

STERLOMAX HAND SANITIZER PROFESSIONAL- alcohol solution

Natures Only Inc.

Sterlomax E-80 P Hand Sanitizer Gel 100mL

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.

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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

SterloMax™
E-80

**PROFESSIONAL
HAND SANITIZER**

Moisturizing & soothing topical solution

KILLS 99.99% GERMS

0.2 Micron Filtered 3.38 FL.OZ (100 ml)

80% ETHANOL

PRODUCED IN
FDA
LICENSED FACILITY

FORMULATED IN ACCORDANCE WITH
WORLD HEALTH ORGANIZATION
RECOMMENDATION

Drug Facts	
Active ingredient Ethanol 80% v/v.....	Purpose Antiseptic
Use To reduce bacteria on the skin that could cause disease. Recommended for repeated use.	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
Warnings Flammable. Keep away from fire or flame.	Other information • Do not store above 104°F (40°C) • May discolour certain fabrics or surfaces
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.	Inactive ingredients Glycerol, Hydrogen Peroxide, Colour, Fragrance, Purified water USP.
Stop use and ask a doctor if irritation or rash appears and lasts.	Questions? xxxxxxx

Distributed by:
Natures Only
Natures Only, Inc.,
18541, Rosenau Drive,
Villa Park, CA 92861, USA
email: info@naturesonly.com
www.naturesonly.com
Net Contents: 3.38 FL.OZ (100 ml)

For general information or questions:
contact@sterlomax.com or
call: xxxxxxxxxx
NDC No.:
Batch No.:
Mfg. Date:
Exp. Date:

Barcode

Please Recycle

100 mL NDC: 79561-002-01

STERLOMAX HAND SANITIZER PROFESSIONAL

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79561-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	18.125 mL in 100 mL
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	0.3 mL in 100 mL
CARMOISINE (UNII: DR4641L47F)	0.15 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79561-002-01	100 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(79561-002)