

BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES WINTER MINT- 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.

50563-367_G0XABW05

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

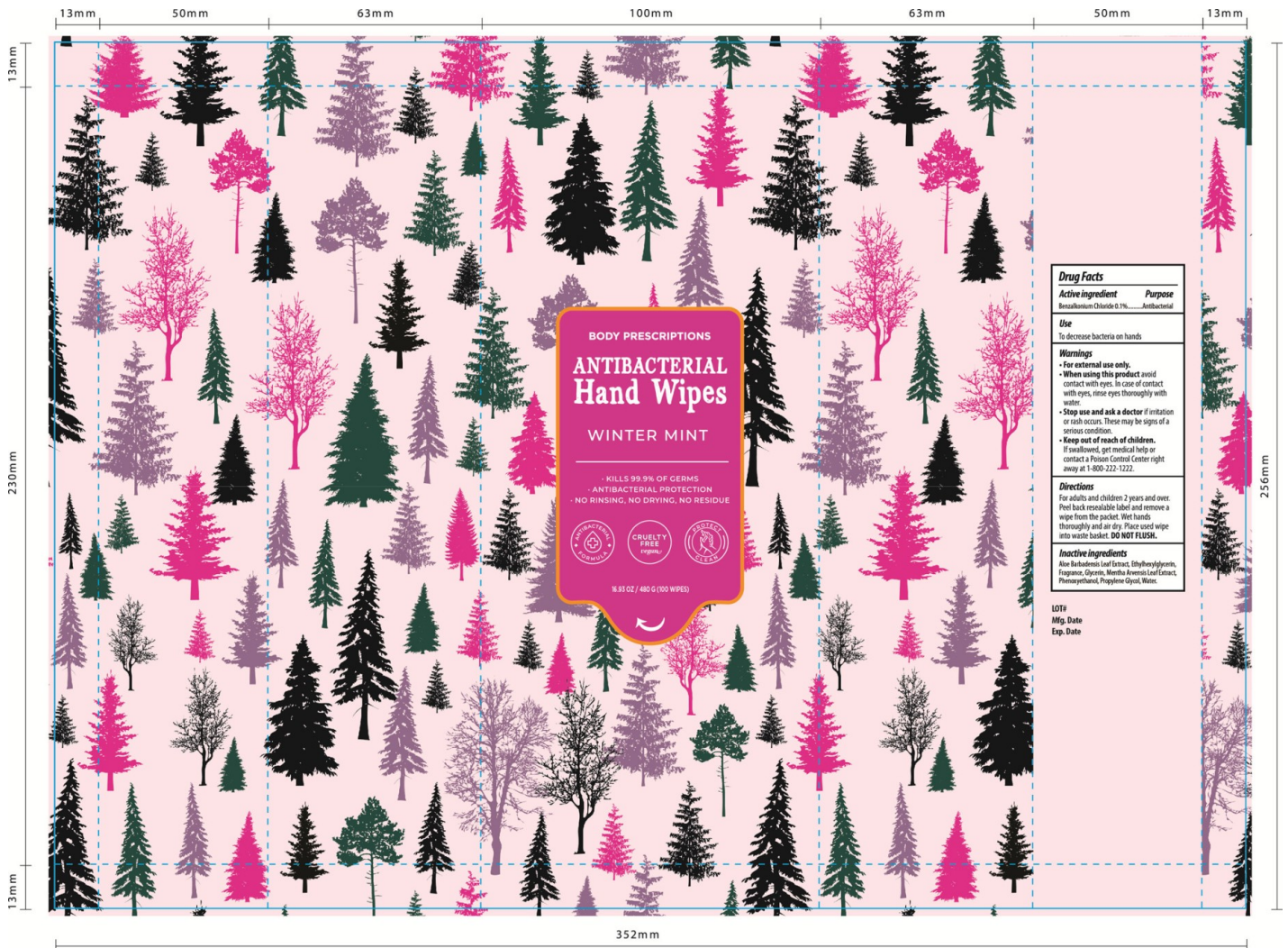
Peel over reusable label and remove a wipe from the packet.

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, Mentha Arvensis Leaf Extract, Phenoxyethanol, Propylene Glycol, Water



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benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-367
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	3.6 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
MENTHA ARVENSIS LEAF (UNII: A4IWO4DDZ9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-367-01	100 in 1 PACKET; Type 0: Not a Combination Product	10/20/2020	

Marketing Information

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(50563-367)

Revised: 10/2020

ENCHANTE ACCESSORIES INC.