SANITIZ ADVANCED HAND SANITIZER- ethyl alcohol gel Tecnoglobal Ph7, 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 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.

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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

water, hydrogen peroxide, glycerin, carbomer, aminomethylpropanol, phenoxyethanol/Iodopropynyl butylcarbamate, tetrasodium EDTA, ext. violet 2, aloe barbadensis leaf juice

Package Label - Principal Display Panel

251 mL NDC: 75470-100-01



Drug Facts

Active ingredient

Ethyl alcohol 80% v/v

Purpose Antimicrobial

Use • Hand sanitizer to help reduce bacteria on the skin that could cause disease • Recommended for repeated use

Warnings

Flammable. Keep away from fire or flame.

For external use only

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

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

Directions • Place enough product in your palm to thoroughly cover your hands • Rub hands together briskly until dry . Children under 6 years of age should be supervised when using this product.

Other information • Do not store above 105° F (40.5° C) . May discolor certain fabrics or surfaces

Inactive ingredients

Water (Aqua)(EAU), Hydrogen Peroxide, Glycerin, Carbomer, Aminomethyl Propanol, Phenoxythanol/lodopropynyl Butylcarbamate, Tetrasodium EDTA, Ext. Violet 2 (Cl 60730), Aloe Barbadensis Leaf Juice.

Formula based of the WHO Guide with the recommended concentration of ethanol, glycerol, and hydrogen peroxide and addition of aloe vera (sabila), as moisturizer, and other ingredients to stabilize formulation.

** Meets Food Code Hand Sanitizers criteria (Section 2-301,16) published by the FDA

Made in Mexico



Distributed by: Mexilink, Inc., Houston, TX 77079

SANITIZ ADVANCED HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:75470-100

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name Strength

PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EDETATE SO DIUM (UNII: MP1J8 420 LU)	
ALOE VERA LEAF (UNII: ZY81Z83H0 X)	
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	

	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:75470-100-01	251 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020		
l	2 NDC:75470-100-02	400 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020		
l	3 NDC:75470-100-03	900 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/20/2020		

Labeler - Tecnoglobal Ph7, S.a. De C.v. (813006665)

Establishment					
Name	Address	ID/FEI	Business Operations		
Tecnoglobal Ph7, S.a. De C.v.		813006665	manufacture(75470-100)		

Revised: 4/2020 Tecnoglobal Ph7, S.a. De C.v.