BODY PRESCRIPTIONS JOY ANTIBACTERIAL HAND WIPES VANILLA PEPPERMINT WINTER BERRY- 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.

50563-363/364/365/366 G0XABW04

BODY PRESCRIPTIONS JOY ANTIBACTERIAL HAND WIPES VANILLA

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Active Ingredient

Benzalkonium Chloride 0.1%

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 reusable 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

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

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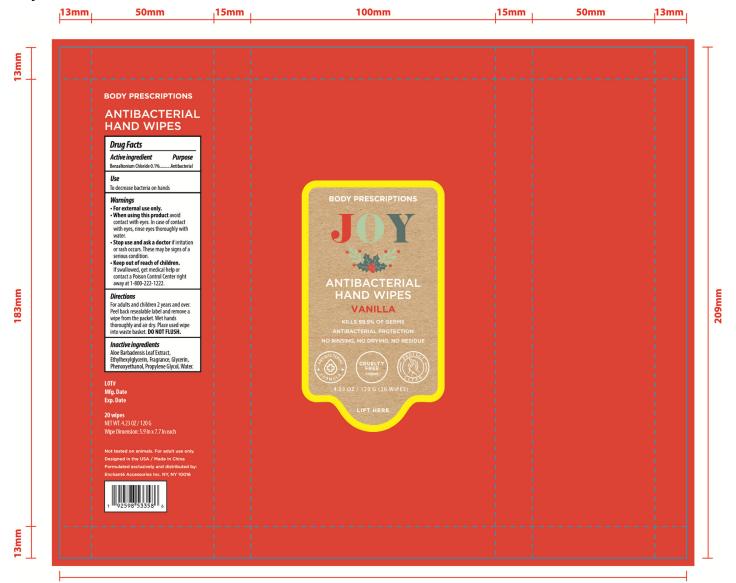
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256mm

BODY PRESCRIPTIONS JOY ANTIBACTERIAL HAND WIPES VANILLA PEPPERMINT WINTER BERRY

benzalkonium chloride kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50563-366

Packaging

I	# Item Code	Package Description	Marketing Start Date	Marketing End Date
I	1 NDC:50563-366-01	1 in 1 KIT	10/20/2020	

Qua	ntity of Parts	
Part	# Package Quantity	Total Product Quantity
Part	1 PACKET	20

1 411 1	TINGKET	20
Part 2	1 PACKET	20

Part 1 of 3

BODY PRESCRIPTIONS JOY ANTIBACTERIAL HAND WIPES VANILLA

benzalkonium chloride solution

Product Information

Item Code (Source) NDC:50563-363

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	4.5 mg	

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: ZY81Z83H0 X)		

	Pa	Packaging			
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:50563-363-01	20 in 1 PACKET; 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	10/20/2020	

Part 2 of 3

BODY PRESCRIPTIONS JOY ANTIBACTERIAL HAND WIPES PEPPERMINT

benzalkonium chloride solution

Product Information	
Item Code (Source)	NDC:50563-364
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	4.5 mg

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)		
ALOE VERA LEAF (UNII: ZY81Z83H0 X)		

Packaging					
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:50563-364-01	20 in 1 PACKET; 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	10/20/2020	

Part 3 of 3

BODY PRESCRIPTIONS JOY ANTIBACTERIAL HAND WIPES WINTER BERRY

benzalkonium chloride solution

Product Information		
Item Code (Source)	NDC:50563-365	
Route of Administration	TOPICAL	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM -	BENZALKONIUM	4.5 mg	

UNII:7N6JUD5X6Y)	CHLORIDE	4.5 mg
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Inactive Ingredients			
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GLYCERIN (UNII: PDC6A3C0OX)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
PROPYLENE GLYCOL (UNII: 6 DC9 Q 16 7 V 3)			
ALOE VERA LEAF (UNII: ZY81Z83H0 X)			

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Marketing Category Application Number or Monograph Citation		n Marketing Start Date Marketing En		
	OTC monograph not final	part333A	10/20/2020	

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	10/20/2020		

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment				
Name	Address	ID/FEI	Business Operations	
Zhejiang Ruolin Hygienic Products Co., Ltd.		415426870	manufacture(50563-366)	

Revised: 10/2020 ENCHANTE ACCESSORIES INC.