# HAND SANITIZER WIPES- alcohol 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.

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## **Antiseptic Hand Sanitizer 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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (75%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Purified 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)

Alcohol 75% v/v. Purpose: Antiseptic

#### **Purpose**

Antiseptic Cloth Wipes

#### Use

for hand sanitizing to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

#### **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.

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#### **Directions**

- Apply to hands and wipe to cover skin completely. 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**

purified water

## Package Label - Principal Display Panel

100 pcs NDC: 77412-011-01





## HAND SANITIZER WIPES

alcohol cloth

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77412-011	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 in 100

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging						
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>			
1 NDC:77412-011-01	100 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020				
Marketing Information						
Marketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not f	nal part333A	03/30/2020				

## Labeler - Shandong Liaocheng Chaoyue Daily Necessities Co., Ltd. (550196375)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Shandong Liaocheng Chaoyue Daily Necessities Co., Ltd.		550196375	manufacture(77412-011)	

Revised: 9/2020 Shandong Liaocheng Chaoyue Daily Necessities Co., Ltd.