

ESCO FRESH PURE MIST- alcohol spray

Arca Inc.

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 70.00%

INACTIVE INGREDIENT

Inactive ingredients:

Water, Glycerin, PEG-60 Hydrogenated Castor Oil, Fragrance

PURPOSE

Purpose: SANITIZER, Antiseptic

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

Directions: Take an appropriate amount on your hands and rub thoroughly to dry.
Inactive ingredients: Water, Glycerin, PEG-60 Hydrogenated Castor Oil, Fragrance
Distributor: Arca Inc. 907-44 Mapo-daeoro, Mapo-gu, Seoul, Republic of Korea
Manufacturer: Ester Co., Ltd. 254 Namdong-ro, Namdong-gu, Incheon, Republic of Korea
MADE IN KOREA
www.escomail.com

FRESH PURE MIST
HAND SANITIZER

Reduces 99.9% of Germs
Spray Type Hand Sanitizer
Keeping Hands Clean without Water

300ml /10.14 fl.oz

ESCO

Drug Fact
Product Name: Esco Fresh Pure Mist
Active ingredients: Alcohol 70.00% **Purpose:** Antiseptic, Sanitizer
Uses: Disinfection of hands and skin **Net Wt:** 300mL /10.14 fl.oz.
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.

ESCO FRESH PURE MIST

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:19339-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	210 mL in 300 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	

PEG-60 Hydrogenated Castor Oil (UNII: 02NG325BQG)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:19339-030-01	300 mL in 1 BOTTLE, SPRAY; 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 - Arca Inc. (688522453)

Registrant - Arca Inc. (688522453)

Establishment

Name	Address	ID/FEI	Business Operations
Ester Co., Ltd.		688425766	manufacture(19339-030)

Revised: 4/2020

Arca Inc.