# BODY PRESCRIPTIONS PUMPKIN SPICE 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.

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50563-432/JAS21FS7

# **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

#### 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, Triehtanolamine, Water, Yellow 5

10344-1-5-9 (JAS21FS7 )













24\*37mm

fifth page 24\*37mm





eighth page 24\*37mm

# **BODY PRESCRIPTIONS PUMPKIN SPICE 65 PERCENT ALCOHOL** ANTIBACTERIAL HAND SANITIZER

ethyl alcohol solution

**Product Type** HUMAN OTC DRUG **Item Code (Source)** NDC:50563-432

**Route of Administration TOPICAL** 

# **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	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:50563-432- 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	
	part333A	03/27/2021	

# Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-432)	

Revised: 3/2021 ENCHANTE ACCESSORIES INC.