

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

ETHYL alcohol 65% v/v. Purpose: Antiseptic

PURPOSE

Antiseptic, Hand Sanitizer

USES

- 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

near or in the eyes. If contact occurs, rinse eyes with water thoroughly.

STOP USE

Stop use and ask a physician if irritation, rash, or redness develops.

KEEP OUT OF REACH OF CHILDREN

If swallowed get medical help or contact a Poison Control Center right away.

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

- Should be stored below 110°F(43°C)
- Can discolor surfaces and some fabrics

INACTIVE INGREDIENTS

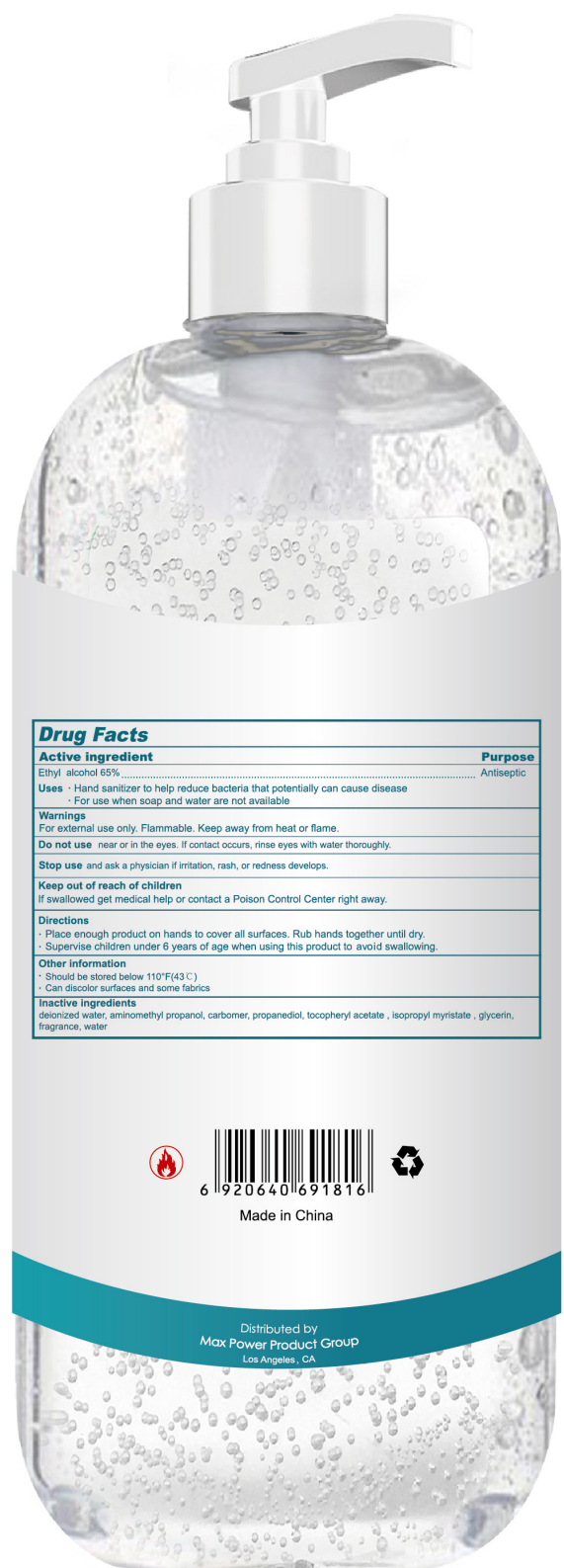
deionized water, aminomethyl propanol, carbomer, propanediol, tocopheryl acetate, isopropyl myristate, glycerin, fragrance, water

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL

500mL NDC: 75328-002-01



946mL NDC: 75328-002-02



Drug Facts

Active ingredient	Purpose
Ethyl alcohol 65%	Antiseptic
Uses - 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 near or in the eyes. If contact occurs, rinse eyes with water thoroughly.	
Stop use and ask a physician if irritation, rash, or redness develops.	
Keep out of reach of children If swallowed get medical help or contact a Poison Control Center right away.	
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 - Should be stored below 110°F(43 C) - Can discolor surfaces and some fabrics	
Inactive ingredients deionized water, aminomethyl propanol, carbomer, propanediol, tocopheryl acetate , isopropyl myristate , glycerin, fragrance, water	



Made in China

Distributed by
Max Power Product Group
Los Angeles, CA

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75328-002
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
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
PROPANEDIOL (UNII: 5965N8W85T)	
GLYCERIN (UNII: PDC6A3C0OX)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75328-002-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/27/2020	
2	NDC:75328-002-02	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/27/2020	

Labeler - CROWN (YANGZHOU) HEALTH & BEAUTY CO., LTD (542978427)

Establishment

Name	Address	ID/FEI	Business Operations
CROWN (YANGZHOU) HEALTH & BEAUTY CO., LTD		542978427	manufacture(75328-002)