

HAND SANITIZER- alcohol spray

LaJoye Cellars

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

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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 eyes 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.

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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 PDC6A3C0OX 1.45 mL

HYDROGEN PEROXIDE BBX060AN9V 0.125 mL
 LINALOOL, (+/-)- D81QY6I88E
 ORANGE OIL AKN3KSD11B
 CITRUS RETICULATA FRUIT OIL 25P9H3QU5E
 WATER 059QF0KO0R

Package Label Principal Display Panel

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation)

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.
- e. LINALOOL, (+/-)- D81QY6I88E
- f. ORANGE OIL AKN3KSD11B
- g. CITRUS RETICULATA FRUIT OIL 25P9H3QU5E

Package Label - Principal Display Panel



Volume - 100ml

GELATIN SHOT TRADING COMPANY

Hand Sanitizer

Fresh Orange Scent

Non-Sterile Solution | Topical Solution
 Alcohol Antiseptic 80%

NDC# 79523-001-01

Drug Facts	Purpose
Active ingredient(s) Denatured 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 • 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 eyes 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, linalool, (+/-)-, orange oil, citrus reticulata fruit oil, water	

100ML NDC#79523-001-01

HAND SANITIZER
 alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79523-001
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
CITRUS RETICULATA FRUIT OIL (UNII: 25P9HBQU5E)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
ORANGE OIL (UNII: AKN3KSD11B)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79523-001-01	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/31/2020	



Volume - 100ml

Seattle
Signs and Banners

GELATIN SHOT TRADING COMPANY

Hand Sanitizer

Fresh Orange Scent

Non-Sterile Solution | Topical Solution

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Marketing Information

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

Labeler - LaJoye Cellars (047352440)

Registrant - LAJOYE CELLARS (047352440)

Establishment

Name	Address	ID/FEI	Business Operations
LAJOYE CELLARS		047352440	manufacture(79523-001)

Revised: 12/2020

LaJoye Cellars