

CANDYLAND HAND SANITIZER CL 200- 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(CL 200)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 with 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

Water

Glycerin,

Acrylates/C10-30 Alkyl Acrylate Crosspolymer,

Fragrance,
 Polysorbate 20,
 Sodium Hydroxide,
 Red 40

Label

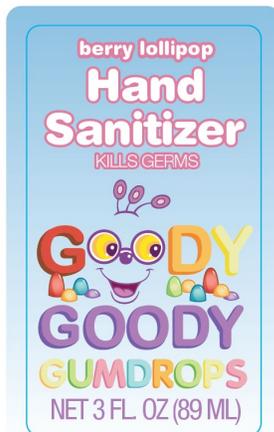
HAND SANITIZER

SCENT:
 BERRY

 HAND SANITIZER
 PANTONE
 1895 @ 50%



FRONT



BACK



CANDYLAND HAND SANITIZER CL 200			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51522-019
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL	
Inactive Ingredients			

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51522-019-01	1 in 1 POUCH	07/16/2020	
1		89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/16/2020	

Labeler - Gold Orient International Limited (679905914)

Establishment

Name	Address	ID/FEI	Business Operations
Gold Orient International Limited		679905914	manufacture(51522-019)

Revised: 7/2020

Gold Orient International Limited