

## **HAND SANITIZER- alcohol gel**

### **A. J. & W. Incorporated**

*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(s)**

Ethyl Alcohol 75%

### **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

Orally.

For other purposes other than specified.

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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### **Directions**

Wet hands thoroughly and 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

Water, Glycerin, Carbomer, Aloe Vera Leaf, Fragrance, FD&C Red No.40, FD&C Yellow No.5

## Package Label - Principal Display Panel

60 ml NDC: 74839-103-60



## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74839-103
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75.59 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER 980 (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:74839-103-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2020	
<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		05/07/2020	

**Labeler** - A. J. & W. Incorporated (064157654)

**Registrant** - A. J. & W. Incorporated (064157654)

**Establishment**

Name	Address	ID/FEI	Business Operations
A. J. & W. Incorporated		064157654	relabel(74839-103)

Revised: 5/2020

A. J. & W. Incorporated