

## **HAND SANITIZER- alcohol gel**

**Vara Home Usa 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.*

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### **Hand Sanitizer Gel**

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

Alcohol 75% 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**

Flammable. Keep away from heat or flame.

For external use only.

#### **Do not use**

- in children less than 2 months of age
- on open skin wounds

#### **When using this product**

do not use in or near the eyes.

#### **Stop use and ask medical doctor**

if irritation or rash appears and lasts.

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

#### **Directions**

- Place enough product in your palm to thoroughly spread on both hands and rub into the skin until dry.
- Children under 6 years of age should be supervised when using this product.

#### **Other information**

- Store below 106F (41F).
- May discolor certain fabrics or surfaces.


**Inactive ingredients**

Water, Glycerin, Triethanolamine, Carbomer

**Package Label - Principal Display Panel**

30 mL NDC: 79060-002-01



<b>Drug Facts</b>	
<b>Active Ingredient[s]</b> Ethyl Alcohol 75%.....	<b>Purpose</b> Antiseptic
<b>Use[s]</b> Helps reduce bacteria on the skin. For use when soap and water are not available.	
<b>Warnings</b> Flammable. Keep away from fire or flame. For external use only.	
<b>Do not use</b> • In children less than 2 months of age. • On open skin wounds.	
<b>When using this product,</b> do not use in or near the eyes. <b>Stop use and ask medical doctor</b> if irritation or rash appears and lasts. <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 in your palm to thoroughly spread on both hands and rub into the skin until dry. • Children under 6 years of age should be supervised when using this product.	
<b>Other Information</b> • Store below 106°F (41°C). • May discolor certain fabrics or surfaces.	
<b>Inactive Ingredients:</b> Water, Glycerin, Triethanolamine, Carbomer.	
<b>Questions?</b> Info@varahomeusa.com	
<b>Distributed by:</b> Vara Home USA LLC 9401-T Southern Pine Blvd. Charlotte NC 28273 Kills 99.99% of common germs. Made in China	
Lot#: 052020 Pro.: 2020/05/10 Exp.: 2022/05/09	
 0 843535 007980	

60 mL NDC:79060-002-02


**Hand Sanitizer Gel**

**KILLS 99.99% GERMS**

WORKS WITHOUT SOAP OR WATER

**Alcohol 75%**

2 FL OZ(60ml)

<b>Drug Facts</b>	
<b>Active Ingredient[s]</b>	<b>Purpose</b>
Ethyl Alcohol 75%.....	Antiseptic
<b>Use[s]</b>	
Helps reduce bacteria on the skin.	
For use when soap and water are not available.	
<b>Warnings</b>	
Flammable. Keep away from fire or flame.	
For external use only.	
<b>Do not use</b>	
• In children less than 2 months of age.	
• On open skin wounds.	
<b>When using this product</b> , do not use in or near the eyes. <b>Stop use and ask medical doctor</b> if irritation or rash appears and lasts. <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 in your palm to thoroughly spread on both hands and rub into the skin until dry.	
• Children under 6 years of age should be supervised when using this product.	
<b>Other Information</b>	
• Store below 106°F (41°C).	
• May discolor certain fabrics or surfaces.	
<b>Inactive Ingredients:</b> Water, Glycerin, Triethanolamine, Carbomer.	
<b>Questions?</b> Info@varahomeusa.com	
<b>Distributed by:</b>	
Vara Home USA LLC	
9401-T Southern Pine Blvd.	
Charlotte NC 28273	
Kills 99.99% of common germs.	
Made in China	
	
Lot#: 052020 Pro.: 2020/05/10 Exp.: 2022/05/09	

1000 mL NDC: 79060-002-03

**Hand Sanitizer Gel**

**KILLS 99.99% GERMS**

WORKS WITHOUT SOAP OR WATER

**Alcohol 75%**

33.8 FL OZ(1000ml)

<b>Drug Facts</b>	
<b>Active Ingredient[s]</b>	<b>Purpose</b>
Ethyl Alcohol 75%.....	Antiseptic
<b>Use[s]</b>	
Helps reduce bacteria on the skin.	
For use when soap and water are not available.	
<b>Warnings</b>	
Flammable. Keep away from fire or flame.	
For external use only.	
<b>Do not use</b>	
• In children less than 2 months of age.	
• On open skin wounds.	
<b>When using this product</b> , do not use in or near the eyes. <b>Stop use and ask medical doctor</b> if irritation or rash appears and lasts. <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 in your palm to thoroughly spread on both hands and rub into the skin until dry.	
• Children under 6 years of age should be supervised when using this product.	
<b>Other Information</b>	
• Store below 106°F (41°C).	
• May discolor certain fabrics or surfaces.	
<b>Inactive Ingredients:</b> Water, Glycerin, Triethanolamine, Carbomer.	
<b>Questions?</b> Info@varahomeusa.com	
<b>Distributed by:</b>	
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Lot#: 052020 Pro.: 2020/05/10 Exp.: 2022/05/09	

# HAND SANITIZER

alcohol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79060-002(NDC:74742-004)
<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	75 mL in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

## Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:79060-002-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2020	
2	NDC:79060-002-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2020	
3	NDC:79060-002-03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2020	

## 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	06/12/2020	

**Labeler** - Vara Home Usa Llc (802033196)

**Registrant** - Yangzhou Jiefiao Tourism-plastic Products Chemical Plant (527742625)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Yangzhou Jiefiao Tourism-plastic Products Chemical Plant		527742625	manufacture(79060-002) , relabel(79060-002)