# STERLOMAX HAND SANITIZER PROFESSIONAL- alcohol solution Natures Only Inc.

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## Sterlomax E-80 P Hand Sanitizer 3.78 L

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

# **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.

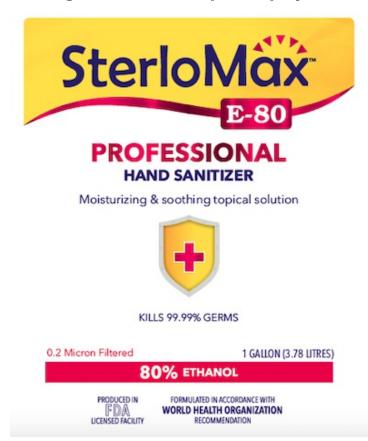
#### Other information

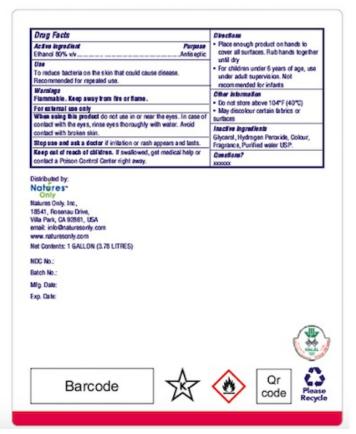
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

### **Inactive ingredients**

Glycerin, Hydrogen peroxide, Purified water USP, Fragrance, Carmoisine

## Package Label - Principal Display Panel





3.78 L NDC: 79561-005-01

## STERLOMAX HAND SANITIZER PROFESSIONAL

alcohol solution

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:79561-005

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

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Ingredient Name	<b>Basis of Strength</b>	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	3.024 L in 3.78 L	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)	0.055 L in 3.78 L		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.0047 L in 3.78 L		
WATER (UNII: 059QF0KO0R)	0.685 L in 3.78 L		
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	0.011 L in 3.78 L		
CARMOISINE (UNII: DR4641L47F)	0.006 L in 3.78 L		

## **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:79561-005- 01	3.78 L in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	

# **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug 5	505G(a)(3)	07/20/2020	

# Labeler - Natures Only Inc. (117570740)

# **Registrant -** Natures Only Inc. (117570740)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
VB MEDICARE PRIVATE LIMITED		650317659	manufacture(79561-005)

Revised: 12/2023 Natures Only Inc.