EQO GEL- alcohol gel
INTERNATIONAL HARBOR LLC

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.

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eQo gel Antibacterial (1 gal, 1000 ml, 500 ml, 250 ml)

Active Ingredient(s)

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.

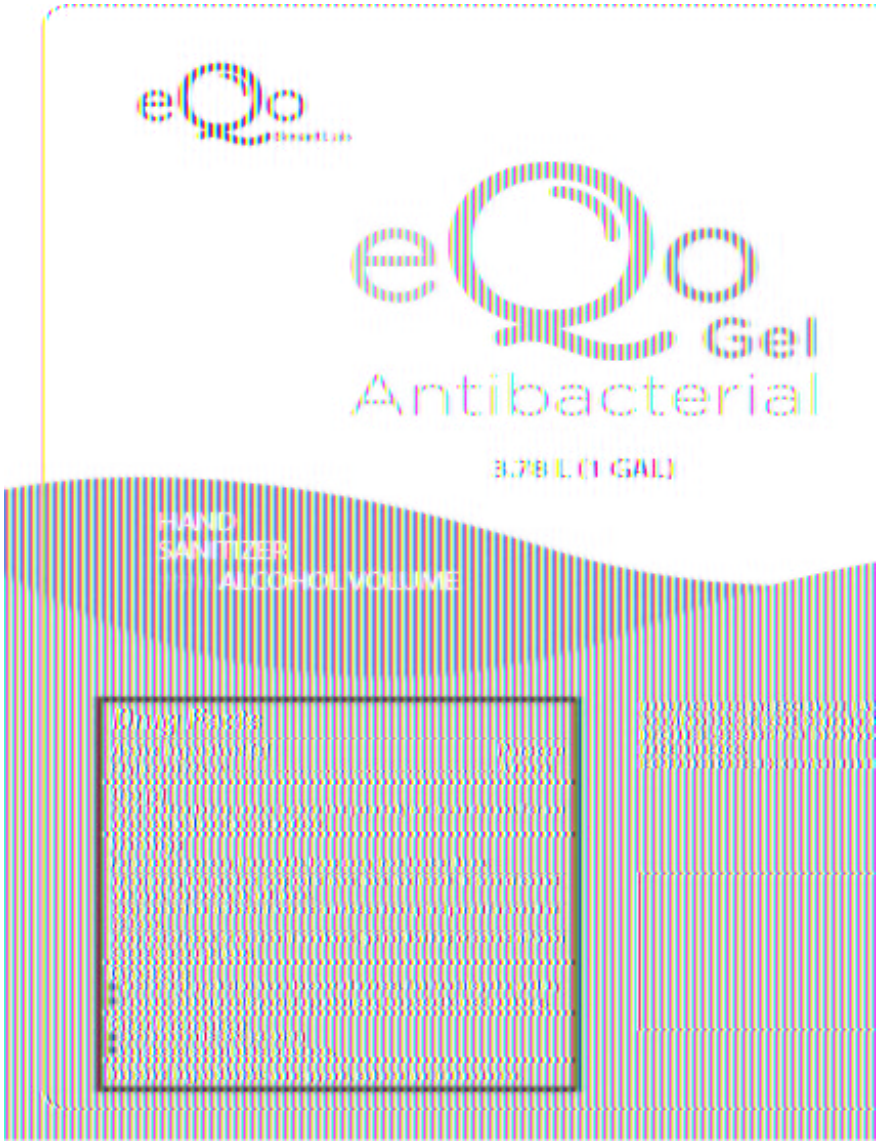
Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

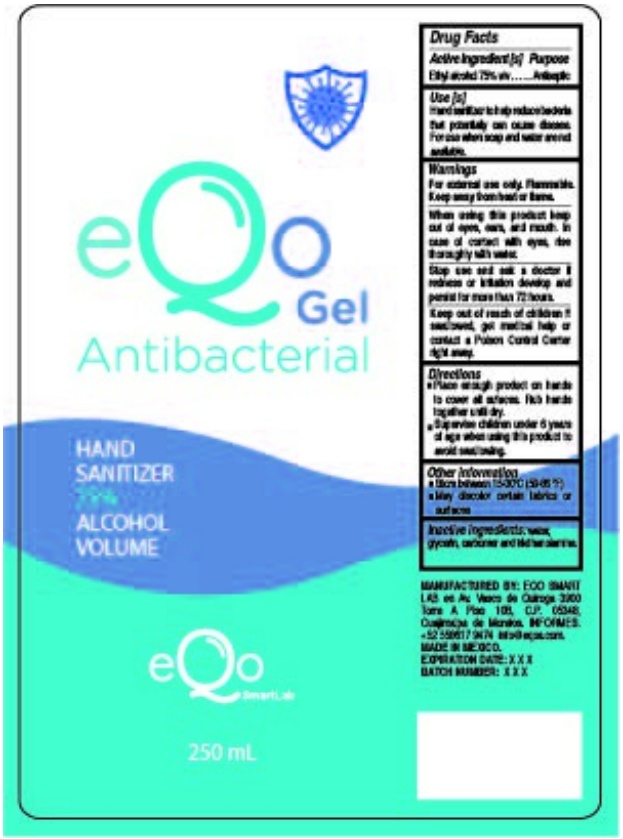
Inactive ingredients

water, glycerin, carbomer, triethanolamine.

