APOL HAND SANITIZER- alcohol gel ECOSEM 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.

80082-201

Active ingredient

Ethanol 65%

Purpose

Antiseptic

Use

Hand clean sanitizer to help reduce bacteria on skin

Warnings

Flammable. Keep away from fire or flame.

For external use only.

When using this product

do not use in or near the eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if

irritation or rash appears and last.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

Children under 6 years of age should be supervised when using this product.

Other information

Store between 15-30C(59-86F)

Avoid freezing and excessive heat above 40C(104F)

Inactive ingredients

Water, Glycerin, Propylene glycol, Carbomer, Aloe Vera gel Triethanolamine, Cinnamomum Cassia Bark Extract, Camellia Sinensis Leaf Extract, Chamaecyparis Lawsoniana Wood Oil

Package Label



- **√** 65% ETHANOL
- **√** ANTISEPTIC
- ▼ MOISTURIZING INGREDIENTS INCLUDE:
 - Aloe Vera gel
 - Camellia Sinensis Leaf Extract
 - Glycerin
 - Cinnamomum Cassia Bark Extract
 - Chamaecyparis Lawsoniana Wood Oil

16.91 OZ / 500ML

MADE IN KOREA

Apol Hand Sanitizer+

Drug Facts

Active ingredient [S] Ethanol 65%

Use[s]

· Hand clean sanitizer to help reduce bacteria on skin

- Warnings Flammable. Keep away from fire or flame
- For external use only.
- When using this product do not use in or near the eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.

 Stop use and ask a doctor if irritation or rash appears and last.

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

Directions

- Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

- Other information
 Store between 15~30C(59-86F)

Store between 15-30C(59-86F)
 Avoid freezing and excessive heat above 40C(104F)
 Inactive ingredients
 Water, Glycerin, Propylene glycol, Carbomer, Aloe Vera gel
 Triethanolamie, Cinnamomum Cassia Bark Extract, Camella Sinensis Leaf Extract,
 Chamaecyparis Lawsoniana Wood Oil

Distributed by : ECOSEM Co., Ltd. 70, Junggado-gil, Gunsan-si, Jeollabuk-do Kore







Strength

APOL HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:80082-201

Route of Administration **TOPICAL**

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 65 mL in 100 mL

Ingredient Name

Inactive Ingredients

CHINESE CINNAMON (UNII: WS4CQ062KM) TROLAMINE (UNII: 903K93S3TK) GREEN TEA LEAF (UNII: W2ZU1RY8B0) CHAMAECYPARIS LAWSONIANA WOOD OIL (UNII: 0H3D02DVNU) WATER (UNII: 059QF0KO0R) GLYCERIN (UNII: PDC6A3C0OX) PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

ALOE VERA LEAF (UNII: ZY81Z83H0X)

CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)

Packaging

# Item Code	Package Description	Date	Date		
1 NDC:80082-201- 01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/19/2020			
Marketing Information					
Marketing Catego	ory Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not f	inal part333A	08/19/2020			

Labeler - ECOSEMCO., LTD (695632865)

Registrant - ECOSEM CO., LTD (695632865)

Establishment						
Name	Address	ID/FEI	Business Operations			
ECOSEM CO., LTD		695632865	manufacture(80082-201)			

Revised: 8/2020 ECOSEM CO., LTD