

## **HAND SANITIZER- isopropyl alcohol solution**

### **Joosie Vapes**

*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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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- 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)**

Isopropyl 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**

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.

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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, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

# HAND SANITIZER TOPICAL SOLUTION



479-968-3352

*Thank you for your support!*

ISOPROPYL ALCOHOL  
ANTISEPTIC 75%  
NON-STERILE SOLUTION

**100ml**

**NDC# 74404-075-100**

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient</b> Isopropyl alcohol 75%w/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> <b>For external use only. Flammable. Keep away from heat or flame.</b>	
<b>Do not use</b> *On child or unless 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> glycerin, hydrogen peroxide, purified water USP	

# HAND SANITIZER TOPICAL SOLUTION



972-501-0266

*Thank you for your support!*

ISOPROPYL ALCOHOL  
ANTISEPTIC 75% **100ml**  
NON-STERILE SOLUTION

NDC# 74404-075-100

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient</b> Isopropyl alcohol 75%w/	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>	
*On 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.	
*Super vise childr en 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> glycerin, hydrogen peroxide, purified water, USP	

# HAND SANITIZER TOPICAL SOLUTION



903-645-7960

*Thank you for your support!*

ISOPROPYL ALCOHOL  
ANTISEPTIC 75% **100ml**  
NON-STERILE SOLUTION

NDC# 74404-075-100

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient</b>	.....Antiseptic
Isopropyl alcohol 75%w/	
<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>	
*On 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> glycerin, hydrogen peroxide, purified water USP	



# HAND SANITIZER TOPICAL SOLUTION



**LoneStar**  
PIPELINE CONTRACTORS  
*Building on integrity*

*Thank you for your support!*

ISOPROPYL ALCOHOL  
ANTISEPTIC 75% **100ml**  
NON-STERILE SOLUTION

NDC# 74404-075-100

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient</b> Isopropyl alcohol 75% w/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> <b>For external use only. Flammable. Keep away from heat or flame.</b>	
<b>Do not use</b> * On 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.	
<b>Other information</b> * Super viscous children under 6 years of age when using this product to avoid swallowing * Store between 15-30°C (59-86°F) * Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

# HAND SANITIZER TOPICAL SOLUTION



325-676-3835

*Thank you for your support!*

ISOPROPYL ALCOHOL  
ANTISEPTIC 75% **100ml**  
NON-STERILE SOLUTION

NDC# 74404-075-100

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient</b> Isopropyl alcohol 75%w/.....	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. <b>Flammable. Keep away from heat or flame.</b>	
<b>Do not use</b> *On 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. *Super viscous 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> glycerin, hydrogen peroxide, purified water USP	

# HAND SANITIZER TOPICAL SOLUTION



505-877-5413

*Thank you for your support!*

ISOPROPYL ALCOHOL  
ANTISEPTIC 75% **100ml**  
NON-STERILE SOLUTION

NDC# 74404-075-100

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient</b> Isopropyl alcohol 75%w/w	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.	
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<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	
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<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

100 ml NDC: 74404-075-10

## HAND SANITIZER

isopropyl alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74404-075
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

**WATER** (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74404-075-10	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Joosie Vapes (060642847)

**Registrant** - Joosie Vapes (060642847)

### Establishment

Name	Address	ID/FEI	Business Operations
Joosie Vapes		060642847	manufacture(74404-075)

Revised: 4/2020

Joosie Vapes