

**YOU GOT THIS 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 70% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**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 heat or flame

**Do not use**

- in children less than 2 months of age
- on open skin wounds

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 or rash occurs.

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.

**Inactive ingredients**

Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol

**Package Label - Principal Display Panel**



FRONT CLEAR LABEL ART



DO NOT PRINT GREY COLOR  
W2.2 X H3.5cm



CAP: PMS WHITE C  
BOTTLE: CLEAR  
RUBBER HOLDER  
PMS 212 C  
SCENT: BERRY  
FILL: CLEAR

## YOU GOT THIS HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51522-008
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51522-008-01	30 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 mono graph not final	part333A	03/30/2020	

**Labeler** - Gold Orient International Limited (679905914)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Gold Orient International Limited		679905914	manufacture(51522-008)

Revised: 5/2020

Gold Orient International Limited