

## ANTISEPTIC HAND SANITIZER- hand sanitizer solution

Pretty Well International Limited

*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.*

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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:

- 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.
- Glycerol (1.45% v/v).
- Hydrogen peroxide (0.125% v/v).
- 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

# BLIWELL®

## ANTISEPTIC HAND SANITIZER



Disinfection Sterilization  
Waterless Quick-drying

75%  
Alcohol

100 ML

99.99%  
EFFECTIVE STERILIZATION

### Drug Facts information

#### Instant Hand Sanitizer

Drug Facts	Purpose
<b>Active ingredient</b> Alcohol 80% v/v.....	Antiseptic
<b>Use</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b> <ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor if</b> irritation or rash occurs. These may be signs of a serious condition.	
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<b>Other information</b> <ul style="list-style-type: none"><li>• Store between 15-30 °C (59-86 °F)</li><li>• Avoid freezing and excessive heat above 40 °C (104 °F)</li></ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP.	
<b>Questions?</b> 86-203-1211876	

[Validity period] Two years [Production date] See Outer Packaging  
[Production Batch Number] See Outer Packaging  
Distributed by: Pretty well international limited  
Address: No.765 CongYun Road, Baiyun District, Guangzhou, China  
Postal Code: 510000



### Purpose

Antiseptic, Hand Sanitizer

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### Package Label - Principal Display Panel

100 mL NDC: 78348-128-01

**BLIWELL**®**Drug Facts information****Instant Hand Sanitizer**

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hand sanitizer solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78348-128
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 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:78348-128-01	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/26/2020	

**Labeler** - Pretty Well International Limited (554534349)

**Registrant** - Pretty Well International Limited (554534349)

**Establishment**

Name	Address	ID/FEI	Business Operations
Baicao Shijia Biological Technology (foshan) Co., Ltd		554534366	manufacture(78348-128)

Revised: 5/2020

Pretty Well International Limited