

STERLOMAX HAND SANITIZER- alcohol gel

Natures Only Inc.

Sterlomax E-80 Hand Sanitizer Gel 236ml

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, Carbomer, Aminomethyl propanol, Tocopheryl Acetate, Propylene glycol, Polyethylene Glycol, Isoprpyle Myristate, Fragrance

Package Label - Principal Display Panel

SterloMax
E-80

ADVANCED HAND SANITIZER

Moisturizing, Soothing & Refreshing Gel

KILLS 99.99% GERMS

8 FL.OZ (236 ml)

80% ETHANOL

PRODUCED IN FDA LICENSED FACILITY
ALCOHOL CONTENT IN ACCORDANCE WITH WORLD HEALTH ORGANIZATION RECOMMENDATION

Drug Facts

Active ingredient Ethanol 80% w/v	Purpose Antiseptic
Uses 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 discolour certain fabrics or surfaces	
Inactive ingredients Glycerin, Hydrogen peroxide solution, Propylene Glycol, Isopropyl Myristate, Tocopheryl acetate, Macrogols, Carbomers, Aminomethyl propanol, Fragrance, Purified Water USP.	
Questions? xxxxxxxxxxx	
Distributed by: Natures Only Natures Only, Inc. 18541, Rosenau Drive, Villa Park, CA 92861, USA email: info@naturesonly.com www.naturesonly.com www.sterlomax.com Net Contents: 8 FL.OZ (236 ml)	
NDC No.: Batch No.: Mfg. Date: Exp. Date:	

Icons: Home, Star, Green Leaf, Barcode, QR code, Recycle

236 mL NDC: 79561-001-01

STERLOMAX HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79561-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	188.8 mL in 236 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	3.4 mL in 236 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.295 mL in 236 mL
WATER (UNII: 059QF0KO0R)	39.5 mL in 236 mL
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	0.047 mL in 236 mL

CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	0.71 mL in 236 mL
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	1.2 mL in 236 mL
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	1.2 mL in 236 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.85 mL in 236 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79561-001-01	236 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(79561-001)

Revised: 12/2023

Natures Only Inc.