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.

Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

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

/

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

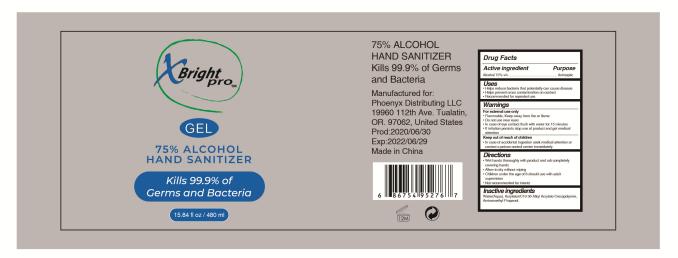
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Inactive ingredients

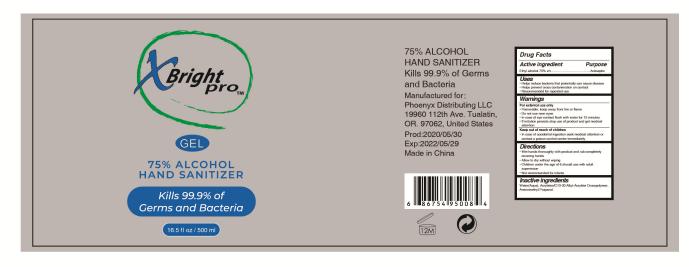
water(Aqua) Acryatesc10-30 Alkyl Acrylate Crosspoymer Aminomethyl Propanol

Package Label - Principal Display Panel

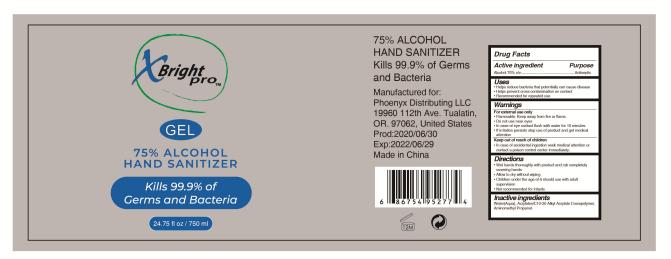
232x83mm



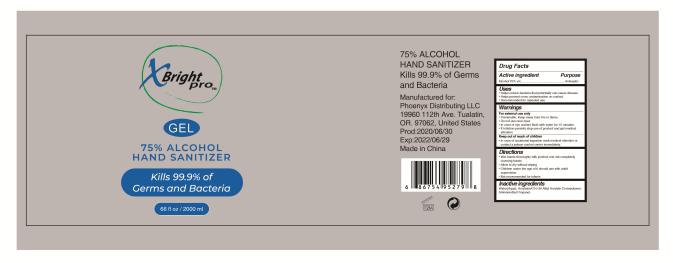
232x83mm



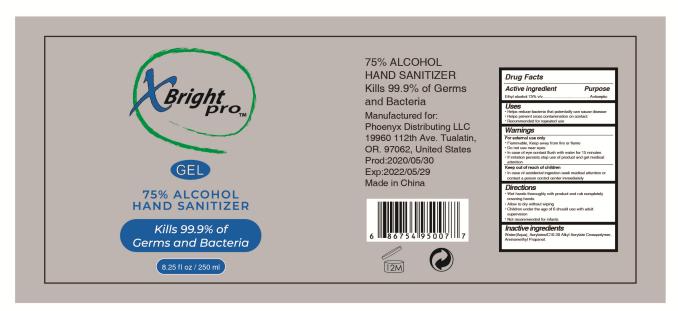
256x90mm



360x110mm



180x75mm



32x59mm

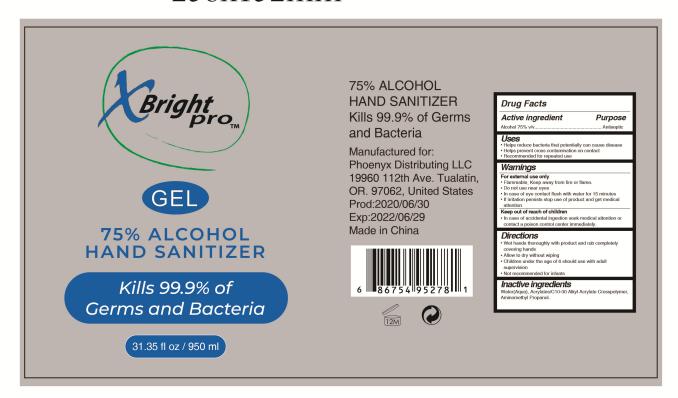




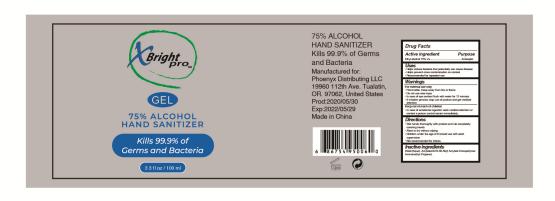
183x85mm



238x132mm



138x47mm



32x59mm





75% ALCOHOL HAND SANITIZER

75% alcohol hand sanitizer gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79316-007	
Route of Administration	TOPICAL			

ı	Active Ingredient/Active Moiety			
ı	Ingredient Name	Basis of Strength	Strength	
ı	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)		

Pá	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:79316-007- 08	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
2	NDC:79316-007- 06	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
3	NDC:79316-007- 07	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
4	NDC:79316-007- 05	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
5	NDC:79316-007- 04	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
6	NDC:79316-007- 02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
7	NDC:79316-007- 09	950 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
8	NDC:79316-007-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
9	NDC:79316-007- 03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
10	NDC:79316-007-10	2000 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(79316-007)

Establishment				
Name	Address	ID/FEI	Business Operations	
Fortress Expert Co., Ltd		543358697	manufacture(79316-007)	

Revised: 6/2020 PHOENYX DISTRIBUTING, LLC