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 (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%

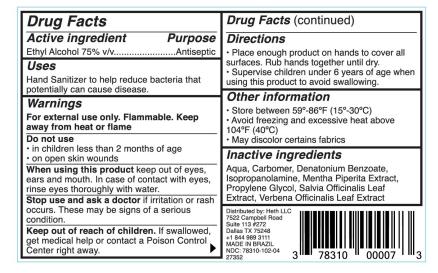
Distributed by: Heth LLC 7522 Campbell Road

Suite 113 #272 Dallas TX 75248 +1 844 989 3111

MADE IN BRAZIL

Drug Facts (continued) **Drug Facts Active ingredient** Purpose **Directions** Ethyl Alcohol 75% v/v...... ..Antiseptic · Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when Uses Hand Sanitizer to help reduce bacteria that using this product to avoid swallowing. potentially can cause disease. Other information Warnings Store between 59°-86°F (15°-30°C) For external use only. Flammable. Keep Avoid freezing and excessive heat above away from heat or flame 104°F (40°C) Do not use May discolor certains fabrics · in children less than 2 months of age Inactive ingredients on open skin wounds Aqua, Carbomer, Denatonium Benzoate, When using this product keep out of eyes, Isopropanolamine, Mentha Piperita Extract, ears and mouth. In case of contact with eves. Propylene Glycol, Salvia Officinalis Leaf rinse eyes thoroughly with water Extract, Verbena Officinalis Leaf Extract Stop use and ask a doctor if irritation or rash Distributed by: Heth LLC 7522 Campbell Road Suite 113 #272 Dallas TX 75248 +1 844 989 3111 MADE IN BRAZIL occurs. These may be signs of a serious Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

NDC: 78310-102-03 27339







B CLEAN HAND SANITIZER

ethyl alcohol gel

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

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	154 g in 220 g		

Inactive Ingredients			
Ingredient Name	Strength		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
MENTHA PIPERITA (UNII: 79 M2M2UDA9)			
ISOPROPANOLAMINE (UNII: UE40BY1BZW)			
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:78310-102- 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 - HETHLLC (080815601)

Registrant - AGE DO BRASIL INDUSTRIA E COMERCIO LT DA. (920307841)

Establishment				
Name	Address	ID/FEI	Business Operations	
AGE DO BRASIL INDUSTRIA E COMERCIO LTDA.		920307841	manufacture(78310-102)	

Revised: 8/2020 HETHLLC