

**GEL SANITIZER- alcohol gel**  
**AAkron Rule Corporation**

*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**

Ethyl Alcohol 70% v/v

**Purpose**

Antimicrobial

**Use**

Hand Sanitizer to help reduce bacteria on skin.

**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** avoid mouth, eyes, and ears. In case of contact with eyes, flush 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 and call Poison Control.

**Directions**

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age.

**Other information**

- Store in 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

Aloe Vera, Carbomer, D&C Green #5, D&C Yellow #10, Water, Trolamine

## Product label

<p><b>Drug Facts</b> (continued)</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help and call Poison Control.</p> <p><b>Directions</b> ■ Place enough product on hands to cover all surfaces. Rub hands together until dry. ■ Supervise children under 6 years of age.</p> <p><b>Other information</b> ■ Store in 15-30C (59-86F). ■ Avoid freezing and above 40C (104F)</p> <p><b>Inactive ingredients</b> Water, Glycerin, Thickener, Ph balancer, Fragrance (coconut)</p> <p><b>Manufactured by:</b> AAkron Rule Corp., Sale Creek, TN 37373 Exp. XX/XXXX PO XXXXX 1oz/30ml</p>	<div style="border: 1px solid black; height: 150px; width: 100%;"></div>	<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active ingredient(s)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Ethyl Alcohol 70% v/v .....</td> <td>Antimicrobial</td> </tr> </tbody> </table> <p><b>Use(s)</b> Hand Sanitizer helps reduce bacteria on skin.</p> <p><b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame. Do not use</b> ■ in children less than 2 months of age ■ on open skin wounds</p> <p><b>When using this product</b> avoid mouth, eyes, and ears. In case of contact with eyes, flush with water.</p> <p><b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition. ▶</p>	Active ingredient(s)	Purpose	Ethyl Alcohol 70% v/v .....	Antimicrobial
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## GEL SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69394-004
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69394-004-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/28/2020	
2	NDC:69394-004-02	89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/28/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/28/2020	

**Labeler** - AAkron Rule Corporation (002434389)

Revised: 7/2022

AAkron Rule Corporation