ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION- alcohol solution Ecolab Inc.

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. 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 (equivalent to 73.53% w/w)

Purpose

Antiseptic

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.

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)
- for emergency medical information call 1-800-328-0026

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-sterile Solution 5 US Gal (18.9L) Ecolab Inc 1 Ecolab Place St. Paul, MN 55102 (USA)



Alcohol Antiseptic 80% **Topical Solution**

Hand Sanitizer Non-sterile Solution

5 US Gal (18.9 L)

Drug Facts

Active ingredient

Alcohol 80% v/v (equivalent to 73.53% w/w)

Purpose

 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 fire or flame.

- in children less than two 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 promptly and thoroughly with water.

Stop use and ask a doctor if irritation or rash. 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

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Questions? call 1-800-352-5326

Ecolab Inc · 1 Ecolab Place · St. Paul MN 55102 USA

Ecolab FG: 6302293

Nalco Part#: WHOSAN80



Alcohol Antiseptic 80% Topical Solution



Hand Sanitizer · Non-sterile Solution Desinfectante de manos · Solución no estéril

KEEP OUT OF REACH OF CHILDREN FOR INSTITUTIONAL USE ONLY See precaution and first aid on side panel.

MANTENGASE FUERA DEL ALCANCE DE LOS NIÑOS SOLO PARA USO INSTITUCIONAL Consulte las precauciones y primeros auxilios en el panel lateral.

Net Contents: 1 US qt (946 ml)

Active ingredient: Alcohol, 80% v/v (equivalent to 73.53% w/w)

1111129



SDA-NC-872

Distributed by | Distribuido por: Ecolab Inc. 1 Ecolab Place St. Paul, MN 55102 USA Made in USA 776838/8000/0420

Alcohol Antiseptic 80% Topical Solution

Drug Facts

Active ingredient Alcohol, 80% v/v (equivalent to 73.53% w/w)... Purpose

- Uses
 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 fire or flame.
- Do not use
 in children less than two 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 promptly and thoroughly with water.

Stop use and ask a doctor if irritation or rash. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control

- Directions
 Place enough product on hands to cover all surfaces. Rub hands together until dry.
 Supervise children under six 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)

 For emergency medical information call 1-800-328-0026

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Questions? Call 1-800-352-5326

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This product may be patented | Este producto puede ser patentado: www.ecolab.com/patents

EC LAB

Alcohol Antiseptic 80% Topical Solution



Hand Sanitizer Non-sterile Solution

Active Ingredient: 80% v/v Alcohol (equivalent to 73.53% w/w)

6000271

Net Contents: 16.9 fl oz (500 mL)



Drug Facts

Active ingredient

Alcohol 80% v/v (equivalent to 73.53% w/w) ...

Purpose

■ Hand Sanitizer to help reduce bacterial 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.

in children less than two 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

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 six years of age when using this product to avoid swallowing.

Other information

- Store between 15-30°C (59-86°F)

 Avoid freezing and excessive heat above 40°C (104°F)

 for emergency medical information in USA, call
- 1 800 328 0026

Inactive ingredients glycerin, hydrogen peroxide purified water USP

Questions? call 1 800 352 5326

This product may be patented: www.ecolab.com/patents

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HAND SANITIZER

Non-sterile Solution

Alcohol Antiseptic 80% Topical Solution

Active Ingredient: Alcohol 80% v/v (equivalent to 73.53% w/w)

6000272

Net Contents: 1 US GAL (3.78L)

776842/8500/0402

Drug Facts

Active ingredient
Alcohol 80% v/v (equivalent to 73.53% w/w)

Use
■ Hand Sanitizer to help reduce bacterial that potentially can cause disease. For use when soap and water are not available.

Warnings
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP.

Questions? call 1 866 781 8787

This product may be patented: www.ecolab.com/patents

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ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION

alcohol solution

Product Information

HUMAN OTC DRUG NDC:47593-624 Product Type Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

8	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47593-624- 12	18.9 L in 1 PAIL; Type 0: Not a Combination Product	04/14/2020	
2	NDC:47593-624- 21	208 L in 1 DRUM; Type 0: Not a Combination Product	04/14/2020	
3	NDC:47593-624- 65	0.5 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/14/2020	

4	NDC:47593-624- 23	0.946 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/14/2020	
5	NDC:47593-624- 91	1272 L in 1 CONTAINER; Type 0: Not a Combination Product	04/14/2020	
6	NDC:47593-624- 35	2000 L in 1 CONTAINER; Type 0: Not a Combination Product	04/14/2020	
7	NDC:47593-624- 11	3.78 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/14/2020	

Labeler - Ecolab Inc. (006154611)

Revised: 4/2020 Ecolab Inc.