ULTRA DEFENSE SANI SMART VANILLA LAVENDER HAND SANITIZER- alcohol denat. 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 Vanilla Lavender Hand Sanitizer

Active ingredient

Alcohol Denat. 62%

Purpose

Antiseptic

Use

Use for hand-washing to decrease bacteria on the skin, only when water it 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

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 77F (20-25C)

Do not store above 110F (43C)

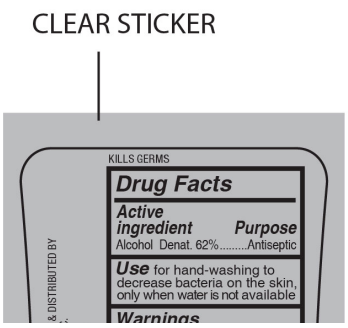
You may report a serious adverse reaction to this product to Report Reaction, LLC, PO Box 22, Plainsboro, NJ 08536

Inactive ingredients

Water,

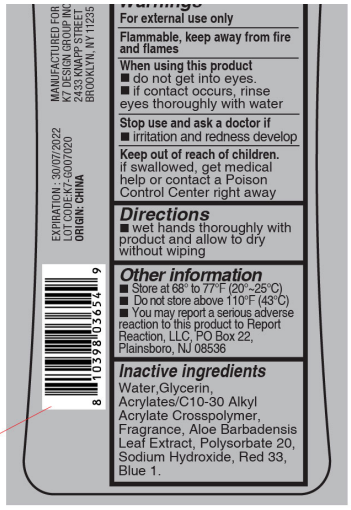
Glycerin,
Acrylates/C10-30 Alkyl Acrylate Crosspolymer,
Fragrance,
Aloe Barbadensis Leaf Extract,
Polysorbate 20,
Sodium Hydroxide,
Red 33,
Blue 1

Label



PANTONE
2582 @30%

SCENT:
LAVENDER



ULTRA DEFENSE SANI SMART VANILLA LAVENDER HAND SANITIZER

alcohol denat. gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51522-055
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51522-055-01	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(51522-055)

Revised: 8/2020 Gold Orient International Limited