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

PackageLabel 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

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Volume - 100ml	Hand Sanitizer			o ulleistaston		iy rrom neat o	5	sars and mout sh occurs. Th	et medica	surfaces. en using tl		vide, linalool,
Section Signs and Banners	Fresh Orange Scent Non-Sterile Solution Topical Solution Alcohol Antiseptic 80% NDC# 79523-001-01	Drug Facts	Active ingredient(s) Denatured Alcohol 80% v/v	Use(s) Hand conition to halm reduce harteria that	ings	use only. Flammable. Keep	skin w	using this product keep ou use and ask a doctor if irrit	ut of reach of children. If swallowe ions	enough product on Hands to cover rvise children under 6 years of age	information between 15-3	• Avoid freezing and excessive neat above 4UL (104F) Inactive ingredients - glycerin,hydrogen peroxide, linal
100ML NDC#79523-001-01									·			

HAND SANITIZER alcohol spray Product Information

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Product T ype		UMAN OTC DRUG	Item Code	e (Source)	IN	DC:79523-001
Route of Administ	ration T	OPICAL				
Active Ingredie	nt/Active Moiet	y				
	Ingredie	nt Name		Basis of S	trength	Strength
ALCOHOL (UNII: 3k	K9958V90M) (ALCO	HOL - UNII:3K9958V90) M)	ALCOHOL		80 mL in 100 mL
Inactive Ingred	ionte					
macuve mgreu		gredient Name				Strength
CITRUS RETICULA						strength
GLYCERIN (UNII: PE					1.45 mL in 1	100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)0.125 mL in 100 mL						
WATER (UNII: 059Q						
LINALOOL, (+/-)- (UNII: D8 1Q Y6 I8 8 E)					
ORANGE OIL (UNII:	AKN3KSD11B)					
Product Charac	teristics					
Color		Score				
Shape		Size				
Flavor		Imprin	nt Code			
Contains						
D 1 1						
Packaging						
# Item Code	F	ackage Description	I	Marketin Dat	•	Marketing End Date
1 NDC:79523-001-		E, SPRAY; Type 0: Not	a Combination	07/31/2020		
01	Product					

LOGAL 27 EIRE FIGIETEL UNION EST 1978		GELATI HOT RADIN OMPAN	G		Purpose Antiseptic	can cause disease. For use when soap and water are not available.	or flame		In case of contact	ese may be signs of a serious condition. help or contact a Poison Control Center right away.	Rub hands together until dry. He sconduct to social cuellowing		ve 40C (104F) peroxide, linalool, (+/-)-, orange oll, citrus reticulata fruit oll, water
Volume - 100	nl	Hand Sanitize	r			potentially c	r from heat or flame		ars and mout	h occurs. These n get medical help	all surfaces. Ru when using this		0C (104F) kide, linalool
Sector Signs and Ba	<i>H</i>	Fresh Orange Scent n-Sterile Solution Topical Solu Alcohol Antiseptic 80% NDC# 79523-001-01	tion	Drug Facts	Active ingredient(s) Denatured Alcohol 80% v/v	tizer to help reduce bacteria that	Warnings For external use only. Flammable. Keep away	vo not use • on children less than 2 months of age	open skin wounds using this product keep out of e	Stop use and ask a doctor if irritation or ras Keep out of reach of children. If swallowed,	Directions • Place enough product on Hands to cover al • currents children inder 6 veers of are wh	rmation veen 15-30C (59-86F)	 Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients - glycerin,hydrogen peroxide, lina
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OTC monograph not final	part333A	noer or monograph citation	03/30/20		, o u		Jaie	1		e ui	ig El	iu D	att

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