**ULTRA DEFENSE SANI SMART 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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**Ultra Defense Sani Smart Hand Sanitizer**

for hand washing to decrease bacteria on the skin only when water is not available.

**Drug Facts**
**Active Ingredients**

Ethyl Alcohol 65%

**Purpose**

Antiseptic

- wet hands thoroughly with product and allow to dry without wiping

**Inactive Ingredients:**

Water(Aqua), Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Sodium Hydroxide, Fragrance (Parfum)

**Warning**

- For External Use Only.
- Flammable, keep away from fire and flames

Keep out of reach of children.

When using this product

- do not get into eyes.
- if contact occurs, rinse eyes thoroughly with water

Stop us 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.




尺寸：47x100mm
正标材质：乳白PE+光油
背标材质：透明BOPP+光油

173x68 mm

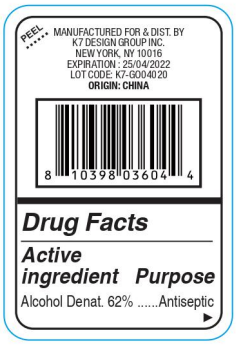

NET 7.6 FL. OZ (225 ML)
Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance,
Polysorbate 20,Sodium Hydroxide.


front back

60 mL

front

60 mL





FOLD OUT LABEL ON BACK

# ULTRA DEFENSE SANI SMART HAND SANITIZER

alcohol gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:51522-001 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ALCOHOL** (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 65 mL in 100 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | 33 mL in 100 mL |
| **POLYSORBATE 20** (UNII: 7T1F30V5YH) | |
| **CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)** (UNII: 71DD5V995L) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:51522-001-01 | 59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| **2** | NDC:51522-001-02 | 59 mL in 1 TUBE; Type 0: Not a Combination Product | 03/30/2020 | |
| **3** | NDC:51522-001-03 | 225 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |
| **4** | NDC:51522-001-04 | 236 mL in 1 BOTTLE, PUMP; 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(51522-001) |

Revised: 4/2020 Gold Orient International Limited