**HAND SANITIZER- alcohol gel**
**Grupo De Zavaleta, 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.*

---

**Grupo de Zavaleta 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. 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)**

Alcohol 80% 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**


946 mL NDC: 77471-001-06


236 mL NDC: 77471-001-05


220 L NDC: 77471-001-04


473 mL NDC: 77471-001-03


3.8 L NDC: 77471-001-02


946 mL NDC: 77471-001-01


# HAND SANITIZER

alcohol gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:77471-001 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ALCOHOL** (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 80 mL in 80 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **FRAGRANCE LAVENDER & CHIA F-153480** (UNII: SXS9CO2TZK) | 80 mL in 80 mL |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | 80 mL in 80 mL |
| **SULISOBENZONE** (UNII: 1W6L629B4K) | 80 mL in 80 mL |
| **GLYCERIN** (UNII: PDC6A3C0OX) | 80 mL in 80 mL |
| **WATER** (UNII: 059QF0KO0R) | |
| **CARBOMER 1342** (UNII: 809Y72KV36) | 80 mL in 80 mL |
| **ISOPROPYL MYRISTATE** (UNII: 0RE8K4LNJS) | 80 mL in 80 mL |
| **GLYCERYL CAPRATE** (UNII: 197M6VFC1W) | 80 mL in 80 mL |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:77471-001-01 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/15/2020 | |
| **2** | NDC:77471-001-02 | 3800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/15/2020 | |
| **3** | NDC:77471-001-03 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/15/2020 | |
| **4** | NDC:77471-001-04 | 220000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/15/2020 | |
| **5** | NDC:77471-001-05 | 236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/15/2020 | |
| **6** | NDC:77471-001-06 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/15/2020 | |

## Marketing Information

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

**Labeler -** Grupo De Zavaleta, S.a. De C.v. (951577304)

Revised: 5/2020 Grupo De Zavaleta, S.a. De C.v.