MS. GERMSAFE ANTIBACTERIAL HAND SANITIZER- ethyl alcohol spray The Germ Safe Company Llc

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.

Ms. Germ Safe ANTIBACTERIAL HAND SANITIZER SPRAY

Drug Facts

Active ingredient

Ethyl alcohol 70%

Purpose

Antiseptic

Uses

• hand sanitizer to decrease bacteria on the skin • recommended for repeated use • for use when soap and water are not available.

Warnings

Flammable, keep away from fire/flame For external use only

Do not use • in children less than 2 months of age • on open skin wounds. **When using this product** • do not get into eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if • irritation and redness develop • condition persists for more than 72 hours.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• wet hands thoroughly with product and allow to dry without wiping • supervise children under 6 years of age when using this product to avoid swallowing.

Other information

store between 15-30°C (59-86°F)
 avoid freezing and excessive heat above 40°C

(104°F).

Inactive ingredients

water, fragrance, limonene, aloe vera (Aloe barbadensis) leaf extract, O-phenylphenol, bronopol, dichlorobenzyl alcohol, linalool, hexyl cinnamal, lactic acid, phenoxyethanol, butylphenyl methylpropional, citric acid, caprylyl glycol, citronellol, vitamin E, sodium benzoate, benzyl alcohol, geraniol, citral, amyl cinnamal, benzyl benzoate, denatonium benzoate.

Ouestions?

+1-909-442-0096

You may also report serious side effects to this phone number.

Mon-Fri 9:00 AM - 5:00 PM

Distributed by: The Germ Safe Company, LLC 5 Rosalie Drive - Plainview, NY-11803

MADE IN BRAZIL

NDC: 74415-001-02

NDC: 74415-001-03

NDC: 74415-001-05

850018863001

850018863018

850018863025

70% ETHYL ALCOHOL

CLEAN FRESH

With Moisturizing

Aloe Vera and Vitamin E

36M

NOT TESTED ON ANIMALS

Packaging



ANTIBACTERIAL HAND SANITIZER

SPRAY

70% ETHYL ALCOHOL

CLEAN FRESH

With Moisturizing

Aloe Vera and Vitamin E

Net contents 3.3 fl oz (98 mL)

Drug Facts

Active ingredient Purpose Ethyl alcohol 70%......Antiseptic

Uses • hand sanitizer to decrease bacteria on the skin-recommended for repeated use-for use when soap and water are not available.

Warnings Flammable, keep away from fire/flame For external use only

Do not use • in children less than 2 months of age • on open skin

wounds.

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if

irritation and redness develop
condition persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • wet hands thoroughly with product and allow to dry without wiping • supervise children under 6 years of age when using this product to avoid swallowing.

Drug Facts (continued)

Other information • store between 15-30°C (59-86°F) • avoid freezing and excessive heat above 40°C (104°F).

Inactive ingredients water, fragrance, limonene, aloe vera (Aloe barbadensis) leaf extract, O-phenylphenol, bronopol, dichlorobenzyl alcohol, linalool, hexyl cinnamal, lactic acid, phenoxyethanol, butylphenyl methylpropional, citric acid, caprylyl glycol, citronellol, vitamin E, sodium benzoate, benzyl alcohol, geraniol, citral, amyl cinnamal, benzyl benzoate, denatonium benzoate,

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Distributed by: The Germ Safe Company, LLC 5 Rosalie Drive - Plainview, NY-11803 MADE IN BRAZIL NDC: 74415-001-02





ANTIBACTERIAL HAND SANITIZER

SPRAY

70% ETHYL ALCOHOL

CLEAN FRESH

With Moisturizing Aloe Vera and Vitamin E

Net contents 5.0 fl oz (148 mL)









Drug Facts

Uses

- · hand sanitizer to decrease bacteria on the skin
- · recommended for repeated use
- · for use when soap and water are not available

Warnings

Flammable, keep away from fire / flame For external use only

Do not use • in children less than 2 months of age • on open

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water.

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Directions • wet hands thoroughly with product and allow to dry without wiping • supervise children under 6 years of age when using this product to avoid swallowing.

Other information • store between 15-30°C (59-86°) avoid freezing and excessive heat above 40°C (104°F).

Inactive ingredients water, fragrance, limonene, aloe vera (Aloe barbadensis) leaf extract, O-phenylphenol, bronopol, dichlorobenzyl alcohol, linalool, hexyl cinnamal, lactic acid, phenoxyethanol, butylphenyl methylpropional, citric acid, caprylyl glycol, citronellol, vitamin E, sodium benzoate, benzyl alcohol, geraniol, citral, amyl cinnamal, benzyl benzoate, denatonium benzoate.

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Distributed by: The Germ Safe Company, LLC 5 Rosalie Drive - Plainview, NY-11803

MADE IN BRAZIL NDC: 74415-001-03



ANTIBACTERIAL **HAND** SANITIZER SPRAY

70% ETHYL ALCOHOL

CLEAN FRESH

With Moisturizing Aloe Vera and Vitamin E

Net contents 8.45 fl oz (250 mL)

Drug Facts

Active ingredient

Purpose

Ethyl alcohol 70%...... Antiseptic

- · hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- · for use when soap and water are not available

Warnings

Flammable, keep away from fire / flame For external use only

Do not use • in children less than 2 months of age • on open skin wounds.

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if • irritation and redness develop · condition persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • wet hands thoroughly with product and allow to dry without wiping • supervise children under 6 years of age when using this product to avoid swallowing.

Other information • store between 15-30° C (59-86°) avoid freezing and excessive heat above 40°C (104°F).

Inactive ingredients water, fragrance, limonene, aloe vera (Aloe barbadensis) leaf extract, O-phenylphenol, bronopol, dichlorobenzyl alcohol, linalool, hexyl cinnamal, lactic acid, phenoxyethanol, butylphenyl methylpropional, citric acid, caprylyl glycol, citronellol, vitamin E, sodium benzoate, benzyl alcohol, geraniol, citral, amyl cinnamal, benzyl benzoate, denatonium benzoate.

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Distributed by: The Germ Safe Company, LLC 5 Rosalie Drive - Plainview, NY-11803

NDC: 74415-001-05









MS. GERMSAFE ANTIBACTERIAL HAND SANITIZER

ethyl alcohol spray

Product Information

HUMAN OTC DRUG **Product Type** Item Code (Source) NDC:74415-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
2-PHENYLPHENOL (UNII: D343Z75HT8)	
BRONOPOL (UNII: 6PU1E16C9W)	
DICHLOROBENZYL ALCOHOL (UNII: 1NKX3648J9)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHAHEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.BETACITRONELLOL, (R)- (UNII: P010UT964K)	
.ALPHATOCOPHEROL (UNII: H4N855PNZ1)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GERANIOL (UNII: L837108USY)	
CITRAL (UNII: T7EU0O9VPP)	
.ALPHAAMYLCINNAMALDEHYDE (UNII: WC51CA3418)	
BENZYL BENZOATE (UNII: N863NB338G)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:74415- 001-02	98 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/10/2020		
2	NDC:74415- 001-03	148 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/10/2020		
3	NDC:74415- 001-05	250 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/10/2020		

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
part333A	06/10/2020			
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date		

Labeler - The Germ Safe Company Llc (122485376)

Establishment					
Name	Address	ID/FEI	Business Operations		
GYP Comercio Atacadista de Cosmeticos Ltda		898631755	manufacture(74415-001)		