

## **TIODIZE HAND SANITIZER- isopropyl alcohol liquid**

**Tiodize, 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.*

-----

### **Hand Sanitizer Spray**

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.

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, hydrogen peroxide, purified water USP

### Hand Sanitizer 88.7mL (3oz) 77089-075-01

<p><b>Drug Facts:</b> Registered: FDA, USP, WHO</p> <hr/> <table><thead><tr><th>Active ingredient[s]</th><th>Purpose</th></tr></thead><tbody><tr><td>Isopropyl Alcohol 75% v/v.....</td><td>Antiseptic</td></tr></tbody></table> <hr/> <p><b>Use[s]</b></p> <ul style="list-style-type: none"><li>• Hand Sanitizer to help reduce bacteria.</li><li>• Recommended for repeated use.</li></ul> <hr/> <p><b>Warnings:</b></p> <ul style="list-style-type: none"><li>• For external use only.</li></ul> <hr/> <p><b>Flammable:</b></p> <ul style="list-style-type: none"><li>• Keep away from heat or flame.</li><li>• Do not store above 104°F/40°C.</li></ul> <hr/> <p><b>When using this product:</b></p> <ul style="list-style-type: none"><li>• Keep out of eyes, ears, and mouth.</li><li>• In case of contact with eyes, flush thoroughly with water.</li><li>• Avoid contact with broken skin.</li></ul> <hr/> <p><b>Stop use and ask a doctor:</b></p> <ul style="list-style-type: none"><li>• If irritation and redness develop and persist more for than 72 hours.</li></ul> <hr/> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center immediately.</p> <hr/> <p><b>Directions</b></p> <ul style="list-style-type: none"><li>• Spray directly on hands and rub in thoroughly.</li><li>• For children under 6 years of age, use adult supervision.</li><li>• Not recommended for infants.</li></ul> <hr/> <p><b>Inactive Ingredients</b> glycerin, hydrogen peroxide, purified water USP</p>	Active ingredient[s]	Purpose	Isopropyl Alcohol 75% v/v.....	Antiseptic	 <p><b>Hand Sanitizer</b></p>  <p><b>Registered: FDA</b></p> <p>www.tiodize.com</p> <p>NDC: 77089-075-01</p> <p><b>3.0 fl oz (88.7mL)</b></p>
Active ingredient[s]	Purpose				
Isopropyl Alcohol 75% v/v.....	Antiseptic				

### Hand Sanitizer 710mL (24oz) 77089-075-02 Front and Back Label



***D99***

***Hand  
Sanitizer***

**REGISTERED**

**FDA**

NDC: 77089-075-02

***ISOPROPYL ALCOHOL 75%...***

**24 FL.OZ. (1 PT. 8 OZ.) 710 ml.**



# **D99** Hand Sanitizer

**Drug Facts:** Registered: FDA, USP, WHO

**Active ingredient[s]**

**Purpose**

Isopropyl Alcohol 75% v/v.....Antiseptic

**Use[s]**

- Hand Sanitizer to help reduce bacteria.
- Recommended for repeated use.

**Warnings:**

- For external use only.

**Flammable:**

- Keep away from heat or flame.
- Do not store above 104°F/40°C.

**When using this product:**

- Keep out of eyes, ears, and mouth.
- In case of contact with eyes, flush thoroughly with water.
- Avoid contact with broken skin.

**Stop use and ask a doctor:**

- If irritation and redness develop and persist more for than 72 hours.

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

**Directions**

- Spray directly on hands and rub in thoroughly.
- For children under 6 years of age, use adult supervision.
- Not recommended for infants.

**Inactive Ingredients** glycerol, hydrogen peroxide, purified water USP

**Hand Sanitizer 3.785L (1 Gallon) 77089-075-03**



TIODIZE®

# **D99**

# ***Hand Sanitizer***

**REGISTERED  
FDA**

NDC: 77089-075-03

***ISOPROPYL ALCOHOL 75%...***

**1 GAL/3.785 LITERS**



# D99<sup>®</sup>

# Hand Sanitizer

**Drug Facts:** Registered: FDA, USP, WHO

**Active ingredient[s]**

**Purpose**

Isopropyl Alcohol 75% v/v.....Antiseptic

**Use[s]**

- Hand Sanitizer to help reduce bacteria.
- Recommended for repeated use.

**Warnings:**

- For external use only.

**Flammable:**

- Keep away from heat or flame.
- Do not store above 104°F/40°C.

**When using this product:**

- Keep out of eyes, ears, and mouth.
- In case of contact with eyes, flush thoroughly with water.
- Avoid contact with broken skin.

**Stop use and ask a doctor:**

- If irritation and redness develop and persist more for than 72 hours.

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

**Directions**

- Spray directly on hands and rub in thoroughly.
- For children under 6 years of age, use adult supervision.
- Not recommended for infants.

**Inactive Ingredients** glycerol, hydrogen peroxide, purified water USP

## TIODIZE HAND SANITIZER

isopropyl alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77089-075
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

UNII:ND2M416302)		ALCOHOL	in 100 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0K00R)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:77089-075-01	88.7 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77089-075-02	710 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/07/2020	
3	NDC:77089-075-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2020	
<b>Marketing Information</b>				
<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** - Tiodize, Inc. (042235226)

**Registrant** - Tiodize, Inc. (042235226)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Tiodize, Inc.		042235226	manufacture(77089-075)