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.

Hand Sanitizer

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Active Ingredient(s)

Alcohol 65% 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.

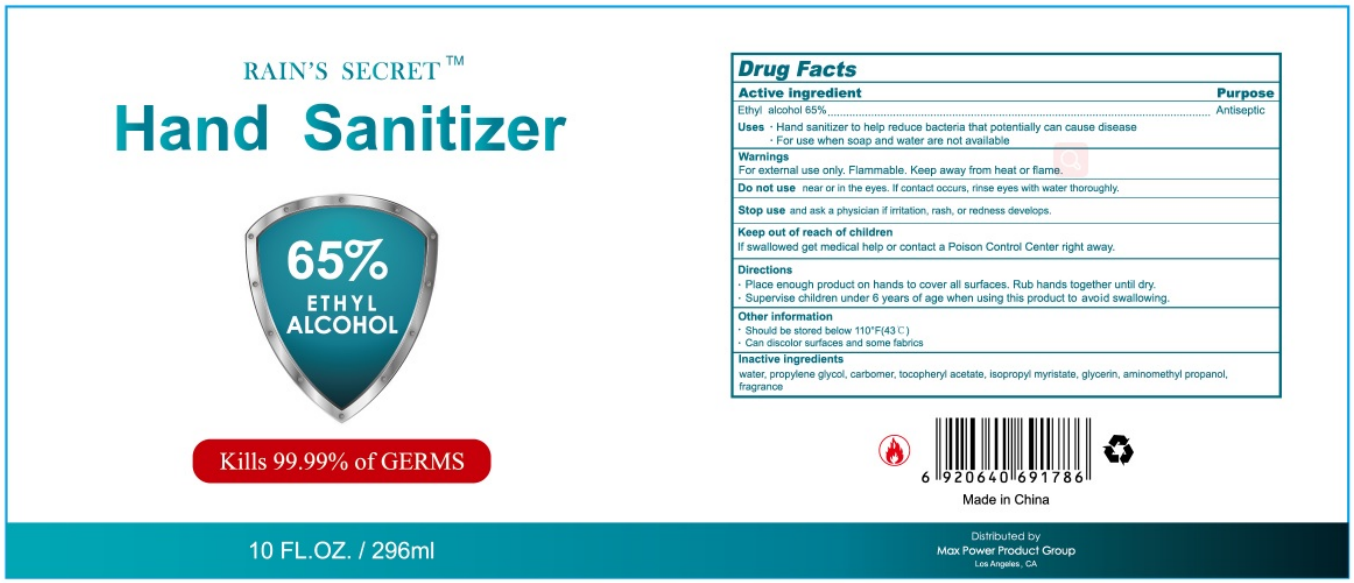
Other information

- 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:75328-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
COSTUS ROOT OIL (UNII: 2WF6750061)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75328-101-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75328-101-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75328-101-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75328-101-04	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75328-101-05	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75328-101-06	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75328-101-07	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:75328-101-08	1890 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:75328-101-09	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(75328-101)

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