

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

GRUPO
DEZA



Hand Sanitizer

KILLS 99.99% OF GERMS*

**32 FL OZ.
946 ML.**

946 mL NDC: 77471-001-06

GRUPO
DEZA



Hand Sanitizer

KILLS 99.99% OF GERMS*

**8 OZ.
236 ML.**

236 mL NDC: 77471-001-05

GRUPO
DEZA



Hand Sanitizer

KILLS 99.99% OF GERMS*

**220 LTS.
58.1 GAL.**

220 L NDC: 77471-001-04

GRUPO
DEZA



Hand Sanitizer

KILLS 99.99% OF GERMS*

**16 Oz /
473 ML**

473 mL NDC: 77471-001-03

GRUPO
DEZA



Hand Sanitizer

KILLS 99.99% OF GERMS*

**1 Gal /
3.8 Lts**

3.8 L NDC: 77471-001-02

GRUPO
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Hand Sanitizer

KILLS 99.99% OF GERMS*

**32 FL OZ.
946 ML.**

946 mL NDC: 77471-001-01

DRUG FACTS

ACTIVE INGREDIENT

ETHYL ALCOHOL 70%.....

PURPOSE

ANTISEPTIC

USES

TO DECREASE BACTERIA ON THE SKIN THAT COULD CAUSE DISEASE RECOMENDED FOR REPEATED USE.

WARNINGS

FOR EXTERNAL USE ONLY: HANDS.

FLAMMABLES

KEEP AWAY FROM THE FIRE OR FLAME.

WHEN USING THIS PRODUCT

KEEP OUT OF EYES. IN A CASE OF CONTACT WITH EYES, FLUSH THOROUGHLY WITH WATER. AVOID CONTACT WITH BROKEN SKIN. DON NOT INHALE OR INGEST.

STOP USE AND ASK A DOCTOR IF

IRRITATION AND REDNESS DEVELOP. CONDITION PERSISTS FOR MORE THAN 72 HOURS.

KEEP OUT OF CHILDEN

IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

WET HANDS THOROUGHLY WITH PRODUCT AND ALLOW TO DRY WITHOUT WIPING, FOR CHILDEN UNDER 6, USE ONLY UNDER ADULT SUPERVISION. NOT RECOMENDED FOR INFANTS.

OTHER INFORMATION

DO NOT STORE ABOVE 105° F. MAY DISCOLOR SOME FABRICS. HARMFUL TO WOOD FINISHES AND PLASTICS.

INACTIVE INGREDIENTS

WATER, GLYCERYL CAPRYLATE/CAPRATE, GLYCERIN, ISOPROPYL MYSTRATE, TOCOPHERYL ACETATE, ACRYLATES/C10-30 ALBYL ACRYLATE CROSSPOLYMER, FRAGRANCE, BENZOPHENONE-4.

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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.