

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.

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 76.448% 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

The image shows a product label for Hemirus Hand Sanitizer Gel 65%. The label is primarily white with green accents. At the top left, there is a green circular icon with the text "Scent of Orange". To the right of this is the brand name "hemirus" in a lowercase, sans-serif font, with the tagline "TREND HUNTER OF URBAN STYLE" underneath. The main product name "Hand Sanitizer Gel 65%" is prominently displayed in a large, bold, sans-serif font. Below this, it says "Alcohol Antiseptic 65% v/v Topical Solution". On the left side, there is a circular icon showing hands being washed, with the text "Instant Hand Sanitizer! Kills 99.9% of Most Common Germs! 100ml / 3.38 FL.OZ". On the right side, there is a detailed information box with a green border. This box contains the following text: "Hemirus Hand Sanitizer Gel 65%", "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.", "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, PHENOXYETHANOL, TROLAMINE, CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED), METHYLPARABEN, ORANGE, ISOPROPYL MYRISTATE, FRAGRANCE, D&C ORANGE NO. 4", "Manufactured by WoosinCosmetics Inc.", "33, Sudo-ro, 125beon-gil, Bucheon-si, Gyeonggi-do, Korea 14491", "Made in Korea", and a barcode with the number "8 809035 140932".



Scent of Orange



Hemirus
TREND HUNTER OF URBAN STYLE



Hand Sanitizer Gel 65%
Alcohol Antiseptic 65% v/v
Topical Solution



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

Hemirus Hand Sanitizer Gel 65%

Drug Facts
Active Ingredient(s).....Purpose
Alcohol 65% v/v.....Antiseptic

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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

Manufactured by WoosinCosmetics Inc.
33, Sudo-ro, 125beon-gil, Bucheon-si, Gyeonggi-do, Korea
14491

Made in Korea



8 809035 141342

HEMIRUS HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74351-2102
Route of Administration	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
D&C ORANGE NO. 4 (UNII: Q1LIY3BO0U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
ORANGE (UNII: 5EVU04N5QU)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74351-2102-1	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/07/2020	
2	NDC:74351-2102-2	100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/07/2020	

Hemirus Hand Sanitizer Gel 65%

Drug Facts

Active Ingredient[s].....**Purpose**
Alcohol 65% v/v.....**Antiseptic**

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/07/2020	05/07/2024

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

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

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 5/2020

Woosin Cosmetics Co., Ltd.