

HAND SANITIZER- ethyl alcohol liquid
STILL VALLEY SPIRITS LLC

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.

STILL VALLEY SPIRITS Hand Sanitizer

Drug Facts

Active ingredient(s)

Denatured Ethyl Alcohol 80% v/v

Purpose(s)

Antiseptic

Uses(s)

Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap or water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- on 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

- Spray 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 (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredient(s)

- Distilled or Boiled Water, Hydrogen Peroxide, Glycerin

Formula Based on FDA Compounding Guidelines for consumer and healthcare personnel use, issued March 2020.

Best used for refilling spray bottles.

Not for human consumption. External use only.

Produced by Still Valley Spirits LLC Puyallup, WA

Contents may separate naturally. Shake well.

Packaging

Hand Sanitizer



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25.36 FL OZ (750 ML)

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ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78684-080
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
WATER (UNII: 059QF0KO0R)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78684-080-01	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/15/2020	

Labeler - STILL VALLEY SPIRITS LLC (122659099)

Establishment

Name	Address	ID/FEI	Business Operations
STILL VALLEY SPIRITS LLC		122659099	manufacture(78684-080)

Revised: 6/2020

STILL VALLEY SPIRITS LLC