

## **KOVA CARE 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 between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

### **Inactive ingredients**

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

Glycol, PEG-8 Dimethicone, Triisopropanolamine, Linalool, FD&C #1

## Kova Care



3.3 FL OZ (100mL)

DRUG FACTS	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl Alcohol 70% v/v.....	Antiseptic
<b>Warnings</b>	
Flammable. Keep away from fire or flame.	
For external use only	
Avoid contact in or near eyes. Stop use and ask a doctor if irritation or rash appears and lasts. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Other Information</b>	
Store below 110°F (43°C)	
May discolor certain fabrics or surfaces	
<b>Directions</b>	
Put enough sanitizer in your palm to cover your hands. Rub your hands together briskly till dry. Children under 6 years of age should be supervised when using product.	
<b>Inactive ingredients</b>	
Water, Aloe Barbadensis, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Propylene Glycol, PEG-8 Dimethicone, Triisopropanolamine, Linalool, FD&C Blue #1	

Manufactured in USA  
Kova Laboratories

## KOVA CARE HAND SANITIZER

hand sanitizer gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79417-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 L in 100 L

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	28.397 L in 100 L
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.05 L in 100 L
LINALOOL, (+/-)- (UNII: D81QY6I88E)	0.07 L in 100 L
CARBOMER 1342 (UNII: 809Y72KV36)	0.27 L in 100 L

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.5 L in 100 L
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	0.3 L in 100 L
TRIISOPROPANOLAMINE (UNII: W9EN9DLM98)	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:79417-001-03	0.1 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/02/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/26/2020	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Kova Laboratories, Inc.		193055027	label(79417-001) , manufacture(79417-001)