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

50563-355/356/357/358 G0XABW02

BODY PRESCRIPTIONS Antibacterial HAND WIPES WINTER BERRY

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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.

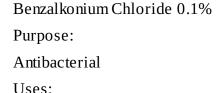
Inactive ingredients

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

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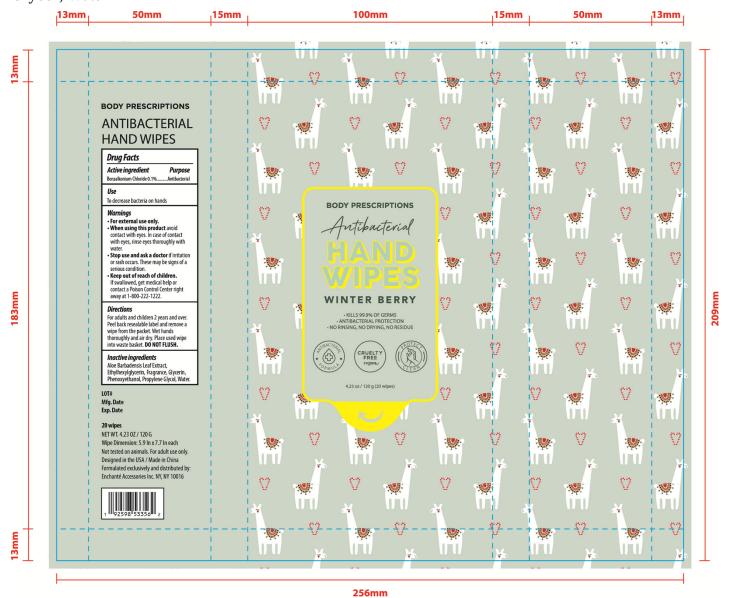
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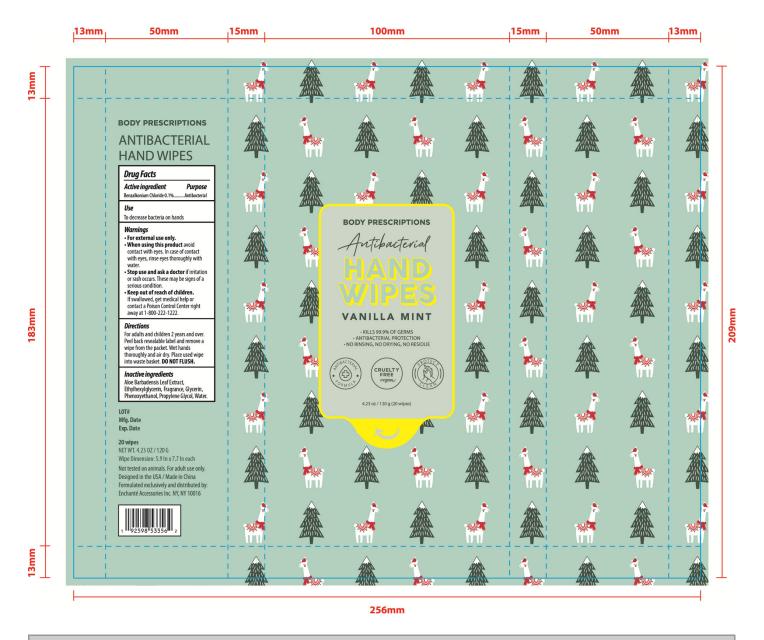
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BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES WINTER BERRY PEPPERMINT VANILLA MINT

benzalkonium chloride kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50563-358

1	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:50563-358-01	1 in 1 KIT	10/20/2020			

Quant	tity of Parts	
Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	20
Part 2	1 PACKET	20

Part 3 1 PACKET		20				
Part 1 of 3						
BODY PRESCI benzalkonium chloric		S ANTIBACTERIAL HAN	ND WIP	ES WINT	ER BEI	RRY
Product Informati	on					
Item Code (Source)		NDC:50563-355				
Route of Administration	ion	TOPICAL				
A stime Image disease	/A -4:					
Active Ingredient/		redient Name		Dagic of C	twonath	Strength
BENZALKO NIUM CHL UNII:7N6 JUD5 X6 Y)		5UM2KM3W7) (BENZALKONIUM -		Basis of S BENZALKONII CHLORIDE	_	4.5 mg
Inactive Ingredien	ıts					
		Ingredient Name			Stre	ngth
WATER (UNII: 059QF0F						
GLYCERIN (UNII: PDC6		ATHON				
PHENO XYETHANOL (U						
PROPYLENE GLYCOL						
ALOE VERA LEAF (UN						
,		,				
Packaging						- 15
# Item Code		Package Description	Marketii	ng Start Date	Marketin	g End Date
1 NDC:50563-355-01 2	0 in 1 PACKET;	Type 1: Convenience Kit of Co-Package				
Marketing Info	rmation					
Marketing Category		on Number or Monograph Citation	Marketi	ng Start Date	Marketin	g End Date
OTC monograph not fina	nl part333A		10/20/202	_		
Part 2 of 3						

BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES PEPPERMINT

benzalkonium chloride solution

Product Information	
Item Code (Source)	NDC:50563-356
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	4.5 mg

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
PHENO XYETHANO L (UNII: HIE492ZZ3T)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			

ı	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:50563-356-01	20 in 1 PACKET; Type 1: Convenience Kit of Co-Package		

Marketing Inform	mation		
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 ANTIBACTERIAL HAND WIPES VANILLA MINT

benzalkonium chloride solution

Product Information	
Item Code (Source)	NDC:50563-357
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6JUD5X6 Y)	BENZALKONIUM CHLORIDE	4.5 mg

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GLYCERIN (UNII: PDC6 A3C0 OX)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
PHENO XYETHANO L (UNII: HIE492ZZ3T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				

ı	Packaging					
ı	# Ite	n Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:50	563-357-01 20 in 1 PA	CKET; Type 1: Convenience Kit of Co-Pa	ckage		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
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(50563-358)				

Revised: 10/2020 ENCHANTE ACCESSORIES INC.