# BODY PRESCRIPTIONS HAND SANITIZER TRIO CRANBERRY WINTER BERRY PEPPERMINT- 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\_346/347/348/349\_BUX0ABS8

# **BODY PRESCRIPTIONS Cranberry antibacterial HAND SANITIZER**

BODY PRESCRIPTIONS Cranberry antibacterial HAND SANITIZER

### **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 two months of age
- on open skin wounds

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.

#### **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, Triethanolamine, Tocopheryl Acetate, Yellow 5

# **BODY PRESCRIPTIONS Winter Berry antibacterial HAND SANITIZER**

BODY PRESCRIPTIONS Winter Berry antibacterial HAND SANITIZER

# **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

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 two months of age
- on open skin wounds

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.

#### **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, Triethanolamine, Tocopheryl Acetate, Yellow 5

### **BODY PRESCRIPTIONS Peppermint antibacterial HAND SANITIZER**

BODY PRESCRIPTIONS Peppermint antibacterial HAND SANITIZER

# **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

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 two months of age
- on open skin wounds

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.

#### **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

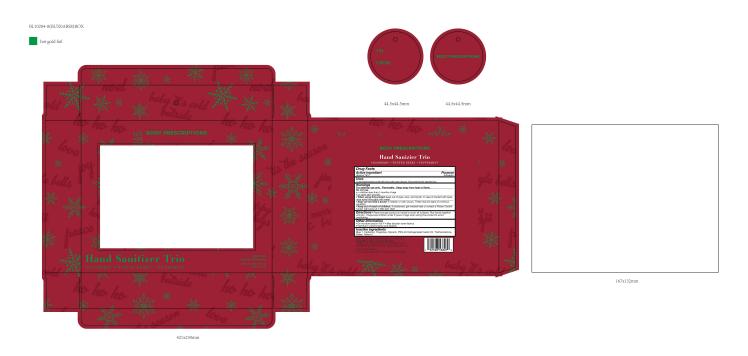
Do not store above 105F

May discolor some fabrics

Harmful to wood finishes and plastics

#### **Inactive Ingredients**

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



BL10284-8(BUX0ABS8)label

hot gold foil



# BODY PRESCRIPTIONS HAND SANITIZER TRIO CRANBERRY WINTER BERRY PEPPERMINT

alcohol kit

# **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:50563-349

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-349-01	1 in 1 KIT	10/06/2020	

Quan	Quantity of Parts			
Part #	Package Quantity	Total Product Quantity		
Part 1	1 BOTTLE	60 mL		
Part 2	1 BOTTLE	60 mL		
Dant 2	1 D∩TTI E	60 mI		

# Part 1 of 3

# **BODY PRESCRIPTIONS CRANBERRY ANTIBACTERIAL HAND SANITIZER**

alcohol solution

# **Product Information**

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

Item Code (Source)	NDC:50563-346
Route of Administration	TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

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)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
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

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 3

# BODY PRESCRIPTIONS WINTER BERRY ANTIBACTERIAL HAND SANITIZER

alcohol solution

<b>Product Information</b>	
Item Code (Source)	NDC:50563-347
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			
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
CARBOMER 940 (UNII: 4Q93RCW27E)			
TROLAMINE (UNII: 9O3K93S3TK)			
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 N	NDC:50563-347- )1	60 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

# Part 3 of 3

# **BODY PRESCRIPTIONS PEPPERMINT ANTIBACTERIAL HAND SANITIZER**

alcohol solution

## **Product Information**

Item Code (Source) NDC:50563-348

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

**ALCOHOL** (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 75 mL in 100 mL

### **Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

GLYCERIN (UNII: PDC6A3C0OX)

GLICERIN (UNII. PDC6A3C0UA)

CARBOMER 940 (UNII: 4Q93RCW27E)

TROLAMINE (UNII: 903K93S3TK)

 $\textbf{POLYOXYL} \ \textbf{40} \ \textbf{HYDROGENATED} \ \textbf{CASTOROIL} \ (\textbf{UNII:} \ 7 \textbf{YC} 6 8 6 \textbf{GQ} 8 \textbf{F})$ 

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

.ALPHA.-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)

#### **Packaging**

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50563-348-	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	

		_	
<b>T</b> /	<b>4</b>	T £	<b>4</b>
IVI ar	VATINO	Into	rmation
MIGH	MC UIIE	TIII U	rmation

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

# Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-349)

Revised: 10/2020 ENCHANTE ACCESSORIES INC.