

**HAND SANITIZER- alcohol gel**  
**Biominales Pharma, LLC**

*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.*

-----

**HAND SANITIZER**

**DRUG FACTS**

**Active ingredient**

Ethyl alcohol 70% v/v

**Purpose**

Antiseptic

**Inactive ingredients**

Carbomer, Glycerin, Propylene Glycol, Aminomethyl Propanol, Isopropyl Myristate, Tocopheryl Acetate, Purified Water, Fragrance.

**Use (s)**

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when water and soap 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 or 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 poison control center right away.

**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.

**Manufactured for and  
Distributed by:**

Biominales Pharma, LLC  
Boca Raton, Florida 33442

**PRINCIPAL DISPLAY PANEL - 3,785 mL Bottle Label**

BIOMINERALES

PHARMA

HAND SANITIZER - GEL

Kills more than 99.99% of germs

Prevention:

Keep away from heat / sparks / open flames / hot surfaces.

No Smoking. Keep container tightly closed.

Response:

IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice / attention. In case of fire:

Use dry sand, dry chemical or alcohol - resistant foam for extinction.

Storage:

Store in a well-ventilated place. Keep cool. Store Between

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

40 °C (104 °F)

Disposal:

Dispose of contents / container to an approved waste disposal plant.

Active Ingredients: Ethyl Alcohol 70% v/v

NDC: 77110-270-01

Manufactured for and

Distributed by:

Biominales Pharma, LLC

Boca Raton, Florida 33442

[www.biominalespharma.com](http://www.biominalespharma.com)

Net Contents

1 Gal. (3,785 mL)



# HAND SANITIZER - GEL

*Kills more than 99.99% of germs*

**Prevention:**

Keep away from heat / sparks / open flames / hot surfaces.  
 No Smoking. Keep container tightly closed.

**Response:**

IF IN EYES: Rinse cautiously with water for several minutes.  
 Remove contact lenses, if present and easy to do. Continue rinsing.  
 If eye irritation persists: Get medical advice / attention. In case of fire:  
 Use dry sand, dry chemical or alcohol - resistant foam for extinction.

**Storage:**

Store in a well-ventilated place. Keep cool. Store Between  
 15-30 °C (59 - 86 °F). Avoid freezing and excessive heat above  
 40 °C (104 °F)

**Disposal:**

Dispose of contents / container to an approved waste disposal plant.

**Active Ingredients:** Ethyl Alcohol 70% v/v

NDC: 77110-270-01



**Manufactured for and  
 Distributed by:**  
 Biominerales Pharma, LLC  
 Boca Raton, Florida 33442  
[www.biomineralespharma.com](http://www.biomineralespharma.com)

**Net Contents**  
**1 Gal. (3,785 mL)**

**DRUG FACTS**

<b>Active ingredient</b>	<b>Purpose</b>
Ethyl alcohol 70% v/v.....	Antiseptic

**Inactive ingredients**  
 Carbomer, Glycerin, Propylene Glycol, Aminomethyl Propanol,  
 Isopropyl Myristate, Tocopheryl Acetate, Purified Water, Fragrance.

**Use (s)** Hand sanitizer to help reduce bacteria that potentially  
 can cause disease. For use when water and soap 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  
 or 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 poison control center right away.

**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.

**HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77110-270
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)	Alcohol	70 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77110-270-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2020	
2	NDC:77110-270-06	944 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2020	
3	NDC:77110-270-02	472 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2020	
4	NDC:77110-270-03	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2020	
5	NDC:77110-270-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2020	
6	NDC:77110-270-05	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333E	06/15/2020	

**Labeler** - Biominerales Pharma, LLC (117489663)

### Establishment

Name	Address	ID/FEI	Business Operations
Biominerales Pharma, LLC		117489663	MANUFACTURE(77110-270)

Revised: 6/2020

Biominerales Pharma, LLC