

DEL LAGO RESORT AND CASINO HAND SANTITIZER- alcohol gel

Lago Resort & Casino, 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.

del Lago Hand Sanitizer

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

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) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, 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. Carbomer

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

For hand washing to decrease bacteria on the skin - Recommended for repeated use.

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 occurs. These may be signs of a serious condition.

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

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

Wet hands thoroughly with product, and allow to dry without wiping. For children under six, use only under adult supervision.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
- May discolor some fabrics. Harmful to wood finishes and plastics

Inactive ingredients

glycerin, hydrogen peroxide, carbomer, and purified water USP

Package Label - Principal Display Panel



DEL LAGO RESORT AND CASINO HAND SANTITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80431-001	
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	
	GLYCERIN (UNII: PDC6A3C0OX)		1.45 mL in 100 mL	
	HYDROGEN PEROXIDE (UNII: BBX060AN9V)		0.125 mL in 100 mL	
	WATER (UNII: 059QF0KO0R)			
	METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)		4 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80431-001-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:80431-001-16	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
Marketing Information				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	OTC monograph not final	part333A	03/30/2020	

Labeler - Lago Resort & Casino, LLC (080370504)

Registrant - Lago Resort & Casino, LLC (080370504)

Establishment

Name	Address	ID/FEI	Business Operations
Lago Resort & Casino, LLC		080370504	manufacture(80431-001)

Revised: 9/2020

Lago Resort & Casino, LLC