

**MCCLAINS EXTRA STRENGTH AND MOISTURE HAND SANITIZER ORIGINAL-
isopropyl alcohol liquid
McClain's Health LLC**

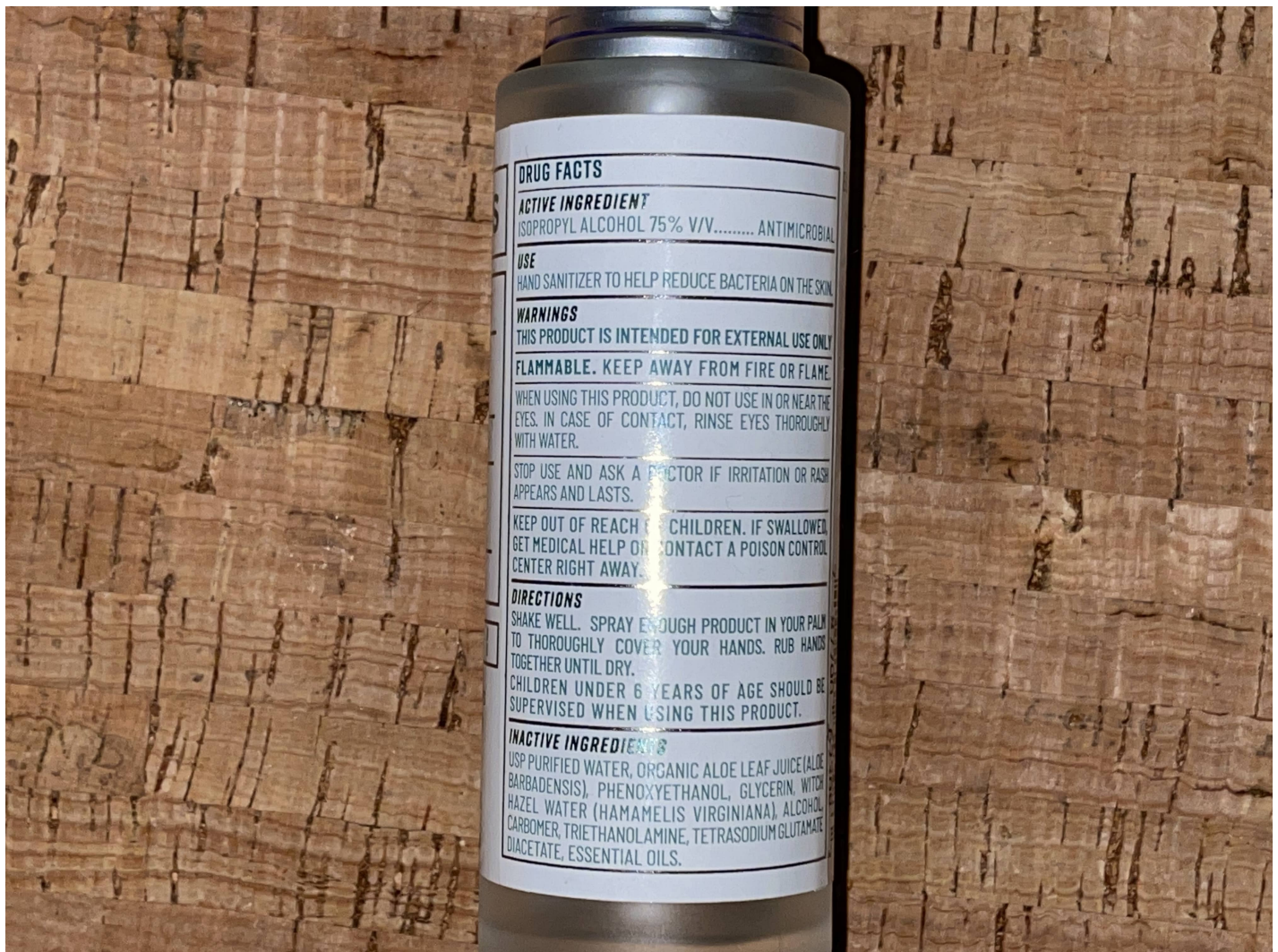
Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Hand sanitizer

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 CDC recommendations:

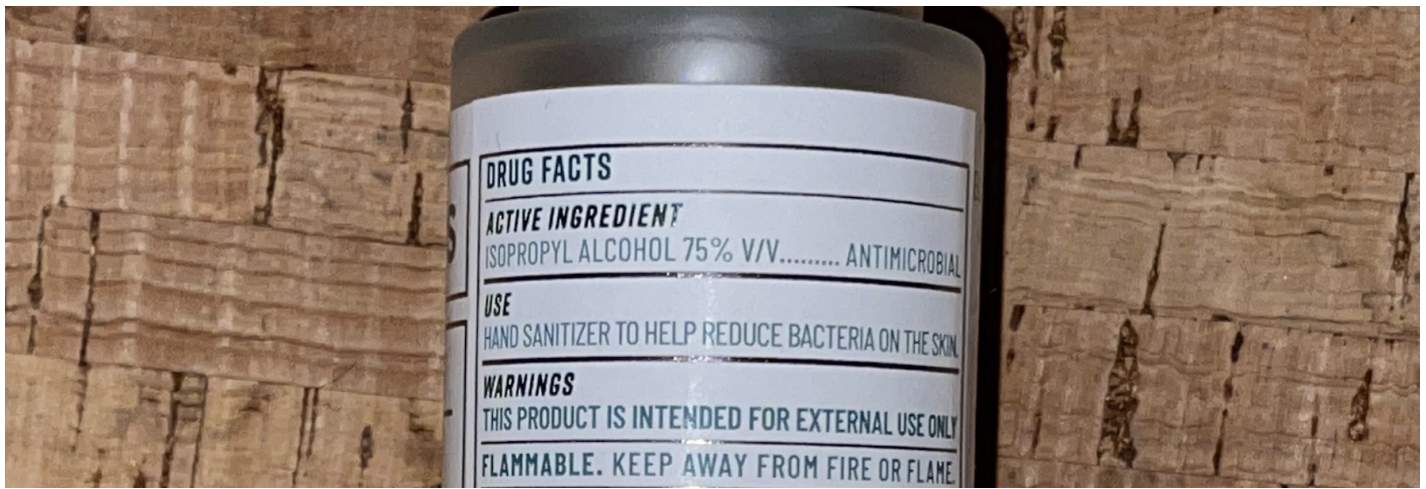
- Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- Glycerol (1.45% v/v).
- Sterile distilled water or boiled cold water.

