WE CARE SANITIZING WIPE- alcohol cloth Guangzhou Baihua 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.

Purpose

Antiseptic, WE CARE Sanitizing Wipes

Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

This is a sanitizing wipe 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 sanitizing wipe 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. 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.

Use

Alcohol Sanitizing Wipes to help reduce bacteria on skin. 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.

Stop use and ask a doctor if irritation occurs. This may be sign of a serious condition.

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

Directions

- Thoroughly wipe hands, fingers and wrists.
- Supervise children under 6 years of age when using this product.

Other information

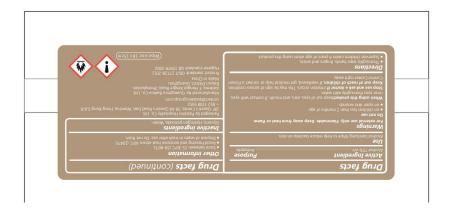
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
- Dispose of wipes in trash after use. Do not flush.

Inactive ingredients

glycerin, hydrogen peroxide, RO pure water

Package Label - Principal Display Panel

WE CARE wipe 1pc NDC: 77665-103-01





50 wipes NDC: 77665-101-01



WE CARE SANITIZING WIPE

alcohol cloth

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77665-103

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	--------------------------	----------

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M) ALCOHOL 75 mL in 100 mL

Inactive Ingredients

mactive myredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL	
WATER (UNII: 059QF0KO0R)		

Packaging

1	- 			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:77665-103-	1 mL in 1 PACKAGE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	08/03/2020		

Labeler - Guangzhou Baihua Co., Ltd. (545015588)

Registrant - Guangzhou Baihua Co., Ltd. (545015588)

Establishment					
Name	Address	ID/FEI	Business Operations		
Guangzhou Baihua Co., Ltd		545015588	manufacture(77665-103)		

Revised: 12/2021 Guangzhou Baihua Co., Ltd.