CANDYLAND HAND SANITIZER CL100- alcohol gel Gold Orient International Limited

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.

CandyLand(CL100)Hand Sanitizer

Active ingredient

Alcohol Denat. 62%

Purpose

Antiseptic

Use

Use for hand-washing to decrease bacteria on the skin, only when water is not available.

Warnings

For external use only.

Flammable, keep away from fire and flames

When using this product

- do not get into eyes.
- if contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if

irritation and redness develop

Keep out of reach of children

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

Directions

• wet hands thoroughly with product and allow to dry without wiping.

Other information

- Store at 68 to 77F (20-25C)
- Do not store above 110F (43C)
- You may report a serious adverse reaction to this product to Report Reaction, LLC, PO Box 22, Plainsboro, NJ 08536

Inactive ingredients

Label





FRONT













BACK STICKER/ FOLD UP BOOKLET

CANDYLAND HAND SANITIZER CL100

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51522-026

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)
ALCOHOL (UNII: 3K9958V90M) ALCOHOL 62 mL in 100 mL

Ingredient Name Strength POLYSORBATE 20 (UNII: 7T1F30 V5YH) FD&C YELLOW NO. 5 (UNII: 1753WB2F1M) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) WATER (UNII: 059QF0 KOOR) GLYCERIN (UNII: PDC6A3COOX) CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) SODIUM HYDROXIDE (UNII: 55X04QC32I)

| F | Packaging | | | | | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|--|--|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | | | | |
| 1 | NDC:51522-026- 01 | 1 in 1 CASE | 07/17/2020 | | | | | | |
| 1 | | 30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination | | | | | | | |

| Prod | uct | | | | | | | | | |
|-------------------------|--|----------------------|--------------------|--|--|--|--|--|--|--|
| | | | | | | | | | | |
| | | | | | | | | | | |
| Marketing Information | | | | | | | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | | | | | | |
| OTC monograph not final | part333A | 07/17/2020 | | | | | | | | |
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Labeler - Gold Orient International Limited (679905914)

| Establishment | | | | | | | | |
|-----------------------------------|---------|-----------|------------------------|--|--|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | | | |
| Gold Orient International Limited | | 679905914 | manufacture(51522-026) | | | | | |

Revised: 7/2020 Gold Orient International Limited