

HAND SANITIZER- alcohol liquid
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

Alcohol 80% v/v.

Purpose

Antiseptic

Use(S)

helps reduce bacteria that can cause disease 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 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 between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

Drug Facts (continued)

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
glycerin, hydrogen peroxide, purified water USP

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

Drug Facts

Active ingredient(s)	Purpose
Alcohol 80% v/v.....	Antiseptic

Use(s) helps reduce bacteria that can cause disease 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 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. ▶

Drug Facts

Active ingredient(s)

Alcohol 80% v/v.....Antiseptic

Use(s)

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 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 15-30C (59-86F)

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Dist By: Willamia Distilling
Buffalo, NY 14213



HAND SANITIZER

alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69394-001

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: PDC6A3C00X)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69394-001-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	
2	NDC:69394-001-02	89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	
3	NDC:69394-001-03	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/04/2020	

Labeler - AAkron Rule Corporation (002434389)

Revised: 7/2022

AAkron Rule Corporation