

HAND SANITIZER GEL- alcohol gel

Value Products 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.

Hand Sanitizer Gel

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) (70%, 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 (2% v/v).
- c. Hydrogen peroxide (0.13% v/v).
- d. Dipropylene Glycol/Fragrance - (0.1% v/v).
- e. Tert-Butyl Alcohol/thickener (0.04% v/v).
- f. Water (agua).

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)

Ethyl Alcohol 70% v/v. Purpose: Antibacterial Agent

Purpose

Antibacterial Agent

Use

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

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, rinse eyes thoroughly with water.

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.
- 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

Water (agua), glycerin, hydrogen peroxide, Fragrance, Thickener

Package Label - Principal Display Panel

<p>Drug Facts</p> <table border="1"> <tr> <td>Active Ingredient</td> <td>Purpose</td> </tr> <tr> <td>Ethyl Alcohol 70% v/v.....</td> <td>Antibacterial Agent</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> • Hand sanitizer to help reduce bacteria that potentially can cause disease. • For use when soap and water are not available. <p>Warnings</p> <p>Flammable. Keep away from fire or flame.</p> <p>For external use only.</p> <p>When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.</p> <p>Stop use and ask a doctor if irritation or rash appears and lasts.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> • 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. <p>Other Information</p> <ul style="list-style-type: none"> • Store between 15°-30°C (59°-86°F) • Avoid freezing and excessive heat above 40°C (104°F) 	Active Ingredient	Purpose	Ethyl Alcohol 70% v/v.....	Antibacterial Agent	 <p>ProNature EARTH CONSCIOUS</p> <p>HAND SANITIZER GEL Gel Alcohólica Antiséptico para Manas</p> <p>70% Ethyl Alcohol Contains Emollients</p> <p>Antimicrobial Hand Sanitizer</p> <ul style="list-style-type: none"> • Premium pH balanced formula • Leaves hands soft and moisturized • Meets USDA Efficacy Guidelines for E3 Hand Sanitizers <p>Net Contents: 1 gallon (3.785 L)</p>	<p>Drug Facts (continued)</p> <p>Inactive Ingredients Water (Aqua), Glycerin, Hydrogen Peroxide, Fragrance, Thickener</p> <p>ProNature™ Hand Sanitizer Gel is intended for use as a no-rinse hand sanitizer. It is a premium quality pH balanced formula that is mild on the skin, yet effective enough to meet USDA efficacy guidelines for E3 hand sanitizers. ProNature™ Hand Sanitizer Gel contains emollients that leave your hands feeling soft and moisturized.</p> <p>Designed in California. Made in USA. © Copyright 2020</p> <p>REORDER PN 18303</p> <p>Scan this code with mobile device (QR reader APP required) to visit our website to learn more!</p> <p>Distributed by: Blue Ribbon Supply Company S. San Francisco, CA 94080 USA www.blueribbonssupply.com</p> 
Active Ingredient	Purpose					
Ethyl Alcohol 70% v/v.....	Antibacterial Agent					

Net Contents: 1 gallon (3.785L), Reorder PN 18303

HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77715-2665
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DIPROPYLENE GLYCOL (UNII: E107L85C40)	0.1 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.13 mL in 100 mL
WATER (UNII: 059QF0K00R)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	0.04 mL in 100 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77715-2665-2	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Drug Facts

Active Ingredient Ethyl Alcohol 70% v/v **Purpose** Antibacterial Agent

Uses

- Hand sanitizer to help reduce bacteria that potentially can cause disease.
- For use when soap and water are not available.

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, rinse eyes thoroughly with water.

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.
- Supervise children under 5 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)



ProNature
EARTH CONSCIOUS

HAND SANITIZER GEL
Gel Alcohólica Antiséptico para Manas

70% Ethyl Alcohol Contains Emollients

Antimicrobial Hand Sanitizer

- Premium pH balanced formula
- Leaves hands soft and moisturized
- Meets USDA Efficacy Guidelines for E3 Hand Sanitizers

Net Contents: 1 gallon (3.785 L)

Drug Facts (continued)

Inactive Ingredients
Water (Aqua), Glycerin, Hydrogen Peroxide, Fragrance, Thickener

ProNature™ Hand Sanitizer Gel is intended for use as a no-rinse hand sanitizer. It is a premium quality pH balanced formula that is mild on the skin, yet effective enough to meet USDA efficacy guidelines for E3 hand sanitizers. ProNature™ Hand Sanitizer Gel contains emollients that leave your hands feeling soft and moisturized.

Designed in California. Made in USA.
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REORDER PN 18303

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Distributed by:
Blue Ribbon Supply Company
S. San Francisco, CA 94080 USA
www.blueribbonssupply.com

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Value Products Inc. (050514124)

Establishment

Name	Address	ID/FEI	Business Operations
Value Products Inc.		050514124	manufacture(77715-2665)

Revised: 1/2022

Value Products Inc.