

**BODY PRESCRIPTIONS 65 PERCENT ALCOHOL ANTIBACTERIAL HAND  
SANITIZER SWEET PINE- 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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**50563-463 / JAS21XS7**

**Active Ingredient**

Alcohol: 65% (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**

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

**Directions**

Wet hands thoroughly with product and allow to dry without wiping

For children under 6, use only under adult supervision

Not recommended for infants

## Other information

Do not store above 105F

May discolor some fabrics

Harmful to wood finishes and plastics

Not tested on animals

For adult use only

## Inactive ingredients

Water, Glycerin, PEG-40 Hydrogenated Castor Oil, Carbomer, Fragrance, Triethanolamine, Blue 1, Yellow 5

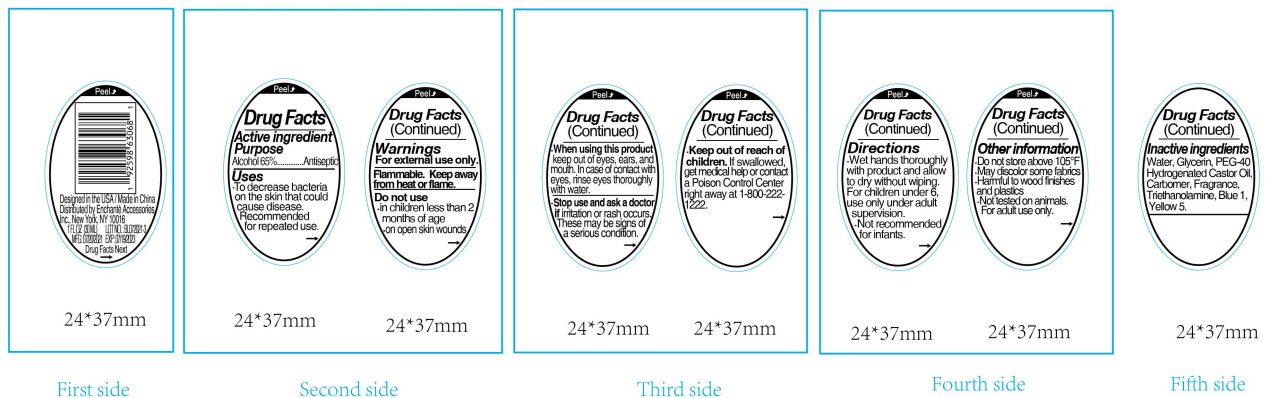
10375~10377-11 (JAS21XS7)

FILL COLOR =  
PANTONE 7717 C @ 30%

Hot matt silver



24\*37mm



# BODY PRESCRIPTIONS 65 PERCENT ALCOHOL ANTIBACTERIAL HAND SANITIZER SWEET PINE

ethyl alcohol solution

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:50563-463 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL                  | 65 mL in 100 mL |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>TROLAMINE</b> (UNII: 9O3K93S3TK)                           |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                               |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                            |                 |
| <b>CARBOMER 940</b> (UNII: 4Q93RCW27E)                        |                 |
| <b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F) |                 |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)               |                 |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)                 |                 |

**Packaging**

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                           | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|--|-----------------------------|---------------------------|
| 1        | NDC:50563-463-01 | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/04/2021                  |                           |

**Marketing Information**

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final   | part333A  | 07/04/2021                  |                           |

**Labeler** - ENCHANTE ACCESSORIES INC. (186050696)**Establishment**

| <b>Name</b>                               | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|---|----------------|---------------|----------------------------|
| Xiamen Afgamarine Biotechnology Co., Ltd. |                | 420485152     | manufacture(50563-463)     |

Revised: 7/2021

ENCHANTE ACCESSORIES INC.