

**HAND SANITIZER- alcohol liquid**  
**BioBx 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.*

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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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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right

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

The image shows the principal display panel of a hand sanitizer refill package. At the top, a blue banner contains the text "HAND SANITIZER REFILL" repeated three times. Below this, the "bioBX" logo is visible, featuring a stylized orange cross and blue water droplets. The main text reads "ADVANCED Hand Sanitizer" in large blue letters. Below this, an orange banner states "KILLS 99.99% OF ILLNESS CAUSING GERMS". Underneath, it says "CREATED BY HEALTHCARE PROFESSIONALS". At the bottom left, the word "Refill" is written in orange, with "16.9 FL OZ (500mL)" below it. On the right side, there is a table with two columns: "Active Ingredient" and "Purpose". The active ingredient is "Ethyl alcohol 70% v/v" and the purpose is "Antiseptic". Below the table, there are sections for "Uses", "Warnings", "Directions", "Other information", and "Inactive Ingredients". The "Inactive Ingredients" list includes Water, Carbomer, Aloe Barbadosensis Leaf Juice, Disopropylamine, Glycerin, Isopropyl Myristate, and Citrus Fragrance. At the bottom right, there is a barcode with the number "8 50017 73501 9" and a small American flag logo with the text "PROUDLY MADE IN THE USA".

**HAND SANITIZER REFILL HAND SANITIZER REFILL HAND SANITIZER REFILL**

bioBX

**ADVANCED Hand Sanitizer**

**KILLS 99.99% OF ILLNESS CAUSING GERMS**

CREATED BY HEALTHCARE PROFESSIONALS

**Refill**

16.9 FL OZ (500mL)

Active Ingredient	Purpose
Ethyl alcohol 70% v/v	Antiseptic

**Uses**  
Hand Sanitizer to help reduce bacteria on the skin that could cause disease.  
Recommended repeated use after touching hard surfaces.

**Warnings**  
Flammable. Keep away from fire or flame.  
For external use only.  
When using this product do not use in or near eyes or mouth.  
In case of contact, rinse eyes thoroughly with water.  
Stop use and ask a doctor if irritation or rash appears and lasts.  
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

**Directions:**  
- Place a generous amount on your palm to thoroughly cover your hands.  
- Rub hands briskly until dry.  
- Children under 6 years of age should be supervised when using this product.

**Other information:**  
Store below 110F (43C)- May discolor certain fabrics or surfaces

**Inactive Ingredients:**  
Water, Carbomer, Aloe Barbadosensis Leaf Juice, Disopropylamine, Glycerin, Isopropyl Myristate, Citrus Fragrance

Manufactured by Monarch PCM  
7333 Jack Newell Blvd, North Suite 100  
Forth Worth, TX 76118

**NDC - 70154-175-16**

PROUDLY MADE IN THE USA

8 50017 73501 9

Designed by bioBX LTD  
<https://biobx.com>

060 mL NDC: 79187-080-02

# HAND SANITIZER

alcohol liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79187-080
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

## Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:79187-080-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	03/30/2020	

**Labeler** - BioBx LTD (117541478)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
BioBx LTD		117541478	manufacture(79187-080)

Revised: 6/2020

BioBx LTD