# BODY PRESCRIPTIONS VANILLA MINT ANTIBACTERIAL HAND SANITIZER- ethyl alcohol solution

#### **ENCHANTE ACCESSORIES INC.**

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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50563-273/ G0XAHS12

#### **Active Ingredient**

Alcohol: 75% (v/v)

#### **Purpose**

Antiseptic

#### Use

- To decrease bacteria on the skin that could cause disease
- ■Recommended for repeated use

#### WARNINGS

For external use only

Flammable. Keep away from heat or flame

Do not use

in children less than two months of age

on open skin wounds

When using this product, keep out of eyes, ears, and mouth In case of contact with eyes, rinse eyes thoroughly with water

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition

#### keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away at 1-800-222-1222

#### **Directions**

Place enough product on hands to cover all surfaces. Rub hands together untill dry.

Supervise children under six years of age when using this product to avoid swallowing

#### Other information

Do not store above 105F

May discolor some fabrics

Harmful to wood finishes and plastics

### **Inactive ingredients**

Carbomer, Fragrance, Glycerin, PEG-40 Hydrogenated Castor Oil, Red 4, Triehtanolamine, Water, Yellow 5

220x80mm

## BODY PRESCRIPTIONS VANILLA MINT ANTIBACTERIAL HAND SANITIZER

ethyl alcohol solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-273	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
TROLAMINE (UNII: 903K93S3TK)			
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
CARBOMER 940 (UNII: 4Q93RCW27E)			
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			

ı	Packaging			
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date

1 NDC:50563-273-01 355	mL in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2020	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/30/2020	

## Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-273)	

Revised: 10/2020 ENCHANTE ACCESSORIES INC.