

**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 440g and kit**

**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%

Manufactured by: Age do  
 Brasil Ind. e Com. LTDA.  
 Vinhedo SP  
 CEP 13288-169  
 Brazil

Distributed by: Heth LLC  
 7522 Campbell Road  
 Suite 113 #272  
 Dallas TX 75248  
 +1 844 989 3111

MADE IN BRAZIL

Warning! Flammable liquid and vapor

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredient</b> Ethyl Alcohol 75% v/v.....Antiseptic	<b>Purpose</b>	<b>Directions</b>	
<b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease.		<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
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<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.		  	
		Warning! Highly flammable liquid and vapor	
		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	



**HAND SANITIZER**

**ALCOHOL-BASED GEL**  
 moisturizing

alcohol 75%      16.9 FL OZ (500 mL)

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 moisturizing

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# B CLEAN HAND SANITIZER

ethyl alcohol gel

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78310-101
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	308 g in 440 g

## Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
ISOPROPNOLAMINE (UNII: UE40BY1BZW)	
VERBENA OFFICINALIS LEAF (UNII: 3289NQE84P)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
SAGE (UNII: 065C5D077J)	
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78310-101-03	440 g in 1 BOTTLE; Type 0: Not a Combination Product	06/03/2020	
2	NDC:78310-101-04	440 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/03/2020	
3	NDC:78310-101-05	1320 g in 1 KIT; Type 0: Not a Combination Product	07/31/2020	
4	NDC:78310-101-06	1320 g in 1 KIT; Type 0: Not a Combination Product	07/31/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/03/2020	

**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(78310-101)

Revised: 8/2020

HETHLLC