

HAND SANITIZER- alcohol gel
FARMIRAL, 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.

HAND SANITIZER GEL

DOSAGE AND ADMINISTRATION

Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry.

INACTIVE INGREDIENTS

Inactive ingredients Water (Aqua), Glycerin, Carbomer, Triethanolamine

INDICATIONS

Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry.

KEEP OUT OF REACH OF CHILDREN

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

ACTIVE INGREDIENT

Active ingredient. Ethyl Alcohol 70% v/v...

PURPOSE

Purpose Antmicrobial

WARNINGS AND PRECAUTIONS

Store below 110°F (43°C)

Children under 6 years of age should be supervised when using.

WARNING

Warnings

For external use only. Flammable. Keep away from heat or flame

STOP USE

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

PACKAGE LABEL

155MM

MADE IN MEXICO
Distributed by
SBL Brands, LLC
Las Vegas, NV 89119
MedicallyMinded.us



MEDICALLY MINDED™

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v.....	Antimicrobial

Use: Hand sanitizer to help reduce bacteria on skin.

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, flush 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 immediately.

Directions: Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using.

Other Information: Store below 110°F (43°C)

Inactive Ingredients: Water, Copolymer, Glycerin, Triethanolamine.

70MM



Hand Sanitizer Gel

ANTIMICROBIAL FORMULA



250.359MN1
LOTE Y FECHA DE EXPIRACIÓN
IMPRESAS EN EL ENVASE



8.5 FL OZ / 250 mL



MEDICALLY MINDED™

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v.....	Antimicrobial

Use: Hand sanitizer to help reduce bacteria on skin.

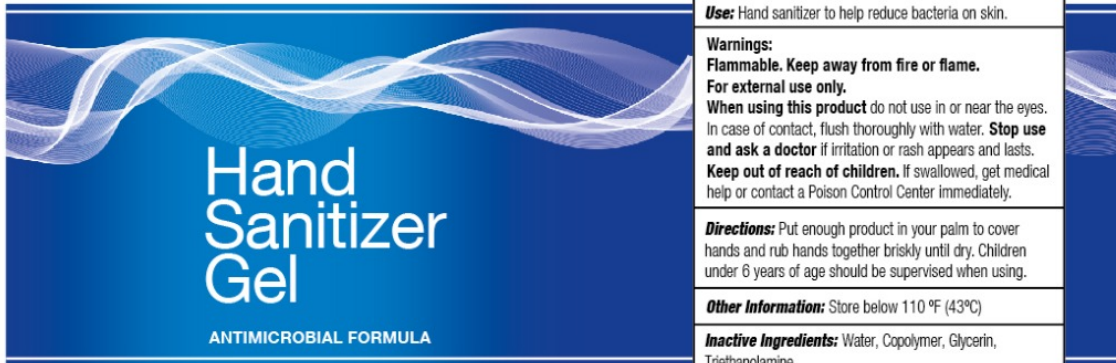
Warnings:
Flammable. Keep away from fire or flame.
For external use only.
When using this product do not use in or near the eyes. In case of contact, flush thoroughly with water. **Stop use and ask a doctor** if irritation or rash appears and lasts. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

Directions: Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using.

Other Information: Store below 110 °F (43°C)

Inactive Ingredients: Water, Copolymer, Glycerin, Triethanolamine.

(110 mm)



Hand Sanitizer Gel

ANTIMICROBIAL FORMULA

500.358MMC1

Distributed by
SBL Brands, LLC
Las Vegas, NV 89119
MedicallyMinded.us



MADE IN MEXICO

LOTE Y FECHA DE EXPIRACIÓN IMPRESAS EN EL ENVASE

16.9 FL OZ (500 mL)

6.75"
(171 mm)



Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer Gel Non-sterile Solution
1000 mL (33.8 fl. oz.)

Drug Facts	
Active ingredient. Ethyl Alcohol 70% v/v	Purpose Antimicrobial
Use[s] 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	
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.	
Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Children under 6 years of age should be supervised when using.	
Other information • Store below 110°F (43°C)	
Inactive ingredients Water (Aqua), Methacrylic Acid (ethyl acrylate copolymer), Glycerin, Triethanolamine	
Distributed by SBI Brands, LLC MedicallyMinded.us MADE IN MEXICO	

NET CONTENTS
1000 mL
(33.8 fl. oz.)

HAND SANITIZER
alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78814-6000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.025 mL in 1 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.01 mL in 1 mL
WATER (UNII: 059QF0K00R)	0.205 mL in 1 mL
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	0.06 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78814-6000-1	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	
2	NDC:78814-6000-2	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	
3	NDC:78814-6000-3	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/08/2020	

Labeler - FARMIRAL, S.A. DE C.V. (951579167)

Registrant - FARMIRAL, S.A. DE C.V. (951579167)

Establishment

Name	Address	ID/FEI	Business Operations
FARMIRAL, S.A. DE C.V.		951579167	manufacture(788 14-6000)

Revised: 6/2020

FARMIRAL, S.A. DE C.V.