

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. Water.
- e. Thickener (0.3% v/v).
- f. Fragrance (0.1% v/v).

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

glycerin, hydrogen peroxide, water, thickener, fragrance

Package Label - Principal Display Panel

PRIDE LINE

HAND SANITIZER GEL

ANTIMICROBIAL HAND SANITIZER

FOR INDUSTRIAL USE ONLY
KEEP OUT OF THE REACH OF CHILDREN

DRUG FACTS

Active ingredient Ethyl Alcohol 70% w/v **Purpose** Antiseptic

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Inactive Ingredients: thickener, fragrance, glycerin, hydrogen peroxide, water

Net contents:

- 1 U.S. Gallon

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.

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

For more ingredient information visit www.valueproductsinc.com or call 633-444-8344

Value Products Inc.
Chemical Compounding & Packaging

2128 Industrial Dr • Stockton, CA 95206 • tel: (209)-983-4000 fax: (209) 983-4080 • www.ValueProductsInc.com CODE# 2660

HAND SANITIZER GEL

alcohol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:77715-2660

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
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	0.03 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)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	0.1 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:77715-2660-1	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

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HAND ANTIMICROBIAL HAND SANITIZER

SANITIZER

GEL

FOR INDUSTRIAL USE ONLY
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not			

final	part 555A	05/30/2020	
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Labeler - Value Products Inc. (050514124)

Establishment

Name	Address	ID/FEI	Business Operations
Value Products Inc.		050514124	manufacture(77715-2660)

Revised: 1/2022

Value Products Inc.