

ENVIROSAN- alcohol aerosol, spray
Shenzen Smoore Technology Limited

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.

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

Drug Facts

Active Ingredients: Alcohol 62% v/v.....

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Drug Facts (cont.)

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Questions or Comments? Call 800-582-5273 Monday through Friday 9:00 AM to 5:00 PM PST.

Manufactured for Vitamist By: Mayor Labs, Inc. 3015 S. 48th St STE 101, Tempe, AZ 85282, USA

net 0.47 fl. oz. (14mL)

VITAMIST™ Pioneers In Misting™
Moisturizing Formula
Enviroosan
 Hand Sanitizer Non-sterile Solution (14mL)

Alcohol Antiseptic 62%
 Topical Solution

SAFETY SEAL

net 0.47 fl. oz. (14ml)

ENVIROSAN			
alcohol aerosol, spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77063-0129-1
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	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
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77063-0129-1	14 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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

Labeler - Shenzhen Smoore Technology Limited (529125922)

Registrant - Shenzhen Smoore Technology Limited (529125922)

Establishment

Name	Address	ID/FEI	Business Operations
Shenzhen Smoore Technology Limited		529125922	manufacture(77063-0129) , pack(77063-0129) , label(77063-0129)

Revised: 12/2020

Shenzhen Smoore Technology Limited