HAND SANITIZER- sanitizer gel gel
GDRG2, 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.

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) (73%, 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 (1.00% v/v).
c. Carbopol 940 (0.45% v/v).
d. Triethanolamine (0.25% v/v).
e. Sterile deionized 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)

Ethyl Alcohol 73% v/v. Purpose: Antiseptic

Purpose

Antimicrobial

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 heat or flame. For external use only.

Do not use

- in or near the eyes

When using this product do not use it in or near the eyes. In case of contact with eyes, 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.

Stop use and ask a doctor if irritation or rash appears and lasts.

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Directions

- Put enough product in palm to cover hands and rub hands together briskley until dry.
- Children under 6 years of age should be supervised when using this product.

Other information

- Store below 110F (43C)
- May discolor certain fabrics

Inactive ingredients

Deionized Water, Glycerol, Carbopol 940, Triethanolamine

Package Label - Principal Display Panel

29 mL NDC: 76999-7117-6

60 mL NDC: 76999-7094-5

250 mL NDC: 76999-7056-3

HAND SANITIZER
sanitizer gel gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76999-7131(NDC:56084-001)
Route of Administration	EXTRACORPOREAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	40.8 mL in 60 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.6 mL in 60 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.27 mL in 60 mL
CUPRIC BIS(TRIETHANOLAMINE) (UNII: YBM44X0B6H)	0.15 mL in 60 mL
WATER (UNII: 059QF0KO0R)	15.18 mL in 60 mL

Product Characteristics			
Color	white (Clear)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76999-7131-5	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/05/2020	

HAND SANITIZER

sanitizer gel gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76999-7056(NDC:56084-005)
Route of Administration	EXTRACORPOREAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	170 mL in 250 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	2.5 mL in 250 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	1.125 mL in 250 mL
CUPRIC BIS(TRIETHANOLAMINE) (UNII: YBM44X0B6H)	0.625 mL in 250 mL
WATER (UNII: 059QF0KO0R)	63.25 mL in 250 mL

Product Characteristics			
Color	white (Clear)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76999-7056-3	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/05/2020	

HAND SANITIZER

sanitizer gel gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76999-7117(NDC:56084-003)
Route of Administration	EXTRACORPOREAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	19.72 mL in 29 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.29 mL in 29 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.1305 mL in 29 mL
CUPRIC BIS(TRIETHANOLAMINE) (UNII: YBM44X0B6H)	0.0725 mL in 29 mL
WATER (UNII: 059QF0KO0R)	7.337 mL in 29 mL

Product Characteristics			
Color	white (Clear)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76999-7117-6	29 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/05/2020	

Labeler - GDRG2, Inc. (099224092)

Revised: 4/2020 GDRG2, Inc.