JMJ CATALINA- ethyl alcohol gel JMJ CATALINA USA 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.

JMJ Catalina HAND SANITIZER

Drug Facts

Active Ingredient(s)

Ethyl alcohol 70% v/v

Purpose

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

- 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 for 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 Water, Carbomer, Aminomethyl propanol, Triethanolamine, Aloe, Fragrance, Glycerin, Propylene glycol, Tocopheryl acetate

Topical Solution

KILLS 99.99% OF GERMS* INCLUDING COVID-19

MADE IN U.S.A.

Peach

Manufactured by:

JMJ Catalina U.S.A.LLC

Tucson, AZ 85714

Packaging



JMJ CATALINA

ethyl alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78938-333	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)			
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			
TROLAMINE (UNII: 9O3K93S3TK)			
ALOE (UNII: V5VD430 YW9)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	PEACH, ORANGE, CITRUS	Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:78938-333-25	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020		
2	NDC:78938-333-27	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020		
3	NDC:78938-333-29	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/11/2020		

Labeler - JMJ CATALINA USA LLC (072604132)

Establishment				
Name	Address	ID/FEI	Business Operations	
JMJ CATALINA USA LLC		072604132	manufacture(78938-333)	

Revised: 6/2020 JMJ CATALINA USA LLC