

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.

Active Ingredient

Ethyl Alcohol 80% 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 above 40C (104F)

Inactive ingredients

Water, Glycerin, Thickener, Ph balancer, Fragrance

Package Label - Principal Display Panel

Drug Facts (continued)

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Manufactured by: AAkron Rule Corp., Sale Creek, TN 37373

AD COPY
1.29 in. W x 1.58 in. H

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Use(s) Hand Sanitizer helps reduce bacteria on skin.

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SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69394-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CETEARETH-5 (UNII: 2AAD28764Q)	
CYCLOHEXANE (UNII: 48K5MKG32S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:69394-002-01	29 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/28/2020	
2	NDC:69394-002-02	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