ULTRA DEFENSE SANI SMART 15 PK 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.

Active Ingredient(s)

Alcohol Denat. 62%

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer 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 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

• Wet hands thorough; y with product and allow to dry without wiping

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, water, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance, Polysorbate 20, Sodium Hydroxide

Package Label - Principal Display Panel



JAR LABEL SIZE







正面

















ULTRA DEFENSE SANI SMART 15 PK HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51522-005

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)ALCOHOL65 mL in 100 mL

Inactive Ingredients Ingredient Name Strength CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO) POLYSORBATE 20 (UNII: 7T1F30V5YH) SODIUM HYDROXIDE (UNII: 55X04QC32I) GLYCERIN (UNII: PDC6A3C0OX) WATER (UNII: 059QF0KOOR)

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:51522-005- 01	1 in 1 JAR	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(51522-005)					

Revised: 4/2020 Gold Orient International Limited