

**PREMIUM HAND SANITIZER GEL- 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.*

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**Ester Co., Ltd. (JW Commerce) - PREMIUM HAND SANITIZER Gel**

**ACTIVE INGREDIENT**

Active ingredients: ALCOHOL 70%

**INACTIVE INGREDIENT**

Inactive ingredients:

Water, Glycerin, Carbomer, Triethanolamine, Fragrance, Aloe Arborescens Leaf Extract, polysorbate 20

**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 our 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

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

<b>Drug Facts</b>	
<b>Active Ingredient</b> Alcohol 70%	<b>Purpose</b> Antiseptic
<b>Uses</b> ■ Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame.</b> <b>Do not use</b> ■ in children less than 2 months of age. ■ on open skin wounds. <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> ■ Apply this product to your hands and wipe ■ Supervise children under 6 years of age when using this product to avoid swallowing.	
<b>Other Information</b> ■ Store between 15-30C (59-86F) ■ Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive Ingredients</b> Water, carbomer, triethanolamine, polysorbate 20, aloe arborescens leaf extract, fragrance	

## PREMIUM HAND SANITIZER GEL

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74004-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	350 mL in 500 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
WATER (UNII: 059QF0K00R)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)				
ALOE ARBORESCENS LEAF (UNII: 09TD8L5SQV)				
TROLAMINE (UNII: 9O3K93S3TK)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:74004-001-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/08/2020	
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final		part333A	06/08/2020	

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

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Ester Co., Ltd.		688425766	manufacture(74004-001)