

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER DUO LAVENDER AND BERRIES- alcohol
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.

50563-297-298-299/ BUX0ABS7

BODY PRESCRIPTIONS HAND SANITIZER ANTIBACTERIAL LAVENDER
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Active Ingredient

Alcohol 75%

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

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

Do not use

- in children less than 2 months of age
- on open skin wounds

Stop use and ask a doctor if skin 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

Directions

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

Supervise children under 6 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

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

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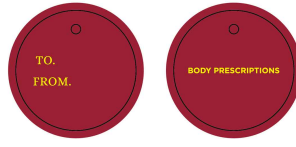
May discolor some fabrics

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Inactive Ingredients

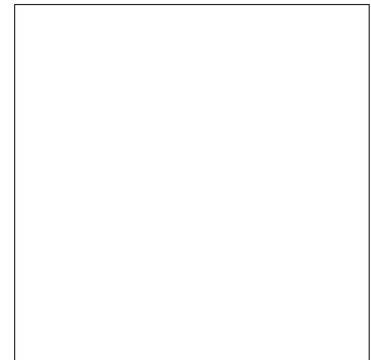
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hot gold foil

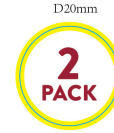
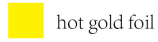


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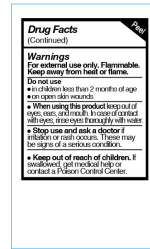
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BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER DUO LAVENDER AND BERRIES

alcohol kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-299
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:50563-299-01	1 in 1 KIT	10/06/2020
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Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	60 mL
Part 2	1 BOTTLE	60 mL

Part 1 of 2

BODY PRESCRIPTIONS HAND SANITIZER ANTIBACTERIAL LAVENDER

alcohol solution

Product Information

Item Code (Source)	NDC:50563-297
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-297-01	60 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/06/2020	

Part 2 of 2

BODY PRESCRIPTIONS HAND SANITIZER ANTIBACTERIAL BERRIES

alcohol solution

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OTC monograph not final	part333A	10/06/2020	

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-299)

Revised: 10/2020

ENCHANTE ACCESSORIES INC.