# 75% ALCOHOL HAND SANITIZER- 75% alcohol hand sanitizer gel PHOENYX DISTRIBUTING, 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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#### 75% ALCOHOL HAND SANITIZER

## Active Ingredient(s)

Alcohol 75% v/v.

## Purpose

Antiseptic

#### Use

Helps reduce bacea at pontentially can caus dsease

Helps prevent Cross contamination on contact

Recommended for repeated use

## Warnings

For external use only

Flammable, Keep away from fire or flame

Do not use near eyesIn case of eye contact flush with water for 15 minutes

If imitation persists stop use of product and get medical attention

Keep out of reach of childrenIn case of accidental ingestion seek medical attention or contact a poison contro center immediately

#### Do not use

• Do not use in or near the eyes. In case of contact with eyes flush thoroughly with water for 15 minutes

When using this product

Do not use in or near the eyes. In case of contact with eyes flush thoroughly with water

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Keep out of reach of children. case of accidental ingestion seek medical attention or contact a poison contro center immediately

#### Directions

Wet hands thoroughly with product and rub completely Covering hands Allow to dry without wiping children under the age of 6 should use with adult supervision Not recommended for infants

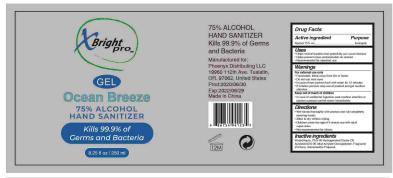
### Other information

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## **Inactive ingredients**

Water(Aqua), PEG-40 Hydrogenated Castor Oil, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance (Parfum) Aminomethyl Propanol

## Package Label - Principal Display Panel





















## 75% ALCOHOL HAND SANITIZER

75% alcohol hand sanitizer gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79316-008
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		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			
WATER (UNII: 059QF0KO0R)			
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)			
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)			
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			

	Packaging				
	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
l	1 NDC:79316-008-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
	2 NDC:79316-008-01	250 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 - PHOENYX DISTRIBUTING, LLC (128029831)

Establishment				
Name	Address	ID/FEI	Business Operations	
PHOENYX DISTRIBUTING, LLC		128029831	label(79316-008)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Fortress Expert Co., Ltd		543358697	manufacture(79316-008)	

Revised: 6/2020 PHOENYX DISTRIBUTING, LLC