

GERM FREE PLUS ANTIBACTERIAL HAND SANITIZER- alcohol gel
Rompac, Inc.

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.

Germ Free + Antibacterial Hand Sanitizer

Drug Facts

Active Ingredient

Ethyl Alcohol 70%

Purpose

Antibacterial

Inactive ingredients

Water, Carbomer, Triethanolamine, Glycerin

Uses

For hand washing to reduce the bacteria on the skin, recommended for repeated use.

Directions

Wet hands thoroughly with product and allow to dry without wiping.

Warnings

For external use only: hands. Flammable, keep away from fire or flame. When using this product, keep out of eyes. In case of contact with eyes rinse with water. Stop use and ask a doctor if irritation and redness develop and persist.

Keep out of reach of children.

If swallowed, get medical help immediately.

Do not store above 105°F

PRINCIPAL DISPLAY PANEL - 1 Gallon Bottle Label

Rompac

Germ-Free +

70% ALCOHOL

Antibacterial Hand Sanitizer

GEL

1 Gallon (3.785 liters)

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Antibacterial Hand Sanitizer GEL

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Manufactured for
Rompac, Inc.
2507 N. Grand Avenue
Nogales, Arizona 85621
Tel (520)394-4249

Made in Mexico
1 Gallon (3.785 liters)



GERM FREE PLUS ANTIBACTERIAL HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79357-001 |
| 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: 059QF0K00R) | |

CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)

Triethanolamine Lactate (UNII: 064C51N81O)

GLYCERIN (UNII: PDC6A3C0OX)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:79357-001-01 | 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/08/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC MONOGRAPH NOT FINAL | part333A | 07/08/2020 | |

Labeler - Rompac, Inc. (066717747)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|------------------------|
| Distribuidora Química Textil S.A. de C.V. | | 811522390 | MANUFACTURE(79357-001) |

Revised: 7/2020

Rompac, Inc.