ULTRA DEFENSE SANI SMART MIDNIGHT MERMAID- 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 Midnight Mermaid

Active Ingredient

Alcohol Denat. 62%

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 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

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 77°F (20°~25°C)

Do not store above 110°F (43°C)

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

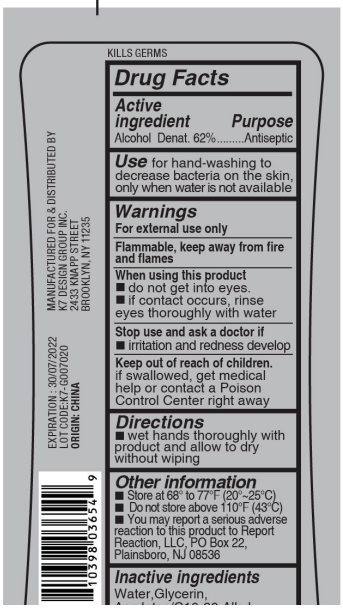
Inactive ingredients

Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance, Aloe Barbadensis Leaf

Extract, Polysorbate 20, Sodium Hydroxide, Blue 1.

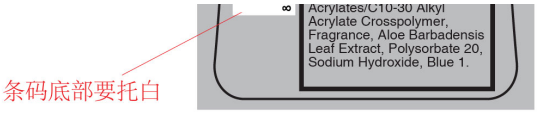
Label

CLEAR STICKER



PANTONE
318 @30%

SCENT:
OCEAN BREEZE



ULTRA DEFENSE SANI SMART MIDNIGHT MERMAID

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51522-058
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**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51522-058-01	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/05/2020	

Labeler - Gold Orient International Limited (679905914)

Establishment

Name	Address	ID/FEI	Business Operations
Gold Orient International Limited		679905914	manufacture(51522-058)

Revised: 8/2020 Gold Orient International Limited