ANTIBACTERIAL HAND WIPES- benzalkonium chloride cloth Orange (Fujian) Sanitary Products Co., Ltd.

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.

81614-015-20 81614-015-50 Antibacterial Hand Wipes Benzalkonium Chloride

Active Ingredient(s)

BENZALKONIUM CHLORIDE 0.15% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Antibacterial Hand Wipes

Use

USES: Single use wipes to cleanse hands and help prevent the spread of bacteria.

Warnings

- For external use only.
- Do not replace wipes used for medical procedures.
- These wipes are meant for general cleansing.
- Flammable. Keep away fire or sources of heat.
- Avoid contact with eyes.
- If eyes contact occurs, flush eyes with water.
- Store at room temperature 59 °F□15°C□-86 °F□30°C□.

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. 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.

If irritation and redness develop. If condition continues, consult your health care practitoner.

- Keep out of reach of children.
- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

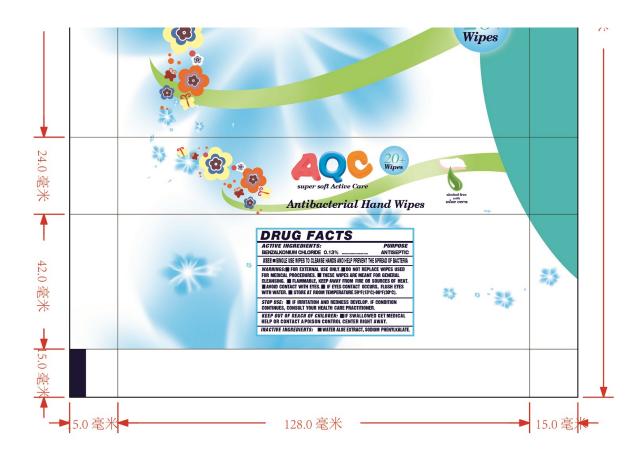
WATER, ALOE EXTRACT, SODIUM PHENYLKALATE

Package Label - Principal Display Panel

20 cloth NDC: 81614-015-20

配专兰版一支

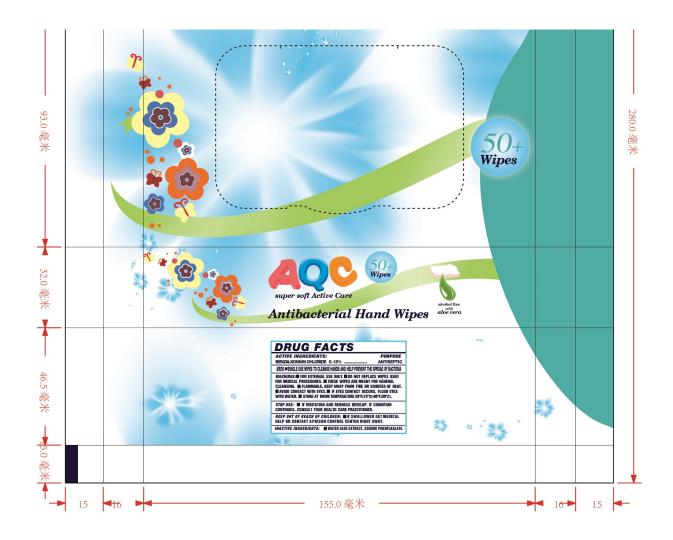




50 cloth NDC: 81614-015-50

配专兰版一支





ANTIBACTERIAL HAND WIPES

benzalkonium chloride cloth

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81614-015	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
ALOE (UNII: V5VD430YW9)			
SODIUM PHENYLLACTATE (UNII: KYI2U2BS89)			

WATER	(UNII:	059QF0KO0R	.)
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P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:81614-015- 20	20 in 1 PACKAGE	02/17/2021		
1		5.75 g in 1 PATCH; Type 0: Not a Combination Product			
2	NDC:81614-015- 50	50 in 1 PACKAGE	02/17/2021		
2		6 g in 1 PATCH; 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	02/17/2021	

Labeler - Orange (Fujian) Sanitary Products Co., Ltd. (715236216)

Registrant - Orange (Fujian) Sanitary Products Co., Ltd. (715236216)

Establishment				
Name	Address	ID/FEI	Business Operations	
Orange (Fujian) Sanitary Products Co., Ltd.		715236216	manufacture(81614-015)	

Revised: 2/2021 Orange (Fujian) Sanitary Products Co., Ltd.