

**BODY PRESCRIPTIONS BUTTER PECAN 65 PERCENT ALCOHOL 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.

50563-434/JAS21FS9

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

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

10344-3-7-11 (JAS21FS9)

 hot matte finish silver



24*37mm



BODY PRESCRIPTIONS BUTTER PECAN 65 PERCENT ALCOHOL ANTIBACTERIAL HAND SANITIZER

ethyl alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-434
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
TROLAMINE (UNII: 903K93S3TK)	

WATER (UNII: 059QF0KO0R)

GLYCERIN (UNII: PDC6A3C0OX)

CARBOMER 940 (UNII: 4Q93RCW27E)

POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

FD&C RED NO. 4 (UNII: X3W0AM1JLX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-434-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/27/2021	

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-434)

Revised: 3/2021

ENCHANTE ACCESSORIES INC.