

FRESH WAVE IAQ HAND RUB- 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 rub manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Rub Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand rub 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 Rub

Use

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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

- 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

 freshwaveAQ Natural Odor Eliminator																							
ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION																							
ANTISEPTIC HAND RUB NON-STERILE SOLUTION																							
 8 16920 00646 2																							
Manufactured by: OMI Industries 1300 Barbour Way, Rising Sun, IN 47040 USA FreshWaveAQ.com • 800-998-6367 18155	2 qt./64 fl. oz. (1.89 L) NDC: 75399-016-00																						
<table border="1"><tr><td colspan="2">Drug Facts</td></tr><tr><td>Active ingredient[s] Alcohol 80% v/v.....</td><td>Purpose Antiseptic</td></tr><tr><td colspan="2">Use[s] Health sanitizer to help reduce bacteria that potentially can cause disease.</td></tr><tr><td colspan="2">Warnings For external use only. Flammable. Keep away from heat or flame</td></tr><tr><td colspan="2">Do not use • in children less than 2 months of age • on open skin wounds</td></tr><tr><td colspan="2">When using this product keep out of eyes, ears, mouth. In case of contact with eyes, rinse eyes thoroughly with water.</td></tr><tr><td colspan="2">Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</td></tr><tr><td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td></tr><tr><td colspan="2">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.</td></tr><tr><td colspan="2">Other information • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)</td></tr><tr><td colspan="2">Inactive ingredients glycerin, hydrogen peroxide, purified water USP</td></tr></table>		Drug Facts		Active ingredient[s] Alcohol 80% v/v.....	Purpose Antiseptic	Use[s] Health sanitizer to help reduce bacteria that potentially can cause disease.		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, 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.		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	
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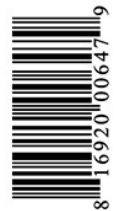
ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION

ANTISEPTIC HAND RUB
NON-STERILE SOLUTION

1 Gallon (3.79 L)
NDC: 75399-017-00

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Use[s]	
Health sanitizer to help reduce bacteria that potentially can cause disease.	
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Manufactured by: OMI Industries
1300 Barbour Way, Rising Sun, IN 47040 USA
FreshWaveIAQ.com • 800-998-6367
18156



FRESH WAVE IAQ HAND RUB

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75399-016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 L in 100 L

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 L

WATER (UNII: 059QF0KO0R)	18.425 L in 100 L
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75399-016-00	1.89 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/04/2020	

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/04/2020	

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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75399-017-00	3.79 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/04/2020	

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/04/2020	

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Labeler - OMI Industries (556609311)

Establishment

Name	Address	ID/FEI	Business Operations
OMI Industries		039890657	manufacture(75399-016, 75399-017)

Revised: 5/2020

OMI Industries