HAND SANITIZER- alcohol solution Aura Cacia

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)

Alcohol 80% v/v. Purpose: Antiseptic

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.

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

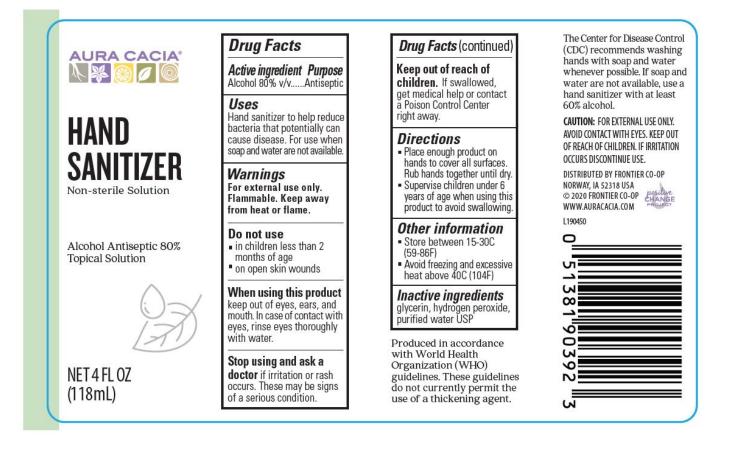
Hand Sanitizer

Non-sterile Solution

Alcohol Anticeptic 80%

Topical Solution

NET 4 fl oz 118mL



Purpose

Antiseptic, Hand Sanitizer



Route of Administr	ation	TOPICAL				
Active Ingredier	nt/Active Moi	etv				
Ingredient Name			Basis	of Strength	Strength	
ALCOHOL (UNII: 3К9958 V90М) (ALCOHOL - UNII:3К9958 V90М)			ALCOHO	L	80 mL in 100 mL	
Inactive Ingredi	ents					
Ingredient Name					Strength	
GLYCERIN (UNII: PD	C6A3C0OX)		1.5 mL in 100 mL			
HYDROGEN PEROXIDE (UNII: BBX060AN9V)				0.45 mL in 100 mL		
WATER (UNII: 059QF	0KO0R)					
Packaging						
# Item Code		Package Description	Marketing	Start Date	Marketing End Date	
1 NDC:74246-101-01		TLE; Type 0: Not a Combination Pro	0			
Marketing In	formation					
			tion Marketing	Start Date	Marketing End Date	
Marketing Catego	ry Applicat	ion Number or Monograph Cita		Start Dute	Marketing Life Date	
		ion Number or Monograph Cita	04/03/2020	Juit Dute	Marketing Life Date	

Labeler - Aura Cacia (088851855)

Establishment						
Name	Address	ID/FEI	Business Operations			
Aura Cacia		088851855	manufacture(74246-101)			

Revised: 4/2020

Aura Cacia