

## **ISSACTIZER- hand sanitizer gel**

### **AWSM Marcin Szakoła**

*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.*

-----

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)**

Alcohol 70% 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 6 years old
- 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 12 years of age when using this product to avoid swallowing.

### **Other information**

- Store between 10-26C (50-79F)
- Avoid freezing and excessive heat above 40C (104F)

### **Inactive ingredients**

Alcohol, Aqua, Acrylates Copolymer, Perfum, Glycerin, Panthenol, Aloe Barbadensis Leaf Extract, Triethanolamine, Sodium Benzoate, Potassium Sorb

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

500 mL NDC: 79887-113-52

**Issactizer**

**HAND SANITIZER GEL**

ALCOHOL ANTISEPTIC 70%    TOPICAL SOLUTION    NON-STERILE SOLUTION

**500 ml**

**Active ingredient:**  
Alcohol 70% v/v

**Use:**  
Hand sanitizer to help reduce bacteria that potentially can be disease. For use when soap and water are not available.

**Warning:**  
For external use only. Flammable. Keep away from heat and flame.

**Do not use:**  
in children less than 6 years old on open skin wound.  
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 for use:**  
Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under twelve years of age when using this product to avoid swallowing.

**Other information:**  
Store between 10 and 26C.  
Avoid freezing and excessive heat above 40C

**Inactive Ingredients:** Alcohol Denat., Aqua, Acrylates Copolymer, Parfum, Glycerin, Panthenol, Aloe Barbadensis Leaf Extract, Triethanolamine, Sodium Benzoate, Potassium Sorb  
SN/ Expiration Date: On bottle

**Manufactured for:**  
Wisconsin Wine and Spirits INC



200 mL NDC: 79887-113-22

**Issactizer**

**HAND SANITIZER GEL**

ALCOHOL ANTISEPTIC 70%    TOPICAL SOLUTION    NON-STERILE SOLUTION

**200 ml**

**Active ingredient:**  
Alcohol 70% v/v

**Use:**  
Hand sanitizer to help reduce bacteria that potentially can be disease. For use when soap and water are not available.

**Warning:**  
For external use only. Flammable. Keep away from heat and flame.

**Do not use:**  
in children less than 6 years old on open skin wound.  
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 for use:**  
Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under twelve years of age when using this product to avoid swallowing.

**Other information:**  
Store between 10 and 26C.  
Avoid freezing and excessive heat above 40C

**Inactive Ingredients:** Alcohol Denat., Aqua, Acrylates Copolymer, Parfum, Glycerin, Panthenol, Aloe Barbadensis Leaf Extract, Triethanolamine, Sodium Benzoate, Potassium Sorb  
SN/ Expiration Date: On bottle

**Manufactured for:**  
Wisconsin Wine and Spirits INC



**ISSACTIZER**

hand sanitizer gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79887-113
<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	80 mL in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ALOE (UNII: V5VD430YW9)	1 mL in 100 mL
GLYCERIN (UNII: PDC6A3C00X)	1.45 mL in 100 mL
PANTHENOL (UNII: WW9CM0067Z)	1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	1 mL in 100 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79887-113-22	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:79887-113-52	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

## 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	08/03/2020	

**Labeler** - AWSM Marcin Szakoła (422446268)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
AWSM Marcin Szakoła		422446268	manufacture(79887-113)

Revised: 4/2021

AWSM Marcin Szakoła