

SOART HAND SANITIZER- alcohol gel
Ester 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.

ACTIVE INGREDIENT

Active ingredients: ALCOHOL 70%

INACTIVE INGREDIENT

Inactive ingredients:

Water, Glycerin, Carbomer, Tetrahydroxypropyl Ethylenediamine, Fragrance, Aloe Arborescens Leaf Extract, Butylene Glycol, Camellia Sinensis Leaf Extract

PURPOSE

Purpose: ANTISEPTIC

WARNINGS

Warnings:

Flammable, Keep away from fire or flame

For external use only

When using this product do not use in or near the eyes.

In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or redness develops.

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

KEEP OUT OF REACH OF CHILDREN

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

Uses

Uses:

For handwashing when water is not available to decrease bacteria on the skin

- After changing diapers
- After assisting ill persons
- Before contact with a person under medical care or treatment
- Recommended for repeated use

Directions

Directions:

- Apply palmful to hands
- Rub hands together vigorously until dry
- Supervise children in the use of this product

Other Information

Other Information:

Store at room temperature: 15°~30 °C (59°~86 °F)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

HAND SANITIZER GEL

Drug Facts	
Active Ingredients	Purpose
Alcohol 70.0%	Antiseptic
Use	
For handwashing when water is not available to decrease bacteria on the skin - After changing diapers - After assisting ill persons - Before contact with a person under medical care or treatment - Recommended for repeated use	
Warnings	
- Flammable, Keep away from fire or flame - For external use only - When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. - Stop use and ask a doctor if irritation or redness develops. - Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.	
Directions	
- Apply palmful to hands - Rub hands together vigorously until dry - Supervise children in the use of this products	
Other Information	
- Store at room temperature: 15°~30° C (59°~86° F)	
Inactive Ingredients	
Water, Glycerin, Carbomer, Tetrahydroxypropyl Ethylenediamine, Fragrance, Aloe Arborescens Leaf Extract, Butylene Glycol, Camellia Sinensis Leaf Extract	
Manufacturer : Ester Co., Ltd. 26B-1L Namdong Industrial Complex, 254 Namdongseo-ro, Namdong-gu, Incheon, S. Korea	

MADE IN KOREA

Net Wt : 16.9 Fl. Oz. / 500ml

SOART HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:740 04-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	350 g in 500 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
EDETOL (UNII: Q4R969U9FR)	
ALOE ARBORESCENS LEAF (UNII: 09TD8L5SQV)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74004-050-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/01/2020	

Labeler - Ester Co., Ltd. (688425766)**Registrant** - Ester Co., Ltd. (688425766)**Establishment**

Name	Address	ID/FEI	Business Operations
Ester Co., Ltd.		688425766	manufacture(74004-050)

Revised: 11/2020

Ester Co., Ltd.