

**INNOVATE HAND SANITIZER- ethyl alcohol spray**  
**MCCORD RESEARCH**

*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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**INNOVATE HAND SANITIZER**

***Active Ingredient***

Ethyl Alcohol

***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 15-30°C (59-86F)

Avoid freezing and excessive heat above 40°C (104F)

## Inactive Ingredients

Water, Glycerin, Pyrus Malus (Apple) Fruit Extract, Fragrance.

## Product Label

NDC 71358-019-01

**Innovate**  
MEDICAL LLC

**Hand Sanitizer**

8 fl oz (237 mL)

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl Alcohol 64% w/v	Antiseptic
<b>Uses</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.	
<b>Do not use</b> • in children less than 2 months of age • on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> 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> Water, Glycerin, Pyrus Malus (Apple) Fruit Extract, Fragrance.	

**WOMEN OWNED**

Made in U.S.A. for Innovate Medical, LLC  
Johnson City, Tennessee 37604  
1-866-839-7874  
Reorder: CLN-10003 R1666

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## INNOVATE HAND SANITIZER

ethyl alcohol spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71358-019
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	640 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>APPLE</b> (UNII: B423VGH5S9)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71358-019-01	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/09/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/09/2020	

**Labeler** - MCCORD RESEARCH (010011284)

## Establishment

Name	Address	ID/FEI	Business Operations
Wasatch Product Development, LLC		962452533	manufacture(71358-019)

Revised: 1/2022

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