

HAND SANITIZER- alcohol gel
HS HomeWorx LLC

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)

Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic

Use

to help reduce bacteria on skin

Warnings

For external use only. Flammable. Keep away from fire, high heat or flame.

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Avoid contact with broken skin. Do not inhale and ingest.

Stop use and ask a doctor if irritation or redness occurs.

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

Directions

- Dispense into hands, rub thoroughly until dry.

Other information

- May discolor certain fabrics or surfaces.

- Do not store above 110F (43C)

Inactive ingredients

Water (Aqua), Glycerin, Butylene Glycol, Fragrance (Parfum), Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Aloe Barbadosensis Leaf Extract, Artemisia Argyi Leaf Extract, Cnidium Monnieri Fruit Extract, Sargassum Fusiforme Extract.

Package Label - Principal Display Panel

236 mL NDC: 81282-033-01



HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|-----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:8 128 2-033 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 75 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------|-----------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 1 mL in 100 mL |
| WATER (UNII: 059QF0KO0R) | 22 mL in 100 mL |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | 1 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:81282-033-01 | 236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 12/01/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 12/01/2020 | |

Labeler - HS HomeWorx LLC (080653110)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|------------------------|
| COSBE LABORATORY INC | | 543033650 | manufacture(81282-033) |

Revised: 12/2020

HS HomeWorx LLC