

## **ESCO PERFECT HAND CLEANER- alcohol gel**

**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.*

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### **ACTIVE INGREDIENT**

Active ingredients: ALCOHOL 62.00%

### **INACTIVE INGREDIENT**

Inactive ingredients:

Water, Butylene Glycol, Polysorbate 60, Carbomer, Triethanolamine, Isopropyl Myristate, Fragrance, Isopropyl Palmitate

### **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 - ESCO PERFECT HAND CLEANER 30mL, 20ea Carton



## PACKAGE LABEL - ESCO PERFECT HAND CLEANER 1.5mL, 100ea Carton



## ESCO PERFECT HAND CLEANER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:19339-010
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62.0 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Polysorbate 60 (UNII: CAL22UVI4M)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
Isopropyl Palmitate (UNII: 8CRQ2TH63M)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:19339-010-02	20 in 1 CARTON	03/01/2020	
1	NDC:19339-010-01	30 mL in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:19339-010-04	100 in 1 CARTON	03/01/2020	
2	NDC:19339-010-03	1.5 mL in 1 PACKET; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/01/2020	

**Labeler** - Arca Inc. (688522453)

**Registrant** - Arca Inc. (688522453)

## Establishment

Name	Address	ID/FEI	Business Operations
Ester Co., Ltd.		688425766	manufacture(19339-010)