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 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%

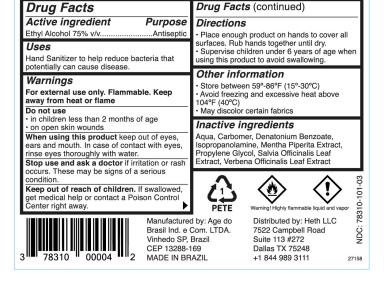
Manufactured by: Age do Brasil Ind. e Com. LTDA. Vinhedo SP CEP 13288-169 Brazil

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 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: 79 M2M2UDA9)			
ISOPROPANOLAMINE (UNII: UE40 BY1BZW)			
VERBENA OFFICINALIS LEAF (UNII: 3289 NQE84P)			
DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)			
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 - HETHLLC (080815601)

 $\pmb{Registrant} \textbf{-} \textbf{ AGE DO BRASIL INDUSTRIA E COMERCIO LTDA. (920307841)}$

Establishment				
Name	Address	ID/FEI	Business Operations	
AGE DO BRASIL INDUSTRIA E COMERCIO LTDA.		920307841	manufacture(78310-101)	

Revised: 8/2020 HETHLLC