Formulation:



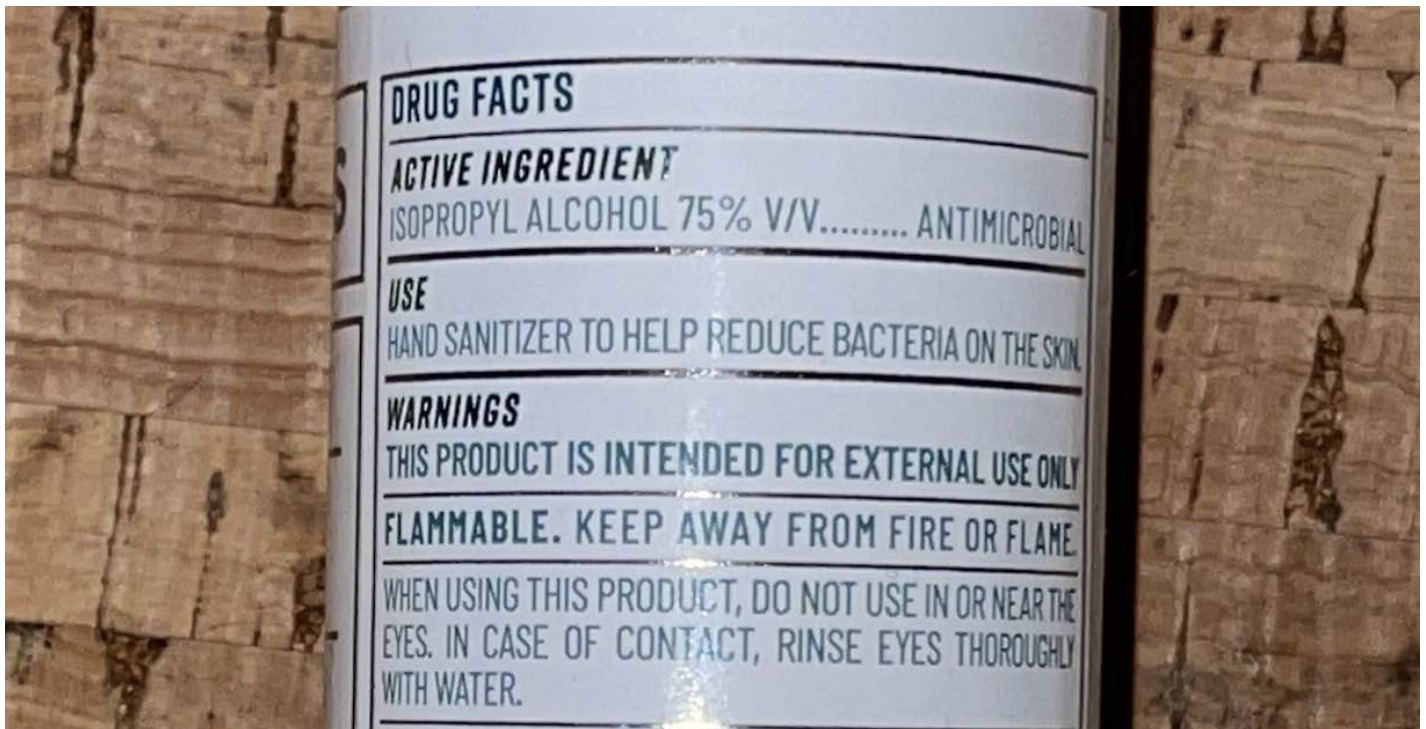
Active Ingredient(s)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic



