HAND SANITIZER- isopropyl alcohol spray Scientia Labs, 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.

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 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

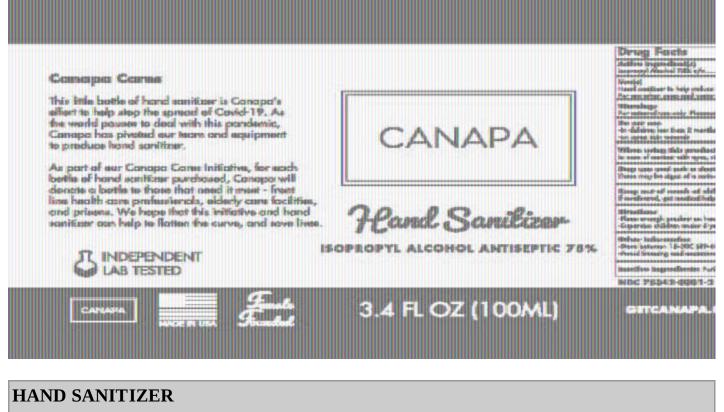
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

100 ml NDC: 75342-0001-2



isopropyl alcohol spray

Product Information									
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:75342-0001					
Route of Administration	TOPICAL								
Active Ingredient/Active Moiety									
Ingredient Name			Basis of Str	rength	Strength				
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)			ISOPROPYL ALCOHOL		75 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)								
Packaging								
# Item Code		Package Description	Marl	eting Start Date	Marketing End Date			
# Item Code	100 mL ir Product	Package Description 1 BOTTLE, SPRAY; Type 0: Not a Combination	Mark 04/27/20	Date	-			
 # Item Code 1 NDC:75342-0001- 2 	Product	1 BOTTLE, SPRAY; Type 0: Not a Combination		Date	-			
 # Item Code 1 NDC:75342-0001- 2 	Product	1 BOTTLE, SPRAY; Type 0: Not a Combination		Date	-			
# Item Code 1 NDC:75342-0001-	iforma	1 BOTTLE, SPRAY; Type 0: Not a Combination	04/27/20	Date	-			

Labeler - Scientia Labs, LLC (116937691)

Establishment

Name	Address	ID/FEI	Business Operations
Scientia Labs, LLC		116937691	manufacture(75342-0001)

Revised: 4/2020

Scientia Labs, LLC