

HAND SANITIZER- alcohol liquid

Ginesis Natural Products

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.

Hand Sanitizer

DRUG FACTS

Active ingredient

Ethyl Alcohol 80%

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 fire or flames.

Do not use

- on children less than 2 months of age
- on open skin wounds

When using this product avoid contact with eyes, ears and mouth. In case of contact flush eyes with water.

Stop use and ask doctor if redness or irritation develop. 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 (59-86°F)
- Avoid freezing and excessive heat above 40° (104°F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

DIST. BY CJH

2501 COUNTY RD 8

WATERLOO, AL 35677

PRINCIPAL DISPLAY PANEL - 59 ML Bottle Label

GINESIS

Alcohol Antiseptic 80%
Topical Solution


Hand Sanitizer
Non-Sterile Solution

2 FL OZ. (59 ML)

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DIST. BY CJH
2501 COUNTY RD 8
WATERLOO, AL 35677
www.ginesis.com • 1-800-492-4818
made in the USA
*kills 99.99% of most common germs that may cause illness



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HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79703-080
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
glycerin (UNII: PDC6A3C0OX)	
hydrogen peroxide (UNII: BBX060AN9V)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79703-080-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020	
2	NDC:79703-080-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020	
3	NDC:79703-080-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020	
4	NDC:79703-080-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020	
5	NDC:79703-080-10	3784 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/31/2020	

Labeler - Ginesis Natural Products (621843130)

Establishment

Name	Address	ID/FEI	Business Operations
Ginesis Natural Products		621843130	MANUFACTURE(79703-080)

Revised: 8/2020

Ginesis Natural Products