

## **FOODAROM HAND SANITIZER ETHANOL 70% - alcohol liquid**

**Foodarom USA 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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### **Active Ingredient**

Alcohol 71.28% v/v.

### **Purpose**

Antiseptic

### **Uses**

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.

### **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**

ethyl lactate, glycerin, purified water

### **Package Label - Principal Display Panel**

**Alcohol Antiseptic 70% Topical Solution (Hand Sanitizer)**

Internal code: MET00XXXXX  
 Expiration date: June 2023  
 Lot: 302-200610-001

Volume of product: 22094 ml

Manufactured by:  
 FOODAROM USA, INC.  
 5525 West 1730 South, Suite 202  
 Salt Lake City, Utah 84104  
 Tel: 801-975-2604  
[csw@foodarom.com](mailto:csw@foodarom.com)



Made in USA

<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Alcohol 71.28% v/v	<b>Purpose</b> 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. Do not use <ul style="list-style-type: none"> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul> 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.	
<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 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> ethyl lactate, glycerin, purified water	

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 alcohol liquid

Product Information				
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78968-001	
<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	71.28 mL in 100 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	GLYCERIN (UNII: PDC6 A3C0 OX)			
	ETHYL LACTATE (UNII: F3P750 VW8 I)			
	WATER (UNII: 059 QF0 KO0 R)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78968-001-	22094 mL in 1 CONTAINER; Type 0: Not a Combination	06/23/2020	

1	01	Product	06/23/2020	
2	NDC:78968-001-02	198860 mL in 1 CONTAINER; Type 0: Not a Combination Product	06/23/2020	
3	NDC:78968-001-03	939066 mL in 1 CONTAINER; Type 0: Not a Combination Product	06/23/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/23/2020	

**Labeler** - Foodarom USA Inc. (960317282)

Revised: 6/2020

Foodarom USA Inc.