BODY PRESCRIPTIONS HAND SANITIZER TRIO SPEARMINT UNSCENTED CITRUSalcohol

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_253/254/255/256_G0ABHS12

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER Spearmint

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER Spearmint

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, Hands

Flammable. Keep away from heat and flame

When using this product, keep out of eyes.

In case of contact with eyes, flush thoroughly with water

Avoid contact with broken skin

Do not inhale or ingest

Stop Use

Stop use and ask a doctor if skin irritation develops

keep out of reach of children

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately

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

Inactive ingredients

Water, Glycerin, PEG-40 Hydrogenated Castor Oil, Carbomer, Triethanolamine, Aloe Barbadensis Leaf Extract, Blue 1, Yellow 5

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER Unsented

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Purpose:

Antiseptic

Uses:

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Warnings

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Keep out of reach of children

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately

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

Inactive Ingredients

Water, Glycerin, PEG-40 Hydrogenated Castor Oil, Carbomer, Triethanolamine, Aloe Barbadensis Leaf Extract, Red 33, Blue 1

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER Citrus

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER Citrus

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, Hands

Flammable. Keep away from heat and flame

When using this product, keep out of eyes.

In case of contact with eyes, flush thoroughly with water

Avoid contact with broken skin

Do not inhale or ingest

Stop Use

Stop use and ask a doctor if skin irritation develops

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately

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

Inactive Ingredients

Water, Glycerin, PEG-40 Hydrogenated Castor Oil, Carbomer, Triethanolamine, Aloe Barbadensis Leaf Extract, Yellow 5, Red 4





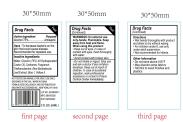


10269-3 (G0ABHS12) label

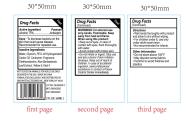












BODY PRESCRIPTIONS HAND SANITIZER TRIO SPEARMINT UNSCENTED CITRUS

alcohol kit

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-256	

]	Packaging			
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-256-01	1 in 1 KIT	09/11/2020	

Quantity of Parts			
Part #	Package Quantity	Total Product Quantity	
Part 1	1 BOTTLE	60 mL	
Part 2	1 BOTTLE	60 mL	
Part 3	1 BOTTLE	60 mL	

Part 1 of 3

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER SPEARMINT

alcohol solution

Product Information		
Item Code (Source)	NDC:50563-253	
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)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:50563-253- 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	09/11/2020	

Part 2 of 3

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER UNSCENTED

alcohol solution

Product Information	
Item Code (Source)	NDC:50563-254
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)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-254- 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	09/11/2020			

Part 3 of 3

BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER CITRUS

alcohol solution

Product Information	
Item Code (Source)	NDC:50563-255
Route of Administration	TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	75 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
TROLAMINE (UNII: 9O3K93S3TK)				
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
FD&C RED NO. 4 (UNII: X3W0 AMIJLX)				

]	Packaging				
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50563-255- 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	09/11/2020		

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	09/11/2020		

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment					
Name	Address	ID/FEI	Business Operations		
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture (50563-256)		

Revised: 9/2020 ENCHANTE ACCESSORIES INC.