

**POLTONE HAND SANITIZER- alcohol gel**  
**DONGBANGCOSMETICS 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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**ACTIVE INGREDIENT**

Active ingredients: ALCOHOL 62.0%

**INACTIVE INGREDIENT**

Inactive Ingredients:

Water, Carbomer, Triethanolamine, Polyoxyethylene Hydrogenated Castor Oil, Lavandula Angustifolia (Lavender) Oil, Methylparaben, Butylene Glycol, Hexylene Glycol, Strawberry Extract, Sophora Extract, Mulberry Root Extract, Glycyrrhiza Extract, Grapefruit Extract, Green Tea Extract

**PURPOSE**

Purpose: SANITIZER

**WARNINGS**

Warnings:

1. Do not use the product on the following areas:

Around the eyes and ears, in the mouth, large body parts and damaged skin(Irritation may occur)

2. If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist.

1) Hypersensitivity symptoms, e.g. rash, erythema, itchiness, and edema

2) Skin irritation symptoms

3. Other precautions

1) For external use only (do not swallow).

2) Avoid contact with eyes. If contact occurs, wash with clean water and consult a doctor or pharmacist.

3) Be careful not to inhale vapors in cases of extended or prolonged use. (Repeating inhaling of large amounts of ethanol vapor may cause irritation of the mucous membranes and headaches).

(Limited to ethanol-containing products)

4) If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal.

5) Do not use sealed bandages, cast bandages, or packs as they may cause irritation.

6) Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns.

7) Use only for the intended purposes.

4. Precautions for storage

1) Keep away from direct sunlight and do not expose the product to heating devices or flame.

2) Keep out of reach of children and go to the hospital immediately if swallowed.

3) After use, close the lid completely to prevent the product from drying or foreign objects from getting inside the container.

4) Storing the product in a different container may cause accidents or deterioration of quality.

Therefore, keep the product in its original container.

Dust or foreign substances may get on the product while using it.

## KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children and go to the hospital immediately if swallowed.

## Uses

Uses:

Disinfection of hands and skin

## Directions

Directions:

Take an appropriate amount on your hands and rub thoroughly to dry.

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

**+ 의약외품**

**POLTONE**  
PREMIUM SKIN CARE

끈적이지 않으며, 물과 비누없이도 간편하게 문질러  
언제 어디서나 사용가능하며 효과적인 살균효과가 있습니다.

**POLTONE**  
PREMIUM SKIN CARE

**POLTONE Hand Sanitizer**  
폴톤 핸드 세니타이저

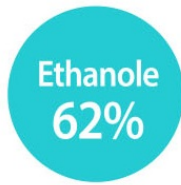
끈적이지 않으며, 물과 비누없이도 간편하게 문질러  
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**Hand Sanitizer**

**99.9%**  
살균효과

<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
ALCOHOL 62.0%	SANITIZER
<b>Uses</b>	
Disinfection of hands and skin	
<b>Warnings</b>	
<b>1. Do not use the product on the following areas:</b> Around the eyes and ears, in the mouth, large body parts and damaged skin (Irritation may occur)	
<b>2. If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist.</b> 1) Hypersensitivity symptoms, e.g. rash, erythema, itchiness, and edema 2) Skin irritation symptoms	
<b>3. Other precautions</b>	
1) For external use only (do not swallow).	
2) Avoid contact with eyes. If contact occurs, wash with clean water and consult a doctor or pharmacist.	
3) Be careful not to inhale vapors in cases of extended or prolonged use. (Repeating inhaling of large amounts of ethanol vapor may cause irritation of the mucous membranes and headaches). (Limited to ethanol-containing products)	
4) If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal.	
5) Do not use sealed bandages, cast bandages, or packs as they may cause irritation.	
6) Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns.	

Moisture / Clean / Mild



100 ml / 3.38 FL.OZ

7) Use only for the intended purposes.

**4.Precautions for storage**

- 1) Keep away from direct sunlight and do not expose the product to heating devices or flame.
- 2) Keep out of reach of children and go to the hospital immediately if swallowed.
- 3) After use, close the lid completely to prevent the product from drying or foreign objects from getting inside the container.
- 4) Storing the product in a different container may cause accidents or deterioration of quality. Therefore, keep the product in its original container.  
*Dust or foreign substances may get on the product while using it.*

**Directions**

Take an appropriate amount on your hands and rub thoroughly to dry.

**Inactive ingredients**

Water, Carbomer, Triethanolamine, Polyoxyethylene Hydrogenated Castor Oil, Lavandula Angustifolia (Lavender) Oil, Methylparaben, Butylene Glycol, Hexylene Glycol, Strawberry Extract, Sophora Extract, Mulberry Root Extract, Glycyrrhiza Extract, Grapefruit Extract, Green Tea Extract

Manufacturer: DONGBANG COSMETICS Co.,Ltd.

39, Gajaeul-  
Net Wt:  
100mL / 3.52 Fl. Oz.

MADE IN KOREA



**POLTONE HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74002-5000
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
Methylparaben (UNII: A218C7H9T)	
Butylene Glycol (UNII: 3XUS85K0RA)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74002-5000-1	100 mL in 1 CONTAINER; 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** - DONGBANGCOSMETICS CO.,LTD (694452564)

**Registrant** - DONGBANGCOSMETICS CO.,LTD (694452564)

## Establishment

Name	Address	ID/FEI	Business Operations
DONGBANGCOSMETICS CO.,LTD		694452564	manufacture(74002-5000)

Revised: 4/2020

DONGBANGCOSMETICS CO.,LTD