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.

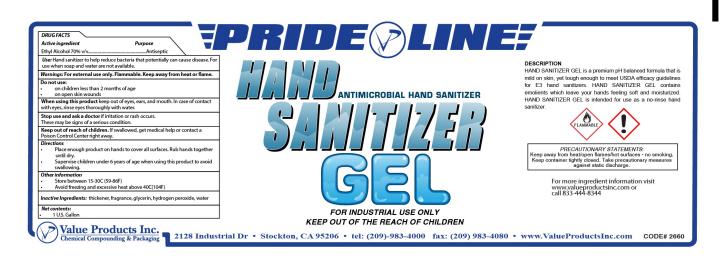
Other information

- 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



HAND SANITIZER GEL alcohol gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:77715-2660

Active Ingredient/Active Moiety

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	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		

l	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	



Marketing In	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not	~~+777 A	02/20/2020		

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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.