

CHECKERS HAND SANITIZER GEL- alcohol gel

Applichem, 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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Medicinal ingredient: Ethyl alcohol 70% v/v

Purpose

Antiseptic, Hand Sanitizer

Use

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

- in 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.

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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

Water (Aqua), Glycerin, Hydrogen Peroxide, Alkyl Acrylate Crosspolymer, Triethanolamine, Aloe, Lauryl Alcohol, Myristyl Alcohol, Fragrance (Parfum), PEG Dimethicone

Package Label - Principal Display Panel

| | | | |
|--|---|--|--|
|   HAND SANITIZER GEL Fresh Scent DESINFECTANTE PARA LAS MANOS Fresco Aroma 70% ALCOHOL ANTISEPTIC 3.78 L 1 US. GAL. www.checkerscleaningsupply.com - 800.265.5756 | DRUG FACTS INFORMACIÓN DE MEDICACIÓN Active ingredient and Purpose / Ingrediente activo y propósito Medicinal ingredient / Ingrediente medicinal: Ethyl alcohol 70% v/v Antiseptic / Antiséptico | DO NOT USE / NO UTILICE <ul style="list-style-type: none">• On children less than 2 months of age.• En niños menores de 2 años de edad.• On open skin wounds.• En heridas abiertas en la piel. When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Cuando use este producto , manténgalo alejado de los ojos, oídos y boca. En caso de contacto con los ojos, enjuague bien con agua. Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Suspenda su uso y consulte a un médico si se produce irritación o erupción. Pueden ser signos de una afección grave. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Mantener fuera del alcance de los niños. En caso de ingerir, busque ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato. | DIRECTIONS / INSTRUCCIONES <ul style="list-style-type: none">• Place enough product on hands to cover all surfaces. Rub hands together until dry.• Aplique suficiente producto en las manos para cubrir toda la superficie. Frote las manos juntas hasta que sequen bien.• Supervise children under 6 years of age when using this product to avoid swallowing.• Supervise a los niños menores de 6 años cuando usen este producto, para evitar que lo ingieran. OTHER INFORMATION INFORMACIÓN ADICIONAL <ul style="list-style-type: none">• Store between / Almacenar entre 15-30C (59-86F)• Avoid freezing and excessive heat above• Evite la congelación y el calor excesivo por encima de 40C (104F) Inactive ingredients / Ingredientes inactivos Water (Aqua/ Agua), Glycerin, Hydrogen Peroxide, Alkyl Acrylate Crosspolymer, Triethanolamine, Aloe, Lauryl Alcohol, Myristyl Alcohol, Fragrance (Parfum), PEG Dimethicone |
| | USE / USO Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. Desinfectante para las manos que ayuda a reducir las bacterias que potencialmente pueden causar enfermedades. Para ser usado cuando no hay agua y jabón disponibles. | WARNINGS / ADVERTENCIAS For external use only. Flammable. Keep away from heat or flame. Sólo para uso externo. Inflamable. Mantener alejado del calor o llamas. | MADE IN THE USA / HECHO EN EE.UU. |
| | Distributed by / Distribuido por Checkers Cleaning Supply LLC, Holly MI, 48442 | | |
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3800 mL NDC: 74751-005-01

| | | | |
|--|---|--|---|
|   HAND SANITIZER GEL Fresh Scent DESINFECTANTE PARA LAS MANOS Fresco Aroma 70% ALCOHOL ANTISEPTIC 236 mL 8 FL. OZ. www.checkerscleaningsupply.com - 800.265.5756 | DRUG FACTS INFORMACIÓN DE MEDICACIÓN Active ingredient and Purpose / Ingrediente activo y propósito Medicinal ingredient / Ingrediente medicinal: Ethyl alcohol 70% v/v Antiseptic / Antiséptico | DO NOT USE / NO UTILICE <ul style="list-style-type: none">• On children less than 2 months of age.• En niños menores de 2 años de edad.• On open skin wounds.• En heridas abiertas en la piel. When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Cuando use este producto , manténgalo alejado de los ojos, oídos y boca. En caso de contacto con los ojos, enjuague bien con agua. Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Suspenda su uso y consulte a un médico si se produce irritación o erupción. Pueden ser signos de una afección grave. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Mantener fuera del alcance de los niños. En caso de ingerir, busque ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato. | DIRECTIONS / INSTRUCCIONES <ul style="list-style-type: none">• Place enough product on hands to cover all surfaces. Rub hands together until dry.• Aplique suficiente producto en las manos para cubrir toda la superficie. Frote las manos juntas hasta que sequen.• Supervise children under 6 years of age when using this product to avoid swallowing.• Supervise a los niños menores de 6 años cuando usen este producto, para evitar que lo ingieran. OTHER INFORMATION INFORMACIÓN ADICIONAL <ul style="list-style-type: none">• Store between / Almacenar entre 15-30C (59-86F)• Avoid freezing and excessive heat above• Evite la congelación y el calor excesivo por encima de 40C (104F) Inactive ingredients / Ingredientes inactivos Water (Aqua/ Agua), Glycerin, Hydrogen Peroxide, Alkyl Acrylate Crosspolymer, Triethanolamine, Aloe, Lauryl Alcohol, Myristyl Alcohol, Fragrance (Parfum), PEG Dimethicone |
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236 mL NDC: 74751-005-08

CHECKERS HAND SANITIZER GEL

alcohol gel

Product Information

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|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74751-005 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|----------------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70.6586 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|---------------------|
| TROLAMINE (UNII: 9O3K93S3TK) | 0.6023 mL in 100 mL |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) | 0.0216 mL in 100 mL |
| MYRISTYL LACTATE (UNII: 1D822OC34X) | 0.2656 mL in 100 mL |
| WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED) | 0.0187 mL in 100 mL |
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C) | 7.6152 mL in 100 mL |
| GLYCERIN (UNII: PDC6A3C0OX) | 1.3344 mL in 100 mL |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | 0.1258 mL in 100 mL |
| WATER (UNII: 059QF0K00R) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | 0.2665 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:74751-005-01 | 3800 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/07/2020 | |
| 2 | NDC:74751-005-08 | 236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/06/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part333A | 08/06/2020 | |

Labeler - Applichem, Inc (039829528)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|----------------|----------------|---------------|----------------------------|
| Applichem, Inc | | 039829528 | manufacture(74751-005) |

