

## **B CLEAN HAND SANITIZER- ethyl alcohol gel HETH 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.*

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### **B Clean - Hand Sanitizer (AQUA)**

#### **Active Ingredient**

Ethyl Alcohol 75% v/v. Purpose: Antiseptic

#### **Purpose**

Antiseptic, Hand Sanitizer

#### **Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease.

#### **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.

#### **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 59°-86°F (15°-30°C)
- Avoid freezing and excessive heat above 104°F (40°C)
- May discolor certain fabrics

## Inactive Ingredients

Aqua, Carbomer, Denatonium Benzoate, Isopropanolamine, Mentha Piperita Extract, Propylene Glycol, Salvia Officinalis Leaf Extract, Verbena Officinalis Leaf Extract

## Package Label - Principal Display Panel

B CLEAN

HAND SANITIZER

ALCOHOL-BASED GEL

moisturizing

alcohol 75%

Distributed by: Heth LLC

7522 Campbell Road

Suite 113 #272

Dallas TX 75248

+1 844 989 3111

MADE IN BRAZIL

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredient</b>	<b>Purpose</b>	<b>Directions</b>	
Ethyl Alcohol 75% v/v.....	Antiseptic	• Place enough product on hands to cover all surfaces. Rub hands together until dry.	
<b>Uses</b>		• Supervise children under 6 years of age when using this product to avoid swallowing.	
Hand Sanitizer to help reduce bacteria that potentially can cause disease.		<b>Other information</b>	
<b>Warnings</b>		• Store between 59°-86°F (15°-30°C)	
For external use only. Flammable. Keep away from heat or flame		• Avoid freezing and excessive heat above 104°F (40°C)	
<b>Do not use</b>		• May discolor certain fabrics	
• in children less than 2 months of age		<b>Inactive ingredients</b>	
• on open skin wounds		Aqua, Carbomer, Denatonium Benzoate, Isopropanolamine, Mentha Piperita Extract, Propylene Glycol, Salvia Officinalis Leaf Extract, Verbena Officinalis Leaf Extract	
<b>When using this product</b> keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.			
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.			
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.			
			
			
	Manufactured by: Age do Brasil Ind. e Com. LTDA. Vinhedo SP, Brazil CEP 13288-169 MADE IN BRAZIL	Distributed by: Heth LLC 7522 Campbell Road Suite 113 #272 Dallas TX 75248 +1 844 989 3111	NDC: 78310-101-04 27157



The label features a teal background with a white stylized 'B' logo containing a green leaf. Below the logo, the word 'CLEAN' is written in teal. The main text 'HAND SANITIZER' is in large white letters. Underneath, 'ALCOHOL-BASED GEL' is in white, and 'moisturizing' is in teal. At the bottom, 'alcohol 75%' is in white and '16.9 FL OZ (500 mL)' is in teal.

## B CLEAN HAND SANITIZER

ethyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78310-300
<b>Route of Administration</b>	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	60 kg in 100 kg

Inactive Ingredients	
Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
ISOPROSPANOLAMINE (UNII: UE40BY1BZW)	
VERBENA OFFICINALIS LEAF (UNII: 3289NQE84P)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
SAGE (UNII: 065C5D077J)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78310-300-01	4.4 kg in 1 BOTTLE; Type 0: Not a Combination Product	08/07/2020	
2	NDC:78310-300-02	3.32 kg in 1 BOTTLE; Type 0: Not a Combination Product	08/07/2020	
3	NDC:78310-300-03	1.66 kg in 1 BOTTLE; Type 0: Not a Combination Product	08/07/2020	
4	NDC:78310-300-05	0.44 kg in 1 BOTTLE; Type 0: Not a Combination Product	08/07/2020	
5	NDC:78310-300-04	0.865 kg in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/07/2020	
6	NDC:78310-300-06	0.22 kg in 1 BOTTLE; Type 0: Not a Combination Product	08/07/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/07/2020	

**Labeler** - HETH LLC (080815601)

**Registrant** - AGE DO BRASIL INDUSTRIA E COMERCIO LTDA. (920307841)

### Establishment

Name	Address	ID/FEI	Business Operations
AGE DO BRASIL INDUSTRIA E COMERCIO LTDA.		920307841	manufacture(78310-300)

