

HAND SANITIZER- alcohol spray

Peter Thomas Roth Labs, 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.

PETER THOMAS ROTH HAND SANITIZER, Alcohol Antiseptic 80% Tropical Solution

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

Package Label - Principal Display Panel

SECTION GETS OVERLAPPED/COVERED BY UPC AND DISTRO LINE - PEEL BACK TO SEE ART.

PETER THOMAS ROTH CLINICAL SKIN CARE
Alcohol Antiseptic 80% Topical Solution
HAND SANITIZER
Non-Sterile Solution
57 ml / 2 fl oz

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

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

Inactive ingredients
glycerin, hydrogen peroxide, purified water USP

Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v	Antiseptic

Use(s)

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Del. by: **PETER THOMAS ROTH** Labs LLC
New York, New York 10022
Made in USA #JD-03-007
PETER THOMAS ROTH.COM

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PETER THOMAS ROTH

CLINICAL
SKIN
CARE

Alcohol
Antiseptic 80%
Topical Solution

**HAND
SANITIZER**

Non-Sterile
Solution

180 ml / 6 fl oz

Drug Facts

Active Ingredient	Purpose
Alcohol 80% v/v	Antiseptic

Use(s)
• Hand sanitizer to help reduce bacteria 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

Dist. by © PETER THOMAS ROTH® Labs, LLC
New York, New York 10022
Made in USA #30-01-088
PETERTHOMASROTH.COM

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6.625"

2.625"

PETERTHOMASROTH

CLINICAL SKIN CARE

Alcohol Antiseptic 80% Topical Solution

HAND SANITIZER

Non-Sterile Solution

60 ml / 2 fl oz

Dist. by: ©PETERTHOMASROTH® Labs LLC
New York New York 10022
Made in USA #30-03-005
PETERTHOMASROTH.COM

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Drug Facts

Active Ingredient	Purpose
Alcohol 80% v/v	Antiseptic
Use(s)	
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HAND SANITIZER

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54031-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54031-030-03	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/06/2020	
2	NDC:54031-030-01	57 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/06/2020	
3	NDC:54031-030-02	180 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/06/2020	

Labeler - Peter Thomas Roth Labs, LLC (780458944)**Registrant** - Peter Thomas Roth Labs, LLC (780458944)

Revised: 5/2020

Peter Thomas Roth Labs, LLC