BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZERS 2 PACK WILD BERRY SCENTED VANILLA SCENTED- 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.

50563-384/385/386 G1ABHS02

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER WILD BERRY SCENTED

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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

Do not use

- in children less than 2 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 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 right away at 1-800-222-1222

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

Carbomer, Fragrance, Glycerin, PEG-40 Hydrogenated Castor Oil, Triethanolamine, Water

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24*37mm



24*37mm

Drug Facts

24*37mm

24*37mm



first page



second page



third page



10315-2 (G1ABHS02) label

24*37mm



24*37mm



first page

24*37mm



second page

24*37mm



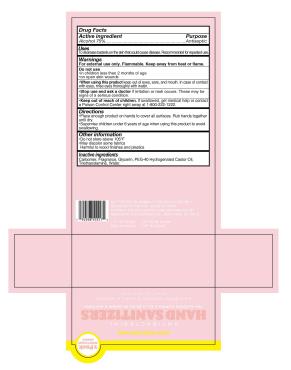
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10315-2 (G1ABHS02)

outside 157*207mm



inside 157*207mm

CLEAN HANDS
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BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZERS 2 PACK WILD BERRY SCENTED VANILLA SCENTED

alcohol kit

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:50563-386

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50563-386-01	1 in 1 KIT	10/30/2020	

uantity	

Quan	Quality of Lates					
Part #	Package Quantity	Total Product Quantity				
Part 1	1 BOTTLE	30 mL				
Part 2	1 BOTTLE	30 mL				

Part 1 of 2

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER WILD BERRY SCENTED

alcohol solution

Product Information

Item Code (Source) NDC:50563-384

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

ALCOHOL (UNII: 3K9958V90M) (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)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-384- 01	30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

l	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
l	OTC monograph not final	part333A	10/30/2020	

Part 2 of 2

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER VANILLA SCENTED

alcohol solution

Product Information Item Code (Source) NDC:50563-385 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: PDC6 A3C0 OX)					
CARBOMER 940 (UNII: 4Q93RCW27E)					
TROLAMINE (UNII: 9O3K93S3TK)					
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)					

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OTC monograph not final	part333A	10/30/2020					

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OTC monograph not final	part333A	10/30/2020					

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment						
Name	Address	ID/FEI	Business Operations			
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-386)			

Revised: 11/2020 ENCHANTE ACCESSORIES INC.