CARE1 ISOPROPYL RUBBING ALCOHOL 72% - isopropyl alcohol liquid Lauree 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.

Care1 ISOPROPYL RUBBING ALCOHOL 72%- isopropyl alcohol liquid

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. Isopropyl Alcohol (75%, 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.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Isopropyl Alcohol 72% v/v. Purpose: Antiseptic

Purpose

First aid antiseptic

Use

Helps prevent the risk of infection in minor cuts, scrapes and burns.

Warnings

For external use only. Flammable. Keep away from heat or flame

Ask a doctor before use

for deep wounds, animal bites or serious burns

•do not get into eyes

- do not apply over large area of the body
- do not use longer than 1 week

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

- clean the affected area
- apply 1 to 3 times daily

Other information

- does not contain, nor is intended as a substitute for grain or ethyl alcohol
- will produce serious gastric disturbances if taken internally

Inactive ingredients

Purified water USP

Package Label - Principal Display Panel

473 ml NDC: 78975-505-05



CARE1 ISOPROPYL RUBBING ALCOHOL 72%

isopropyl alcohol liquid

Product Information								
Product Type	HUMAN OTC DRUG	Item Code (Source) NDO		NDC:789	C:78975-505			
Route of Administration	TOPICAL							
Active Ingredient/Active Moiety								
Ing		Basis of Str	ength	Strength				

ISOPROPYL ALCOHOL UNII:ND2M416302)	ISOPROPYL ALCOHOL	72 mL in 100 mL	
Inactive Ingredients			
	Ingredient Name		Strength
WATER (UNII: 059QF0KO	0 R)		
Product Characteris			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			
Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Dat
	mL in 1 BOTTLE; Type 0: Not a Combination Produc	_	
	Care 1 72% 72% Sopropyi	and burns. Warnings For external use only. If taken internally, Firammable, keep aw use only in a well- Ask a doctor before u or serious burns. When using this prod d on to get into eye d on to eye into eye d on to eye into eye d on to eye into eye d on to reach of to contact a Polson Cont Directions Licen affected area apply small amoun if bandaged, let dn may be covered w Other information store at contain, r Inactive ingrediet	Summer is a substitute for grain or ethyl alcohol
Maxbating Inform	Use in a well ventilated area; fumes can be harmful. 16 FL OZ (1 PT) 473 mL	8	F.P.O. 55799 9
Marketing Infor			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/02/2020	

Labeler - Lauree LLC (102938225)

Registrant - Care 1 (066368393)						
Establishment						
Name	Address	ID/FEI	Business Operations			
Lauree LLC		102938225	manufacture(78975-505)			

Revised: 10/2020

Lauree LLC