HAND SANITIZER- alcohol gel CROWN (YANGZHOU) HEALTH & BEAUTY 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.

Active Ingredient(s)

(Ethyl) 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.

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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

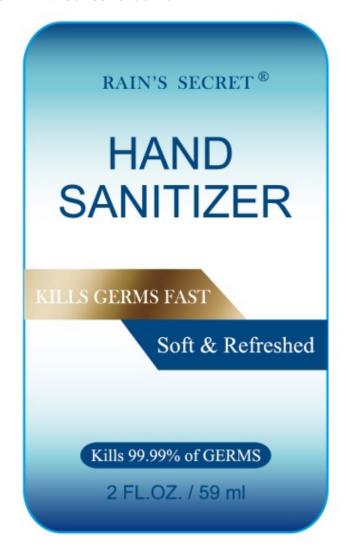
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

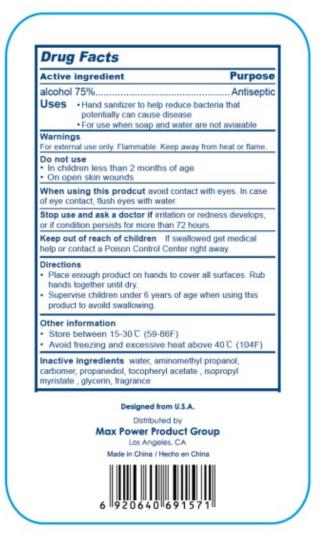
Inactive ingredients

Water, aminomethyl propanol©carbomer©propanediol, tocopheryl acetate, isopropyl myristate, glycerin, fragrance

Package Label - Principal Display Panel

59mL NDC: 75328-001-01





473mL NDC: 75328-001-02





Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75328-001	
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	
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)		
GLYCERIN (UNII: PDC6A3C0OX)		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)		
WATER (UNII: 059QF0KO0R)		
CARBOMER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)		
PROPANEDIOL (UNII: 5965N8W85T)		
AMINO METHYLPRO PANOL (UNII: LU49 E6626Q)		

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:75328-001- 01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020		
2	NDC:75328-001- 02	473 mL in 1 BOTTLE, PUMP; 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 - CROWN (YANGZHOU) HEALTH & BEAUTY CO., LTD (542978427)

Establishment					
Name	Address	ID/FEI	Business Operations		
CROWN (YANGZHOU) HEALTH & BEAUTY CO., LTD		542978427	manufacture(75328-001)		

Revised: 7/2020 CROWN (YANGZHOU) HEALTH & BEAUTY CO., LTD