BACIBAN- gel sanitizer gel
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.

BaciBan Gel

Active ingredient

Active ingredient

Ethyl Alcohol 80%

Drug Facts

Active ingredient **Purpose**

Ethyl Alcohol 80%v/v.....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. Keep out of reach of children. If swallowed, get medical help of contact a Poison Control Center immediately.

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.

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 • Avoid freezing and excessive heat above 40C (104F) • may discolor some fabrics • harmful to wood finishes and plastics

Inactive ingredients • Glycerin, Hydrogen Peroxide, Guaraprolose, Citric Acid, Purified water USP

Visit us at www.BaciBan.com

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BACIBAN

gel sanitizer gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77330-003(NDC:75682-435)
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**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
GUARAPROLOSE (3500 MPA.S AT 1%) (UNII: 3A1I7376TC)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77330-003-01	3758 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2020	
2	NDC:77330-003-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2020	
3	NDC:77330-003-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2020	
4	NDC:77330-003-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2020	
5	NDC:77330-003-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2020	
6	NDC:77330-003-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/29/2020	

Labeler - Bonaventura Industries Inc (117514553)

Registrant - Bonaventura Industries Inc (117514553)

Establishment

Name	Address	ID/FEI	Business Operations
Bonaventura Industries Inc		117514553	relabel(77330-003)

Revised: 8/2020 Bonaventura Industries Inc