

**TRANSFORMERS HAND SANITIZER (TFMR 102)- 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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**Transformers(TFMR 102)Hand Sanitizer**

**Active Ingredient(s)**

Alcohol 62% v/v.

**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 heat or flame

**Do not use**

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

Do not get into eyes.

If contact occurs, rinse eyes thoroughly with water

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 between 66 to 77F (20-25C)
- Do not store above 110F (43C)
- 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 Acrylates Crosspolymer, Fragrance, Polysorbate 20, Sodium Hydroxide, Red 33, Blue 1

# Package Label - Principal Display Panel

## HAND SANITIZER

SCENT:  
CITRUS



HAND SANITIZER  
PANTONE  
7688 @ 70%



FRONT



## TRANSFORMERS HAND SANITIZER (TFMR 102)

alcohol gel

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:51522-037 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M) | ALCOHOL           | 62 mL in 100 mL |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| GLYCERIN (UNII: PDC6A3C0OX)  |          |
| SODIUM HYDROXIDE (UNII: 55X04QC32I)  |          |
| WATER (UNII: 059QF0K00R)   |          |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L)  |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)   |          |
| POLYSORBATE 20 (UNII: 7T1F30 V5YH)   |          |
| CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L) |          |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:51522-037-01 | 1 in 1 POUCH  | 03/30/2020           |                    |
| 1 |                  | 30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                      |                    |

  

| 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(51522-037) |

Revised: 7/2020

Gold Orient International Limited