ALCOHOL SANITIZING WIPES- 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, Alcohol 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.

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Directions

- Wipe hands thoroughly with product.
- Supervise children under 6 years of age when using this product.

Other information

- Tightly seal sticker and close lid between uses to prevent wipes from drying.
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
- Dispose of wipes in trash after use. Do not flush.

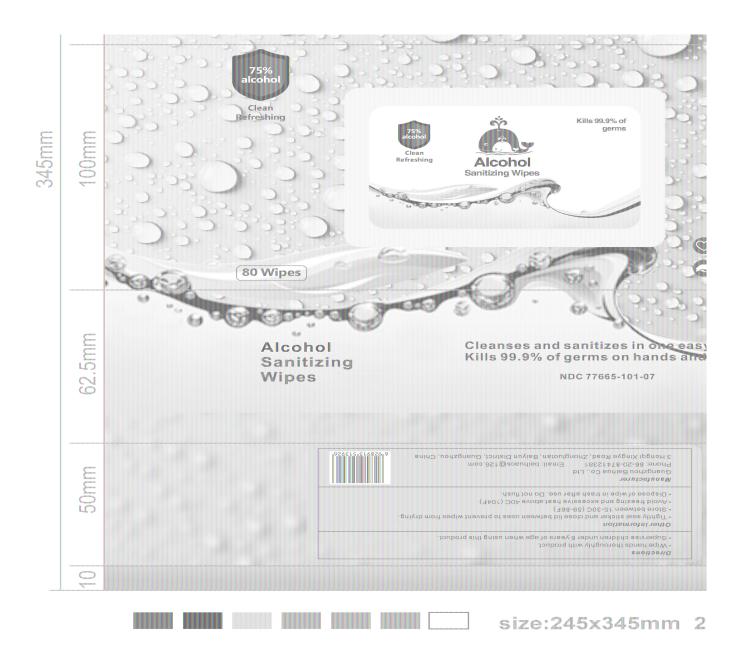
Inactive ingredients

glycerin, hydrogen peroxide, RO pure water

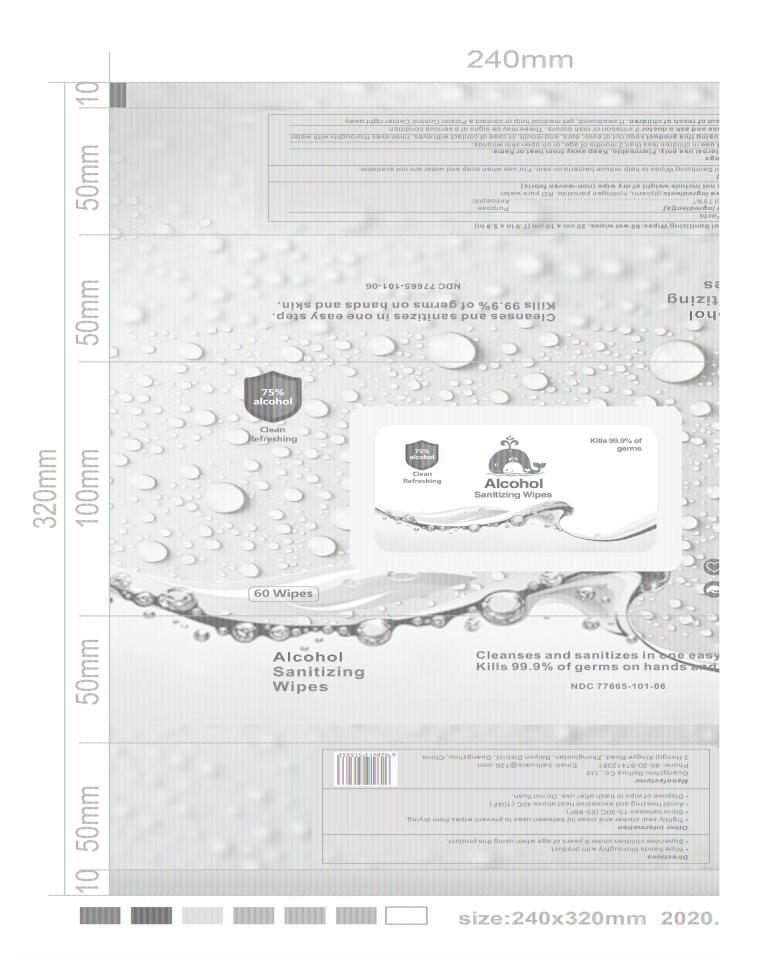
Package Label - Principal Display Panel

80 wipes b NDC: 77665-101-07

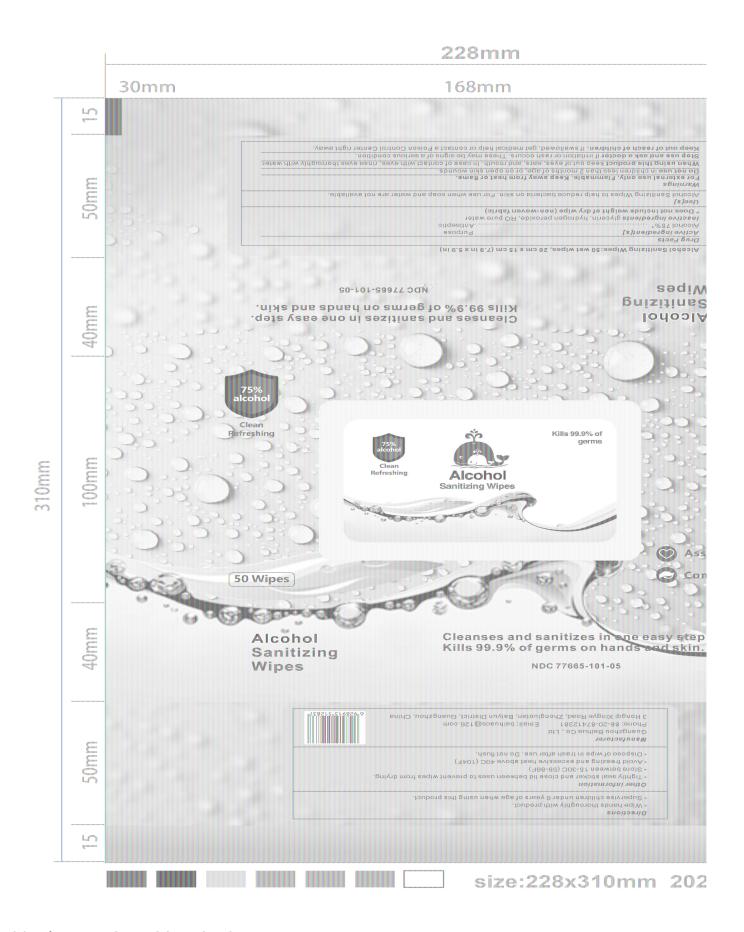




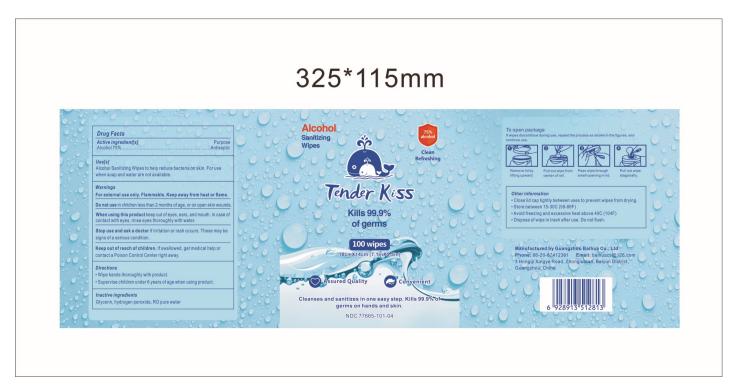
60 wipes b NDC: 77665-101-06



50 wipes b NDC: 77665-101-05



100 wipes NDC: 77665-101-04



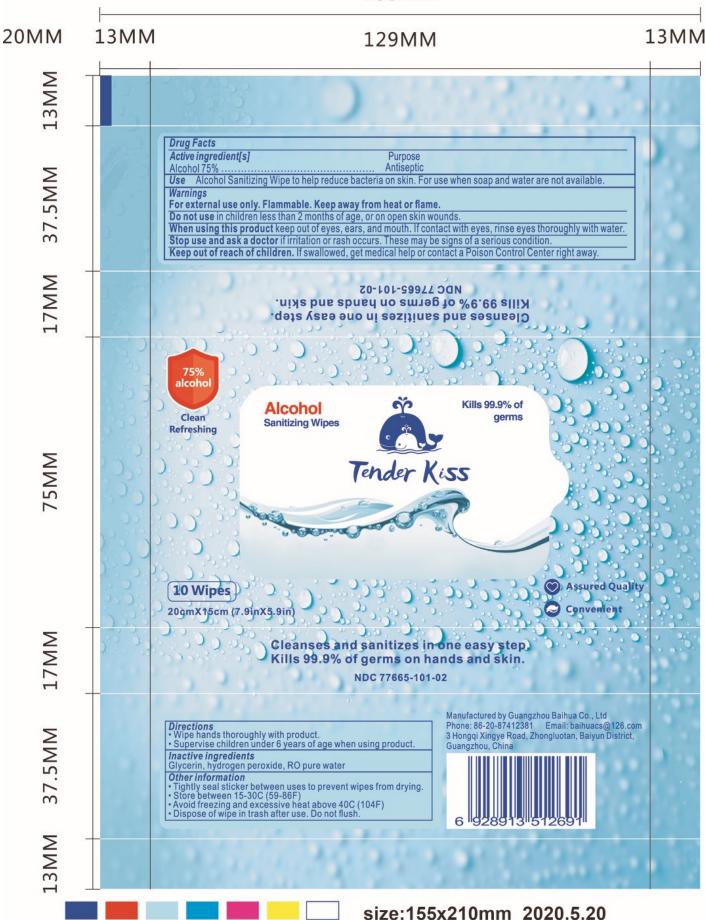
1 wipe NDC: 77665-101-03

120mm



10 wipes NDC: 77665-101-02





50 wipes NDC: 77665-101-01



ALCOHOL SANITIZING WIPES

alcohol cloth

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77665-101
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			
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				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77665- 101-01	50 mL in 1 PACKAGE; Type 0: Not a Combination Product	05/13/2020	
2	NDC:77665- 101-02	10 mL in 1 PACKAGE; Type 0: Not a Combination Product	05/21/2020	
3	NDC:77665- 101-03	1 mL in 1 PACKAGE; Type 0: Not a Combination Product	05/21/2020	
4	NDC:77665- 101-04	100 mL in 1 CANISTER; Type 0: Not a Combination Product	05/30/2020	
5	NDC:77665- 101-05	50 mL in 1 PACKAGE; Type 0: Not a Combination Product	06/02/2020	
6	NDC:77665- 101-06	60 mL in 1 PACKAGE; Type 0: Not a Combination Product	06/18/2020	
7	NDC:77665- 101-07	80 mL in 1 PACKAGE; Type 0: Not a Combination Product	06/18/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/13/2020	

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(77665-101)

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