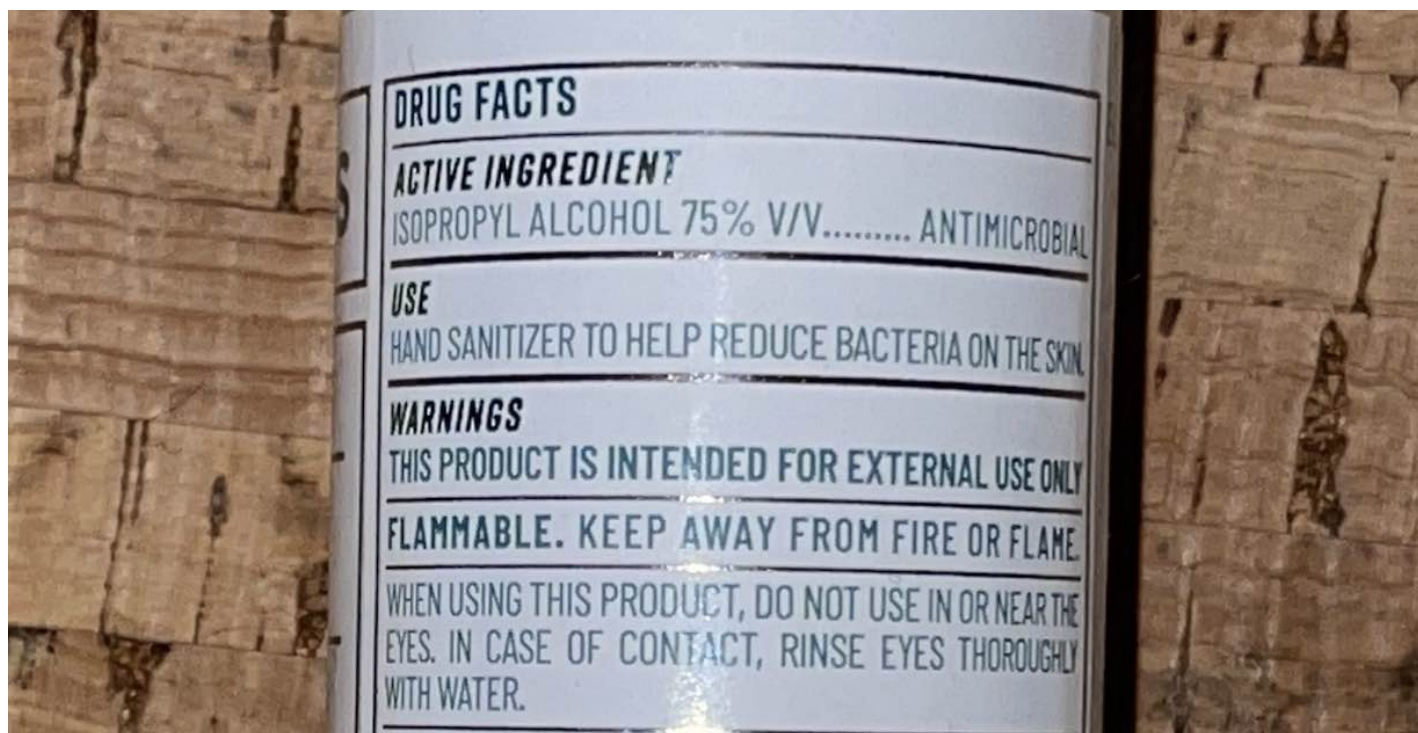
Purpose

Antiseptic, Hand Sanitizer



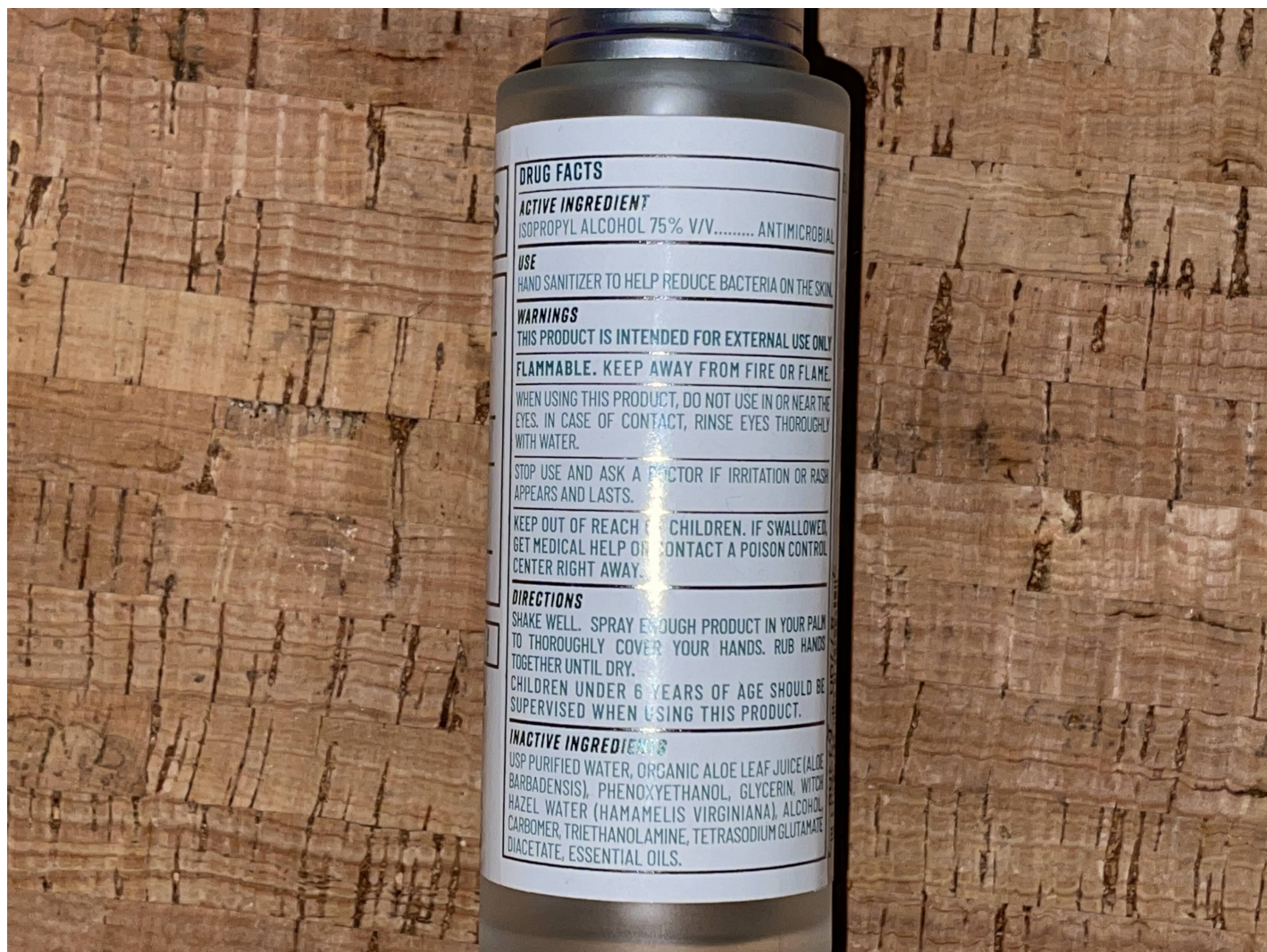
Use

Hand Sanitizer to help reduce bacteria on the skin.



