# FRESH COCONUT HAND SANITIZER- 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.

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# Active Ingredient(s)

Alcohol Denat 80% v/v.

## Purpose

Antiseptic

#### Use

Hand Sanitizer to help reduce bacteria that could 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.
- children under 6 years of age should be supervised when using this product to avoid swallowing.

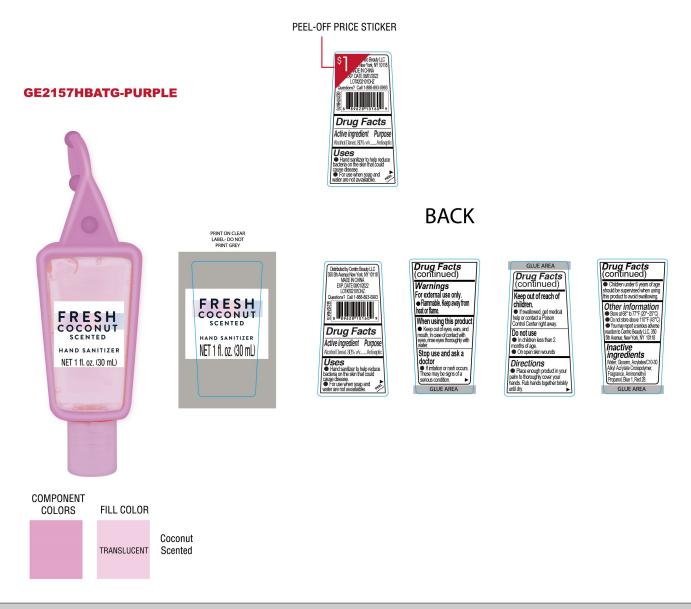
#### Other information

- Store between 68 to 77F(20-25C)
- Do not store above 100F (43C)
- You may report a serious adverse reaction to Centric Beauty LLC, 350 5th Avenue, New York, NY 10118

# **Inactive ingredients**

Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Blue 1, Red 28

# Package Label - Principal Display Panel



# FRESH COCONUT HAND SANITIZER alcohol gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration TOPICAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL
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Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0 Y5NH)	

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:51522-014- 01	30 mL in 1 BOTTLE, PLASTIC; 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** - Gold Orient International Limited (679905914)

Establishment				
Name	Address	ID/FEI	Business Operations	
Gold Orient International Limited		679905914	manufacture(51522-014)	

Revised: 6/2020 Gold Orient International Limited