

## **HAND SANITIZER- isopropyl alcohol solution**

### **Natures Only Inc.**

-----

#### **Steromax I75 Professional Solution 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. Isopropyl Alcohol (75%, 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)**

Isopropyl Alcohol 75% 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, Color

**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)

**75% ISOPROPYL ALCOHOL**

FORMULATED IN ACCORDANCE WITH  
**WORLD HEALTH ORGANIZATION**  
RECOMMENDATION

**Drug Facts**

<b>Active ingredient[s]</b>	<b>Purpose</b>
Isopropyl alcohol 75% 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, Brilliant Blue color, Fragrance, Purified water.

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

Distributed by:

**Natures Only**  
Natures Only, Inc.  
CA 92861, USA  
email: info@naturesonly.com  
www.naturesonly.com

For most recent product information, visit [www.sterlomax.com](http://www.sterlomax.com)

NDC No.: 79561-009-01

Batch No.:

Mfg. Date:

Exp. Date:



Please Recycle

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

500 ml NDC: 79561-009-01

**HAND SANITIZER**

isopropyl alcohol solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79561-009
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	375 mL in 500 mL

**Inactive Ingredients**

Ingredient Name	Strength

<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	7.25 mL in 500 mL
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	0.625 mL in 500 mL
<b>WATER</b> (UNII: 059QF0K00R)	115.875 mL in 500 mL
<b>FRAGRANCE LEMON ORC2001060</b> (UNII: K1725A7G95)	0.5 mL in 500 mL
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	0.75 mL in 500 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79561-009-01	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/21/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	03/30/2020	

**Labeler** - Natures Only Inc. (117570740)

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

### Establishment

Name	Address	ID/FEI	Business Operations
VB MEDICARE PRIVATE LIMITED		650317659	manufacture(79561-009)

Revised: 12/2023

Natures Only Inc.