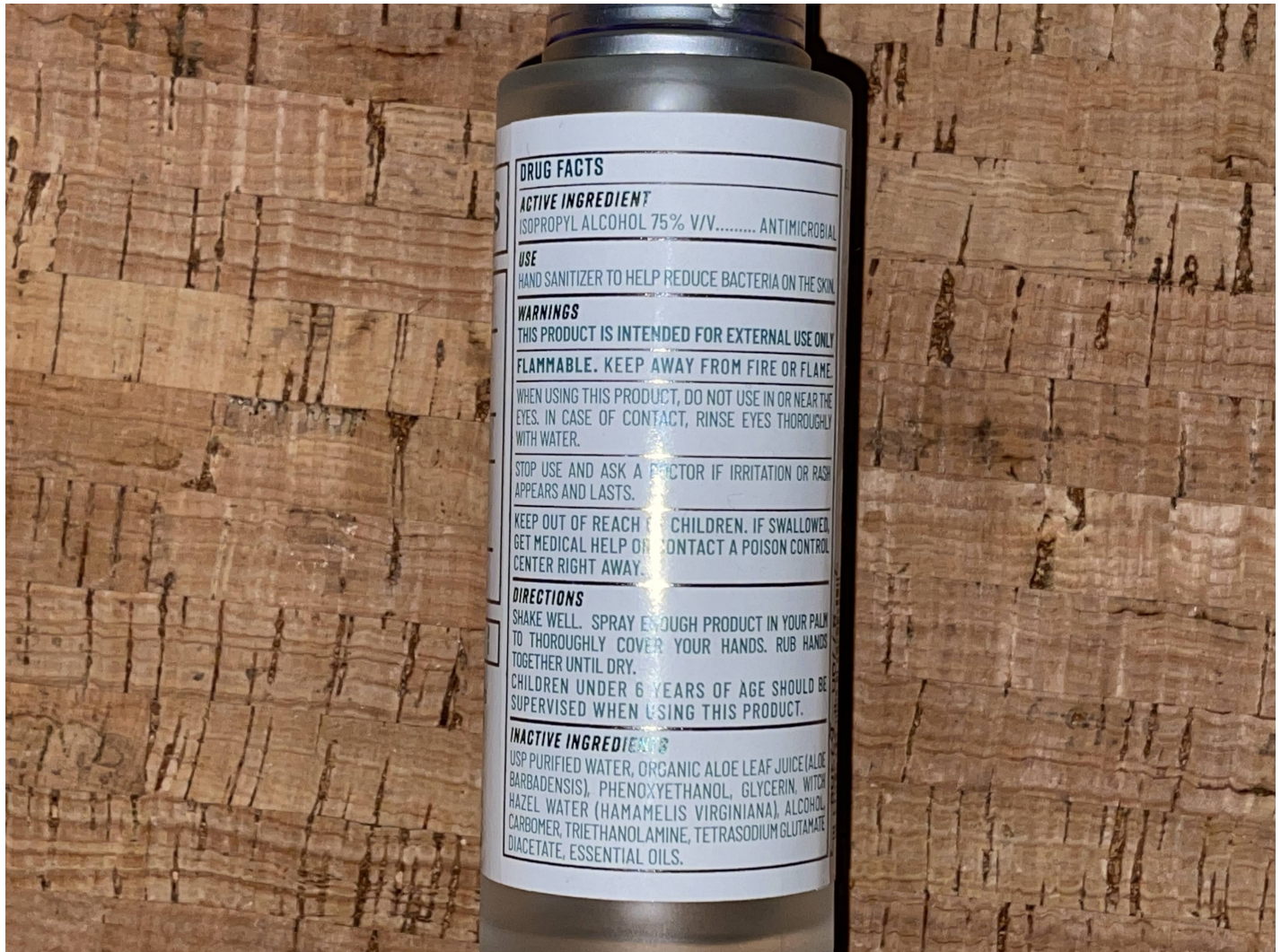
Warnings

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



Do not use

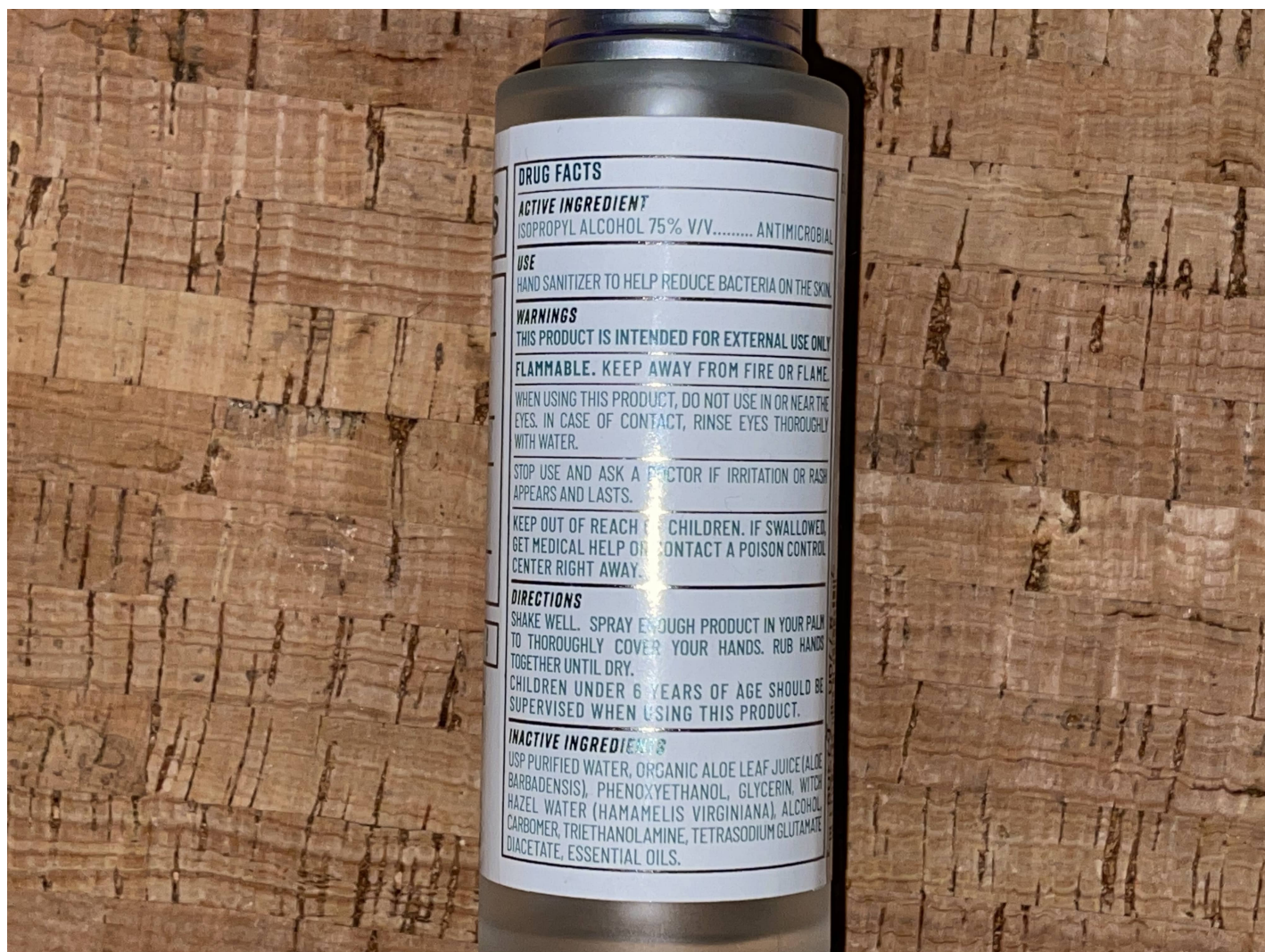
