BEAUTY CONCEPTS ANTIBACTERIAL HAND WIPES COCONUT VANILLA HONEY ALMOND SUGAR 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.

50563-351/352/353/354 G0XABW01

beauty concepts ANTIBACTERIAL HAND WIPES Coconut Vannilla

beauty concepts ANTIBACTERIAL HAND WIPES Coconut Vannilla

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

beauty concepts ANTIBACTERIAL HAND WIPES Honey Almond

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Active Ingredient

Benzalkonium Chloride 0.1% Purpose: Antibacterial

Uses:

■ To decrease bacteria on hands

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beauty concepts ANTIBACTERIAL HAND WIPES Sugar Berry

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Purpose

Antibacterial

Uses

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Warnings

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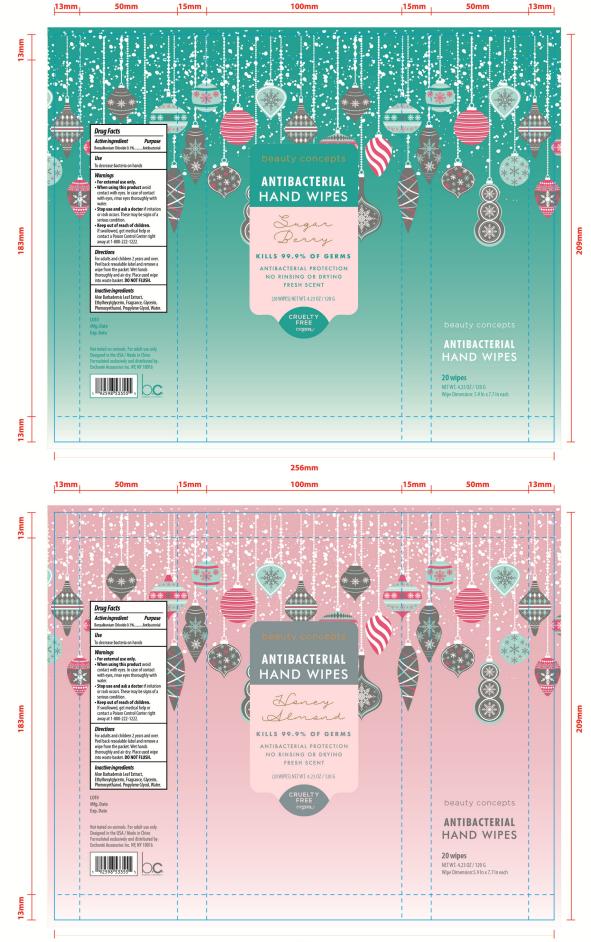
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BEAUTY CONCEPTS ANTIBACTERIAL HAND WIPES COCONUT VANILLA HONEY ALMOND SUGAR BERRY

benzalkonium chloride kit

Dro	duct	Information	
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:50563-354

Packaging

	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:50563-354-01	1 in 1 KIT	10/20/2020	

Quantity of Parts

Quality of Lates				
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

BEAUTY CONCEPTS ANTIBACTERIAL HAND WIPES COCONUT VANILLA

benzalkonium chloride solution

Product Information

Item Code (Source)	NDC:50563-351
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

WATER (UNII: 059QF0KO0R) GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:50563-351-01	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

BEAUTY CONCEPTS ANTIBACTERIAL HAND WIPES HONEY ALMOND

benzalkonium chloride solution

Product Information	
Item Code (Source)	NDC:50563-352
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: PDC6A3C0OX)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				

Pa	ckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 N	IDC:50563-352-01	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

BEAUTY CONCEPTS ANTIBACTERIAL HAND WIPES SUGAR BERRY

benzalkonium chloride solution

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Pro	duct	Inforn	nation
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Item Code (Source) NDC:50563-353

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength	
(BENZALKONIUM CHLORIDE	4.5 mg	

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENO XYETHANO L (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	

Packaging

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I	1 NDC:50563-353-01	20 in 1 PACKET; Type 1: Convenience Kit of Co-Package		

Marketing Information

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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	J

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment				
Name	Address	ID/FEI	Business Operations	
Zhejiang Ruolin Hygienic Products Co., Ltd.		415426870	manufacture(50563-354)	

Revised: 10/2020 ENCHANTE ACCESSORIES INC.