BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER DUO FRESH BERRY SCENTED GRAPEFRUIT 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.

50563-394/395/396 G1ABHS06

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER FRESH BERRY SCENTED

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER FRESH BERRY SCENTED

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

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER GRAPEFRUIT SCENTED

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER GRAPEFRUIT SCENTED

Active Ingredient

Alcohol 75%

Purpose

Antiseptic

Uses

- 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 a sign of 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

2009 Rainbow

24*37mm



24*37mm



first page second page

24*37mm



third page

24*37mm



10315-5 (G1ABHS06) label

24*37mm



24*37mm



first page

24*37mm



second page

24*37mm

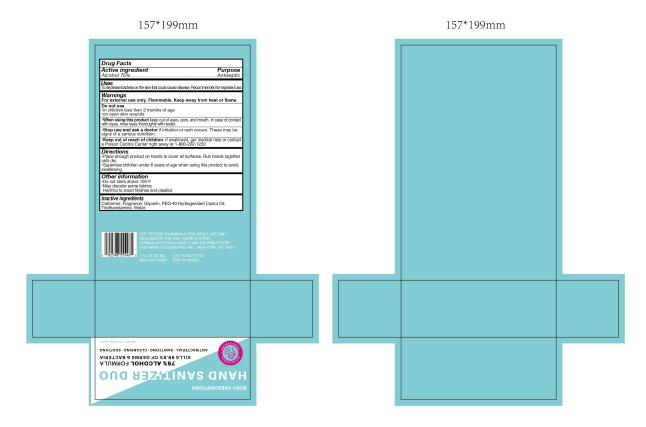


third page





10315-5 (G1ABHS06)



back positive

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER DUO FRESH BERRY SCENTED GRAPEFRUIT SCENTED

alcohol kit

l	Product Information	
ı		

HUMAN OTC DRUG NDC:50563-396 Product Type Item Code (Source)

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50563-396-01	1 in 1 KIT	10/30/2020	

Quant	tity of Parts	
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 FRESH BERRY SCENTED

alcohol solution

Product Information	
Item Code (Source)	NDC:50563-394
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: 903K93S3TK)		
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)		

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:50563-394- 01	30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

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

Part 2 of 2

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER GRAPEFRUIT SCENTED

alcohol solution

Droduct	Information
PIONICI	111101 1111411011

Item Code (Source) NDC:50563-395

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

ı	rictive ingredient/retive tytolety		
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)		

Packaging Marketing Start Marketing End Item Code **Package Description** Date Date 1 NDC:50563-395-01 30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-

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

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

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Package

Establishment			
Name	Address	ID/FEI	Business Operations

420485152

manufacture(50563-396)

Revised: 11/2020 ENCHANTE ACCESSORIES INC.