

ALCOHOL HAND SANITIZING WIPES- alcohol cloth
CHAOZHOU CECILIA TECHNOLOGY 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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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

80 PCS NDC: 80294-003-01

成品尺寸待定

PANTONE 3935 U

PANTONE 7717 C

PANTONE 325 U

PANTONE 803 C

PANTONE Green U

PANTONE 116 C



HAND SANITIZING WIPES		Safe & Refreshing									
<table border="1"> <thead> <tr> <th colspan="3">Drug Facts</th> </tr> </thead> <tbody> <tr> <td> Active ingredients Benzalkonium Chloride 0.13% Ethyl Alcohol _____ </td> <td> Purpose _____ Antimicrobial _____ Antimicrobial </td> <td> Directions To clean: Use fresh wipe to clean and allow to dry naturally, repeat for better results. Children should be supervised when using this product. </td> </tr> <tr> <td> Warnings For external use only. When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. If irritation persists, seek medical attention. Stop use if irritation or perioral rash occurs and seek medical attention. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away. </td> <td> USE Decrease bacteria on the skin. </td> <td> Inactive ingredients Water (Aqua), Propylene Glycol, Glycerin, Polyaminopropyl Biguanide, Panthenol, PEG-40 Hydrogenated Castor Oil, Diethyl Dimethyl Ammonium Chloride, Allantoin, Vitamin E Acetate, PEG-12 Dimethicone, Lemon Extract. </td> </tr> </tbody> </table>			Drug Facts			Active ingredients Benzalkonium Chloride 0.13% Ethyl Alcohol _____	Purpose _____ Antimicrobial _____ Antimicrobial	Directions To clean: Use fresh wipe to clean and allow to dry naturally, repeat for better results. Children should be supervised when using this product.	Warnings For external use only. When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. If irritation persists, seek medical attention. Stop use if irritation or perioral rash occurs and seek medical attention. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	USE Decrease bacteria on the skin.	Inactive ingredients Water (Aqua), Propylene Glycol, Glycerin, Polyaminopropyl Biguanide, Panthenol, PEG-40 Hydrogenated Castor Oil, Diethyl Dimethyl Ammonium Chloride, Allantoin, Vitamin E Acetate, PEG-12 Dimethicone, Lemon Extract.
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alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80294-003
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125
WATER (UNII: 059QF0KO0R)	23.425

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80294-003-01	80 in 1 BAG; 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 - CHAOZHOU CECILIA TECHNOLOGY CO., LTD. (554536556)

Revised: 12/2020

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