

SANITIZER- alcohol liquid
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 Ingredient

Isopropyl Alcohol 70% v/v

Purposes

Antimicrobial

Uses

Hand sanitizer to decrease virus and bacteria on the skin that could cause disease

Recommended for repeated use

Warnings

Flammable, keep away from fire or flame

For external use only: hands

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When using this product

keep out of eyes, do not use in or near eyes.

In case of contact with eyes, flush thoroughly with water

avoid contact with broken skin

do not inhale or ingest

Stop use or ask a doctor if

Irritation and redness develop and 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

Put enough product in your palm cover hands and rub hands together briskly until dry without wiping

for children under 6 years of age should be supervised when using

Other information

Store below 105F (40C)
 may discolour certain fabrics
 harmful to wood finishes and plastics

Inactive ingredients

Purified water (aqua), vegetable glycerine, d-limonene and linalool as fragrance

Principal Display

70% Isopropyl hand sanitizer
 Fresh scent
 with terpene enhanced
 antibacterial protection
 kills 99% of bacteria and germs
 70% isopropyl alcohol
 no ethyl alcohol
 no hydrogen peroxide
 scented with natural terpenes
 helps moisturize with glycerine
 3.4 fluid ounces (100 ml)

SANITIZER			
alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80535-0003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
WATER (UNII: 059QF0K00R)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80535-0003-1	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/19/2020	

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	label(80535-0003) , manufacture(80535-0003) , pack(80535-0003)

Revised: 10/2020

FARMACIA SAN ARCANGEL, S.A DE C.V