

AQUA EZ HAND SANITIZER- isopropyl alcohol gel

Aqua EZ Packaging

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

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

02.jpg

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	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none">• 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.	
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 Water, Carbomer, Triethanolamine	

Aqua EZ
Packaging Inc.

**HAND
SANITIZER**
75% v/v
ISOPROPYL ALCOHOL
SOLUTION
2 FL OZ (59.15 mL)

- Rub hands together briskly until dry.
- See precautions on back label.

0 26497 00131 3
74114-123-02

Questions or Comments
www.aquaezpack.com
Atlanta, GA. 30336

04.jpg



HAND SANITIZER

**75% v/v
ISOPROPYL ALCOHOL
SOLUTION**

16.9 FL OZ (500 mL)

- Rub hands together briskly until dry.
- See precautions on back label.



Questions or Comments
www.aquaezpack.com
Atlanta, GA. 30336



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	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none"> • 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.	
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	
Water, Carbomer, Triethanolamine	

Model: HS16



0 26497 00122 1

74114-123-04

05.jpg



Questions or Comments
www.aquaezpack.com
Atlanta, GA. 30336

Model: HS32



74114 123 05



HAND SANITIZER

**75% v/v
ISOPROPYL ALCOHOL
SOLUTION**

32 FL OZ (946mL)

- Place enough product in your palm to thoroughly cover your hands.
- Rub hands together briskly until dry.
- See precautions on side panel.

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	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none"> • 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.	
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	
Water, Carbomer, Triethanolamine	

06.jpg



Aqua EZ
Packaging inc.

HAND SANITIZER

**75% v/v
ISOPROPYL ALCOHOL
SOLUTION**

126.8 FL OZ (3.75 Liter)

Questions or Comments
www.aquaezpack.com
Atlanta, GA. 30336

Model: HS126



74114-123-06

- Place enough product in your palm to thoroughly cover your hands.
- Rub hands together briskly until dry.
- See precautions on side panel.

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

For external use only. Flammable. Keep away from heat or flame

Do not use

- 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.

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

Water, Carbomer, Triethanolamine

01.jpg

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 For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none"> • 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.	
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 Water, Carbomer, Triethanolamine	

Model: HS4

74114-123-01

HAND SANITIZER

**75% v/v
ISOPROPYL ALCOHOL
SOLUTION**

4 FL OZ (118 mL)

- Rub hands together briskly until dry.
- See precautions on back label.

Questions or Comments
www.aquaezpack.com
Atlanta, GA. 30336

03.jpg



- Place enough product in your palm to thoroughly cover your hands.
- Rub hands together briskly until dry.
- See precautions on back label.



Questions or Comments
www.aquaezpack.com
 Atlanta, GA. 30336



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

For external use only. Flammable. Keep away from heat or flame

Do not use

- 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.

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 Water, Carbomer, Triethanolamine

Model: HS8



74114-123-03

AQUA EZ HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74114-123
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 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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74114-123-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
2	NDC:74114-123-02	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020	
3	NDC:74114-123-03	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020	
4	NDC:74114-123-04	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020	
5	NDC:74114-123-05	3750 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020	
6	NDC:74114-123-06	59.15 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2020	

Labeler - Aqua EZ Packaging (965023448)

Establishment

Name	Address	ID/FEI	Business Operations
Aqua EZ Packaging		965023448	manufacture(74114-123)

Revised: 9/2020

Aqua EZ Packaging