

**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 (220g, 104g, 52g)**

**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	<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>	
<b>Uses</b>		<b>Other information</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease.		<ul style="list-style-type: none"> <li>Store between 59°-86°F (15°-30°C)</li> <li>Avoid freezing and excessive heat above 104°F (40°C)</li> <li>May discolor certain fabrics</li> </ul>	
<b>Warnings</b>		<b>Inactive ingredients</b>	
<p><b>For external use only. Flammable. Keep away from heat or flame</b></p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul> <p><b>When using this product</b> keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p><b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>		<p>Aqua, Carbomer, Denatonium Benzoate, Isopropanolamine, Mentha Piperita Extract, Propylene Glycol, Salvia Officinalis Leaf Extract, Verbena Officinalis Leaf Extract</p>	
<p>Distributed by: Heth LLC 7522 Campbell Road Suite 113 #272 Dallas TX 75248 +1 844 989 3111 MADE IN BRAZIL NDC: 78310-102-03 27339</p>		 <p>3 78310 00006 6</p>	



<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	<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>	
<b>Uses</b>		<b>Other information</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease.		<ul style="list-style-type: none"> <li>Store between 59°-86°F (15°-30°C)</li> <li>Avoid freezing and excessive heat above 104°F (40°C)</li> <li>May discolor certain fabrics</li> </ul>	
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<p>Distributed by: Heth LLC 7522 Campbell Road Suite 113 #272 Dallas TX 75248 +1 844 989 3111 MADE IN BRAZIL NDC: 78310-102-04 27352</p>		 <p>3 78310 00007 3</p>	



**B CLEAN HAND SANITIZER**

ethyl alcohol gel

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78310-102
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	154 g in 220 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: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78310-102-03	220 g in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2020	
2	NDC:78310-102-04	220 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/12/2020	
3	NDC:78310-102-07	104 g in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2020	
4	NDC:78310-102-08	52 g in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2020	
5	NDC:78310-102-05	1320 g in 1 KIT; Type 0: Not a Combination Product	07/31/2020	
6	NDC:78310-102-06	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	06/12/2020	

**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(78310-102)

