

HAND SANITIZER- alcohol gel
Vita Viridens, 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.

Active Ingredient(s)

Alcohol 70% 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.

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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

SAFETY FIRST



HAND SANITIZER
PURE CLEAN
ANTI-BACTERIAL

"KILLS GERMS"



Drug Facts

Active Ingredient	Purpose
Ethyl alcohol 70%	Antiseptic
Hydrogen peroxide 0.125%	

Uses: To decrease bacteria on the skin that could cause disease · recommended for repeated use.

WARNINGS

For External use only: hands

Flammable, keep away from fire or flame.

When using this product · Keep out of eyes. In case of contact with eyes, flush thoroughly with water. · avoid contact with broken skin · do not inhale or ingest.

Stop use and ask doctor if · Irritation and redness develop · condition persists for 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 and allow to dry without wiping · for children under 6, use only under adult supervision · not recommended for infants.

Other Information: Do not store above 105 degrees F · may discolor some fabrics · harmful to wood finishes and plastics.

Inactive Ingredients: Water, Carbomer, Triethanolamine, Glycerine, Hydrogen Peroxide

Made in Mexico

Manufactured by: Av. Cuauhtémoc No. 1475 Int. 5 Santa Cruz Atoyac, Benito Juarez México 03310

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75610-532
Route of Administration	TOPICAL, CUTANEOUS		

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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75610-532-48	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75610-532-04	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75610-532-12	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75610-532-60	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75610-532-37	3785 mL in 1 BOTTLE; 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	

Labeler - Vita Viridens, S.A. de C.V. (951576554)

Registrant - Vita Viridens, S.A. de C.V. (951576554)

Revised: 1/2021

Vita Viridens, S.A. de C.V.