BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES UNSCENTED- benzalkonium chloride solution

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.

50563-343_G1ABCW07

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 eyes thoroughly with water

Stop use and ask a doctor if 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

For adults and children two years and over

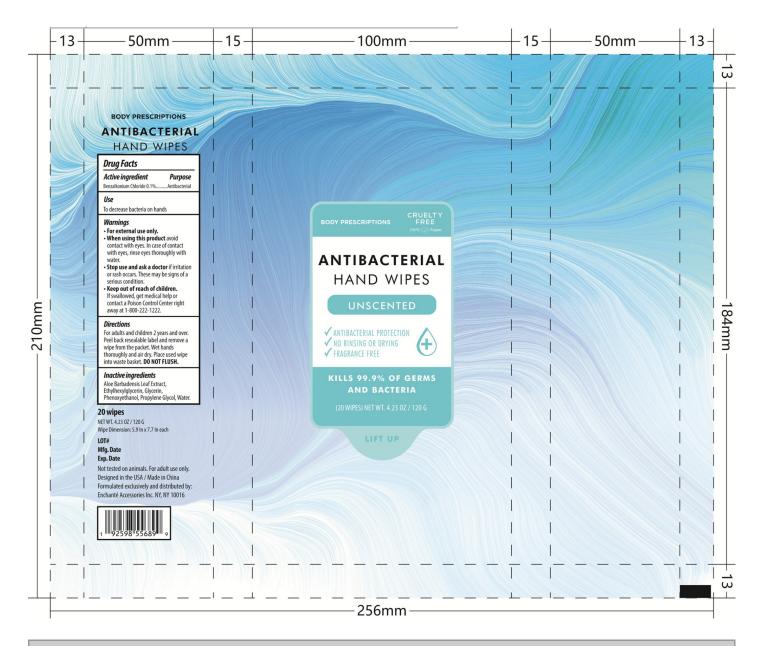
Peel over reusable label and remove a wipe from the packet.

Wet hands thoroughly and air dry.

Place used wipes in to waste basket. Do not flush.

Inactive ingredients

Aloe Barbadensis Leaf Extract, Ethylhexylglycerin, Fragrance, Glycerin, Phenoxyethanol, Propylene Glycol, Rubus Idaeus (Raspberry) Fruit Extract, Water



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benzalkonium chloride solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-343	
Route of Administration	TOPICAL			

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

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		

ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0 X)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50563-343-01	20 in 1 PACKET; Type 0: Not a Combination Product	10/23/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/23/2020	

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment				
Name	Address	ID/FEI	Business Operations	
Zhejiang Ruolin Hygienic Products Co., Ltd.		415426870	manufacture(50563-343)	

Revised: 10/2020 ENCHANTE ACCESSORIES INC.