

STERLOMAX HAND SANITIZER PROFESSIONAL- alcohol solution

Natures Only Inc.

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

Drug Facts	Purpose	Directions
Active ingredient Ethanol 80% v/v	Antiseptic	Place enough product on hands to cover all surfaces. Rub hands together until dry.
Use To reduce bacteria on the skin that could cause disease. Recommended for repeated use.		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 discolor 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.		Caution? xxxxxx
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		

Distributed by:
Natures Only
Natures Only, Inc.,
18541, Rosseau Drive,
Villa Park, CA 92881, USA
email: info@naturesonly.com
www.naturesonly.com
Net Contents: 1 GALLON (3.78 LITRES)

NDC No.:
Batch No.:
Mfg. Date:
Exp. Date:

Barcode

Qr code

Please Recycle

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

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C00X)	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
1	NDC:79561-005-01	3.78 L in 1 BOTTLE; 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(79561-005)