# BESAFE SANITIZING WIPES- alcohol cloth BeSafe Industries, LLC

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, BeSafe Sanitizing Wipes

### **Active Ingredient(s)**

Ethyl Alcohol 75%. Purpose: Antimicrobial

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

Helps reduce bacteria on the skin.

## **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 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.

#### **Directions**

- Use one wipe per object to avoid cross contamination.
- Supervise children under 6 years of age when using this product to avoid swallowing.

#### Other information

- Dispose of wipes in trash after use. Do not flush.
- Tightly close lid between uses to retain moisture.
- Do not reuse or refill this empty container.

## **Inactive ingredients**

glycerin, hydrogen peroxide, RO pure water

## Package Label - Principal Display Panel

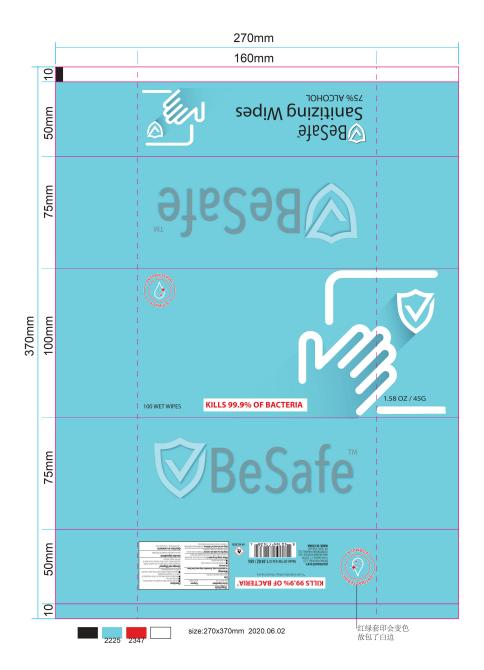
BeSafe 100 wipes Refill NDC: 77693-101-05



