# 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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- Supervise children under 6 years of age when using this product to avoid swallowing.

### Other information

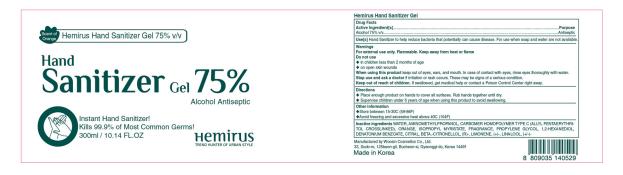
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

### PACKIGING LABEL.PRINCIPAL DISPLAY PANEL

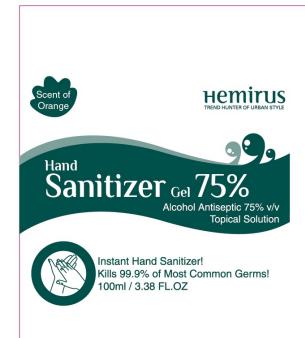




## PANTONE 330C



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#### **Hemirus Hand Sanitizer Gel 75%**

Drug Facts Active Ingredient[s]... Alcohol 75% v/v...

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Inactive ingredients WATER, AMINOMETHYLPROPANOL, CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED), ORANGE, CARBOMER ISOPROPYL MYRISTATE, FRAGRANCE, PROPYLENE GLYCOL, 1,2-HÉXANEDIOL, DENATONIUM BENZOATE, CITRAL, BETA.-CITRONELLOL, (R)-, LIMONENE, (+)-,

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

Made in Korea

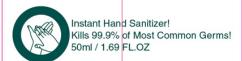


# PANTONE 330C



Hand Sanitizer Gel 75%

Alcohol Antiseptic





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MADE IN KOREA





# Sanitizer Gel 75%

Alcohol Antiseptic





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Made in Korea

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Inactive Ingredients Water, aminomethylpropanol, carbomer homopolymer Type C (allyl pentaerythritol crosslinked), orange, isopropyl myristate, Fragrance, propylene glycol, 1,2-hexanediol, denatonium benzoate, citral, .Beta-citronellol, (r), limonene, (+)-, linalool, (+/-)

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Inactive ingredients water, aminomethylpropanol, carbomer homopolymer type c (allyl pentaerythritol crosslinked), orange, isopropyl myristate, fragrance, propylene glycol, 12-hexanediol, denatonium benzoate, citral, beta-citronellol, (R), limonene, (+)-, linalool, (+/-)

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...Antiseptic

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Alcohol Antisepti





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## HEMIRUS HAND SANITIZER GEL

alcohol gel

#### **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:74351-2007

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)
ALCOHOL (UNII: 3K9958 V90M) To mL

# Ingredient Name PROPYLENE GLYCOL (UNII: 6DC9Q167V3) CITRAL (UNII: T7EU0O9VPP)

.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)

LIMO NENE, (+)- (UNII: GFD7C86Q1W)

LINALOOL, (+/-)- (UNII: D81QY6I88E)

WATER (UNII: 059QF0KO0R)

**Inactive Ingredients** 

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)

ORANGE (UNII: 5EVU04N5QU)

ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)

**DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)** 

1,2-HEXANEDIO L (UNII: TR046 Y3K1G)

#### **Product Characteristics**

1 Toduct Characteristics				
Color	Score			
Shape	Size			

Flavor	Imprint Code	
Contains		

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:74351- 2007-1	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/06/2020	06/30/2020
,	NDC:74351- 2007-2	300 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/06/2020	06/30/2020
₹ .	NDC:74351- 2007-3	100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/06/2020	06/30/2020
4	NDC:74351- 2007-4	50 mL in 1 TUBE; Type 0: Not a Combination Product	04/06/2020	06/30/2020
	NDC:74351- 2007-5	30 mL in 1 TUBE; Type 0: Not a Combination Product	04/06/2020	06/30/2020
h	NDC:74351- 2007-6	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/06/2020	
7	NDC:74351- 2007-7	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/02/2020	06/30/2020
x	NDC:74351- 2007-8	1900 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/07/2020	07/30/2020
9	NDC:74351- 2007-9	3800 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/02/2020	06/30/2020

## Hemirus Sanitizer Gel 75%

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Active Ingredient[s]......Purpose

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## **Marketing Information**

**Marketing End Date** Marketing Category Application Number or Monograph Citation Marketing Start Date 04/02/2020

OTC monograph not final part333A

**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: 11/2020 Woosin Cosmetics Co., Ltd.