B.CLEAN HAND SANITIZER- alcohol gel Marque of Brands Americas, 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.

I dont want germs on my hands (gel) updated

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Ethyl Alcohol 60% v/v

Purpose

Antiseptic

- 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.

Water (Aqua), Aloe Barbadensis Leaf Juice, Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Squalane

Warning

- Flammable, keep away from flame.
- For External Use Only.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse throughly with water.

- in children less than 2 months of age
- on open skin wounds

a doctor if irritation or rash occurs. These may be signs of a serious condition.

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)



B.CLEAN HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73978-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
WATER (UNII: 059QF0KO0R)	
ALPHA-TO CO PHERO L ACETATE (UNII: 9E8 X80 D2L0)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
SQUALANE (UNII: GW89575KF9)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:73978-003- 01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020		
2	NDC:73978-003- 02	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020		
3	NDC:73978-003- 03	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020		
4	NDC:73978-003- 04	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

Labeler - Marque of Brands Americas, LLC (081170908)

Establishment				
Name	Address	ID/FEI	Business Operations	
Marque of Brands Americas, LLC		081170908	manufacture(73978-003)	

Revised: 5/2020 Marque of Brands Americas, LLC