

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.

B Clean - Hand Sanitizer (5L, 1 gal, 0.5 gal, 1L)

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

Drug Facts

Active ingredient Purpose

Ethyl Alcohol 75% v/v.....Antiseptic

Uses

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

NDC: 78310-100-01

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



CLEAN

27342
HAND SANITIZER

ALCOHOL-BASED GEL
moisturizing

alcohol
75%

1.32 GAL (5 L)

B CLEAN HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78310-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	3080 g in 4400 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
ISOPRO PANOLAMINE (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:78310-100-01	4400 g in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2020	
2	NDC:78310-100-02	3200 g in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2020	
3	NDC:78310-100-03	3200 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/31/2020	
4	NDC:78310-100-05	1660 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/31/2020	
5	NDC:78310-100-04	1660 g in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2020	
6	NDC:78310-100-06	865 g in 1 BOTTLE, PUMP; 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(78310-100)

Revised: 8/2020

HETH LLC