SEPTINOL- isopropyl alcohol liquid
Fabulous Innovations LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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.

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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.

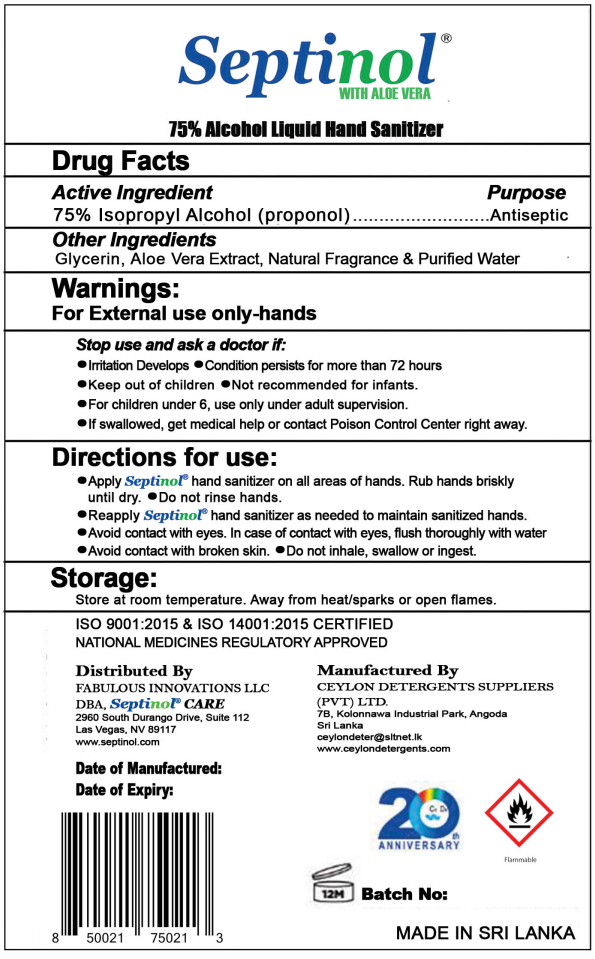
Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



100 ml NDC: 79632-222-02

Septinol®
WITH ALOE VERA

75% Alcohol Liquid Hand Sanitizer

Drug Facts

Active Ingredient	***Purpose***
75% Isopropyl Alcohol (proponol).....	Antiseptic

Other Ingredients
Glycerin, Aloe Vera Extract, Natural Fragrance & Purified Water

Warnings:
For External use only-hands

Stop use and ask a doctor if:
- Irritation Develops
- Condition persists for more than 72 hours
- Keep out of children
- Not recommended for infants.
- For children under 6, use only under adult supervision.
- If swallowed, get medical help or contact Poison Control Center right away.

Directions for use:
- Apply *Septinol®* hand sanitizer on all areas of hands. Rub hands briskly until dry.
- Do not rinse hands.
- Reapply *Septinol®* hand sanitizer as needed to maintain sanitized hands.
- Avoid contact with eyes. In case of contact with eyes, flush thoroughly with water
- Avoid contact with broken skin.
- Do not inhale, swallow or ingest.

Storage:
Store at room temperature. Away from heat/sparks or open flames.

ISO 9001:2015 & ISO 14001:2015 CERTIFIED
NATIONAL MEDICINES REGULATORY APPROVED

Distributed By
FABULOUS INNOVATIONS LLC
DBA, *Septinol® CARE*
2960 South Durango Drive, Suite 112
Las Vegas, NV 89117
www.septinol.com

Manufactured By
CEYLON DETERGENTS SUPPLIERS (PVT) LTD.
7B, Kolonnawa Industrial Park, Angoda
Sri Lanka
ceylondeter@sltnet.lk
www.ceylondetergents.com

Date of Manufactured:
Date of Expiry:

8 50021 75022 0

20 ANNIVERSARY

Flammable

12M **Batch No:**

MADE IN SRI LANKA

500 ml NDC: 79632-222-03

Septinol®
WITH ALOE VERA

75% Alcohol Liquid Hand Sanitizer

Drug Facts

Active Ingredient ***Purpose***
75% Isopropyl Alcohol (proponol).....Antiseptic

Other Ingredients
Glycerin, Aloe Vera Extract, Natural Fragrance & Purified Water

Warnings:

For External use only-hands

Stop use and ask a doctor if:

- Irritation Develops ● Condition persists for more than 72 hours
- Keep out of children ● Not recommended for infants.
- For children under 6, use only under adult supervision.
- If swallowed, get medical help or contact Poison Control Center right away.

Directions for use:

- Apply *Septinol®* hand sanitizer on all areas of hands. Rub hands briskly until dry. ● Do not rinse hands.
- Reapply *Septinol®* hand sanitizer as needed to maintain sanitized hands.
- Avoid contact with eyes. In case of contact with eyes, flush thoroughly with water
- Avoid contact with broken skin. ● Do not inhale, swallow or ingest.

