

BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES VANILLA SUGAR WINTER BERRY HONEY ALMOND 3 PACK SPECIAL OFFER- benzalkonium chloride 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.

50563-441/442/443/444 G1XABW09

BODY PRESCRIPTIONS antibacterial hand wipes VANILLA SUGAR

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Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Use

■ To decrease bacteria on hands

WARNINGS

For external use only

When using this product avoid contact with eyes. In case of contact with eyes, rinse thoroughly with water

Stop use and ask a doctor if irritation or rash occurs. This 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

For adults and children two years and over

Peel over resealable label and remove a wipe from the packet.

Wet hands thoroughly and air dry.

Place used wipes into waste basket. Do not flush.

Inactive ingredients

Water, Glycerin, Ethylhexylglycerin, Aloe Barbadensis Leaf Extract, Phenoxyethanol, Propylene Glycol, Fragrance

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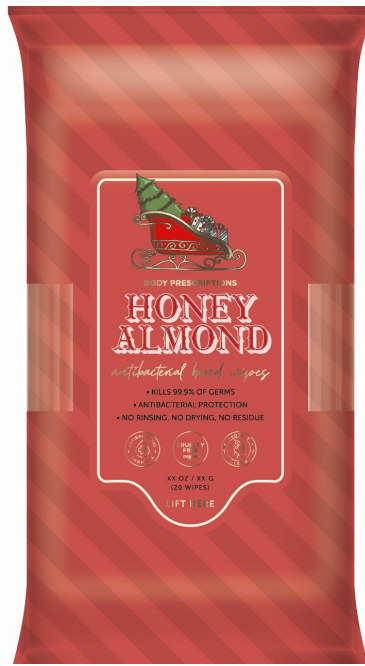
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Wet hands thoroughly and air dry.

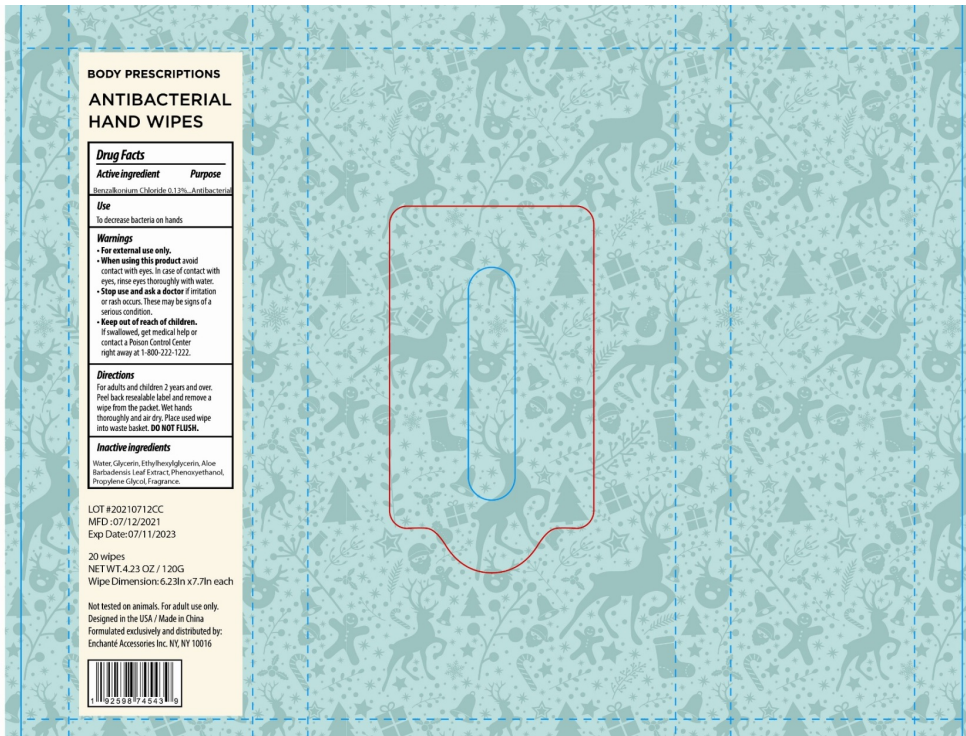
Place used wipes into waste basket. Do not flush.

