# BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER DUO COCONUT SCENTED ALOE 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.

-----

50563-291-292-293/BUX0ABS5

#### BODY PRESCRIPTIONS HAND SANITIZER COCONUT SCENTED

BODY PRESCRIPTIONS HAND SANITIZER COCONUT 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

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 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**

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

#### BODY PRESCRIPTIONS HAND SANITIZER ALOE SCENTED

BODY PRESCRIPTIONS HAND SANITIZER ALOE 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

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 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

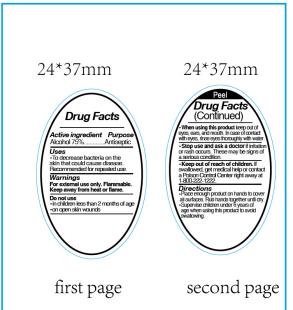
#### **Inactive Ingredients**

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



## 10284-6 (BUX0ABS5) -label

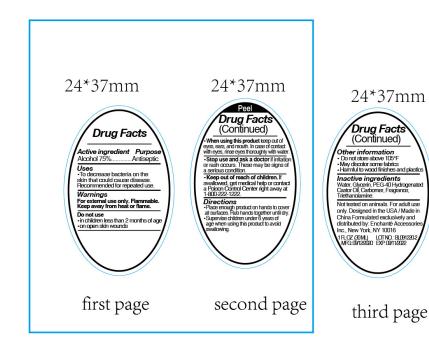




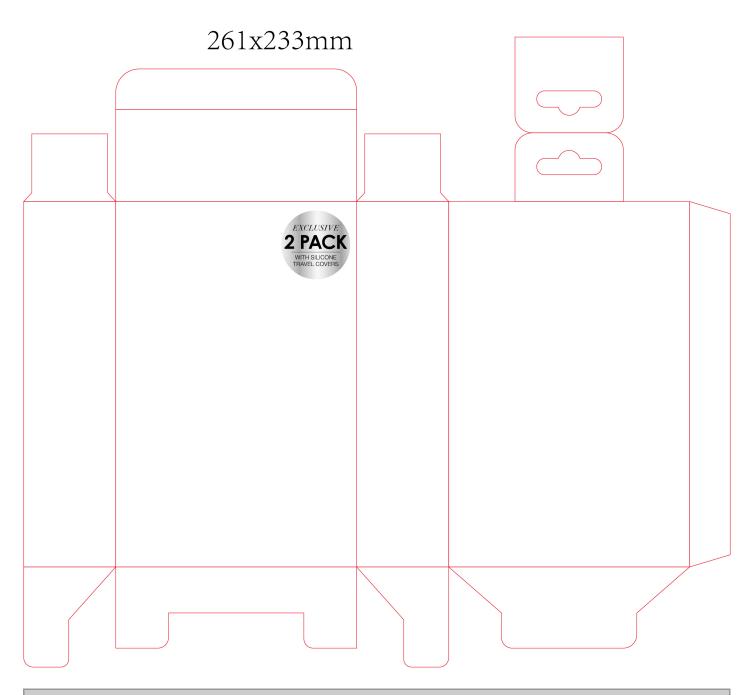


24\*37mm





## 10284-6 (BUX0ABS5) -box



BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER DUO COCONUT SCENTED ALOE SCENTED

alcohol kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-293

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-293-01	1 in 1 KIT	10/06/2020	

Quant	Quantity 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 HAND SANITIZER COCONUT SCENTED**

alcohol solution

Product Information		
Item Code (Source)	NDC:50563-291	
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)			

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:50563-291- 01	30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
ı				

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 ALOE SCENTED**

alcohol solution

Product Information	
Item Code (Source)	NDC:50563-292
Route of Administration	TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>ALCOHOL</b> (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: 903K93S3TK)			
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:50563-292- 01	30 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				

Marketing Information						
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(50563-293)				

Revised: 10/2020 ENCHANTE ACCESSORIES INC.