BIOSSANCE HAND SANITIZER- alcohol gel Amyris, Inc

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.

Biossance Hand Sanitizer

Active Ingredient(s)

Alcohol 70% 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



240 mL NDC: 73517-127-01

BIOSSANCE HAND SANITIZER alcohol gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:73517-127 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
SQUALANE (UNII: GW89575KF9)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
WATER (UNII: 059QF0KO0R)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:73517- 127-01	240 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/15/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/15/2020	

Labeler - Amyris, Inc (185930182)

Establishment			
Name	Address	ID/FEI	Business Operations
Fareva		900400254	manufacture(73517-127)

Revised: 1/2023 Amyris, Inc