

## **LEVEL1 HEALTH HAND SANITIZER- alcohol antiseptic gel**

### **Level 1 Health 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.*

-----

### **Level 1 Health OTC hand sanitizer**

#### **Active Ingredient(s)**

Ethyl Alcohol 70% v/v

#### **Purpose**

Antiseptic

#### **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.

#### **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, Glycerin, Aloe Barbadensis Leaf Juice, Isopropyl Myristate, Vitamine E Acetate, Carbomer, Propylene Glycol, Triethanolamine

#### **Package Label - Principal Display Panel**



LEVEL 1 HEALTH

# HAND SANITIZER

## PREMIUM MOISTURIZING GEL

UNSCENTED

WITH ALOE + VITAMIN E

**70%** | Alcohol Antiseptic

32 FL OZ (946.4 mL)



MADE IN USA

### Drug Facts

Active ingredient(s)	Purpose
Ethyl Alcohol 70% v/v.....	Antiseptic

**Uses**  
• Hand Sanitizer to help reduce bacteria that potentially can cause disease.

**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 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.

**Other Information**  
• Store between 15-30C (59-86F)  
• Avoid Freezing and Excessive Heat above 40C (104F)

**Inactive Ingredients** Purified Water USP, Glycerin, Aloe Barbadosis Leaf Juice, Isopropyl Myristate, Vitamin E Acetate, Carbomer, Propylene Glycol, Triethanolamine

 Distributed by Level 1 Health  
3636 S Geyer Rd, Suite 100  
St. Louis, MO 63127  
www.level1health.com | (314) 238-7348



LEVEL 1 HEALTH

# HAND SANITIZER

## PREMIUM MOISTURIZING GEL

UNSCENTED

WITH ALOE + VITAMIN E

**70%** | Alcohol Antiseptic

10.0 FL OZ (295.7 mL)



MADE IN USA

### Drug Facts

Active ingredient(s)	Purpose
Ethyl Alcohol 70% v/v.....	Antiseptic

**Uses**  
• Hand Sanitizer to help reduce bacteria that potentially can cause disease.

**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 right away.

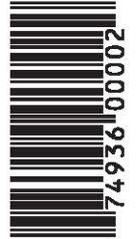
**Directions**  
• Place enough product on hands to cover all surfaces.  
• Rub hands together until dry.  
• Supervise children under 6 years of age when using this product to avoid swallowing.

**Other Information**  
• Store between 15-30C (59-86F)  
• Avoid Freezing and Excessive Heat above 40C (104F)

**Inactive Ingredients** Purified Water USP, Glycerin, Aloe Barbadosis Leaf Juice, Isopropyl Myristate, Vitamin E Acetate, Carbomer, Propylene Glycol, Triethanolamine



Distributed by  
Level 1 Health  
3636 S Geyer Rd., Suite 100  
St. Louis, MO 63127  
www.level1health.com | (314) 238-7348





Distributed by  
Level 1 Health  
3636 S Geyer Rd. Suite 100  
St. Louis, MO 63127  
www.level1health.com  
(314) 238-7348

**LEVEL 1 HEALTH**

**HAND  
SANITIZER**

**PREMIUM  
MOISTURIZING  
GEL**

UNSCENTED

WITH ALOE + VITAMIN E

**70% | Alcohol  
Antiseptic**

8.4 FL OZ (249 mL)



<b>Drug Facts</b>	
<b>Active ingredient(s)</b>	<b>Purpose</b>
Ethyl Alcohol 70% v/v	Antiseptic
<b>Uses</b>	
• Hand Sanitizer to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b>	
For external use only.	
<b>Flammable. Keep away from heat or flame</b>	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> <li>• when using this product keep out of eyes, ears, and mouth, in case of contact with eyes, rinse eyes thoroughly with water.</li> </ul>	
<b>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</b>	
<b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control right away.</b>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• Place enough product on hands to cover all surfaces.</li> <li>• Rub hands together until dry.</li> <li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other Information</b>	
<ul style="list-style-type: none"> <li>• Store between 15-30C (59-86F)</li> <li>• Avoid Freezing and Excessive Heat above 40C (104F)</li> </ul>	
<b>Inactive Ingredients</b> Purified Water USP, Glycerin, Aloe Barbadensis Leaf Juice, Isopropyl Myristate, Vitamin E Acetate, Carbomer, Propylene Glycol, Triethanolamine	

LEVEL 1 HEALTH

Hand Sanitizer

Premium Moisturizing Gel

Unscented

WITH ALOE + VITAMIN E

70% Alcohol Antiseptic

XX FL OZ (XXX.X mL)

MADE IN USA

Distributed by

Level 1 Health

3636 S Geyer Rd. Suite 100

St. Louis, MO 63127

www.level1health.com | (314) 238-7348

**LEVEL1 HEALTH HAND SANITIZER**

alcohol antiseptic gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74936-001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
TROLAMINE (UNII: 9O3K93S3TK)				
GLYCERIN (UNII: PDC6A3C0OX)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
WATER (UNII: 059QF0KO0R)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)				
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)				
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74936-001-32	946.4 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2020	
2	NDC:74936-001-08	249 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2020	
3	NDC:74936-001-10	295.7 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	05/12/2020		

**Labeler** - Level 1 Health LLC (117476751)

**Registrant** - Level 1 Health LLC (117476751)

### Establishment

Name	Address	ID/FEI	Business Operations
Continental Manufacturing Chemist, Inc.		005278007	manufacture(74936-001) , analysis(74936-001) , pack(74936-001) , repack(74936-001) , label(74936-001) , relabel(74936-001)

### Establishment

Name	Address	ID/FEI	Business Operations
Continental Manufacturing Chemist		081171390	manufacture(74936-001) , pack(74936-001) , label(74936-001) , repack(74936-001) , relabel(74936-001) , api manufacture(74936-001)