## AMERIGEL HAND SANITIZER- hand sanitizer gel Kova Laboratories, 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(s)

Alcohol 70% v/v. Purpose: Antiseptic

## **Purpose**

Antiseptic, Hand Sanitizer

#### Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

## Warnings

For external use only. Flammable. Keep away from heat or flame

#### Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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#### Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

### Other information

- Store below 110F (43C)
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## **Inactive ingredients**

Purified water USP, Aloe Barbadensis, acrylates/C10-30 alkyl acrylate crosspolymer, Propylene

## Amerigel Hand Sanitizer 6 oz



# HAND SANITIZER

## **CLEANSE & MOISTURIZE**

Kills 99.99% of Germs\*



## Advanced Hydrating Formula

Contains THREE Premium Moisturizers 6 fl. oz. (177 ml)

## Drug Facts

Active ingredient Ethyl Alcohol 70% v/v.... Purpose

**Uses** ■ For handwashing to decrease bacteria on skin when soap and water are not available.

#### Warnings

For External Use Only

Flammable. Keep Away from Fire or Flame

Do Not Use ■ in children less than 2 months of age. ■ on open skin wounds.

When using this product ■ keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if m irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

**Directions** ■ Wet hands thoroughly with product. ■ Rub hands together briskly until dry. ■ Supervise children under 6 years of age when using product.

Other information ■ Store below 110°F (43°C).

Inactive ingredients Water, Aloe Barbadensis, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Propylene Glycol, PEG-8 Dimethicone, Triisopropanolamine, Linalool, FD&C Blue #1.

Manufactured for:

AMERX HEALTH CARE CORPORATION

A Division of Procyon Corp. Clearwater, FL 33756 1-800-448-9599 www.amerigel.com

UPN M899AS01060 CAT# AS0106

\*Data based on laboratory test. Actual use may vary.

REV 1 05/20



Amerigel Hand Sanitizer 16 oz

## **AMERIGEL®**

## **AMERIGEL®**

# HAND SANITIZER

**CLEANSE & MOISTURIZE** 



Advanced Hydrating Formula
Contains THREE Premium Moisturizers

16 fl. oz. (473 ml)

Drug Facts
Active ingredient
Ethyl Alcohol 70% v/v.....

Uses # For handwashing to decrease bacteria on skin when soap and water are not available.

Warnings

For External Use Only

Flammable. Keep Away from Fire or Flame

Do Not Use ■ in children less than 2 months of age. ■ on open skin wounds.

When using this product **E** keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if ■ irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions ■ Wet hands thoroughly with product. ■ Rub hands together briskly until dry. ■ Supervise children under 6 years of age when using product.

Other information = Store below 110°F (43°C).

Inactive ingredients Water, Aloe Barbadensis, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Propylene Glycol, PEG-8 Dimethicone, Trisopropanolamine, Linalool, FD&C Blue #1.

0.3 L in 100 L

Manufactured for: AMERX HEALTH CARE CORPORATION A Division of Procyon Corp. Clearwater, FL 33756 1-800-448-9599 www.amerigel.com

UPN M899AS01160 CAT# AS0116



REV 1 10/20

Purpose

## AMERIGEL HAND SANITIZER

hand sanitizer gel

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:79417-010

Route of Administration TOPICAL

Active Ingredient/Active Moiety

PEG-8 DIMETHICONE (UNII: GIA7T764OD)

Ingredient Name
Basis of Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII: 3K9958 V90M)
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII: 3K9958 V90M)

Inactive ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)	28.397 L in 100 L		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	0.05 L in 100 L		
LINALOOL, (+/-)- (UNII: D81QY6I88E)	0.07 L in 100 L		
<b>CARBOMER 1342</b> (UNII: 809 Y72KV36)	0.27 L in 100 L		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.5 L in 100 L		

TRIISOPROPANOLAMINE (UNII: W9 EN9 DLM9 8)	0.41 L in 100 L
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	0.003 L in 100 L

Product Characteristics			
Color	blue (Translucent Gel)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
# Item Code Package Description		Marketing Start Date	Marketing End Date	
1 NDC:794	17-010-	.177 L in 1 TUBE; Type 0: Not a Combination Product	07/02/2020	
2 NDC:794		.473 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/02/2020	

## Labeler - Kova Laboratories, Inc. (193055027)

## **Registrant -** Kova Laboratories, Inc. (193055027)

Establishment			
Name	Address	ID/FEI	Business Operations
Kova Laboratories, Inc.		193055027	label(79417-010), manufacture(79417-010)

Revised: 12/2020 Kova Laboratories, Inc.