

SPECTRAGENIX HAND SANITIZER ANTISEPTIC HAND WASH- ethyl alcohol liquid
Medical Chemical Corporation

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.

SpectraGenix Hand Sanitizer

Purpose

Germicide

Active Ingredients

Ethyl Alcohol 70% v/v

Inactive Ingredients

Purified water, Emollients (Laurel, Myristal and Cetyl Lactate,), Aloe Vera, Carbomer, Parabens, Diisopropylamine

Warnings

Warnings: Flammable, keep away from fire or flame. For external use only. Do not use in the eyes. Discontinue use if irritation or redness develops. Keep out of reach of children. In case of ingestion contact poison control center immediately.

Warnings

Danger: Highly flammable liquid and vapor. Keep away from heat, sparks, open flames and hot surfaces. No smoking. Keep container tightly closed. Use only non-sparking tools. Take precautions against static discharge. In case of fire, use fire extinguishers approved for alcohol fires. In case of ingestion contact a poison control center. Discontinue use if irritation or redness develops. Keep out of reach of children.

Directions

Spray about 5 g (1 tsp.) on to one hand and spread over both hands to the wrist. Rub into the skin until dry. Repeat.

Uses

Intended for use as a hand sanitizer to reduce pathogenic bacteria. Recommended for repeated use. For external use on the skin only. Not for use on the eyes.

spectragenixlabel.jpg

SpectraGenix

KILLS 99.99% OF GERMS

MADE IN FDA REGISTERED FACILITY

MADE IN U.S.A.

MADE WITH **ALOE VERA** and LAVENDER OIL

MOISTURIZING HAND SANITIZER

1 U.S. Gal.

Manufactured for: Spectrum Medical Imaging Co. 1721 Stewart St. Santa Monica, CA 90404 Phone: (800) 859-6162 https://ppe.spectrumxray.com

Cat. No. # 20-SP-1GAL-S

M44520SP1GALS0Z

| Drug Facts | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Active Ingredients | Purpose |
| Ethyl Alcohol 70% v/v..... | Germicide |
| Uses: | |
| Intended for use as a hand sanitizer to reduce pathogenic bacteria. Recommended for repeated use. For external use on the skin only. Not for use on the eyes. | |
| Warnings: | |
| <ul style="list-style-type: none"> ■ Danger: Highly flammable liquid and vapor. Keep away from heat, sparks, open flames and hot surfaces. No smoking. Keep container tightly closed. Use only non-sparking tools. Take precautions against static discharge. In case of fire, use fire extinguishers approved for alcohol fires. In case of ingestion contact a poison control center. Discontinue use if irritation or redness develops. Keep out of reach of children. | |
| Directions: | |
| <ul style="list-style-type: none"> ■ Spray about 5g (1tsp.) on to one hand and spread over both hands to the wrist. Rub into the skin until dry. Repeat. | |
| Other Information: | |
| <ul style="list-style-type: none"> ■ Keep tightly closed and protected from light. Store at room temperature. | |
| Inactive Ingredients: | |
| <ul style="list-style-type: none"> ■ Purified water ■ Emollients (Laurel, Myristal and Cetyl Lactate) ■ Aloe Vera ■ Carbomer ■ Parabens ■ Diisopropylamine | |

SPECTRAGENIX HAND SANITIZER ANTISEPTIC HAND WASH

ethyl alcohol liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:12745-850 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------------------------|-------------------|-------------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 55.34 g in 100 mL |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) (DIAZOLIDINYL UREA - UNII:H5RIZ3MPW4) | DIAZOLIDINYL UREA | 0.167 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-------------------------------------------------|------------------|
| SPIKE LAVENDER OIL (UNII: 7S2HYV1VJQ) | 0.02 g in 100 mL |
| CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E) | 4 g in 100 mL |
| CETYL LACTATE (UNII: A7EVH2RK4O) | 0.5 g in 100 mL |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | 0.5 g in 100 mL |
| DIISOPROPYLAMINE (UNII: BR9JLI40NO) | 0.29 g in 100 mL |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start | Marketing End |
|---|-----------|---------------------|-----------------|---------------|
|---|-----------|---------------------|-----------------|---------------|

| # | Item Code | Package Description | Date | Date |
|---|------------------|-----------------------------------------------------------------|------------|------|
| 1 | NDC:12745-850-01 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/23/2020 | |
| 2 | NDC:12745-850-02 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/23/2020 | |
| 3 | NDC:12745-850-03 | 3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/23/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph not final | part333E | 10/23/2020 | |

Labeler - Medical Chemical Corporation (008496861)

Registrant - Medical Chemical Corporation (008496861)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------|---------|-----------|------------------------|
| Medical Chemical Corporation | | 008496861 | manufacture(12745-850) |

Revised: 10/2020

Medical Chemical Corporation