

HYGIENIGEL- hand sanitizer gel
HAIKOWER S.r.l.

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.

Hygienigel Gel - 70%

Dosage and Admin

Place enough HYGIENIGEL on your hands and rub them until dry.

Children under 6 years of age must be supervised when using HYGIENIGEL.

Inactive ingredients

Carbomer, Dmdm Hydantoin, Ethylhexylglycerin, Fragrance, Melaleuca Alternifolia Leaf Oil, Panthenol, Peg/ppg-14/4 Dimethicone, Peg-60 Lanolin, Propylene Glycol, Phenoxyethanol, Triethanolamine, Water

Active Ingredient

Ethyl Alcohol 70% v/v

OTC - Ask Doctor

Stop use and ask a doctor if irritation or rash appears and lasts.

OTC - Do not use

When using this product, do not ingest, inhale or use in or near the eyes. In case of contact, rinse thoroughly with water for at least 2 minutes.

OTC - Keep out of children

Keep out of reach of children.

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

OTC - Purpose

Uses Hand Sanitizer to help reduce bacteria on the skin

OTC - Stop use

Stop use and ask a doctor if irritation or rash appears and lasts.

Warnings

Flammable.

Keep away from flame and fire.

For external use only.

Indication and Usage

Hand Sanitizer to help reduce bacteria on the skin

Label



INSTANT HAND SANITIZER

ENRICHED EMOLLIENT FORMULA
WITH LANOLIN, PANTHENOL,
AND TEA TREE OIL
(NATURAL ANTISEPTIC ESSENTIAL OIL)

HAND
SANITIZER
to help reduce
bacteria on the
skin
Recommended for
repeat use.
FOR EXTERNAL
USE ONLY.



HAIKOWER

INSTANT HAND SANITIZER DRUG FACTS

Active Ingredients Ethyl alcohol 70% v/v... **Purpose** Antimicrobial

Uses Hand Sanitizer to help reduce bacteria on the skin.

Warnings

- Flammable ■ Keep away from heat and heated surfaces
- For external use only.

When using this product, do not ingest, inhale or use in or near the eyes. In case of contact, rinse thoroughly with water for at least 2 minutes.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children.

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

Directions for use

Place enough Hygienigel on your hands and rub them until dry. Children under the age of 6 must be supervised when using Hygienigel.

Other information

Store in a cool place below 110°F (43°C).

Inactive ingredients

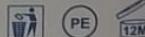
Carbomer, Dextrin, Hydroxyethylcellulose, Ethylhexylglycerin, Fragrance, Melaleuca Alternifolia Leaf Oil, Panthenol, PEG150-140, Dimethicone, Peg-60 Lanolin, Propylene Glycol, Phenylethanol, Triethanolamine, Water.

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Customer care
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Produced by:
HAIKOWER
via Catania, 6, 00041
Albano Laziale RM

169 FL. OZ. (5L)

MADE IN ITALY



HYGIENIGEL

hand sanitizer gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78619-200 |
| 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 |
|--|----------|
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K) | |
| LANOLIN (UNII: 7EV65EAW6H) | |
| TRIETHANOLAMINE LAURATE (UNII: 9403LC9W1J) | |
| WATER (UNII: 059QF0KO0R) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| CARBOMER 1342 (UNII: 809Y72KV36) | |
| FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95) | |
| PANTHENOL (UNII: WW9CM0O67Z) | |
| PEG/PPG-14/4 DIMETHICONE (UNII: 646XNV22YX) | |
| PROPYLENE GLYCOL 1-LAURATE (UNII: M4AW13H75T) | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | |

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:78619-200-07 | 5000 mL in 1 CAN; Type 0: Not a Combination Product | 02/25/2021 | |
| 2 | NDC:78619-200-06 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/25/2021 | |
| 3 | NDC:78619-200-05 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/25/2021 | |
| 4 | NDC:78619-200-04 | 100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/25/2021 | |
| 5 | NDC:78619-200-03 | 70 mL in 1 POUCH; Type 0: Not a Combination Product | 02/25/2021 | |

| | | | | |
|---|------------------|---|------------|--|
| 6 | NDC:78619-200-02 | 30 mL in 1 POUCH; Type 0: Not a Combination Product | 02/25/2021 | |
| 7 | NDC:78619-200-08 | 2 mL in 1 POUCH; Type 0: Not a Combination Product | 02/25/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 02/25/2021 | |

Labeler - HAIKOWER S.r.l. (433503760)

Registrant - MELCHIONNA PLLC (039407173)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------|---------|-----------|---|
| HAIKOWER S.r.l. | | 433503760 | manufacture(78619-200) , label(78619-200) , pack(78619-200) |

Revised: 3/2021

HAIKOWER S.r.l.