## ENVIROSAN- alcohol aerosol, spray Mayor Pharmaceutical Laboratories 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.

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## Hand Sanitizer

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):

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (62%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20 SDA 3-C.
- b. Glycerol (7% v/v).
- c. 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 62% 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.

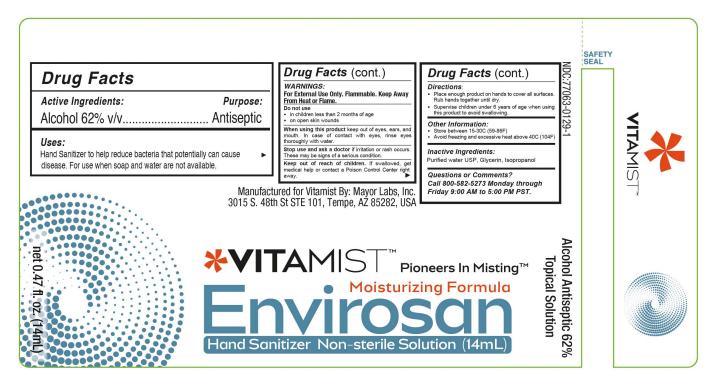
## Other information

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

## **Inactive ingredients**

purified water USP, Glycerin, Isopropanol

# Package Label - Principal Display Panel



# net 0.47 fl. oz. (14ml)

ENVIROSAN									
alcohol aerosol, spray									
<b>Product Information</b>									
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:74668-0129		668-0129					
Route of Administration	TOPICAL								
Active Ingredient/Active Moiety									
Ingred		Basis of Strengt	h	Strength					
ALCOHOL (UNII: 3K9958V90M) (ALC		ALCOHOL	62	mL in 100 mL					

Inactive Ingredients									
		Ingredient Name		Strength					
GLYCERIN (UNII: PDC6A3C0OX)					7 mL in 100 mL				
ISOPROPYL ALCOHOL (UNII: ND2M416302)					3 mL in 100 mL				
W	ATER (UNII: 059QF	0KO0R)							
Р	Packaging								
#	Item Code	Package Description	Marketing Start Date		Marketing End Date				
1	NDC:74668-0129- 1	14 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020						
Marketing Information									
Marketing Category									
	0		Marketing Star	t Date	Marketing End Date				
	0	ory Application Number or Monograph Citation	<b>Marketing Star</b> 03/30/2020	t Date	Marketing End Date				

Labeler - Mayor Pharmaceutical Laboratories inc (096010501)

**Registrant** - Mayor Pharmaceutical Laboratories inc (096010501)

Establishment								
Name	Address	ID/FEI	Business Operations					
Mayor Pharmaceutical Laboratories inc		096010501	manufacture(74668-0129), pack(74668-0129), label(74668-0129)					

Revised: 12/2020

Mayor Pharmaceutical Laboratories inc