

HEMIRUS HAND SANITIZER MIST- alcohol spray
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 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 Hand Sanitizer Mist 75% bottle. The label features the Hemirus logo with the tagline 'TREND HUNTER OF URBAN STYLE' and 'Scent of Orange'. The product name 'Hand Sanitizer Mist 75%' is prominently displayed, along with 'Alcohol Antiseptic 75% v/v Topical Solution'. A circular icon shows hands being sanitized, with the text 'Instant Hand Sanitizer! Kills 99.9% of Most Common Germs! 50ml / 1.69 FL.OZ'. On the right side, there is a detailed information box containing drug facts, warnings, directions, and other information. At the bottom right, there is a barcode with the number 8 809035 146408 and the text 'Made in Korea'.

Hemirus Hand Sanitizer Mist 75%

Drug Facts
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Inactive ingredients WATER, ORANGE, FRAGRANCE, PROPYLENE GLYCOL, 1,2-HEXANEDIOL, DENATONIUM BENZOATE, CITRAL, .BETA.-CITRONELLOL, (R)-, GERANIOL, LIMONENE, (+), LINALOOL, (+/-)

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

Made in Korea

8 809035 146408

HEMIRUS HAND SANITIZER MIST

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74351-210 1
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: 059QF0K00R)	
ORANGE (UNII: 5EVU04N5QU)	
GERANIOL (UNII: L837108USY)	
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:74351-2101-1	50 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/07/2020	

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Marketing Information

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

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(74351-2101)