

YELLOW USA CORP- kg incorporating gel
YELLOW USA CORP

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.

YELLOW - ADVANCED ALCOHOL HAND SANITIZER

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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

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.

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, purified water USP

Package Label - Principal Display Panel



250 ml NDC: 79445-125-26

Other information

- store between 15 - 30°C (59 - 86°F)
- do not store above 40°C (105°F)
- may discolor some fabrics

Inactive ingredients
Isopropyl Alcohol, Hydrogen Peroxide, Carbomer Copolymer Type B, Isopropanolamine, Glycerin, Water

* Effective at eliminating more than 99.99% of many common harmful germs and bacteria in as little as 15 seconds.



LOT
MFD
EXP



0 79445 12526 5

Distributed by:
Yellow USA Corp.
11300 Space Blvd.
Orlando, FL 32837

Made in Brazil



**ADVANCED ALCOHOL
HAND SANITIZER**

REFRESHING GEL

Kills more than **99.99%** of germs*

8.5 FL OZ (250 ml)

Drug Facts

| Active ingredient | Purpose |
|-------------------|---------------|
| Alcohol 75% | Antimicrobial |

Uses • to decrease bacteria on the skin
• recommended for repeated use

Warnings
For external use only
Flammable, keep away from fire or flame

When using this product keep away from eyes. In case of eye contact, rinse eyes with water.

Stop use and ask a doctor if irritation or redness develop or last more than 72 hours

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

Directions • wet hands thoroughly with product
• allow to dry without wiping
• supervise children under 6 years old
• not recommended for infants

GRAY IS TRANSPARENT

YELLOW USA CORP

kg incorporating gel

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79445-125 |
| Route of Administration | TOPICAL, EXTRACORPOREAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 75 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|--------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 1.45 mL in 100 mL |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | 0.125 mL in 100 mL |
| WATER (UNII: 059QF0KO0R) | 20 mL in 100 mL |
| ISOPROPANOLAMINE (UNII: UE40BY1BZW) | 27 mL in 100 mL |
| CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) | 3.5 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:79445-125-26 | 250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 03/30/2020 | |

YELLOW USA CORP

kg incorporating gel

Product Information

| | | | |
|-------------------------|-------------------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79445-126 |
| Route of Administration | TOPICAL, EXTRACORPOREAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 75 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|--------------------|
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | 0.125 mL in 100 mL |
| CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) | 3.5 mL in 100 mL |
| GLYCERIN (UNII: PDC6A3C0OX) | 1.45 mL in 100 mL |
| ISOPROPNOLAMINE (UNII: UE40BY1BZW) | 0.35 mL in 100 mL |
| WATER (UNII: 059QF0K00R) | 20 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:79445-126-51 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/31/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 07/31/2020 | |

Labeler - YELLOW USA CORP (008925051)

Registrant - KG INCORPORATING EMPREENDIMENTOS E SERVICOS (945091407)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

| | | | |
|-----------------|--|-----------|-------------------------------|
| YELLOW USA CORP | | 008925051 | relabel(79445-125, 79445-126) |
|-----------------|--|-----------|-------------------------------|

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|-----------------------------------|
| KERALUX INDUSTRIA E COMERCIO DE COSMETICOS LTDA EPP | | 900345228 | manufacture(79445-125, 79445-126) |

Revised: 6/2020

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