# 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:

- a. 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.
- 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.

# Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

# Purpose

Antiseptic, Hand Sanitizer

<b>BLIWELL</b> <sup>®</sup>		Dru	ig Facts inf	formation
ANTISEPTIC HAND SANITIZER	Disinfection Sterilization Waterless Quick-drying 75% Alcohol	Instant Hand Sanitizer Drug Facts Anise regressions Anise regressi		Pagese
99,99%	500 ML	The foregoing and a set of the set of t		Maste in Chine

## Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. 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

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.



#### Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)



## **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP



Package Label - Principal Display Panel

#### 500 mL NDC: 78348-128-02



ANTISEPTIC	C HAND SA	NITIZER						
hand sanitizer solu	tion							
<b>Product Inform</b>	ation							
Product T ype		HUMAN OTC DRUG	TC DRUG Item Code (Source)			NDC:78348-128		
Route of Administ	ration	TOPICAL						
Active Ingradia	nt/Active Me	io 4.						
Active Ingredie		0						
	_				of Strength	Strength		
ALCOHOL (UNII: 3F	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOH			ALCOHO	DL	80 mL in 100 mL		
Inactive Ingred	ients							
Ingredient Name				Strength				
GLYCERIN (UNII: PI	DC6A3C0OX)				1.45 mL in 100 mL			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL					
WATER (UNII: 059QF0KO0R)								
Packaging								
# Item Code		Package Description		Marketing Start Date		Marketing End Date		
NDC:78348-128- 02 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		05/27/2020						
Marketing Information								
Marketing Categ	ory Applica	tion Number or Monograph Ci	itation N	Aarketin	g Start Date	Marketing End Date		
OTC monograph not	final part333A		0 5/27/20 20					

Labeler - Pretty Well International Limited (554534349)

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

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

Revised: 5/2020

Pretty Well International Limited