

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.

ACTIVE INGREDIENT

Active ingredients: ALCOHOL 62.0 w%

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.

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.


Other Information

Other Information:
■ read the directions and warnings before use
■ store at (1~30°C)

Questions

Questions:
consumer counseling: 82-32-812-6336 / www.zureocosmetics.com

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



Drug Facts	Purpose
Active ingredients ALCOHOL 62.0 w%	SANITIZER
Uses ■ Disinfection of hands and skin	
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.	
Directions ■ Take an appropriate amount on your hands and rub thoroughly to dry.	
Other information ■ read the directions and warnings before use ■ store at (1~30°C)	
Questions consumer counseling: 82-32-812-6336 / www.zureocosmetics.com	
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 DONGBANG COSMETICS Co., Ltd. 39, Gajaeul-ro 32beon-gil, Seo-gu, Incheon, S. Korea Net Wt: 500mL (16.91 Fl. Oz.)	

POLTONE HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74002-5030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	310.0 g in 500 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
Methylparaben (UNII: A2I8C7HI9T)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Hexylene Glycol (UNII: KEH0A3F75J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74002-5030-1	500 mL in 1 BOTTLE, PUMP; 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(74002-5030)