

GUARDEX HAND SANITIZER GEL- isopropyl alcohol 75% gel
21st Century Chemical, 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.

Guardex Hand Sanitizer Gel

Active Ingredient

Isopropyl Alcohol 75%

Purpose

Antiseptic

Uses

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

On 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.

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, Triethanolamine, carbomer, purified water USP

Guardex Hand Sanitizer gel


Clean Hands Start Here.

| | |
|---|------------------------------|
| Drug Facts | |
| Active Ingredient(s) Isopropyl Alcohol 75% | Purpose Antiseptic |
| Uses 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 • on 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. There 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. | |
| 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°-30°C (59°-86°F) • Avoid freezing and excessive heat above 40°C (104°F) | |
| Inactive Ingredients glycerin, hydrogen peroxide, triethanolamine, carbomer, purified water USP | |

For more information please visit www.guardexlabs.com



2960 SW 23rd Terrace
Dania Beach FL 33312





GUARDEX HAND SANITIZER GEL

isopropyl alcohol 75% gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77390-102 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------------|
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 2839 mL in 3785 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| TRIETHANOLAMINE TRISTEARATE (UNII: HOM72YRP1F) | |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |

WATER (UNII: 059QF0KO0R)

(3-BROMOPROPYL)BENZENE (UNII: 6 VX623QN9V)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:77390-102-01 | 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/01/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 07/01/2020 | |

Labeler - 21st Century Chemical, Inc. (037798686)

Registrant - 21st Century Chemical, Inc. (037798686)

Revised: 8/2020

21st Century Chemical, Inc.