

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 on the following body parts.

Around the eyes and ears, in the oral cavity, a wide range of body parts and damaged skin (may have irritating effects)

2. If the following symptoms appear, stop using them immediately and consult a doctor or pharmacist.

1) Hypersensitivity symptoms such as rash, erythema, itching, and edema

2) Skin irritation symptoms

3. Other precautions

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

2) Be careful not to get into your eyes, and if so, rinse well with clean water and consult a doctor or pharmacist.

3) Be careful not to inhale vapor when using it extensively or for a long time (if you drink ethanol vapor in large quantities or repeatedly, irritation to the mucous membrane, headache, etc. may occur). (Only for products containing ethanol)

4) When repeated use on the same site, be careful as the skin may become rough due to degreasing.

5) When used in sealed bandages, cast bandages, packs, etc., irritation symptoms may appear.

6) Do not use this medicine for anal or vaginal poultry as it may cause irritation or chemical burns.

7) Do not use for any purpose.

4. Precautions for storage

1) Avoid shading and keep it in shading.

2) Keep it out of reach of children, and if a child swallows it, go to the hospital right away.

3) After use, close the product completely with a lid to prevent the product from drying out or entering foreign objects.

4) Taking it out of the original container and storing it in another container may cause accidents due to misuse or deterioration in quality, so store it in the original container.

KEEP OUT OF REACH OF CHILDREN

Keep it out of reach of children, and if a child swallows it, go to the hospital right away.

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:

Airtight container, storage at room temperature (1~30°C)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

[Product Name] Poltone Hand Sanitizer Gel + Quasi-drug

+ Quasi-drug


POLTONE

Hand Sanitizer

with Moisturizers

Hand sanitizer used without water
99.9% sanitization

Contains 62% Ethanol Contains moisturizing components Easy sanitization without water

Drug Facts	
Active ingredients ALCOHOL 62.0 w%	Purpose SANITIZER
Uses Disinfection of hands and skin	
Warnings 1. Do not use on the following body parts. Around the eyes and ears, in the oral cavity, a wide range of body parts and damaged skin (may have irritating effects) 2. If the following symptoms appear, stop using them immediately and consult a doctor or pharmacist. 1) Hypersensitivity symptoms such as rash, erythema, itching, and edema 2) Skin irritation symptoms 3. Other precautions 1) For external use only (do not underwear). 2) Be careful not to get into your eyes, and if so, rinse well with clean water and consult a doctor or pharmacist. 3) Be careful not to inhale vapor when using it extensively or for a long time (if you drink ethanol vapor in large quantities or repeatedly, irritation to the mucous membrane, headache, etc. may occur). (Only for products containing ethanol) 4) When repeated use on the same site, be careful as the skin may become rough due to degreasing. 5) When used in sealed bandages, cast bandages, packs, etc., irritation symptoms may appear. 6) Do not use this medicine for anal or vaginal poultice as it may cause irritation or chemical burns. 7) Do not use for any purpose. 4. Precautions for storage 1) Avoid shading and keep it in shading. 2) Keep it out of reach of children, and if a child swallows it, go to the hospital right away. 3) After use, close the product completely with a lid to prevent the product from drying out or entering foreign objects. 4) Taking it out of the original container and storing it in another container may cause accidents due to misuse or deterioration in quality, so store it in the original container.	
Directions Take an appropriate amount on your hands and rub thoroughly to dry.	
Other Information How to save Airtight container, storage at room temperature (1~30 °C)	
Inactive ingredients Water, Carbomer, Triethanolamine, PEG-60 Hydrogenated Castor Oil, Methylparaben, Lavandula Angustifolia (Lavender) Oil, Butylene Glycol, Hexylene Glycol, Fragaria Chiloensis (Strawberry) Fruit Extract, Sophora Angustifolia Root Extract, Morus Alba Bark Extract, Glycyrrhiza Uralensis (Licorice) Root Extract, Citrus Paradisi (Grapefruit) Fruit Extract, Camellia Sinensis Leaf Extract	
DONGBANG COSMETICS Co.,Ltd. 39, Gajaeul-ro 32beon-gil, Seo-gu, Incheon, S. Korea	
Net Wt 500mL / 16.907 Fl. Oz.	

POLTONE HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74002-30 10
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)	
PEG-60 Hydrogenated Castor Oil (UNII: 02NG325BQG)	
Methylparaben (UNII: A2B8C7HI9T)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Hexylene Glycol (UNII: KEH0A3F75J)	
BEACH STRAWBERRY (UNII: 98542F2TQS)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
MORUS ALBA BARK (UNII: 7O71A48NDP)	
GLYCYRRHIZA URALENSIS ROOT (UNII: 42B5YD8F0K)	
GRAPEFRUIT (UNII: O82C39RR8C)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74002-3010-1	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/01/2020	

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

Name	Address	ID/FEI	Business Operations
DONGBANGCOSMETICS CO.,LTD		694452564	manufacture(74002-3010)