

HAND SANITIZER- alcohol gel

Kepter Mexico S.A de C.V

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.

Hand Sanitizer

This is a hand sanitizer manufactured using only the following United States Pharmacopoeia (USP) grade ingredients:

- a. Alcohol (ethanol) (USP of Food Chemical Codex (FCC) grade) (70%, 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. Glycerin (.5% v/v).
- c. Carbopol (.5% v/v).
- d. Triethanolamine (.4% v/v).
- e. Sterile distilled water or boiled cold water.

Active Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Antiseptic Hand Sanitizer to reduce germs on the skin. For use when soap and water not available.

Warnings

For external use only. Flammable. Keep away from open flame and sources of heat.

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 doctor: If irritation, rash or redness occurs. These may be signs of a serious condition.

Keep out reach of children: If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask doctor: If irritation, rash or redness 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

Apply a small amount of product into hands and rub between both sides of hands until dry. Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

Store below 110°F (43°C)

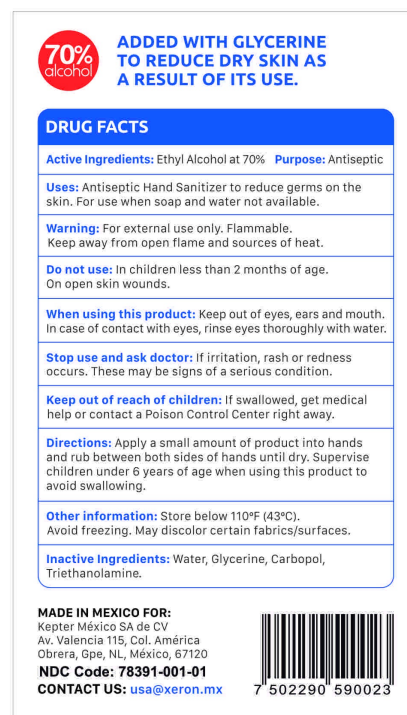
Avoid freezing. May discolor certain fabrics/surfaces.

Inactive Ingredients

Water, Glycerin, Carbopol, Triethanolamine

Package Label - Principal Display Panel

976 ml NDC: 78391-001-01



3786 ml NDC: 78391-001-02



70% alcohol **ADDED WITH GLYCERINE TO REDUCE DRY SKIN AS A RESULT OF ITS USE.**

DRUG FACTS

Active Ingredients: Ethyl Alcohol at 70% **Purpose:** Antiseptic

Uses: Antiseptic Hand Sanitizer to reduce germs on the skin. For use when soap and water not available.

Warning: For external use only. Flammable. Keep away from open flame and sources of heat.

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 doctor: If irritation, rash or redness 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: Apply a small amount of product into hands and rub between both sides of hands until dry. Supervise children under 6 years of age when using this product to avoid swallowing.

Other information: Store below 110°F (43°C). Avoid freezing. May discolor certain fabrics/surfaces.

Inactive Ingredients: Water, Glycerine, Carbopol, Triethanolamine.

MADE IN MEXICO FOR:
Kepter México SA de CV
Av. Valencia 115, Col. América
Obrera, Gpe, NL, México, 67120
NDC Code: 78391-001-02
CONTACT US: usa@xeron.mx


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HAND SANITIZER

alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78391-001 |
| 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: 059QF0KO0R) | 28 mL in 100 mL |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 100 mL |
| TROLAMINE (UNII: 9O3K93S3TK) | 0.4 mL in 100 mL |
| CARBOMER 940 (UNII: 4Q93RCW27E) | 0.5 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:78391-001-01 | 976 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/29/2020 | |
| 2 | NDC:78391-001-02 | 3786 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/29/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 05/29/2020 | |

Labeler - Kepter Mexico S.A de C.V (812889284)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|------------------------|
| Kepter Mexico S.A de C.V | | 812889284 | manufacture(78391-001) |

Revised: 6/2020

Kepter Mexico S.A de C.V