

**ULTRA DEFENSE SANI SMART SWEET CITRUS- 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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**Ultra Defense Sani Smart Sweet Citrus**

***Active Ingredient***

Alcohol Denat. 62%

***Purpose***

Antiseptic

***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 77°F (20°~25°C)

Do not store above 110°F (43°C)

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, Aloe Barbadensis Leaf Extract, Polysorbate 20, Sodium Hydroxide, Yellow 5, Red 40.

Label



CLEAR STICKER



PANTONE  
164 @30%

SCENT:  
SWEET CITRUS

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# ULTRA DEFENSE SANI SMART SWEET CITRUS

alcohol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51522-061
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51522-061-01	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/06/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/06/2020	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Gold Orient International Limited		679905914	manufacture(51522-061)