

## **BIOGENO CARE HAND SANITIZER GEL (ETHANOL)- alcohol gel DERMACOS KOREA**

*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(s)**

Alcohol 70% v/v. Purpose: Antimicrobial

### **Purpose**

Antimicrobial, Hand Sanitizer

### **Use**

Hand sanitizer to help reduce bacteria on the skin.  
Recommended for repeated use.

### **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.

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**

- 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.
- Not recommended for infants.

**Other information**

- Store at room temperature (33.8oF-86oF, 1oC-30oC) and avoid cold or dry place.
- May discolor certain fabrics or surfaces.
- Harmful to wood finishes and plastics.

**Inactive ingredients**

Aloe Vera Gel, Carbomer, Fragrance (Lemon), Glycerin, Green Tea Extract, Purified Water, Rosa Damascena (Rose) Flower Water, Sodium Hyaluronate, Triethanolamine.

**Package Label - Principal Display Panel**



**BIOGENO CARE HAND SANITIZER GEL (ETHANOL)**

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77637-400
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>GREEN TEA LEAF</b> (UNII: WZZU1RY8B0)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
<b>1</b>	NDC:77637-400-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2021	



## Marketing Information

Marketing

Application Number or Monograph

Marketing Start

Marketing End

Category	Citation	Date	Date
OTC monograph not final	part333A	03/30/2021	

**Labeler** - DERMACOS KOREA (695625857)

**Registrant** - DERMACOS KOREA (695625857)

### Establishment

Name	Address	ID/FEI	Business Operations
DERMACOS KOREA		695625857	manufacture(77637-400)

Revised: 3/2021

DERMACOS KOREA