

## **FRIDA 70 ALCOHOL PLUS ALOE HAND SANITIZER- ethyl alcohol gel**

### **Prime Enterprises**

*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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### **Frida Hand Sanity 70% Alcohol + Aloe Hand Sanitizer**

#### ***Active Ingredient***

Ethyl Alcohol 70% v/v

#### ***Purpose***

Antiseptic

#### ***Use***

For hand washing to decrease bacteria on the skin.

#### ***Warnings***

For external use only.

**Flammable:** Do not use near hear, flame or while smoking.

**When using this product:** Keep put of eyer. If product gets into eyes, rinse with water to remove. Avoid contact with broken skin. Do not inhale or ingest.

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

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

#### ***Directions***

- Wet hands thoroughly with product and allow to dry without wiping.
- For children under 6, use only under adult supervision.

#### ***Other Information***

- Do not store above 104 °F.
- May discolor some fabrics, wood finishes and plastics.

#### ***Inactive ingredients***

Aloe Barbadosis Leaf Juice, Aminomethyl Propanol, Carbomer, Glycerin, Isopropyl Myristate, Tocopherol, Water

#### ***Questions and comments***

fussbuster@frida.com

### **Frida Hand Sanity 70% Alcohol + Aloe Hand Sanitizer**

frida  
**HAND  
 SANITY**  
 70% ALCOHOL + ALOE  
 HAND SANITIZER

4 fl oz (118ml)

A LITTLE [SANI] FOR YOUR SANITY

**Drug Facts**

<b>Active Ingredient</b> Ethyl Alcohol 70% v/v	<b>Purpose</b> Antiseptic
<b>Use</b> • For hand washing to decrease bacteria on the skin.	
<b>Warnings</b> For external use only.	
<b>Flammable:</b> Do not use near heat, flame or while smoking.	
<b>When using this product</b> • Keep out of eyes. If product gets into eyes, rinse with water to remove. Avoid contact with broken skin. Do not inhale or ingest.	
<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> • Wet hands thoroughly with product and allow to dry without wiping. • For children under 6, use only under adult supervision.	
<b>Other information</b> • Do not store above 104° F. • May discolor some fabrics, wood finishes and plastics.	
<b>Inactive ingredients</b> Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Carbomer, Glycerin, Isopropyl Myristate, Tocopherol, Water	
<b>Questions and comments</b> fussbuster@frida.com	

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



frida

**FRIDA 70 ALCOHOL PLUS ALOE HAND SANITIZER**

ethyl alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58 443-0 310
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
TOCOPHEROL (UNII: R0ZB2556P8)	
WATER (UNII: 059QF0K00R)	

**Product Characteristics**

<b>Color</b>	white (Colorless)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0310-3	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/27/2020	

**Labeler** - Prime Enterprises (101946028)

**Registrant** - Prime Enterprises (101946028)

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises		101946028	manufacture(58443-0310) , pack(58443-0310) , label(58443-0310) , analysis(58443-0310)

Revised: 4/2020

Prime Enterprises