- keep out of reach of children
- do not use in or near the eyes



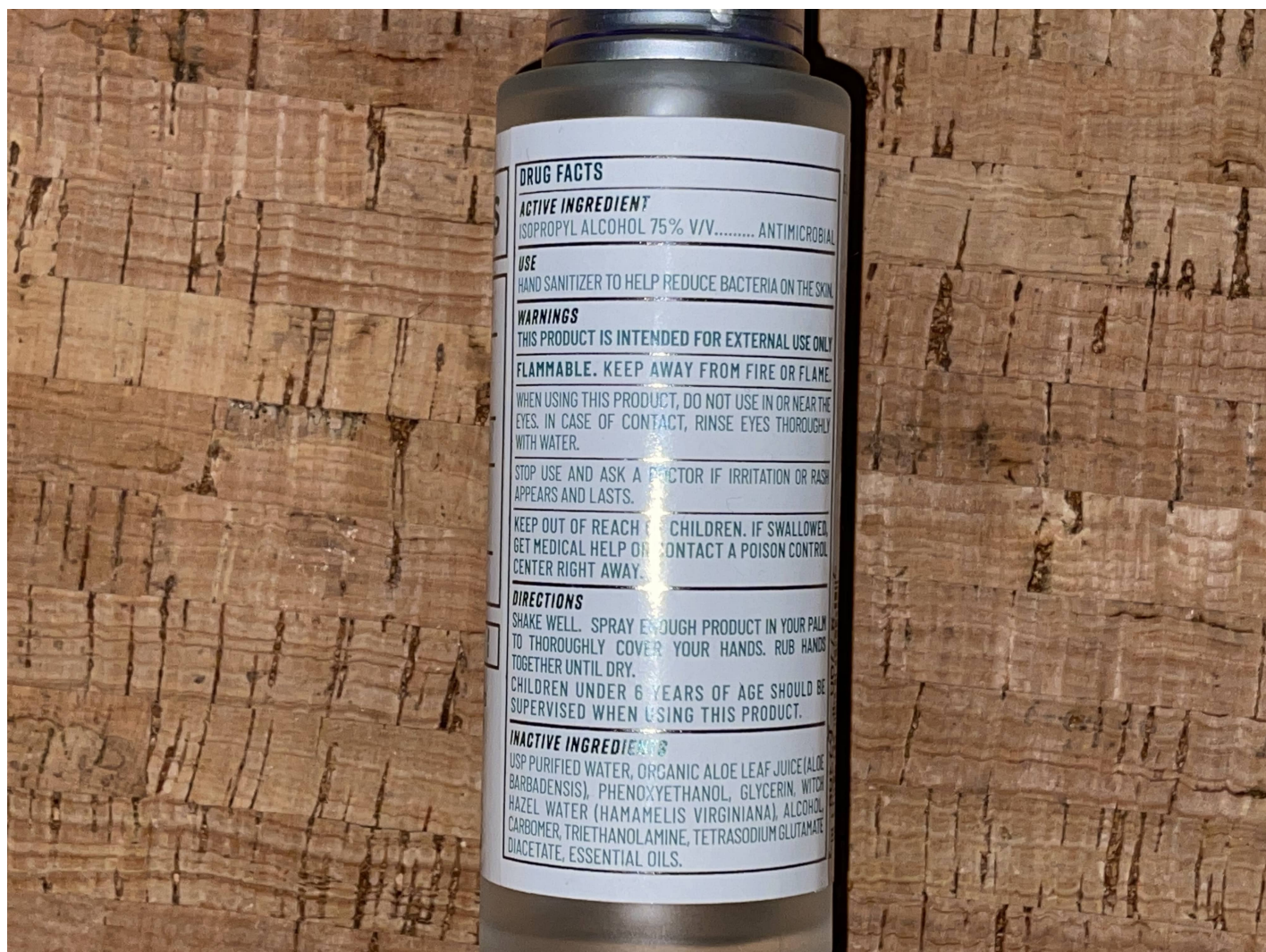
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

