

**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

The image shows the principal display panel of a Hemirus Sanitizer Gel 75% package. The design features a dark green wave graphic with the product name and alcohol content. A circular icon shows hands being sanitized. Text includes 'Scent of Orange', 'Hemirus TREND HUNTER OF URBAN STYLE', 'Instant Hand Sanitizer! Kills 99.9% of Most Common Germs!', and '500ml / 16.91 FL.OZ'. On the right side, there is a detailed information box containing drug facts, warnings, directions, and other information, along with a barcode and the text 'Made in Korea'.

**Hemirus Sanitizer Gel 75%**

Scent of Orange

Hemirus  
TREND HUNTER OF URBAN STYLE

Hand Sanitizer Gel 75%  
Alcohol Antiseptic 75% v/v  
Topical Solution

Instant Hand Sanitizer!  
Kills 99.9% of Most Common Germs!  
500ml / 16.91 FL.OZ

**Hemirus Sanitizer Gel 75%**

**Drug Facts**  
Active ingredient[s].....Purpose  
Alcohol 75% v/v.....Antiseptic  
**Use[s]** 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.

**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** 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, (+/-)-

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

Made in Korea

8 809035 140642

PANTONE 330C

Scent of Orange Hemirus Hand Sanitizer Gel 75% v/v

# Hand Sanitizer Gel 75%

Alcohol Antiseptic



Instant Hand Sanitizer!  
Kills 99.9% of Most Common Germs!  
500ml / 16.91 FL.OZ

**hemirus**  
TREND HUNTER OF URBAN STYLE

### Hemirus Hand Sanitizer Gel

**Drug Facts**  
Active Ingredient(s)..... Purpose  
Alcohol 75% v/v..... Antiseptic

**Use(s)** 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

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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** 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, (-/-)

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

Made in Korea



PANTONE 330C

Scent of Orange Hemirus Hand Sanitizer Gel 75% v/v

# Hand Sanitizer Gel 75%

Alcohol Antiseptic



Instant Hand Sanitizer!  
Kills 99.9% of Most Common Germs!  
300ml / 10.14 FL.OZ

**hemirus**  
TREND HUNTER OF URBAN STYLE

### Hemirus Hand Sanitizer Gel

**Drug Facts**  
Active Ingredient(s)..... Purpose  
Alcohol 75% v/v..... Antiseptic

**Use(s)** 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

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**Directions**

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

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- ◆ Store between 15-30C (59-86F)
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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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Made in Korea



 PANTONE 330C



Hemirus Hand Sanitizer Gel 75% v/v

# Hand Sanitizer Gel 75%

Alcohol Antiseptic



Instant Hand Sanitizer!  
Kills 99.9% of Most Common Germs!  
100ml / 3.38 FL.OZ

**hemirus**  
TREND HUNTER OF URBAN STYLE

## Hemirus Hand Sanitizer Gel

<b>Drug Facts</b>	
Active Ingredient[s].....	Purpose
Alcohol 75% v/v.....	Antiseptic
Use[s] Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b>	
◆ 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.	
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◆ 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.	
<b>Other information</b>	
◆ Store between 15-30C (59-86F)	
◆ Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> 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, (+/-)	

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

Made in Korea



8 809035 140666

 PANTONE 330C

 Hemirus Hand Sanitizer Gel 75% v/v

# Hand Sanitizer Gel 75%

Alcohol Antiseptic



Instant Hand Sanitizer!  
Kills 99.9% of Most Common Germs!  
50ml / 1.69 FL.OZ

**hemirus**  
TREND HUNTER OF URBAN STYLE

## Hemirus Hand Sanitizer Gel

### Drug Facts

Active Ingredient[s]	Purpose
Alcohol 75% v/v	Antiseptic

**Use[s]** 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

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- ◆ on open skin wounds

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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, (+/-)

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

**MADE IN KOREA**



8 809035 140536

Scent of Orange Hemirus Hand Sanitizer Gel 75% v/v

# Hand Sanitizer Gel 75%

Alcohol Antiseptic

 Instant Hand Sanitizer!  
Kills 99.9% of Most Common Germs!  
30ml / 1.01 FL.OZ

**hemirus**  
TREND HUNTER OF URBAN STYLE

## Hemirus Hand Sanitizer Gel

### Drug Facts

Active Ingredient[s]	Purpose
Alcohol 75% v/v .....	Antiseptic

**Use[s]** Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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**MADE IN KOREA**



8 809035 140628

## HEMIRUS HAND SANITIZER GEL

alcohol gel

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:74351-2007

Route of Administration TOPICAL

### 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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
WATER (UNII: 059QF0KO0R)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
ORANGE (UNII: 5EVU04N5QU)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	

### 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	



## Hemirus Hand Sanitizer Gel

### Drug Facts

Active Ingredient[s].....Purpose  
Alcohol 75% v/v.....Antiseptic

Use[s] 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

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Made in Korea



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph 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.