

STERLOMAX HAND SANITIZER PROFESSIONAL- alcohol solution

Natures Only Inc.

Sterlomax E-80 P Hand Sanitizer Sol 500mL

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.

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, Fragrance, Carmoisine

Package Label - Principal Display Panel



PROFESSIONAL HAND SANITIZER

Moisturizing & soothing topical solution



KILLS 99.99% GERMS

0.2 Micron Filtered

16.9 FL.OZ. (500 ml)

80% ETHANOL

FORMULATED IN ACCORDANCE WITH
WORLD HEALTH ORGANIZATION
RECOMMENDATION

Drug Facts

| Active ingredient[s] | Purpose |
|----------------------|------------|
| Ethanol 80% v/v | Antiseptic |

Use[s]

To reduce bacteria on the skin that could cause disease.
Recommended for repeated use.

Warnings

Flammable. Keep away from fire or flame.

For external use only

When using this product do not use in or near the eyes. In case of contact with the eyes, rinse eyes thoroughly with water. Avoid contact with broken skin.

Stop use and ask a doctor if irritation or rash appears and lasts.

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
- For children under 6 years of age, use under adult supervision. Not recommended for infants

Other information

- Do not store above 104°F (40°C)
- May discolor certain fabrics or surfaces

Inactive ingredients

Glycerol, Hydrogen peroxide, Carmoisine color, Fragrance, Purified water.

Questions or comments? Call 1-844-850-9557

Distributed by:

**Natures
Only**

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email: info@naturesonly.com
www.naturesonly.com

For most recent product information, visit
www.sterlomax.com

NDC No.: 79561-003-01

Batch No.:

Mfg. Date:

Exp. Date:



Net Contents:
16.9 FL.OZ. (500 ml)

500 mL NDC: 79561-003-01

STERLOMAX HAND SANITIZER PROFESSIONAL

alcohol solution

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79561-003 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 400 mL in 500 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 7.25 mL in 500 mL |

| | |
|--|---------------------|
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | 0.625 mL in 500 mL |
| WATER (UNII: 059QF0KO0R) | 90.625 mL in 500 mL |
| FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95) | 1.5 mL in 500 mL |
| CARMOISINE (UNII: DR4641L47F) | 0.75 mL in 500 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:79561-003-01 | 500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 07/20/2020 | |

Marketing Information

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

Labeler - Natures Only Inc. (117570740)

Registrant - Natures Only Inc. (117570740)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|------------------------|
| VB MEDICARE PRIVATE LIMITED | | 650317659 | manufacture(79561-003) |

Revised: 12/2023

Natures Only Inc.