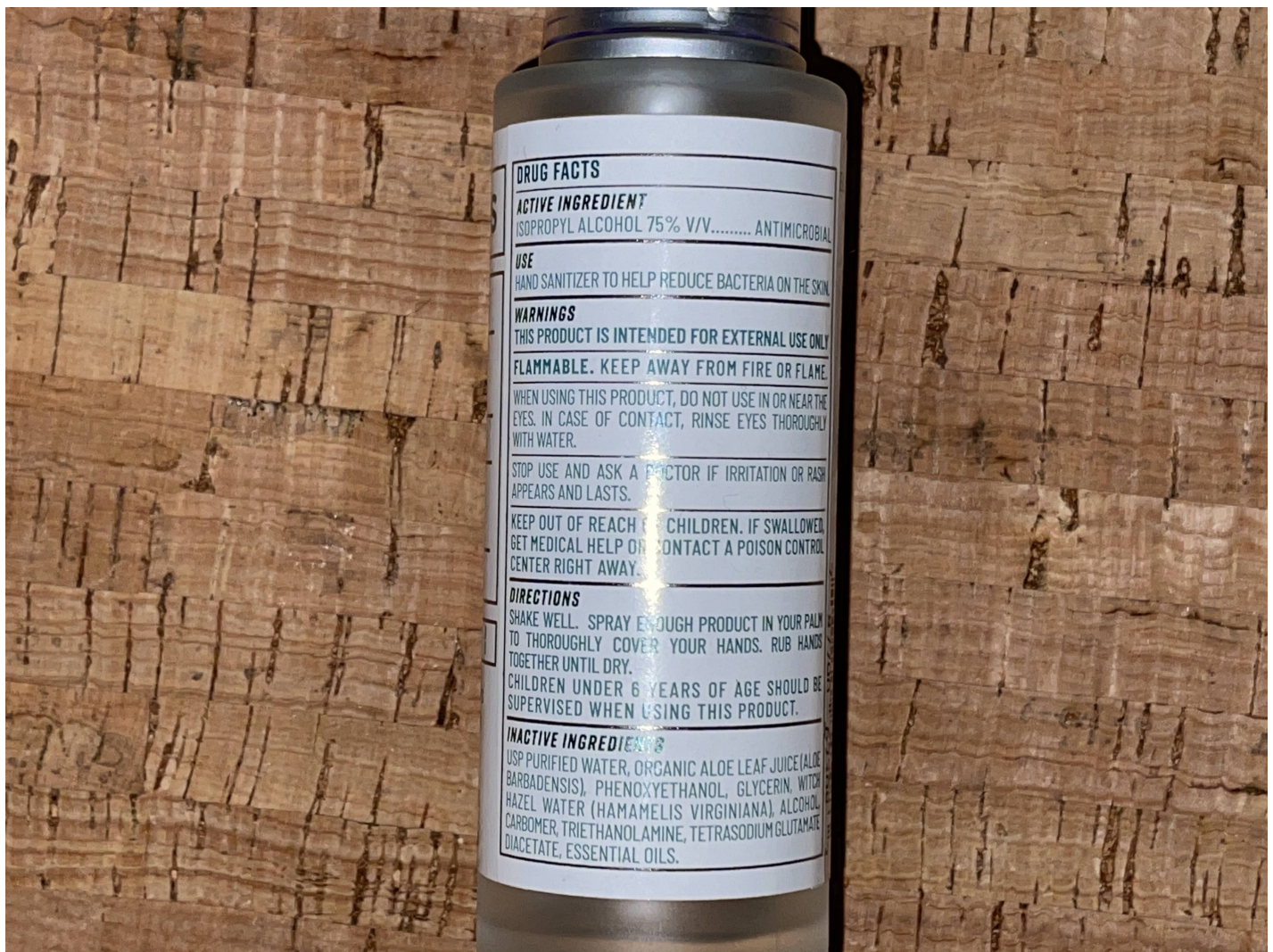
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.



Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

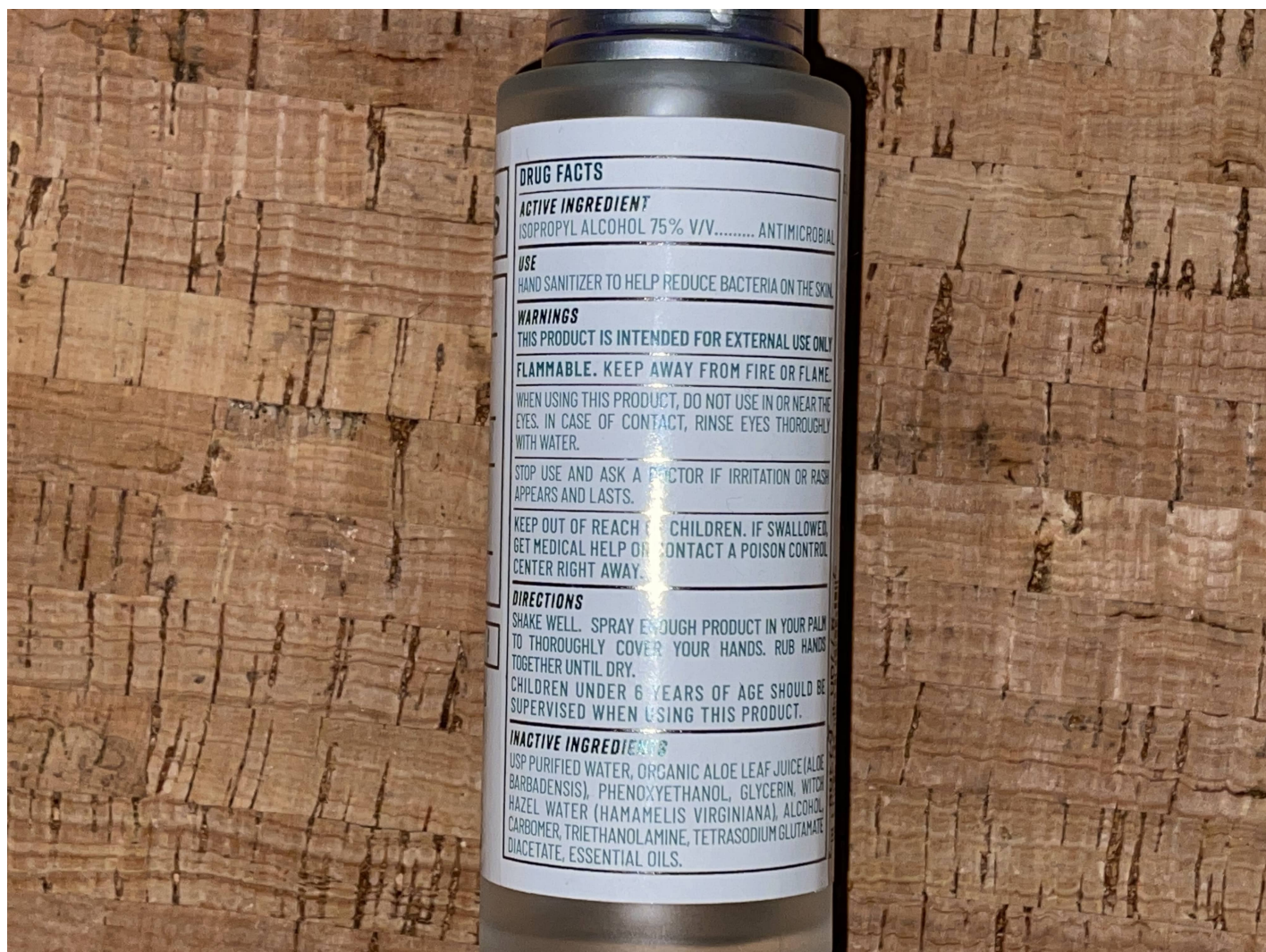


Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.



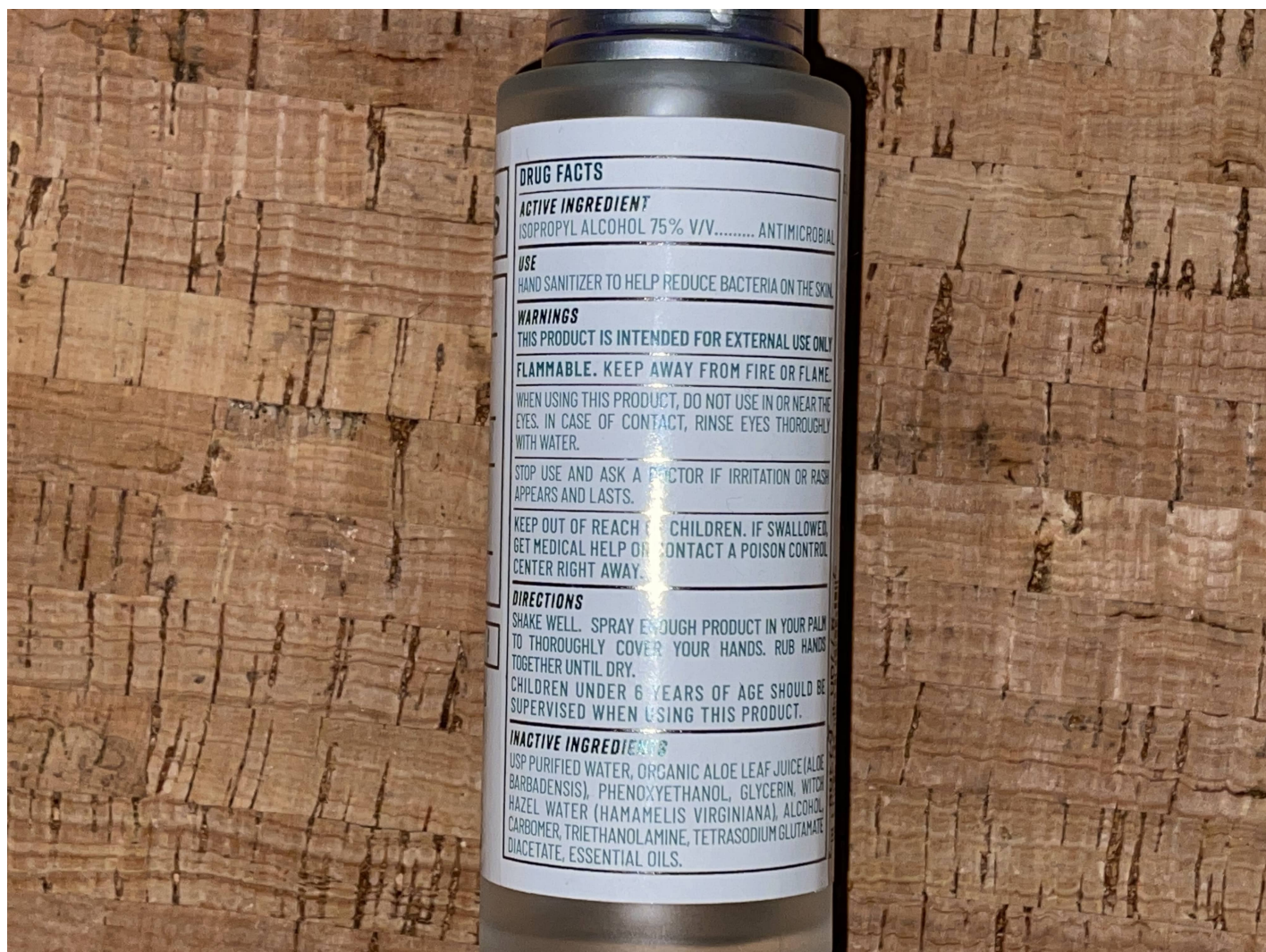
Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.



