

**HAND SANITIZER- alcohol gel**  
**Fareva Morton Grove, 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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- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (78%, 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
- c. Hydroxypropyl cellulose
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Alcohol 78% 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**

glycerin, hydroxypropyl cellulose, water

**Package Label - Principal Display Panel**

236.5 mL NDC: 72686-180-09

**frida**  
**HAND SANITIZER**  
A little [sani] for your sanity  
78% Alcohol 8oz (236.5 mL)

**frida**  
**78% ALCOHOL HAND SANITIZER**

<b>Drug Facts</b>	
<b>Active Ingredient</b> Ethyl Alcohol 78% v/v	<b>Purpose</b> Antiseptic
<b>Use</b>	
<ul style="list-style-type: none"> <li>• For hand washing to decrease bacteria on the skin.</li> <li>• For use when soap and water are not available.</li> </ul>	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>• In children less than 2 months of age</li> <li>• On open wounds</li> </ul>	
<b>Warnings</b>	
<b>For external use only.</b>	
<b>Flammable:</b> Do not use near heat, flame or while smoking.	
<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 rash or irritation develops and lasts.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center immediately.	
<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>• For children under 6, use only under adult supervision.</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>	
Water (Aqua), Glycerin, Hydroxypropylcellulose	
<b>Questions and comments</b>	
fussbuster@frida.com	

Manufactured for:  
Fridababy LLC, Miami FL 33137  
Made in the USA From domestic and imported ingredients  
frida.com

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**HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72686-180
<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	78 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
WATER (UNII: 059QF0K00R)	

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:72686-180-09	236.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

**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	03/30/2020	

**Labeler** - Fareva Morton Grove, Inc. (116752326)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fareva Morton Grove, Inc.		116752326	manufacture(72686-180) , analysis(72686-180) , label(72686-180) , pack(72686-180) , relabel(72686-180) , repack(72686-180)

Revised: 10/2020

Fareva Morton Grove, Inc.