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 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.

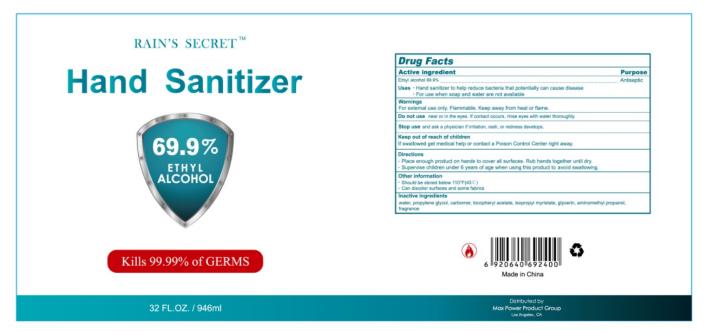
Other information

- 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 | | | |
|---------------------------------|--|-------------------|-------------------|
| l | Ingredient Name | Basis of Strength | Strength |
| l | ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 69.9 mL in 100 mL |

| Inactive Ingredients | | | |
|--|----------|--|--|
| Ingredient Name | Strength | | |
| ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS) | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | |
| WATER (UNII: 059QF0KO0R) | | | |

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

| P | 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.