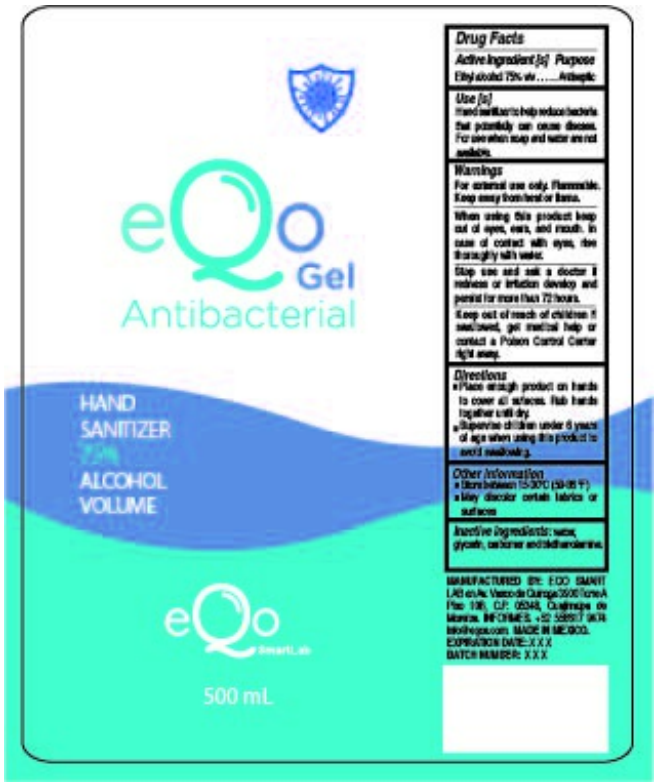
PDP 3785 ml NDC:79838-002-01

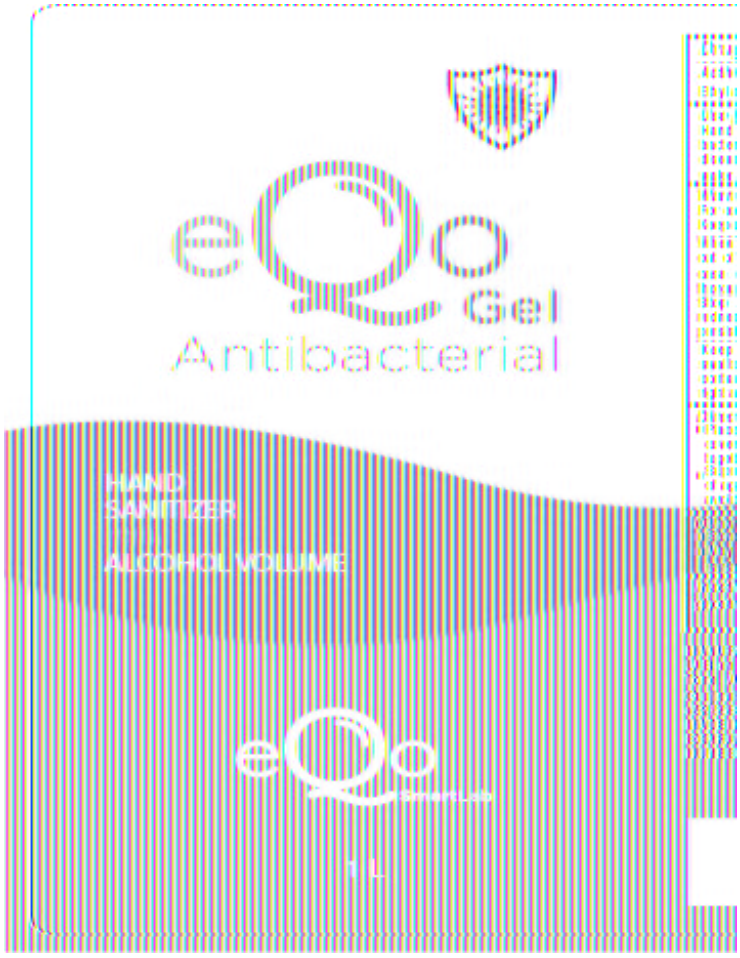


PDP 250 ml NDC:79838-002-02



PDP 500 ml NDC:79838-002-03





PDP 1000 ml NDC:79838-002-04

EQO GEL

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79838-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	1.005 mL in 100 mL
CARBOMER 1342 (UNII: 809Y72KV36)	0.58 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
TRIETHANOLAMINE HYDRIODIDE (UNII: DT98IT03JK)	0.06 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79838-002-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79838-002-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:79838-002-04	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:79838-002-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - INTERNATIONAL HARBOR LLC (117485044)

Registrant - INTERNATIONAL HARBOR LLC (117485044)

Establishment

Name	Address	ID/FEI	Business Operations
INTERNATIONAL HARBOR LLC		117485044	label(79838-002)

Establishment

Name	Address	ID/FEI	Business Operations
Octapod, S.A. de C.V.		951578993	manufacture(79838-002)

Revised: 9/2020 INTERNATIONAL HARBOR LLC