

## **B CLEAN PREMIUM HAND SANITIZER- ethyl alcohol gel**

### **B Holding Group LLC**

*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.

- a. Ethyl Alcohol (62%, v/v)
- b. Water (36.228% v/v).
- c. ALOE Barbadensis Leaf Juice
- d. Maltodextrin
- e. Glycerin
- f. Propylene Glycol
- g. Fragrance
- h. Acrylates/c10-30 Alkyl Arcylate Crosspolymer
- i. Triethanomine
- j. Tocopheryl Acetate

### **Active Ingredient(s)**

Ethyl Alcohol 62% 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.

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 110°F
- May discolor some fabrics

## Inactive ingredients

Water (36.228% v/v).  
ALOE Barbadensis Leaf Juice  
Maltodextrin  
Glycerin  
Propylene Glycol  
Fragrance  
Acrylates/c10-30 Alkyl Arcylate Crosspolymer  
Triethanamine  
Tocopheryl Acetate

## Package Label - Principal Display Panel



# B CLEAN PREMIUM HAND SANITIZER

ethyl alcohol gel

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78396-001
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78396-001-59	59 mL in 1 BOTTLE, DISPENSING; 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** - B Holding Group LLC (006108561)

**Registrant** - B Holding Group LLC (006108561)

## Establishment

Name	Address	ID/FEI	Business Operations
Nantong Health & Beyond Hygienic Products Inc.		421280161	manufacture(78396-001)

