

JASNA PEARL HAND SANITIZER- alcohol gel
ELLA COSMETIC 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

ALCOHOL 70%

PURPOSE

SANITIZER

WARNINGS

For external use only.

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

Disinfection of hands and skin


Directions

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

INACTIVE INGREDIENTS

WATER, GLYCERIN, CARBOMER, TRIETHANOLAMINE, BUTYLENE GLYCOL, CAMELLIA SINENSIS LEAF EXTRACT, GLYCYRRHIZA URALENSIS(LICORICE) ROOT EXTRACT

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

 <p>Jasna Pearl Hand Gel Sanitizer</p> <p>99.9% Sterilization Moisturizing to the skin</p> <p>16.90 Fl. Oz.(500ml)</p>	<p>Drug Facts</p> <table border="1"> <tr> <td>Active Ingredients</td> <td>Purpose</td> </tr> <tr> <td>ALCOHOL 70%</td> <td>SANITIZER</td> </tr> </table> <p>Uses Disinfection of hands and skin</p> <p>Warnings For external use only.</p> <ol style="list-style-type: none"> 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) If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist. <ol style="list-style-type: none"> Hypersensitivity symptoms, e.g.rash, erythema , itchiness, and edema Skin irritation symptoms Other precautions <ol style="list-style-type: none"> For external use only (do not swallow). Avoid contact with eyes, if contact occurs, wash with clean water and consult a doctor or pharmacist. Be careful not to inhale vapors in case of extended or prolonged use. (Repeating inhaling of large amount of ethanlo vapor may cause irritation of the mucous membranes and headaches). If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal. Do not use sealed bandages, cast bandages, or packs as they may cause irritation. 	Active Ingredients	Purpose	ALCOHOL 70%	SANITIZER	<p>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.</p> <p>4. Precautions for storage</p> <ol style="list-style-type: none"> Keep away from direct sunlight and do not expose the product to heating devices or flame. Keep out of reach of children and go to the hospital immediately if swallowed. After use, close the lid completely to prevent the product from drying or foreign objects from getting inside the container. Storing the product in a different container may cause accidents or deterioration of quality. Therefore, keep the product in its original container. <p>Dust or foreign substances may get on the product while using it.</p> <p>Directions Take an appropriate amount on your hands and rub thoroughly to dry.</p> <p>Inactive Ingredients WATER, GLYCERIN, CARBOMER, TRIETHANOLAMINE, BUTYLENE GLYCOL, CAMELLIA SINENSIS LEAF EXTRACT, GLYCYRRHIZA URALENSIS (LICORICE) ROOT EXTRACT</p> <p>Ella Cosmetic Co., Ltd / www.ellacos.co.kr #1-202, 10, Namdongdong-ro 33beon-gil, Namdong-gu, Incheon, Korea</p> <p>Net Wt: 500mL / 16.90 Fl. Oz.</p>
	Active Ingredients	Purpose				
ALCOHOL 70%	SANITIZER					
MADE IN KOREA						

JASNA PEARL HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74003-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	350 mL in 500 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HO M O P O L Y M E R, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)

GREEN TEA LEAF (UNII: W2ZU1RY8B0)

GLYCYRRHIZA URALENSIS ROOT (UNII: 42B5YD8F0K)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74003-030-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/01/2020	

Labeler - ELLA COSMETIC CO., LTD. (693714444)

Registrant - ELLA COSMETIC CO., LTD. (693714444)

Establishment

Name	Address	ID/FEI	Business Operations
ELLA COSMETIC CO., LTD.		693714444	manufacture(74003-030)

Revised: 5/2020

ELLA COSMETIC CO., LTD.