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 (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

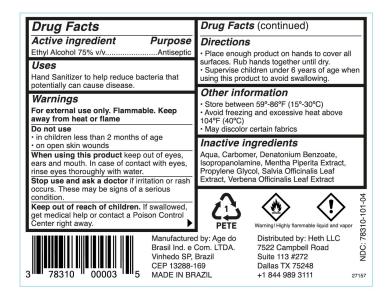
ALCOHOL-BASED GEL

moisturizing

alcohol 75%

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

MADE IN BRAZIL





B CLEAN HAND SANITIZER

ethyl alcohol gel

Product Information				
luct Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78310-300	
e of Administration	TOPICAL			
e or Administration	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)		
ISOPROPANOLAMINE (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)	

Revised: 1/2021 HETH LLC