BACIBAN HAND SANITIZER- alcohol liquid Bonaventura Industries 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.

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)

Active ingredient

Ethyl Alcohol 80% Antiseptic, Hand Sanitize

Drug Facts

Active ingredient

Purpose

Ethyl Alcohol 80%.....Antiseptic, Hand Sanitizer

Uses •Hand sanitizer to help reduce bacteria on the skin

Warnings

For external use only-hands
Flammable. Keep away from heat and 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, flush thorough with water. Stop use and ask a doctor if irritation or rash occurs. These may be signs of serious condition. Keep out of reach of children. If swallowed, get medical help of contact a Poison Control Center immediately.

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 • do not store above 105°F

 may discolor some fabrics • harmful to wood finshes and plastics

Inactive ingredients • Purified water, hydrogen peroxide and Glycerin

Purpose

Antiseptic, Hand Sanitizer

Use

Hand sanitizer to help reduce bacteria on the skin

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.

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.

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

 do not store above 105"F • may discolor some fabrics • harmful to wood finshes and plastics

Inactive ingredients

Purified water, hydrogen peroxide and Glycerin

Package Label - Principal Display Panel

3.78 L NDC: 77330-001-01

Distilled and Bottled for Bonaventura Industries, 8 The Green Ste A Dover DE 1990:



Drug Facts

Active ingredient

Purpose

Ethyl Alcohol 80%......Antiseptic, Hand Sanitizer

Uses •Hand sanitizer to help reduce bacteria on the skin

Warnings

For external use only-hands
Flammable. Keep away from heat and 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, flush thorough with water. Stop use and ask a doctor if irritation or rash occurs. These may be signs of serious condition. Keep out of reach of children. If swallowed, get medical help of contact a Poison Control Center immediately.

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 • do not store above 105°F

 may discolor some fabrics • harmful to wood finshes and plastics

Inactive ingredients • Purified water, hydrogen peroxide and Glycerin

BACIBAN HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77330-001(NDC:55549-001)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:77330-001- 01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020		
2	NDC:77330-001- 02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020		
3	NDC:77330-001- 04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020		
4	NDC:77330-001- 08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020		
5	NDC:77330-001- 16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020		
6	NDC:77330-001- 32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/03/2020		

Labeler - Bonaventura Industries Inc (117514553)

Registrant - Bonaventura Industries Inc (117514553)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bonaventura Industries Inc		117514553	relabel(77330-001)	

Revised: 5/2020 Bonaventura Industries Inc