

## OSONG ANTISEPTIC ALCOHOL- alcohol liquid

Osong 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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**Drug Facts**

alcohol

- instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease
- instant hand antiseptic to decrease bacteria on the skin

KEEP OUT OF REACH OF THE CHILDREN

- Pour a small amount into hands, spread evenly and rub into the skin

For external use only

When using this product

- if following abnormal symptoms persist, discontinue use

Irritation around the eyes, ears, mucous membranes, including the mouth, under the skin irritation and rashes

- Stop immediately and consult a doctor if you experience

1) Hypersensitivity symptoms such as erythema, itching and dermatitis.

2) Skin Irritation

3) Following Instructions when using medication

(1) For external use only (Do not use internally)

(2) Avoid getting into the eyes (if contact occurs, wash well with clean water)

- Be careful not to inhale or use excessively for a long time (ingesting ethanol repeatedly causes irritation to mucous membranes and headaches or other symptoms may appear. When used repeatedly in the same area, skin irritation may occur.

- Do not use the product for a long time in the same area as swelling, inflammation or sickness may occur due to absorption through the skin.

It is not recommended to use this on areas that have been medically treated with a cast or bandage.

- Do not use in combination with soap or antibacterial cleansing agents.

for external use only

water

**Product name: Osong Antiseptic Alcohol**

Volume: Net 16.9 fl.oz. / 500 ml

<b>Drug Facts</b>	
<b><u>Active Ingredients</u></b>	<b><u>Purpose</u></b>
Ethyl Alcohol 83%	Antimicrobial
<b><u>Uses</u></b>	
■ instant healthcare personnel hand antiseptic to reduce bacteria that	

potentially can cause disease

■ instant hand antiseptic to decrease bacteria on the skin

***Warning***

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■ Do not use in combination with soap or antibacterial cleansing agents.

***Directions***

■ Pour a small amount into hands, spread evenly and rub into the skin

***Other Information***

- read the directions and warnings before use

- avoid freezing and excessive heat above 40 degree C (104 degree F)

***Inactive Ingredients***

Water

***Questions or Comments?*** E-mail: [osong111@gmail.com](mailto:osong111@gmail.com)

**[MANUFACTURED BY]**

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MADE IN KOREA

**OSONG ANTISEPTIC ALCOHOL**

alcohol liquid

**Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:81294-0003

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	83 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81294-0003-1	500 mL in 1 POUCH; Type 0: Not a Combination Product	12/25/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/25/2020	

**Labeler** - Osong Co., Ltd. (687859804)

**Registrant** - Osong Co., Ltd. (687859804)

### Establishment

Name	Address	ID/FEI	Business Operations
Osong Co., Ltd.		687859804	manufacture(81294-0003)

Revised: 12/2020

Osong Co., Ltd.