

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. Thickener (0.04% v/v).
- e. Fragrance (0.1% v/v).
- f. Water

Active Ingredient(s)

Alcohol 70% 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

fragrance, thickener, glycerin, hydrogen peroxide, water

Package Label - Principal Display Panel

HAND ANTIMICROBIAL HAND SANITIZER SANITIZER GEL

WARNING:
FLAMMABLE. Causes serious eye irritation. Flammable liquid. Harmful if swallowed.



PRECAUTIONARY STATEMENTS:
Keep away from heat/open flames/hot surfaces - no smoking. Keep container tightly closed. Take precautionary measures against static discharge.

DESCRIPTION

HAND SANITIZER GEL is a premium pH balanced formula that is mild on skin, yet tough enough to meet USDA efficacy guidelines for E3 hand sanitizers. HAND SANITIZER GEL contains emollients which leave your hands feeling soft and moisturized. HAND SANITIZER GEL is intended for use as a no-rinse hand sanitizer.

For more ingredient information visit www.valueproductsinc.com or call 833-444-8344

KEEP OUT OF THE REACH OF CHILDREN

DRUG FACTS	
Active Ingredient	Purpose
Ethyl Alcohol 70% v/v.....	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:	
<ul style="list-style-type: none"> on children less than 2 months of age on open skin wounds 	
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<ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C(104F) 	
Inactive ingredients: thickener, fragrance, glycerin, hydrogen peroxide, water	
Net contents:	VALUE PRODUCTS INC. 2128 Industrial Dr • Stockton, CA 95206 tel: (209)-983-4000 • www.ValueProductsInc.com
16 oz.	

CODE 2665

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
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	0.04 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.13 mL in 100 mL

WATER (UNII: 059QF0KO0R)

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77715-2665-1	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	



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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.