

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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away.

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

1 wipe NDC: 77665-101-03

120mm

13mm

13mm

15mm

30mm

60mm

30mm

15mm

150mm

Drug Facts

Active ingredient(s)	Purpose
Alcohol 75%	Antiseptic

Use Alcohol Sanitizing Wipe to help reduce bacteria on skin. For use when soap and water are not available.

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Clean Refreshing



Tender Kiss

Kills 99.9% of germs

1 wipe

20cm X 15cm (7.9in X 5.9in)



Convenient



Assured Quality

Cleanses and sanitizes in one easy step. Kills 99.9% of germs on hands and skin.
NDC 77665-101-03

Directions

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

Inactive ingredients
 Glycerin, hydrogen peroxide, RO pure water

Other information

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

Manufactured by Guangzhou Baihua Co., Ltd
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 3 Hongqi Xingye Road, Zhongluotan,
 Baiyun District, Guangzhou, China

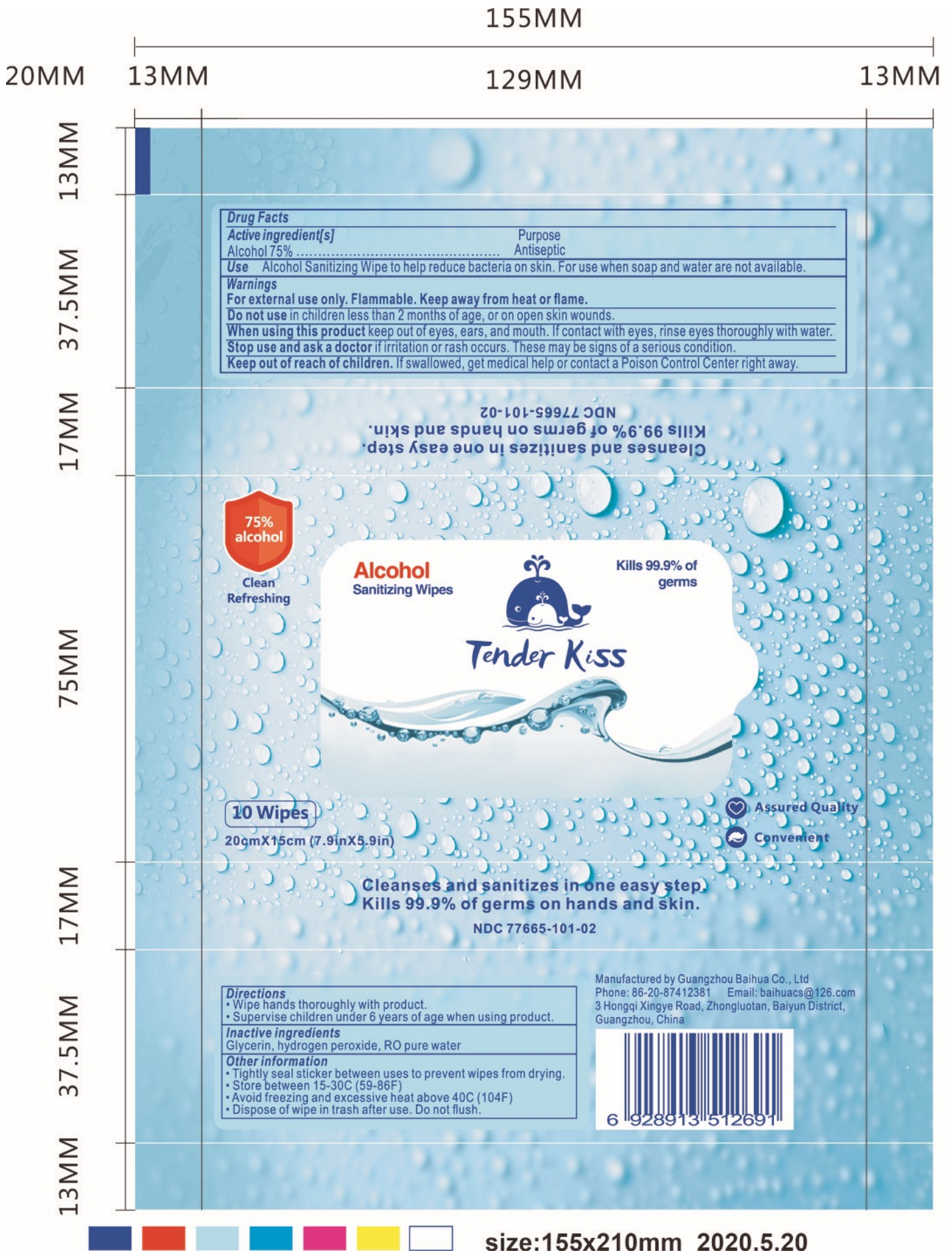


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size:150x120mm 2020.5.20

10 wipes NDC: 77665-101-02



Drug Facts

Active ingredient(s)	Purpose
Alcohol 75%	Antiseptic

Use Alcohol Sanitizing Wipe 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, or on open skin wounds.

When using this product keep out of eyes, ears, and mouth. If 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.

Cleanses and sanitizes in one easy step.
Kills 99.9% of germs on hands and skin.
 NDC 77665-101-02

75% alcohol
 Clean Refreshing



10 Wipes
 20cmX15cm (7.9inX5.9in)

Assured Quality
Convenient

Cleanses and sanitizes in one easy step.
Kills 99.9% of germs on hands and skin.
 NDC 77665-101-02

Directions

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

Inactive ingredients
 Glycerin, hydrogen peroxide, RO pure water

Other information

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

Manufactured by Guangzhou Baihua Co., Ltd
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 Guangzhou, China



size:155x210mm 2020.5.20

20MM

188MM

20MM

13MM

50MM

42MM

100MM

42MM

50MM

13MM

Drug Facts
 Alcohol Sanitizing Wipes: 50 wet wipes, 20 cm x 15 cm (7.9 in x 5.9 in)

Active Ingredient(s)
 Alcohol 75%
 Inactive ingredients glycerin, hydrogen peroxide, 100 pure water

Use(s)
 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, or 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.
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Alcohol Sanitizing Wipes
 Cleanses and sanitizes in one easy step.
 Kills 99.9% of germs on hands and skin.
 NDC 77665-101-01

75% alcohol
 Clean Refreshing



50 Wipes

- 99.9 Highly Effective
- Assured Quality
- Convenient

Alcohol Sanitizing Wipes
 Cleanses and sanitizes in one easy step.
 Kills 99.9% of germs on hands and skin.
 NDC 77665-101-01

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 wipe in trash after use. Do not flush.

Manufacturer
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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: 059QF0K00R)	

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	

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: 5/2020

Guangzhou Baihua Co., Ltd.