Inactive Ingredients

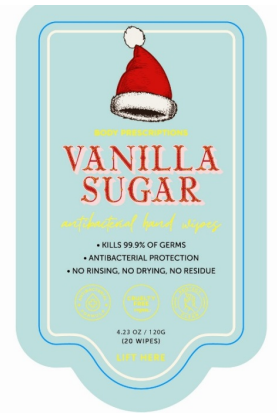
Water, Glycerin, Ethylhexylglycerin, Aloe Barbadensis Leaf Extract, Phenoxyethanol, Propylene Glycol, Fragrance



1

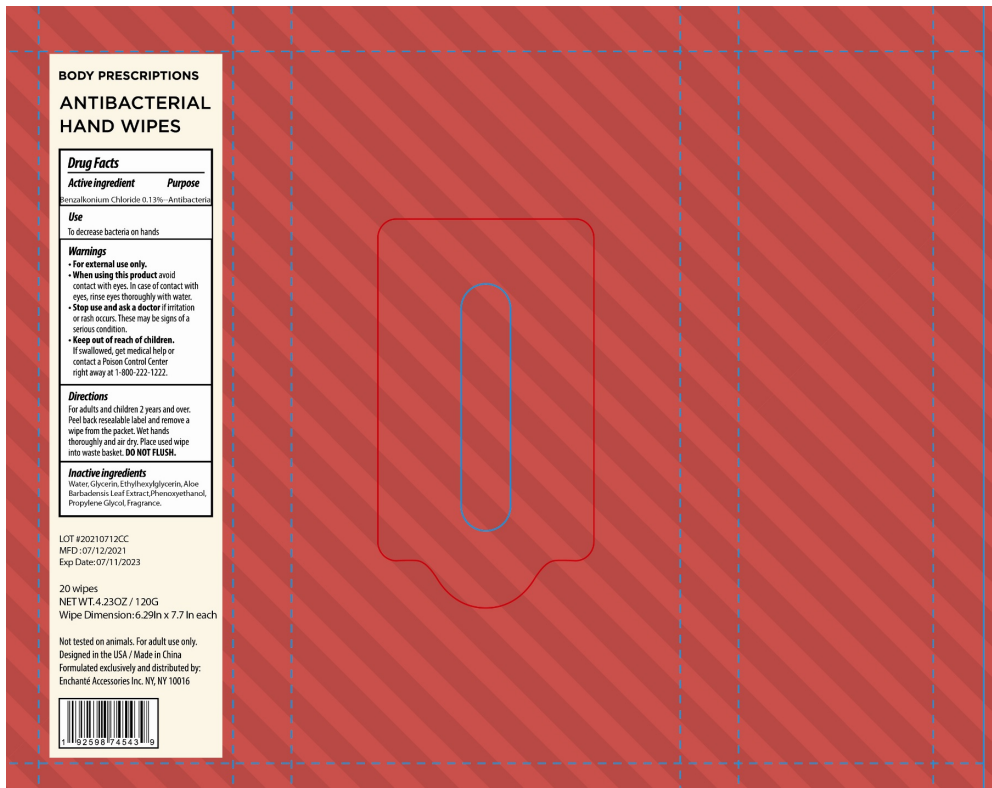


209mm

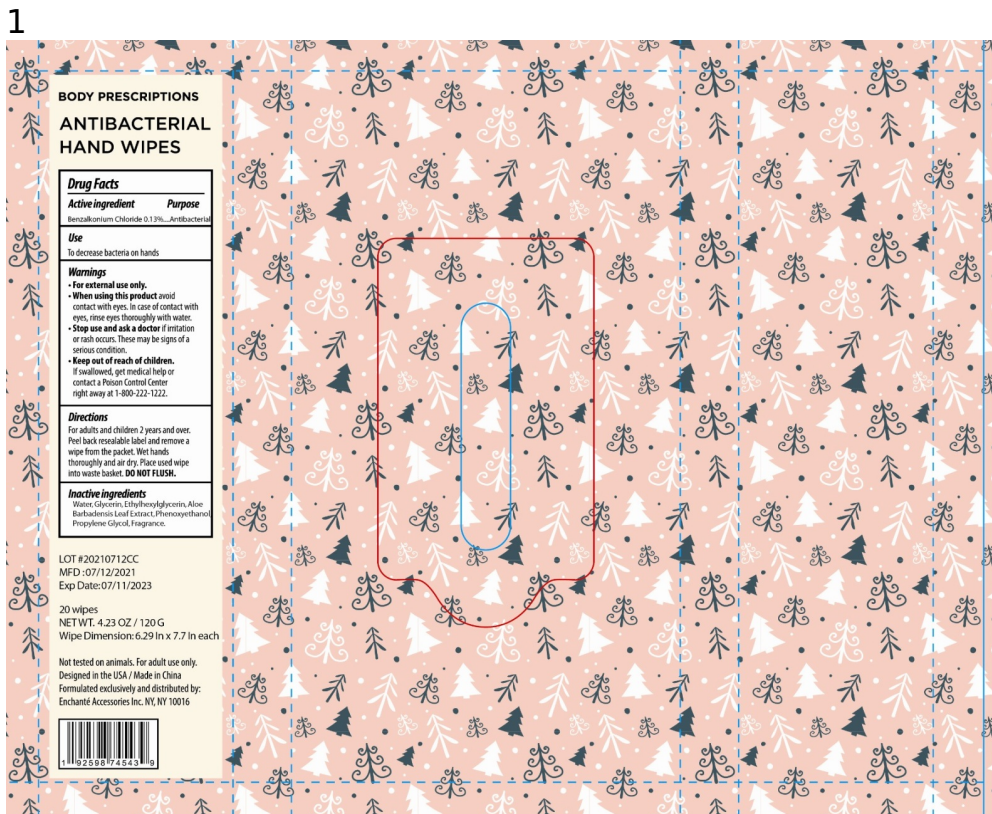
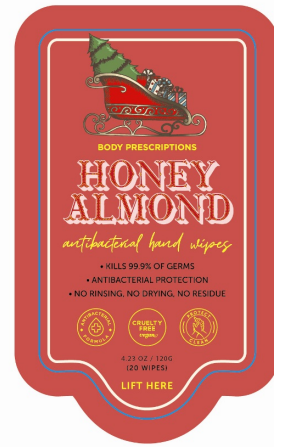


CLEAR SIDE STICKERS
PLEASE PRINT ON CLEAR STICKERS
PLACE ON LEFT AND RIGHT SIDES OF PACKET





209mm



209mm



BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES VANILLA SUGAR WINTER BERRY HONEY ALMOND 3 PACK SPECIAL OFFER
benzalkonium chloride kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50563-444

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-444-01	1 in 1 KIT	07/01/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	20 APPLICATOR	120 mL
Part 2	20 APPLICATOR	120 mL
Part 3	20 APPLICATOR	120 mL

Part 1 of 3

BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES VANILLA SUGAR

benzalkonium chloride solution

Product Information

Item Code (Source)	NDC:50563-441
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-441-01	20 in 1 PACKET		

1	6 mL in 1 APPLICATOR; Type 1: Convenience Kit of Co-Package		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/01/2021	

Part 2 of 3

BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES WINTER BERRY

benzalkonium chloride solution

Product Information

Item Code (Source)	NDC:50563-442
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
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PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-442-01	20 in 1 PACKET		
1		6 mL in 1 APPLICATOR; 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	06/30/2021	

Part 3 of 3

BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES HONEY ALMOND

benzalkonium chloride solution

Product Information

Item Code (Source)	NDC:50563-443
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/01/2021	

final	part333A	07/01/2021	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/01/2021	

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment

Name	Address	ID/FEI	Business Operations
Hangzhou Caring Cleaning Commodity Co., Ltd		413905445	manufacture(50563-444)

Revised: 7/2021

ENCHANTE ACCESSORIES INC.