HAND SANITIZER- alcohol gel Octapod, S.A de C.V.

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.

Active Ingredient(s)

Alcohol 70% 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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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.

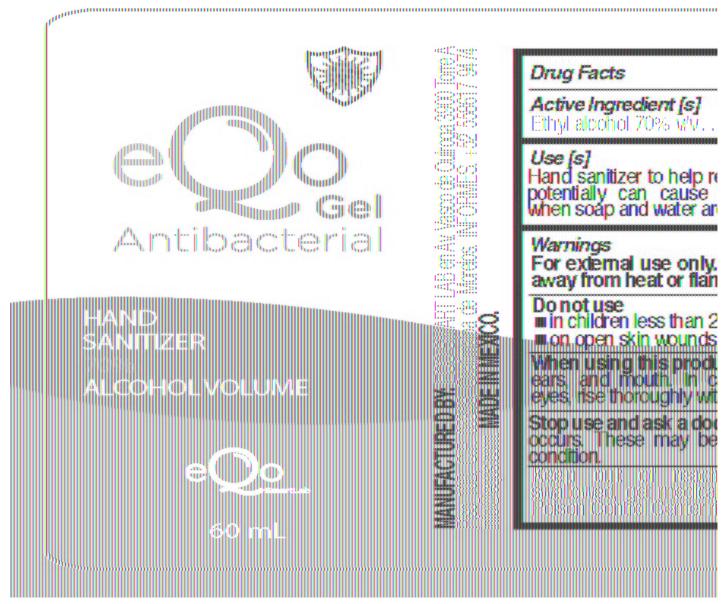
Other information

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

Inactive ingredients

water, glycerin, carbomer, triethanolamine.

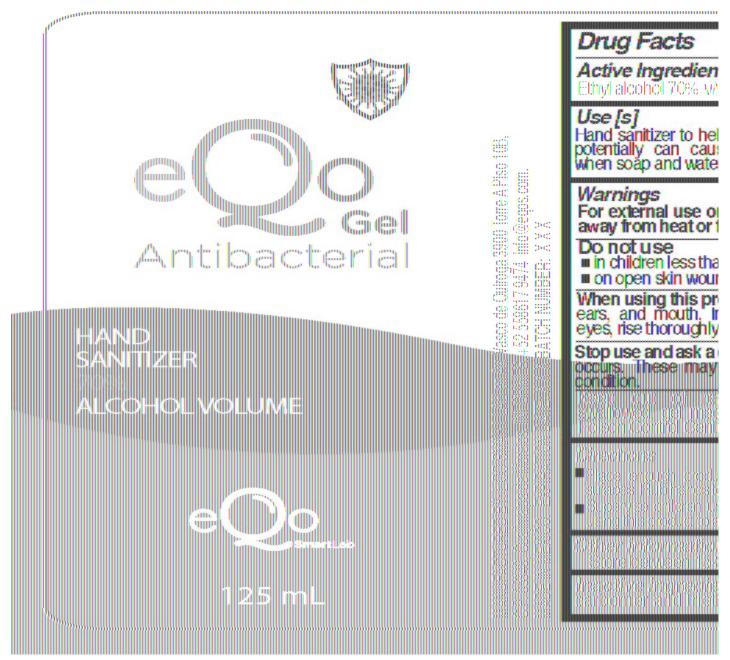
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PDP 125 mL NDC:78800-002-02



