

**BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES COCONUT VANILLA-
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.

G0ABCW11

Active Ingredient

Benzalkonium Chloride 0.1%

Purpose

Antibacterial

Use

- To decrease bacteria on hands

WARNINGS

For external use only

Stop Use

Do not use if you are allergic to any ingredients listed

Discontinue use if irritation or redness occur. Consult a doctor if condition lasts for more than 72 hours

Do not get into eyes. Rinse thoroughly with water if contact occurs

keep out of reach of children

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Directions

For adults and children two years and over

Peel back 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

Water, Glycerin, Ethylhexylglycerin, Vanilla Planifolia Fruit Extract, Cocos Nucifera (Coconut) Oil, Phenoxyethanol, Propylene Glycol, Fragrance



BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES COCONUT VANILLA			
benzalkonium chloride solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-243
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)	
VANILLA PLANIFOLIA FLOWER (UNII: 33NF0M2062)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
COCONUT OIL (UNII: Q9L0O73W7L)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-243-01	3 in 1 PACKAGE	08/19/2020	
1		20 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/19/2020	

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Ruolin Hygienic Products Co., Ltd.		415426870	manufacture(50563-243)

Revised: 8/2020

ENCHANTE ACCESSORIES INC.