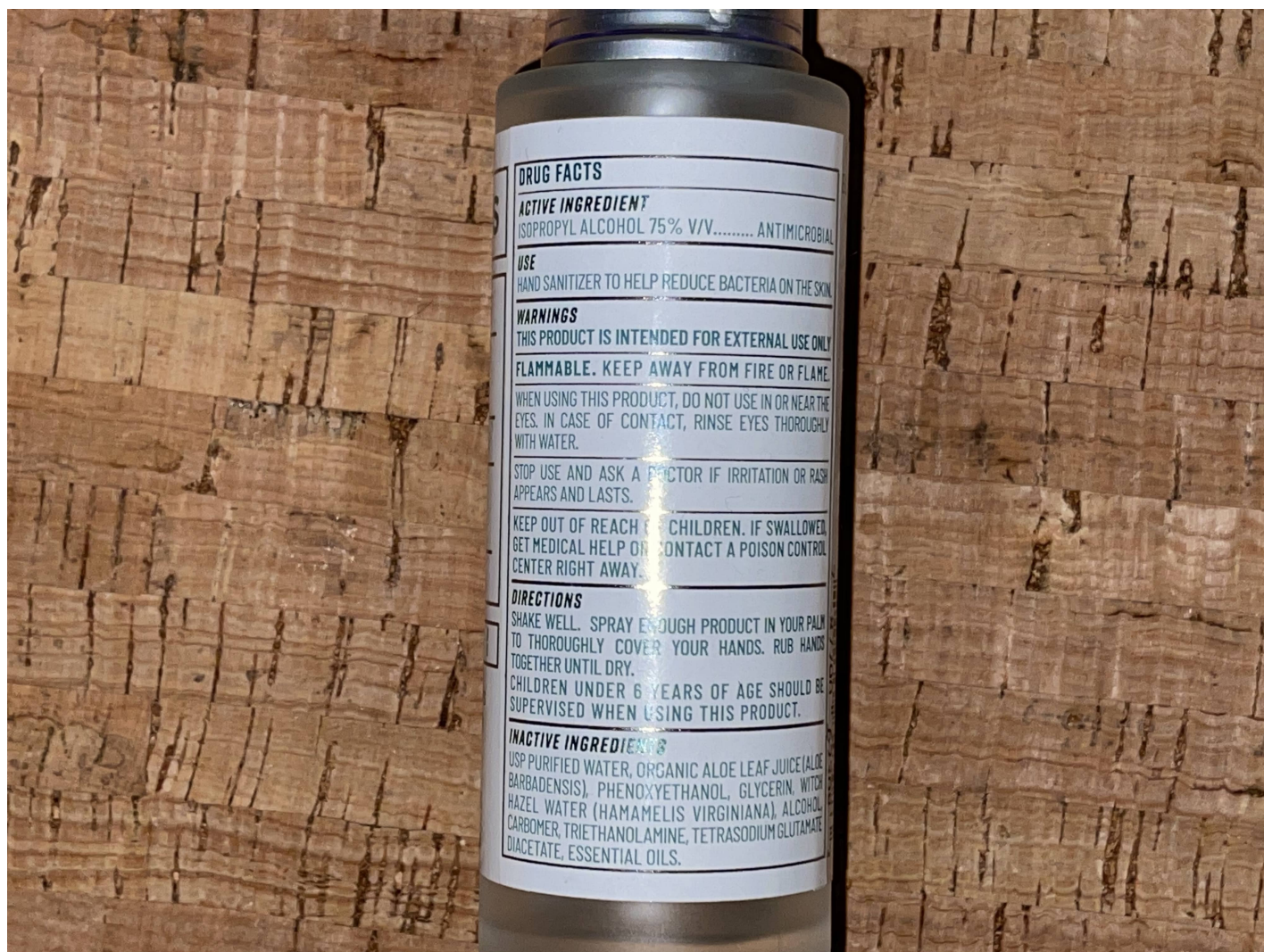
Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)



Inactive ingredients

USP Purified Water, Organic Aloe Leaf Juice, Phenoxyethanol, Glycerin, Witch Hazel Water, Alcohol, Carbomer, Triethanolamine, Tetrasodium Glutamate Diacetate, Essential Oils.



Package Label - Principal Display Panel

60 ml NDC: 81150-001-01



**MCCLAINS EXTRA STRENGTH AND MOISTURE HAND SANITIZER
ORIGINAL**

isopropyl alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81150-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name		Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)		ISOPROPYL ALCOHOL	75 mL in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
LEMON OIL (UNII: I9GRO824LL)				
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)				
CINNAMON OIL (UNII: E5GY4I6YCZ)				
ROSEMARY OIL (UNII: 8LGU7VM393)				
EUCALYPTUS OIL (UNII: 2R04ONI662)				
GLYCERIN (UNII: PDC6A3C0OX)		1.25 mL in 100 mL		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		23 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				
WITCH HAZEL (UNII: 101I4J0U34)		0.25 mL in 100 mL		
CARBOMER 940 (UNII: 4Q93RCW27E)				
CLOVE OIL (UNII: 578389D6D0)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)		0.25 mL in 100 mL		
ALCOHOL (UNII: 3K9958V90M)		0.25 mL in 100 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81150-001-01	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/19/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	11/19/2020	

Labeler - McClain's Health LLC (131111024)

Revised: 11/2020

McClain's Health LLC