

**HEMIRUS HAND CLINIC 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 65% 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, purified water USP

## Package Label - Principal Display Panel

■ PANTONE 330C


|   |   |
|---|---|
|  <b>Hemirus Hand Clinic Gel 65% v/v</b>  | <b>KFDA<br/>Approved</b>                      |
| <b>Hand<br/>Clinic Gel 65%</b><br>Alcohol Antiseptic  |   |
|  Instant Hand Sanitizer!<br>Kills 99.9% of Most Common Germs!<br>500ml / 16.91 FL.OZ   | <b>Hemirus</b><br>TREND HUNTER OF URBAN STYLE |
| <b>Hemirus Hand Clinic Gel</b>  |   |
| <b>Drug Facts</b>   |   |
| <b>Active Ingredient(s)</b> .....   | <b>Purpose</b><br>Antiseptic                  |
| Alcohol 65% v/v   |   |
| <b>Use(s)</b> 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   |   |
| <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.   |   |
| <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.   |   |
| <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.   |   |
| <b>Directions</b>   |   |
| ◆ 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, PHENOXETHANOL, TRICHLAMINE, CARBOMER HOMOPOLYMER TYPE C (ALLYL DIMETHYLAMINE) CROSSLINKED, METHYLURAMINE, ORANGE, ISOPROPYL MYRISTATE, FRAGRANCE, D&G ORANGE NO. 4, PROPYLENE GLYCOL, 1,2-HEXANEDIOL, CITRAL, BETA-CITRONELLOL, (R)-LIMONENE, (+)-LINALOOL, (+)- |   |
| Manufactured by Woorin Cosmetics Co., Ltd. 33, Sudo-ro, 125beon-gil, Bucheon-si, Gyeonggi-do, Korea 14491   |   |
| <b>Made in Korea</b>  |   |
| <br>8 809035 141342  |   |

PANTONE 330C



**Hemirus Hand Clinic Gel 65% v/v**

**Hand Clinic Gel 65%**  
Alcohol Antiseptic



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

**hemirus**  
TREND HUNTER OF URBAN STYLE

**KFDA Approved**

**Hemirus Hand Clinic Gel**

**Drug Facts**

Active Ingredient[s].....Purpose  
Alcohol 65% 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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**Other information**

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**Inactive ingredients** WATER, PHENOXYETHANOL, TROLAMINE, CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED), METHYLPARABEN, ORANGE, ISOPROPYL MYRISTATE, FRAGRANCE, D&C ORANGE NO. 4, PROPYLENE GLYCOL, 1,2-HEXANEDIOL, 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 140932

**HEMIRUS HAND CLINIC GEL**

alcohol gel

**Product Information**

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:74351-2008 |
| <b>Route of Administration</b> | TOPICAL        |                           |                |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 65 mL in 100 mL |

**Inactive Ingredients**

| Ingredient Name                        | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R)               |          |
| TROLAMINE (UNII: 9O3K93S3TK)           |          |
| ORANGE (UNII: 5EVU04N5QU)              |          |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) |          |
| CITRAL (UNII: T7EU0O9VPP)              |          |
| LINALOOL, (+/-)- (UNII: D81QY6I88E)    |          |

|  |  |
|--|--|
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)  |  |
| LIMONENE, (+)- (UNII: GFD7C86Q1W)  |  |
| 1,2-HEXANEDIOL (UNII: TR046Y3K1G)  |  |
| .BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)  |  |
| D&C ORANGE NO. 4 (UNII: Q1LIY3BO0U)  |  |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)  |  |
| METHYLPARABEN (UNII: A2I8C7HI9T)   |  |
| CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) |  |

### Product Characteristics

|          |  |              |  |
|----------|--|--------------|--|
| Color    |  | Score        |  |
| Shape    |  | Size         |  |
| Flavor   |  | Imprint Code |  |
| Contains |  |              |  |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:74351-2008-1 | 500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 02/03/2020           |                    |
| 2 | NDC:74351-2008-2 | 100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 02/03/2020           |                    |

### Hemirus Hand Clinic Gel

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|--|
| <b>Drug Facts</b>  |
| Active Ingredient[s].....Purpose   |
| Alcohol 65% v/v.....Antiseptic   |
| <b>Use[s]</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.  |
| <b>Warnings</b>  |
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Made in Korea



### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

|                         |          |            |  |
|-------------------------|----------|------------|--|
| OTC monograph not final | part333A | 02/03/2020 |  |
|-------------------------|----------|------------|--|

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

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

| <b>Establishment</b>       |                |               |                            |
|----------------------------|----------------|---------------|----------------------------|
| <b>Name</b>                | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
| Woosin Cosmetics Co., Ltd. |                | 688227829     | manufacture(74351-2008)    |

Revised: 5/2020

Woosin Cosmetics Co., Ltd.