Storage:

Store at room temperature. Away from heat/sparks or open flames.

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7B, Kolonnawa Industrial Park, Angoda
Sri Lanka
ceylondeter@sltnet.lk
www.ceylondetergents.com

Date of Manufactured:
Date of Expiry:

8 50021 75023 7

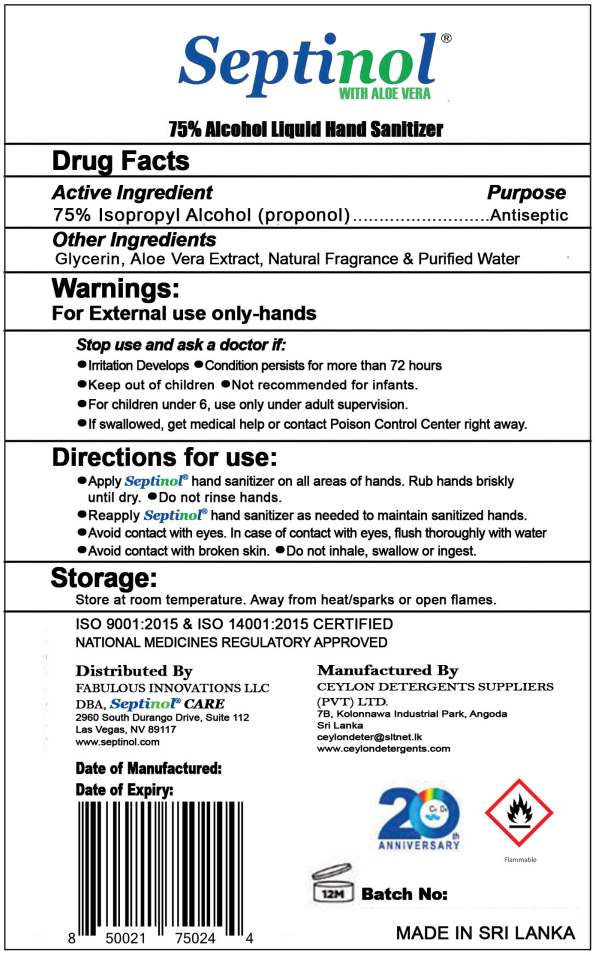
20 ANNIVERSARY

Flammable

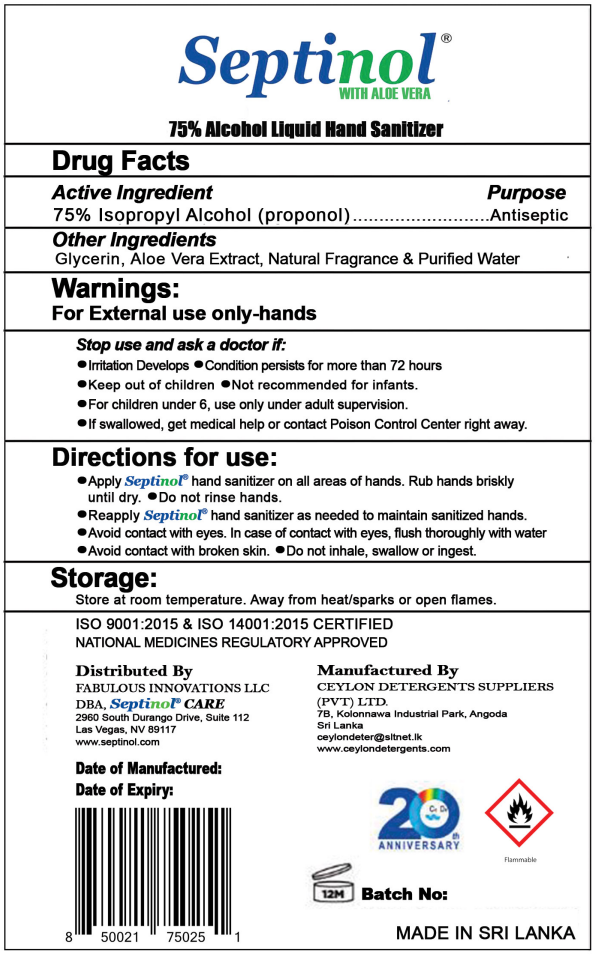
12M **Batch No:**

MADE IN SRI LANKA

2 L NDC: 79632-222-04



4 L NDC: 79632-222-05



SEPTINOL

isopropyl alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79632-222
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79632-222-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2020	
2	NDC:79632-222-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2020	
3	NDC:79632-222-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2020	
4	NDC:79632-222-04	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2020	
5	NDC:79632-222-05	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/10/2020	

Labeler - Fabulous Innovations LLC (117580927)

Establishment

Name	Address	ID/FEI	Business Operations
Fabulous Innovations LLC		117580927	manufacture(79632-222)

Revised: 7/2020 Fabulous Innovations LLC