# YOU ARE THE BEST 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



**CAP: PMS WHITE C BOTTLE: CLEAR** 

RUBBER HOLDER PMS 306 C

**SCENT: BERRY** FILL: CLEAR



Warnings For external use only Flammable, keep away from fire and flames. When using this produc ● do not get into eyes. ● if contact occurs, rinse eyes thoroughly with water. Stop use and ask a doctor if

irrilation and redness develop.

Drug Facts

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

Active ingredient Purpose



# Drug Facts (continued)

## YOU ARE THE BEST HAND SANITIZER

alcohol gel

#### **Product Information**

HUMAN OTC DRUG NDC:51522-009 Product Type Item Code (Source)

TOPICAL **Route of Administration** 

#### **Active Ingredient/Active Moiety**

**Basis of Strength Ingredient Name** 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: 059QF0KO0R) CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L) AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

	Packaging						
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date			
ı	1 NDC:51522-009-01	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 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(51522-009)				

Revised: 5/2020 Gold Orient International Limited