

**HAND SANITIZING- isopropyl alcohol gel**  
**Biominales Pharma**

*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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**HAND SANITIZING**

**DRUG FACTS**

**Active ingredients**

Isopropyl alcohol – 70% v/v

**Purpose**

Antiseptic

**Inactive ingredients**

Deionized water, Carbomer, Propylene Glycol, Triethanolamine, Hydrogen Peroxide.

**Use (s)**

Hand sanitizer to help reduce bacteria that potentially can cause disease.

For use when water and soap are not available.

**Directions**

Rub thoroughly into hands for at least 30 seconds, allow to dry.

Supervise children when they use this product.

Adults and children 2 years and older:

For occasional and personal domestic use.

**Other information**

Store Between 15-30 °C (59 - 86 °F). Avoid freezing and excessive heat above 40 °C (104 °F).

**Cautions and warnings**

- ***For external use only***
- ***Flammable***
- ***Keep away from heat or flame***
- ***Keep out of reach of children***
  
- ***Do not use*** in children less than 2 months of age or on open skin wounds
  
- ***When using this product*** keep our of eyes, ears and mouth.

In case of contact with eyes, rinse eyes thoroughly with water

- These may be signs of a serious condition
- ***Keep out of reach of children***
- If swallowed, get medical help or contact poison control center right away.

***Stop use and ask a doctor*** if irritation or rash occurs.

**Manufactured by:**  
**Hempire Farms, LLC**  
**150 E Palmetto Park Rd**  
**Boca Raton, FL 33432**

**PRINCIPAL DISPLAY PANEL - 473 mL Container Label**

USA  
HEMPIRE  
FARMS

MADE IN  
USA

KILLS HARMFUL BACTERIA/GERMS

16 fl. Oz. (473 mL)

HAND SANITIZING GEL with  
HEMP OIL & ALOE for moisturizing

16 fl. oz.  
(473 mL)

70 %  
v/v

ADVANCED

ISOPROPYL  
ALCOHOL  
PROTECTION

— USA —  
**HEMPIRE FARM**  
 FARMS

KILLS HARMFUL BACTERIA/GERMS  
 TUE DES BACTERIES ET MICROBES NOCIFS

16 fl. Oz. (473 mL)

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 HEMP OIL & ALOE for moisturizing**

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 v/v ALCOHOL  
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Manufactured by:  
 Hempire Farms, LLC  
 150 E Palmetto Park Rd  
 Boca Raton, FL 33432  
 NDC: 77110-600-03

**HAND SANITIZING**

isopropyl alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77110-600
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Isopropyl alcohol (UNII: ND2M416302) (Isopropyl alcohol - UNII:ND2M416302)	Isopropyl alcohol	70 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Carbomer Homopolymer, Unspecified Type (UNII: 0 A5MM307FC)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Trolamine (UNII: 9O3K93S3TK)	
Hydrogen Peroxide (UNII: BBX060AN9V)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77110-600-04	236 mL in 1 CONTAINER; Type 0: Not a Combination Product	09/01/2020	
2	NDC:77110-600-03	473 mL in 1 CONTAINER; Type 0: Not a Combination Product	09/01/2020	
3	NDC:77110-600-02	946 mL in 1 CONTAINER; Type 0: Not a Combination Product	09/01/2020	
4	NDC:77110-600-01	3785 mL in 1 CONTAINER; Type 0: Not a Combination Product	09/01/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333E	09/01/2020	

**Labeler** - Biominerales Pharma (117489663)**Establishment**

Name	Address	ID/FEI	Business Operations
Biominerales Pharma		117489663	MANUFACTURE(77110-600)

Revised: 9/2020

Biominerales Pharma