BeSafe 100 wipes Canister NDC: 77693-101-04



BeSafe 100 wipes NDC: 77693-101-03



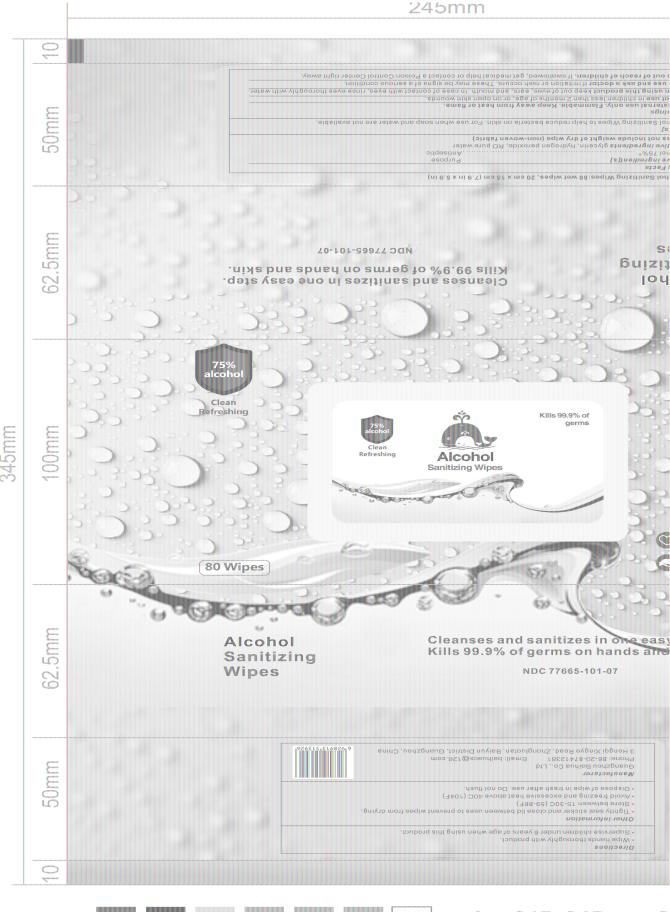
BeSafe 60 wipes NDC: 77693-101-02



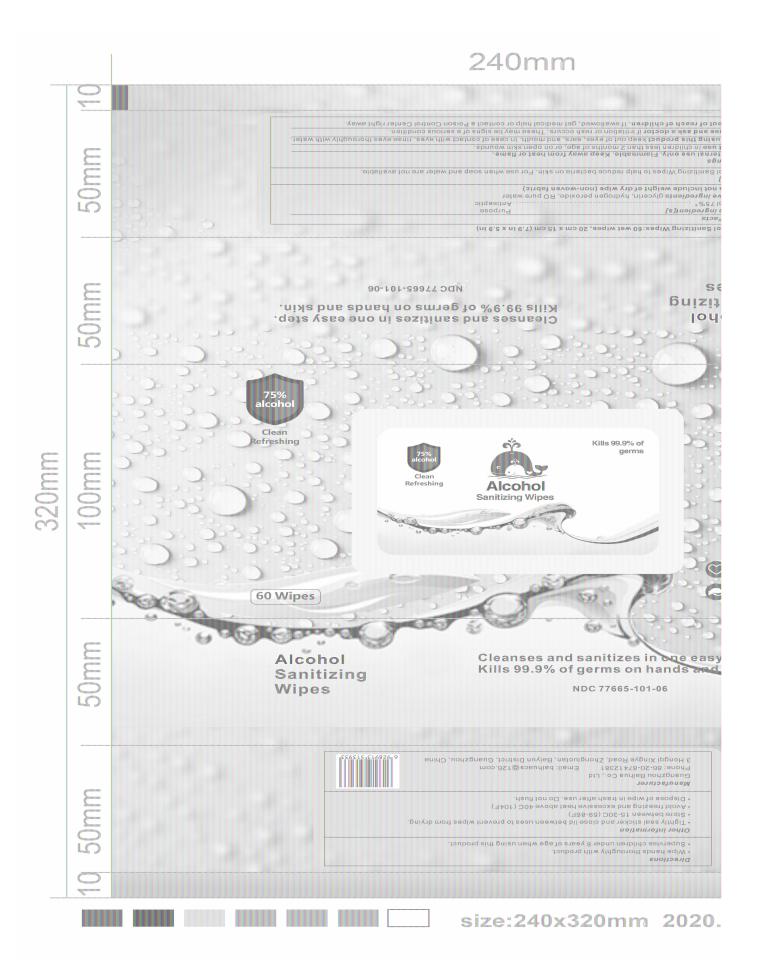
BeSafe 20 wipes NDC: 77693-101-01

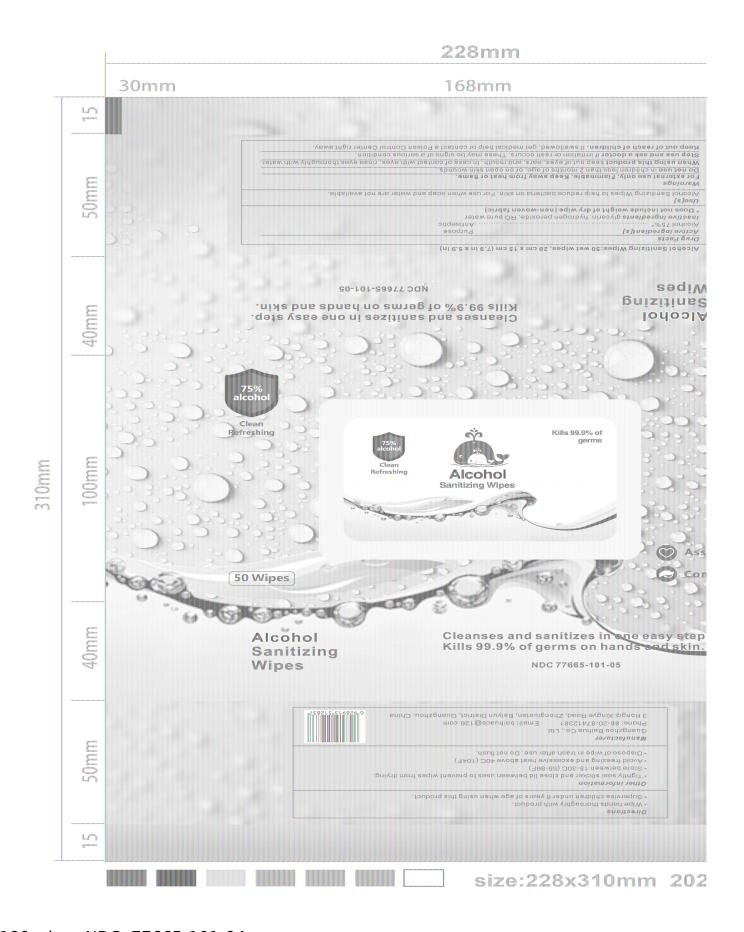


80 wipes b NDC: 77665-101-07

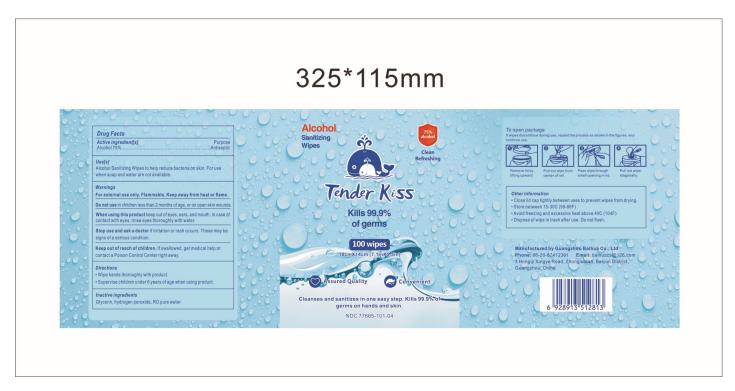


60 wipes b NDC: 77665-101-06





100 wipes NDC: 77665-101-04



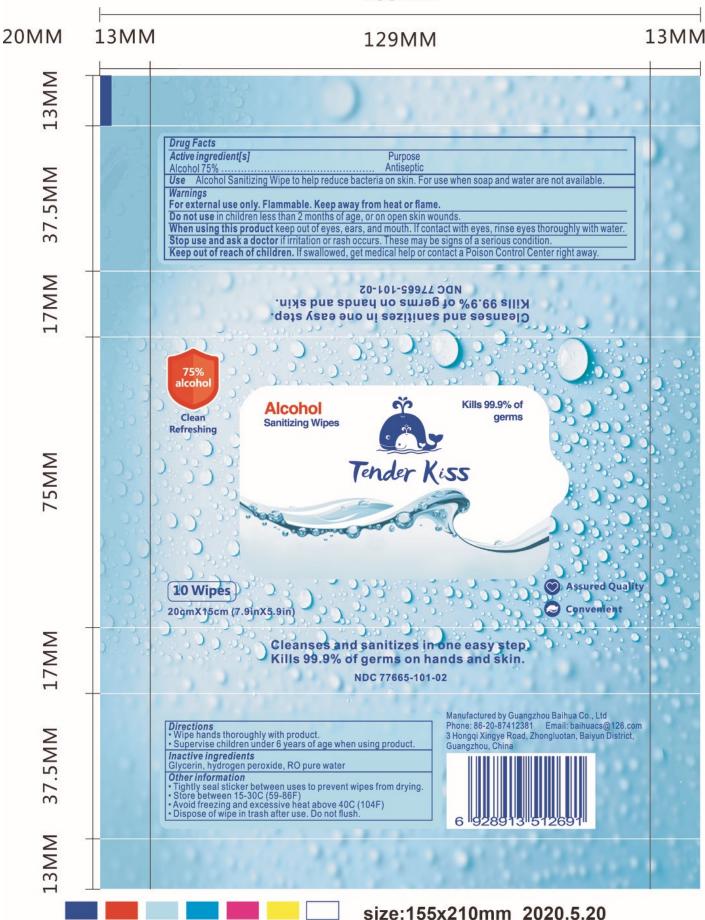
1 wipe NDC: 77665-101-03

## 120mm



10 wipes NDC: 77665-101-02





50 wipes NDC: 77665-101-01



## **BESAFE SANITIZING WIPES**

alcohol cloth

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77693-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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:77693- 101-01	20 mL in 1 PACKAGE; Type 0: Not a Combination Product	07/16/2020	
2	NDC:77693- 101-02	60 mL in 1 PACKAGE; Type 0: Not a Combination Product	07/16/2020	
3	NDC:77693- 101-03	100 mL in 1 PACKAGE; Type 0: Not a Combination Product	07/16/2020	
4	NDC:77693- 101-04	100 mL in 1 CANISTER; Type 0: Not a Combination Product	07/16/2020	
5	NDC:77693- 101-05	100 mL in 1 BAG; Type 0: Not a Combination Product	07/16/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/16/2020	

## **Labeler -** BeSafe Industries, LLC (117481216)

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

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Guangzhou Baihua Co., Ltd		545015588	manufacture(77693-101)	

Revised: 12/2021 BeSafe Industries, LLC