## HAND SANITIZER- isopropyl alcohol gel Enter Labeler Name

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.

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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)

Ethyl Alcohol 75% 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

Isopropyl Alcohol, Glyderol, Distilled Water, Fragrance, Cinnamon Extract

# Package Label - Principal Display Panel

100 ml NDC: 77272-003-10



# HAND SANITIZER

isopropyl alcohol gel

**Product Information** 

Product Type	HUMAN OTC DRUG Item C			Code (Source)			NDC:77272-003	
Route of Adminis	stration	TOPICAL						
Active Ingredie	ent/Active M	loiety						
Ingredient Name					Basis of Strength		Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)								75 mL in 100 mL
Inactive Ingree	dients							
Ingredient Name							Strength	
GLYCERIN (UNII: PDC6A3C0OX)							1.45 mL in 100 mL	
WATER (UNII: 059QF	F0KO0R)							
CINNAMON (UNII: 55	S29HWU6QB)							
FRAGRANCE LAVEN	IDER & CHIA F-	153480 (UNII:	SXS9CO2T	ZK)				
<b>Product Chara</b>	cteristics							
Color			Score					
Shape			Size					
Flavor			Imprint Code					
Contains								
Packaging								
# Item Code Package Descri			ption			ting Star Date	t Ma	rketing End Date
NDC:77272-003- 10100 mL in 1 BOTTLE; Type 0: Not a Combination Product			nation	03/30/202	0			



Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part333A	03/30/2020					

Labeler - Enter Labeler Name (117511562)

Establishment									
Name	Address	ID/FEI	<b>Business Operations</b>						
Enter Establishment Name		117511562	manufacture(77272-003)						

Revised: 2/2022

Enter Labeler Name