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.

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

Warning

- 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 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.







Drug Facts (continued)

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

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Drug Facts (continued)

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FOLD OUT LABEL ON BACK

ULTRA DEFENSE SANI SMART HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51522-002	
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)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)			
GLYCERIN (UNII: PDC6A3C0OX)			
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51522-002- 01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/11/2020	
2	NDC:51522-002- 02	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/11/2020	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	04/11/2020			

Labeler - Gold Orient International Limited (679905914)

Establishment				
Name	Address	ID/FEI	Business Operations	
Gold Orient International Limited		679905914	manufacture(51522-002)	

Revised: 4/2020 Gold Orient International Limited