HAND SANITIZER- alcohol gel FARMACIA SAN ARCANGEL, 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 Ingredients

Ethyl alcohol 70% v/v

Purpose

Antiseptic

Uses

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 throrugly with water

Stop use and ask a doctor

if irritation or rash occurs. These maybe 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

Put 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 (58-86F)

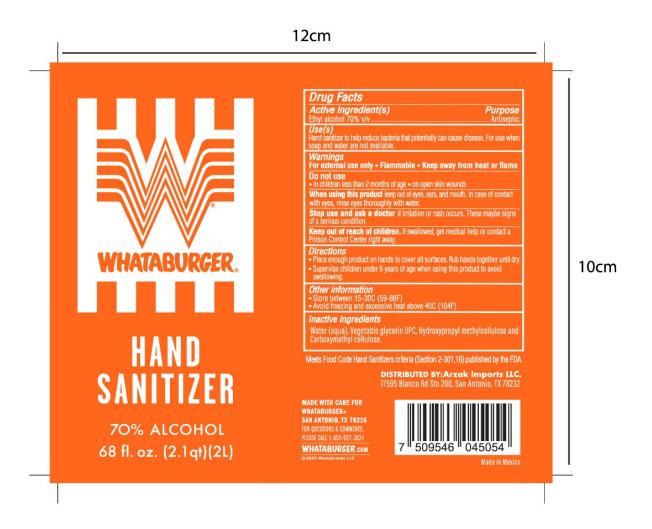
Avoid freezing and excesive heat above 40C (104F)

Inactive ingredients

Water (aqua), Vegetable Glycerine UPC, Hudroxypropyl methylcellulose and carboxymethylcellulose.

Principal Display

Hand sanitizer
70% alcohol
68 fl. oz. (2.1qt) (2L)



Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:80535-0002 Route of Administration TOPICAL

Active Ingredient/Active Moiety

HAND SANITIZER

	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
HYPROMELLOSE 2208 (60000 MPA.S) (UNII: 2F7T07H9ZD)				
GLYCERIN (UNII: PDC6 A3C0 O X)				
CARBO XYMETHYLCELLULO SE (UNII: 05JZI7B19X)				

ı	Packaging				
	# Item Code	Item Code Package Description		Marketing End Date	
	1 NDC:80535- 0002-1	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/23/2020		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	09/23/2020			

Labeler - Farmacia san arcangel, s.a de c.v (951583068)

Registrant - Farmacia san Arcangel, s.a de c.v (951583068)

Establishment				
Name	Address	ID/FEI	Business Operations	
FARMACIA SAN ARCANGEL S.A DE C.V		951583068	manufacture(80535-0002), label(80535-0002), pack(80535-0002)	

Revised: 9/2020 FARMACIA SAN ARCANGEL, S.A DE C.V