PDP 250 mL NDC:78800-002-03



Antibacterial

HAND SANITIZER

ALCOHOL VOLUME



250 mL

Drug

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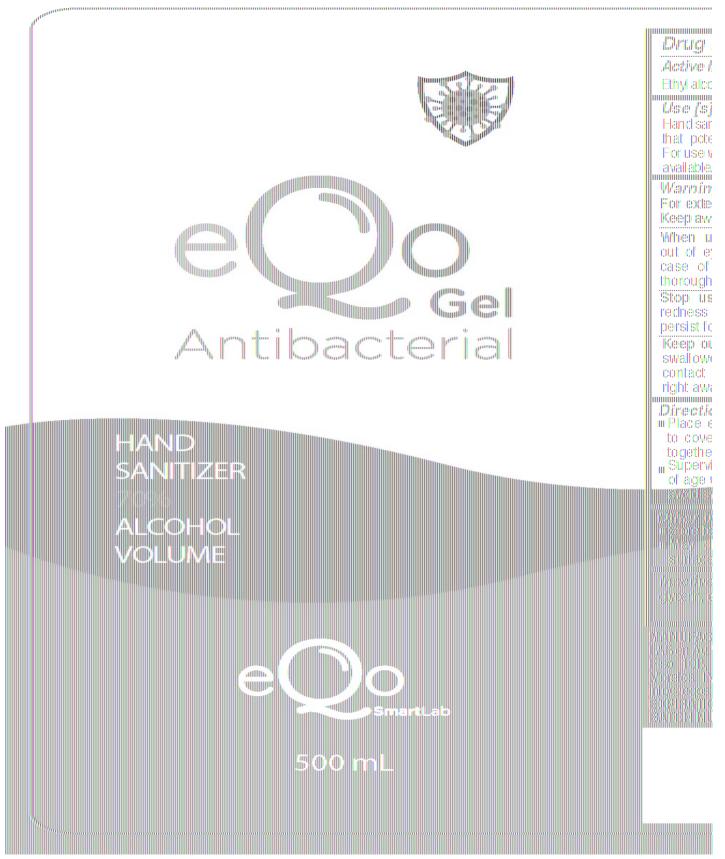
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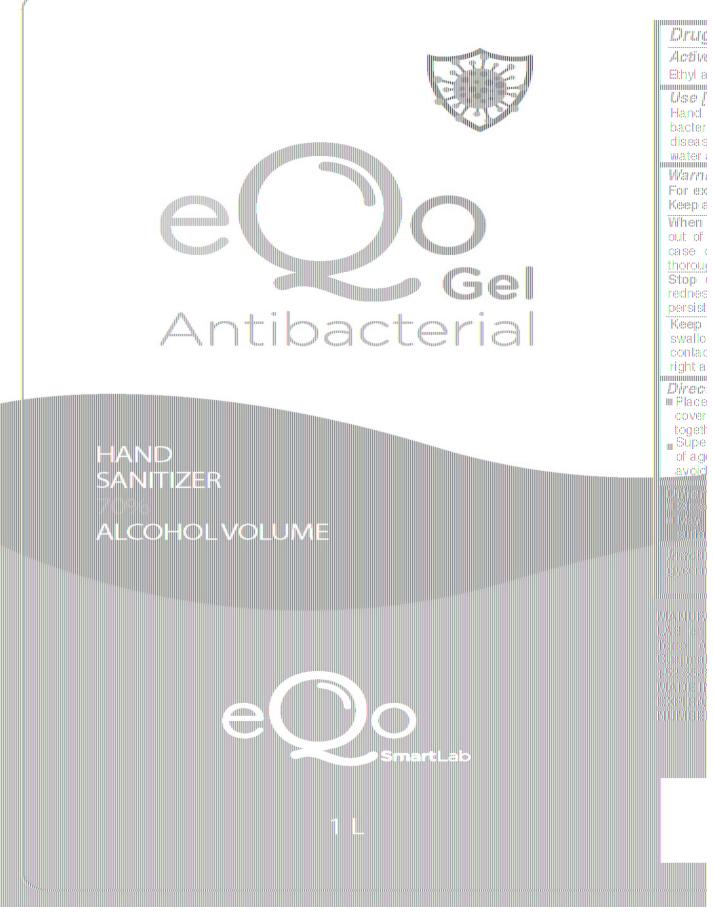
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PDP 1000mL NDC:78800-002-05







3.78 L (1 GAL)

HAND SANITIZER 70% ALCOHOL VOLUME

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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78800-002	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)	1.005 mL in 100 mL		
CARBOMER 1342 (UNII: 809 Y72KV36)	0.58 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			
TRIETHANO LAMINE HYDRIO DIDE (UNII: DT98IT03JK)	0.06 mL in 100 mL		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:78800-002-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
2	NDC:78800-002-02	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
3	NDC:78800-002-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
4	NDC:78800-002-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
5	NDC:78800-002-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
6	NDC:78800-002- 06	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 - Octapod, S.A de C.V. (951578993)

Registrant - Octapod, S.A de C.V. (951578993)

Establishment			
Name	Address	ID/FEI	Business Operations
Octapod, S.A de C.V.		951578993	manufacture(78800-002), pack(78800-002), label(78800-002)

Revised: 9/2020 Octapod, S.A de C.V.