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.

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 thorougly 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: 74839-100-60

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74839-100
Route of Administration	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 YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:74839-100-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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(74839-100)

Revised: 5/2020 A. J. & W. Incorporated