## HEMIRUS HAND SANITIZER GEL- alcohol gel Woosin Cosmetics Co., Ltd.

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.

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#### **Hand Sanitizer**

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) (80%, 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 (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold 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)**

Alcohol 75% v/v. Purpose: Antiseptic

#### Purpose

75% v/v 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.

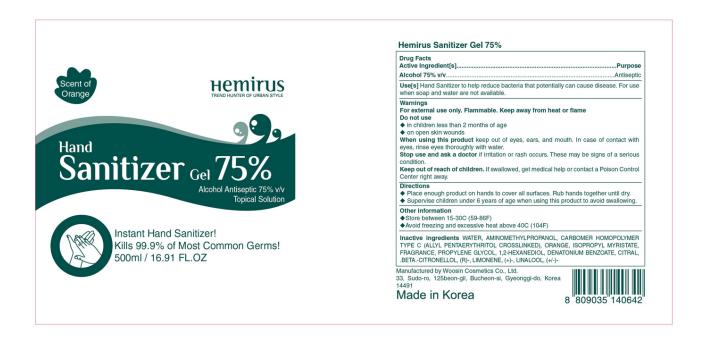
#### Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

### Package Label - Principal Display Panel



#### PANTONE 330C



Sanitizer Get 75%





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#### PANTONE 330C



Sanitizer Gel 75%





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#### Hemirus Hand Sanitizer Gel

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Manufactured by Woosin Cosmetics Co., Ltd. 33, Sudo-ro, 125beon-gil, Bucheon-si, Gyeonggi-do, Korea 14491

Made in Korea



## PANTONE 330C



Hand Sanitizer Gel 75%

Alcohol Antiseptic





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MADE IN KOREA





# Sanitizer Gel 75%

Alcohol Antiseptic





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#### HEMIRUS HAND SANITIZER GEL

alcohol gel

#### **Product Information**

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
CITRAL (UNII: T7EU0O9VPP)		
.BETACITRONELLOL, (R)- (UNII: P01OUT964K)		
LIMO NENE, (+)- (UNII: GFD7C86Q1W)		
LINALOOL, (+/-)- (UNII: D81QY6188E)		
WATER (UNII: 059QF0KO0R)		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)		
ORANGE (UNII: 5EVU04N5QU)		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)		
<b>DENATO NIUM BENZO ATE</b> (UNII: 4YK5Z54AT2)		
1,2-HEXANEDIOL (UNII: TR046 Y3K1G)		

Product Characteristics				
Color	Score			
Shape	Size			
Flavor	Imprint Code			
Contains				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:74351- 2007-1	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/06/2020		
2	NDC:74351- 2007-2	300 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/06/2020		
3	NDC:74351- 2007-3	100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/06/2020		
4	NDC:74351- 2007-4	50 mL in 1 TUBE; Type 0: Not a Combination Product	04/06/2020		
5	NDC:74351- 2007-5	30 mL in 1 TUBE; Type 0: Not a Combination Product	04/06/2020		
6	NDC:74351- 2007-6	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/06/2020		

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Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part333A	04/02/2020					

**Labeler -** Woosin Cosmetics Co., Ltd. (688227829)

Registrant - Woosin Cosmetics Co., Ltd. (688227829)

# Establishment Name Address ID/FEI Business Operations Woosin Cosmetics Co., Ltd. 688227829 manufacture(74351-2007)

Revised: 4/2020 Woosin Cosmetics Co., Ltd.