

**SOPHIA SEOUL GOLDEN- alcohol gel**  
**Seoul Vietnam Cosmetics Joint Stocks Company**

*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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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

**Active Ingredient(s)**

Ethyl Alcohol 72% v/v. Purpose: Antimicrobial

**Purpose**

Antimicrobial

**Use**

Personal hygiene convenience product, for use to wash your hand anytime, anywhere 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.

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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**

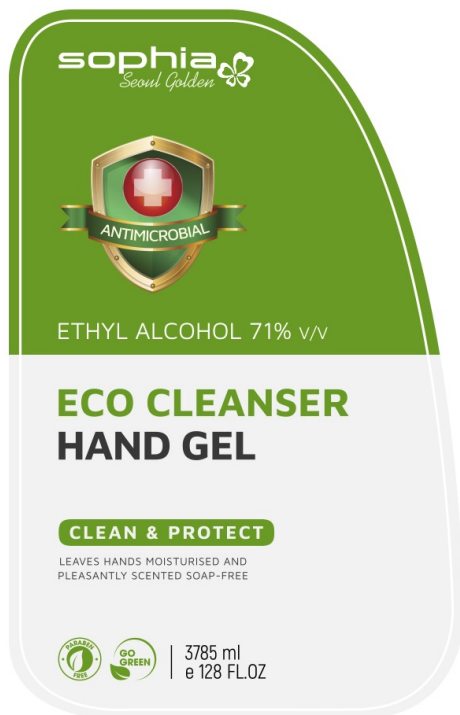
- Store in cool, dry place
- Avoid freezing and excessive heat above 40C (104F)

## Inactive ingredients

Purified water, Propylene glycol, glycerin, carbomer, triethanolamine, aloe barbadensis leaf juice.

## Package Label - Principal Display Panel

3785mL NDC: 78577-122-05



1000mL NDC: 78577-122-05



### Drug Facts

Active ingredient (in 100ml )	Purpose
Ethyl Alcohol 71% v/v.....	Antimicrobial

**Uses**  
Personal hygiene convenience product, for use to wash your hands anytime, anywhere when soap and water are not available.

**Warnings**  
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Flammable. Keep away from fire or flame.

**Do not use:**

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Peel Here →

### Drug Facts (Continued)

**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 in cool, dry place
- Avoid freezing and excessive heat above 40°C (104°F)

**Inactive Ingredients**  
PURIFIED WATER, PROPYLENE GLYCOL, GLYCERIN, CARBOMER, TRIETHANOLAMINE, ALOE BARBADENSIS LEAF JUICE.

**Questions? (+84 272) 6256 188**

**MANUFACTURED BY:**  
**Seoul Vietnam Cosmetics Joint Stocks Company**  
A5, Kizuna 2, B4-3-7-8, Tan Kim IP, Tan Kim Ward, Can Giuoc District, Long An, Vietnam.  
TELEPHONE : (84)(272)(6256188) | FAX : (84)(272)(6256177)  
MADE IN VIETNAM  
NDC 78577-122-05

**FDA**  
REGISTERED

**12M**

8 936124 250453

500mL NDC: 78577-122-04





**Drug Facts**

**Active Ingredient (in 100ml) Purpose**  
Ethyl Alcohol 71% v/v.....Antimicrobial

**Uses**  
Personal hygiene convenience product, for use to wash your hands anytime, anywhere when soap and water are not available.

**Warnings**  
For external use only  
Flammable. Keep away from fire or flame.

**Do not use:**  

- in children less than 2 months of age
- on open skin wound

**When using this product** keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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

Peel Here ➔

**Drug Facts (Continued)**

**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 in cool, dry place.
- Avoid freezing and excessive heat above 40°C (104°F).

**Inactive Ingredients**  
PURIFIED WATER, PROPYLENE GLYCOL, GLYCERIN, CARBOMER, TRIETHANOLAMINE, ALOE BARBADENSIS LEAF JUICE.

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 TELEPHONE : (84)(272)(6256188)  
 FAX : (84)(272)(625617)  
 MADE IN VIETNAM  
 NDC 78577-122-03

**FDA REGISTERED** 8 936124 250392

100mL NDC: 78577-122-02



### Drug Facts

Active ingredient (in 100ml )	Purpose
Ethyl Alcohol 71% v/v.....	Antimicrobial

**Uses**  
Personal hygiene convenience product, for use to wash your hands anytime, anywhere when soap and water are not available.

**Warnings**  
For external use only  
Flammable. Keep away from fire or flame.

**Do not use:**

- in children less than 2 months of age
- on open skin wound

**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. They might be signs of serious conditions.

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

Peel Here →

### Drug Facts (Continued)

**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 in cool, dry place
- Avoid freezing and excessive heat above 40°C (104°F)

**Inactive Ingredients**  
PURIFIED WATER, PROPYLENE GLYCOL, GLYCERIN, CARBOMER, TRIETHANOLAMINE, ALOE BARBADENSIS LEAF JUICE.

**Questions? (+84 272) 6256 188**

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Seoul Vietnam Cosmetics Joint Stocks Company  
A5, Kizuna 2, B4-3-7-8, Tan Kim IP, Tan Kim Ward, Can Giuoc District, Long An, Vietnam.  
TELEPHONE : (84)(272)(6256188) | FAX : (84)(272)(6256177)  
MADE IN VIETNAM  
NDC 78577-122-02



8 936124 250439

50mL NDC: 78577-122-01



## Drug Facts

**Active ingredient (in 100ml ) Purpose**  
Ethyl Alcohol 71% v/v.....Antimicrobial

### Uses

Personal hygiene convenience product, for use to wash your hands anytime, anywhere when soap and water are not available.

### Warnings

For external use only

Flammable. Keep away from fire or flame.

### Do not use:

- in children less than 2 months of age
- on open skin wound

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Peel Here →

## Drug Facts (Continued)

### 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 in cool, dry place
- Avoid freezing and excessive heat above 40°C (104°F)

### Inactive Ingredients

PURIFIED WATER, PROPYLENE GLYCOL, GLYCERIN, CARBOMER, TRIETHANOLAMINE, ALOE BARBADENSIS LEAF JUICE.

### Questions? (+84 272) 6256 188

### MANUFACTURED BY:

Seoul Vietnam Cosmetics Joint Stocks Company  
A5, Kizuna 2, B4-3-7-8, Tan Kim IP, Tan Kim Ward, Can Gio District, Long An, Vietnam.  
TELEPHONE : (84)(272)(6256188) | FAX : (84)(272)(6256177)  
MADE IN VIETNAM  
NDC 78577-122-01



## SOPHIA SEOUL GOLDEN

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78577-122
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

### Inactive Ingredients

Ingredient Name				Strength
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
TROLAMINE (UNII: 9O3K93S3TK)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78577-122-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
2	NDC:78577-122-02	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
3	NDC:78577-122-03	200 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/26/2020	
4	NDC:78577-122-04	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/26/2020	
5	NDC:78577-122-05	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/26/2020	
6	NDC:78577-122-06	3785 mL in 1 CAN; Type 0: Not a Combination Product	05/26/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	05/26/2020	

**Labeler** - Seoul Vietnam Cosmetics Joint Stocks Company (556883359)

**Registrant** - Seoul Vietnam Cosmetics Joint Stocks Company (556883359)

## Establishment

Name	Address	ID/FEI	Business Operations
Seoul Vietnam Cosmetics Joint Stocks Company		556883359	manufacture(78577-122)

Revised: 6/2020

Seoul Vietnam Cosmetics Joint Stocks Company