# HAND SANITIZER- alcohol liquid BG Products, Inc.

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

#### 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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away.

#### 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

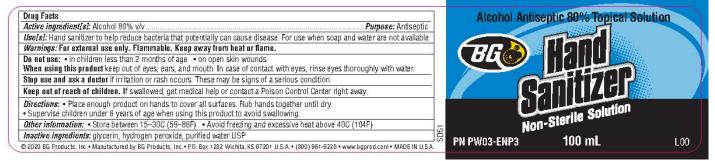
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

# Package Label - Principal Display Panel

#### 100 mL NDC: 74302-100-01



# HAND SANITIZER

alcohol liquid

Product Information							
Product Type	HUMAN OTC DRUG	Item Code	(Source)	NE	DC:74302-100		
Route of Administration	TOPICAL						
Active Ingredient/Active Moiety							
Ingre	dient Name		Basis of Streng	th	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)							
ALCOHOL (UNII: 3K9958V90M) (AL	COHOL - UNII:3K9958V90M)		ALCOHOL		80 mL in 100 mL		
ALCOHOL (UNII: 3K9958V90M) (AL Inactive Ingredients	COHOL - UNII:3K9958V90M)		ALCOHOL		80 mL in 100 mL		
Inactive Ingredients	COHOL - UNII:3K9958V90M) ngredient Name		ALCOHOL		80 mL in 100 mL		
Inactive Ingredients			ALCOHOL 1.45 mL in	St	rength		
Inactive Ingredients	ngredient Name			<b>St</b> 100 m	<b>rength</b> L		
Inactive Ingredients In GLYCERIN (UNII: PDC6A3C0OX)	ngredient Name		1.45 mL in	<b>St</b> 100 m	<b>rength</b> L		
Inactive Ingredients In GLYCERIN (UNII: PDC6A3C0OX) HYDROGEN PEROXIDE (UNII: BBX0	ngredient Name		1.45 mL in	<b>St</b> 100 m	<b>rength</b> L		

#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1		100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/10/2020				
Marketing Information							
	Marketing Catego	ory Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
0'	TC monograph not f	inal part333A (	04/10/2020				

Labeler - BG Products, Inc. (065736522)

**Registrant -** BG Proudcts, Inc. (078750501)

Revised: 5/2020

BG Products, Inc.