

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.

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", and "Other information". The "Uses" section states that the product helps reduce bacteria on the skin that can cause disease and is recommended for repeated use after touching hard surfaces. The "Warnings" section notes that the product is flammable, should be kept away from fire, and is for external use only. It also advises not to use it near eyes or mouth and to rinse eyes with water if contact occurs. The "Directions" section instructs to place a generous amount on the palm, cover the hands, and rub until dry, with a note to supervise children under 6 years of age. The "Other information" section states to store the product below 110F (43C) and that it may discolor certain fabrics or surfaces. Below the "Other information" section, there is a list of "Inactive Ingredients": Water, Carbomer, Aloe Barbadensis Leaf Juice, Disopropylamine, Glycerin, Isopropyl Myristate, Citrus Fragrance. The manufacturer information is provided: "Manufactured by Monarch PCM, 7333 Jack Newell Blvd, North Suite 100, Forth Worth, TX 76118". The NDC number is "70154-175-16". At the bottom right, there is a barcode with the number "8 50017 73501 9" and a "PROUDLY MADE IN THE USA" logo.

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 can 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 Barbadensis 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>

240 mL NDC: 79187-080-08

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79187-080
Route of Administration	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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79187-080-08	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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

Labeler - BioBx LTD (117541478)

Establishment

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

Revised: 6/2020

BioBx LTD