ALCOHOL 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.

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) (80%, 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. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. 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)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer 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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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

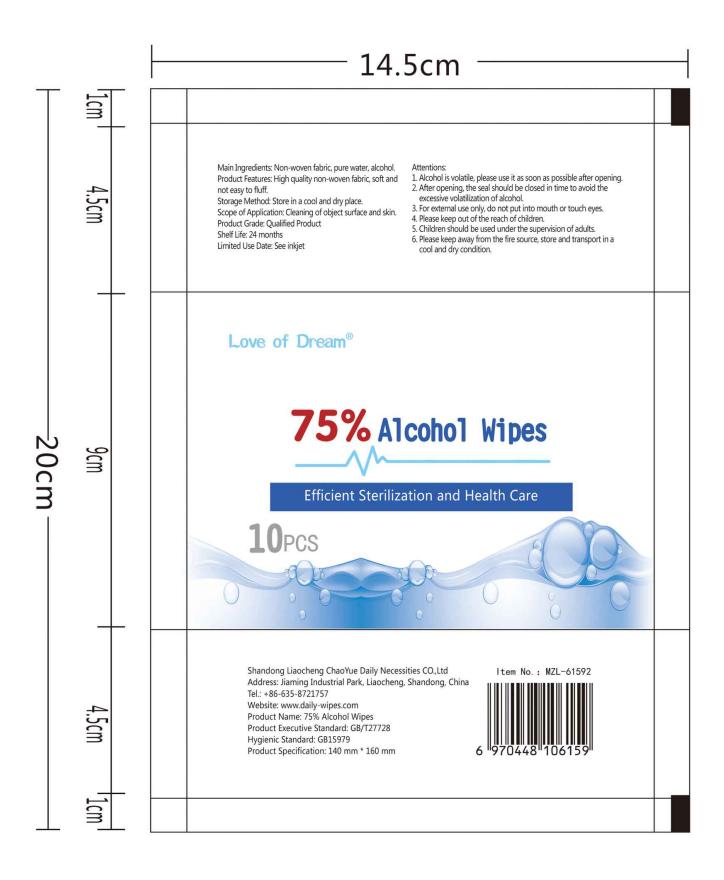
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

77412-206-01



ALCOHOL MI	DEC							
ALCOHOL WI alcohol cloth	PES							
Product Informat	ion							
Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:774	NDC:77412-206		
Route of Administra	tion	TOPICAL						
Active Ingredient	Active Moi	ety						
Ingredient Name					Basis of St	rength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)				1	ALCOHOL		75 in 100	
Inactive Ingredie	nts							
Ingredient Name					Strength			
WATER (UNII: 059QF0KO0R)								
Packaging								
# Item Code	P	Package Description	Μ	Marketing Start Date		Marketi	Marketing End Date	
1 NDC:77412-206-01	10 in 1 BAG; Ty	ype 0: Not a Combination Produc	t 03/	03/30/2020				
Marketing Information								
Marketing Categor	y Application Number or Monograph Citation		itation	Marketing Start Date		e Marke	Marketing End Date	
OTC monograph not final part333A				03/30/2020				

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

Establishment

Name	Address	ID/FEI	Business Operations
Shandong Liaocheng Chaoyue Daily Necessities Co., Ltd.		550196375	manufacture(77412-206)

Revised: 7/2020

Shandong Liaocheng Chaoyue Daily Necessities Co., Ltd.