

FRESH WAVE IAQ ANTISEPTIC 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.


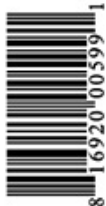
Other information

- 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

 <p>freshwaveAQ Natural Odor Eliminator</p> <p>ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION</p> <p>ANTISEPTIC HAND RUB NON-STERILE SOLUTION</p> <p>2 fl. oz. L (59mL) NDC: 75399-012-00</p>	<p>Drug Facts</p> <table border="1"><thead><tr><th>Active ingredient[s]</th><th>Purpose</th></tr></thead><tbody><tr><td>Alcohol 80% v/v.....</td><td>Antiseptic</td></tr></tbody></table> <p>Use[s] Health sanitizer to help reduce bacteria that potentially can cause disease.</p> <p>Warnings For external use only. Flammable. Keep away from heat or flame</p> <p>Do not use</p> <ul style="list-style-type: none">• in children less than 2 months of age• on open skin wounds <p>When using this product keep out of eyes, ears, mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <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. <p>Other information</p> <ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F) <p>Inactive ingredients glycerin, hydrogen peroxide, purified water USP</p>	Active ingredient[s]	Purpose	Alcohol 80% v/v.....	Antiseptic	 <p>8 16920 00599 1</p>
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Alcohol 80% v/v.....	Antiseptic					
<p>Manufactured by: OMI Industries 1300 Barbour Way, Rising Sun, IN 47040 USA FreshWaveAQ.com • 800-998-6367</p>						

Package Label - Principal Display Panel



ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION

ANTISEPTIC HAND RUB
NON-STERILE SOLUTION



Manufactured by: OMI Industries
1300 Barbour Way, Rising Sun, IN 47040 USA
FreshWaveIAQ.com • 800-998-6367

8 fl. oz. (236mL)
NDC: 75399-014-00

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	
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FRESH WAVE IAQ ANTISEPTIC HAND RUB

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75399-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	18.425 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75399-012-00	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part333A	04/15/2020	
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OTC monograph not final	part333A	04/15/2020	

Labeler - OMI Industries (556609311)

Registrant - OMI Industries (556609311)

Establishment			
Name	Address	ID/FEI	Business Operations
OMI Industries		039890657	manufacture(75399-012, 75399-014)