

BEBESUP HAND SANITIZER(ETHANOL)- alcohol gel
AJ Co., Ltd.

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.

AJ Co., Ltd. - Bebesup Hand Sanitizer(Ethanol)

Alcohol

Carbomer, Citrus Paradisi (Grapefruit) Fruit Extract, Fragrance, Tromethamine, Water

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

keep out of reach of the children

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.

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 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.

for external use only

Drug Facts

Active Ingredient

Alcohol 62% ----- Antibacterial

Purpose

Uses

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

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 1-30°C (33.8-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive Ingredients

Water, Fragrance, Carbomer, Citrus Paradisi (Grapefruit) Fruit Extract, Tromethamine

BEBESUP HAND SANITIZER(ETHANOL)

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75356-0002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	310 mL in 500 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GRAPEFRUIT (UNII: O82C39RR8C)	
TROMETHAMINE (UNII: 023C2WHX2V)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75356-0002-1	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/10/2020	

Labeler - AJ Co., Ltd. (631079605)

Registrant - AJ Co., Ltd. (631079605)

Establishment

Name	Address	ID/FEI	Business Operations
AJ Co., Ltd.		631079605	manufacture(75356-0002) , label(75356-0002) , pack(75356-0002)

Revised: 10/2020

AJ Co., Ltd.