

ANTISEPTIC WIPES- benzalkonium chloride cloth
Shandong Liaocheng Chaoyue Daily Necessities 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.

sanitizing antiseptic wipes

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. BENZALKONIUM CHLORIDE (0.13% v/v).
- b. CETYLPYRIDINIUM CHLORIDE(0.02% v/v).
- c. PROPYLENE GLYCOL(0.1% v/v).
- d. PHENOXYETHANOL(0.02% v/v).
- e. EDETATE DISODIUM(0.001% v/v).
- f. ANHYDROUS CITRIC ACID(0.001% v/v).
- g. ALOE VERA LEAF(0.01% v/v).
- h. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

BENZALKONIUM CHLORIDE 0.13% v/v.

Purpose

Antiseptic

Use

Decreases bacteria on the skin

Warnings

For external use only. Flammable. Keep away from heat or flame

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.

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.

Directions

- Open package. Pull wipe. Close package to remain moisture
- Wet hands thoroughly with product. Allow to dry without rinsing

Other information

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

Inactive ingredients

CETYLPYRIDINIUM CHLORIDE(0.02% v/v).

PROPYLENE GLYCOL(0.1% v/v).

PHENOXYETHANOL(0.02% v/v).

EDETATE DISODIUM(0.001% v/v).

ANHYDROUS CITRIC ACID(0.001% v/v).

ALOE VERA LEAF(0.01% v/v).

FRAGRANCE

WATER

Package Label - Principal Display Panel

77412-012-01



ANTISEPTIC WIPES

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77412-012
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 in 100

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.01
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	0.001
CETYLPIRIDINIUM CHLORIDE ANHYDROUS (UNII: 6BR7T22E2S)	0.02
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.1
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.02
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	0.001

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77412-012-01	100 in 1 PACKAGE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77412-012-02	10 in 1 PACKAGE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Shandong Liao Cheng Chaoyue Daily Necessities Co., Ltd. (550196375)

Establishment

Name	Address	ID/FEI	Business Operations
Shandong Liao Cheng Chaoyue Daily Necessities Co., Ltd.		550196375	manufacture(77412-012)

Revised: 2/2021

Shandong Liao Cheng Chaoyue Daily Necessities Co., Ltd.