1.45 mL in 100 n 0.125 mL in 100 18.425 mL in 10 *keting Start Date	nL nL 0 mL Marketing End
GLYCERIN (UNII: PD HYDROGEN PEROX WATER (UNII: 059Q) Packaging # Item Code 1 NDC:75399-003-	Ing C6A3COOX) CIDE (UNII: BBX06 F0KO0R) 236 mL in 1 BOT Product formation	0AN9V) Package Description		Mat 0 4/15/2	1.45 mL in 100 n 0.125 mL in 100 18.425 mL in 10 *keting Start Date	nL nL 0 mL Marketing End

Labeler - OMI Industries (556609311)

Registrant - OMI Industries (556609311)

Establishment			
Name	Address	ID/FEI	Business Operations
OMI Industries		039890657	manufacture(75399-001, 75399-003)

Revised: 4/2020

OMI Industries