

## **HAND GEL SANITIZER- alcohol gel**

### **Allied Pressroom Products**

*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 Gel Ethyl Alcohol Sanitizer**

This is an ethanol based hand sanitizer manufactured following the CDC recommendation of using an alcohol concentration of more than 60 % v/v alcohol when soap and water is not available.

It is manufactured by gelling a 70 % ethanol solution with the the minimum of an acrylate polymer to create a clear gel that is easy to apply and does not evaporate as readily as the liquid versions to provide sufficient dwell time to be effective.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product::

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerin (1.00 % v/v)..
- c. Polypropylene Glycol (1.2 % v/v)..
- d. Acrylate Polymer (0.3% v/v).
- e. Sterile distilled water or boiled cold water.

No other materials are used.

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

Ethyl 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.

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

Water, Polypropylene Glycol, glycerin, Acrylate polymer.

### Package Label - Principal Display Panel

3785 ml NDC 78851-333-05

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Ethyl alcohol 70% v/v	Antiseptic
<b>Use[s]</b> - Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b> • in children less than 2 months of age • on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30°C (59-86°F). • Avoid freezing and excessive heat above 40°C (104°F).	
<b>Inactive Ingredients</b> - Water, Polyethylene Glycol, Glycerin, Acrylate Polymer.	



BATCH #  
EXPIRE ON:

Contains: 70% Ethyl Alcohol & Emollients (Glycerin).

**IF SOAP AND WATER ARE NOT READILY AVAILABLE, USE AN ALCOHOL-BASED HAND SANITIZER THAT CONTAINS AT LEAST 60% ALCOHOL.**  
- Stated by the CDC

NDC 78851-333-05  
3,785 mL



**ALLIED PRESSROOM PRODUCTS**  
4814 Persimmon Ct Monroe, NC 28110  
office: 800-327-8487 | info@alliedchem.com

IMPORTANT NOTICE - The following is made in lieu of all warranties, expressed or implied. Sellers only obligation shall be to replace such quantity of the product proved to be defective. Neither seller nor manufacturer shall be liable for any injury, loss or damage, direct, incidental or consequential arising out of the use or the inability to use this product. Before using, users shall determine the suitability of the product for their intended use, and user assumes all risk and liability whatsoever in connection therewith. The foregoing may not be altered except by an agreement signed by officers of seller and manufacturer.

946 ml NDC 78851-333-04



<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Ethyl alcohol 70% v/v .....	<b>Purpose</b> Antiseptic
<b>Use[s]</b> - Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. 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> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• Place enough product on hands to cover all surfaces. 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 15-30°C (59-86°F)</li> <li>• Avoid freezing and excessive heat above 40°C (104°F)</li> </ul>	
<b>Inactive Ingredients</b> - Water, Polyethylene Glycol, Glycerin, Acrylate Polymer.	
<b>ALLIED PRESSROOM PRODUCTS</b> 4814 Persimmon Ct Monroe, NC 28110	800-327-8487 • info@alliedchem.com www.alliedpressroomproducts.com



**70% ALCOHOL BASED SANITIZER**

Contains: 70% Ethyl Alcohol & Emollients (Glycerin).

**IF SOAP AND WATER ARE NOT READILY AVAILABLE,  
USE AN ALCOHOL-BASED HAND SANITIZER THAT  
CONTAINS AT LEAST 60% ALCOHOL.**  
- Stated by the CDC

**NDC 78851-333-02  
120 mL.**

<b>BATCH #</b>	<b>EXPIRE ON:</b>
----------------	-------------------

105 ml NDC 78851-333-01 back

<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Ethyl alcohol 70% v/v .....	<b>Purpose</b> Antiseptic
<b>Use[s]</b> - Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. 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> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• Place enough product on hands to cover all surfaces. 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 15-30°C (59-86°F)</li> <li>• Avoid freezing and excessive heat above 40°C (104°F)</li> </ul>	
<b>Inactive Ingredients</b> - Water, Polyethylene Glycol, Glycerin, Acrylate Polymer.	
<b>ALLIED PRESSROOM PRODUCTS</b> 4814 Persimmon Ct Monroe, NC 28110	800-327-8487 • info@alliedchem.com www.alliedpressroomproducts.com



# HAND GEL

**70% ALCOHOL BASED SANITIZER**

Contains: 70% Ethyl Alcohol & Emollients (Glycerin).

**IF SOAP AND WATER ARE NOT READILY AVAILABLE,  
USE AN ALCOHOL-BASED HAND SANITIZER THAT  
CONTAINS AT LEAST 60% ALCOHOL.**

**- Stated by the CDC**

**NDC 78851-333-01**

**105 mL.**

<b>BATCH #</b>	<b>EXPIRE ON:</b>
----------------	-------------------

NDC: 78851-333-01 front

105 ml

**HAND GEL SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78851-333
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	1.2 mL in 100 mL
ALLYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (LOW ALLYL METHACRYLATE) (UNII: P180E777XB)	0.3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78851-333-01	105 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2020	
2	NDC:78851-333-02	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2020	
3	NDC:78851-333-03	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2020	
4	NDC:78851-333-04	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2020	
5	NDC:78851-333-05	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/19/2020	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	06/19/2020	

**Labeler** - Allied Pressroom Products (069895618)**Registrant** - Allied Pressroom Products (069895618)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Allied Pressroom Products		069895618	manufacture(78851-333)

