

HAND SANITIZER WITH REAL LEMON ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION- alcohol solution

Fabrizia 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.

Hand Sanitizer with Real Lemon Alcohol Antiseptic 80% Topical Solution

Active Ingredient

Alcohol 80% v/v. Purpose: Antiseptic

Use

Hand Sanitizer to help reduce bacteria that potentially cause disease. For use when soap and water are not available.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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 eyes thoroughly with water

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.

Inactive ingredients: glycerin, tert-butyl alcohol, bitrex (denatonium benzoate), hydrogen peroxide, lemon oil, purified water

Other information

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

Package Label - Principal Display Panel

Fabrizia

Hand Sanitizer

with Real Lemon

Alcohol Antiseptic 80% Topical Solution

Non-Sterile Solution

118 ml

**When Life Gives You Lemons –
Make Hand Sanitizer!**

Fabrizia is known for producing great tasting liqueurs and cocktails, but during these difficult times we are utilizing our resources to produce much needed hand sanitizer. This product was made in accordance with World Health Organization and FDA guidelines for producing hand sanitizers. We are continuing to donate hand sanitizer to first responders, hospitals, and local government agencies as needed.



Made in the USA
Fabrizia Spirits, LLC
Salem, NH

MSRP \$5.99



Fabrizia

**HAND
SANITIZER**
with Real Lemon

**Alcohol Antiseptic 80%
Topical Solution**
Non-sterile Solution

Not For Consumption

118 ml.

Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v	Antiseptic

Use

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

Warnings

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Do not use

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

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TOPICAL SOLUTION**

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77322-005
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
LEMON OIL (UNII: I9GRO824LL)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77322-005-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
2	NDC:77322-005-02	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
3	NDC:77322-005-03	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
4	NDC:77322-005-04	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Fabrizia Spirits, LLC (063388203)

Establishment

Name	Address	ID/FEI	Business Operations
Fabrizia Spirits, LLC		063388203	manufacture(77322-005)

Revised: 5/2020

Fabrizia Spirits, LLC