

**HAND SANITIZER- ethyl 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.*

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**Hand Sanitizer**

Hand Sanitizer

**Active Ingredient(s)**

Alcohol 69.9% 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  
 Propylene Glycol  
 Glycerin  
 Isopropyl Myristate  
 Tocopheryl Acetate  
 Carbomer  
 Aminomethyl Propanol  
 Fragrance

**Package Label - Principal Display Panel**



HAND SANITIZER			
ethyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75328-201
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	69.9 mL in 100 mL	
Inactive Ingredients			
Ingredient Name	Strength		
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
COSTUS ROOT OIL (UNII: 2WF6750061)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75328-201-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75328-201-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75328-201-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75328-201-04	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75328-201-05	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75328-201-06	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75328-201-07	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:75328-201-08	1890 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:75328-201-09	3780 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** - CROWN (YANGZHOU) HEALTH & BEAUTY CO., LTD. (542978427)

### Establishment

Name	Address	ID/FEI	Business Operations
CROWN (YANGZHOU) HEALTH & BEAUTY CO., LTD.		542978427	manufacture(75328-201)

Revised: 7/2020

CROWN (YANGZHOU) HEALTH & BEAUTY CO., LTD.