

AMPHORA AROMATICS HAND SANITIZER- hand sanitizer gel
QINGDAO AMPHORA AROMATICS CO.,LTD

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.

75235-001

Amphora Aromatics Hand Sanitizer

Active Ingredient(s)

Ethyl Alcohol 75% v/v

Purpose

Antimicrobial

Use

- Hand Sanitizer to help reduce bacteria on the skin that could cause disease
- Recommended for repeated use

Warnings

Flammable;Keep away from fire or flame.

For external use only.

When using this product, do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Do not use

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Directions

- Put enough product in your palm to thoroughly cover your hands
- Rub hands together briskly until dry

Children under 6 years of age should be supervised when using this product

Other information

Store below 110F (43C)

May discolor certain fabrics or surfaces

Inactive ingredients

water(Aqua),carbomer,glycerin,lemon oil,triethanolamine.

Package Label - Principal Display Panel



AMPHORA AROMATICS HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75235-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients				
Ingredient Name			Strength	
TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
LEMON OIL (UNII: I9GRO824LL)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75235-001-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	04/14/2020	

Labeler - QINGDAO AMPHORA AROMATICS CO.,LTD (530220834)

Establishment			
Name	Address	ID/FEI	Business Operations
QINGDAO AMPHORA AROMATICS CO.,LTD		530220834	manufacture(75235-001)

Revised: 9/2020

QINGDAO AMPHORA AROMATICS CO.,LTD