# HAND SANITIZER- alcohol gel GUTIERREZ RAZO Y ASOCIADOS, 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.

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#### HAND SANITIZER GEL DEFENSE

#### 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

#### **USES**

Use[s]

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

#### **KEEP AWAY FROM CHILDREN**

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

#### **PURPOSE**

Purpose Antmicrobial

#### WARNINGS AND PRECAUTIONS

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

#### **WARNINGS**

Warnings

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

#### **ACTIVE INGREDIENT**

Active ingredient. Ethyl Alcohol 70% v/v

### **ASK A DOCTO**

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

#### **STOP USE**

Stop use and ask a doctor if irritation or rash occurs.

#### PACKAGE LABEL





## HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78770-4000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
AI	LCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients	
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Ingredient Name	Strength
TRIETHANO LAMINE CAPRO YL GLUTAMATE (UNII: 0 F2FO57253)	0.002 mL in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.0375 mL in 1 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.002 mL in 1 mL
WATER (UNII: 059QF0KO0R)	0.2585 mL in 1 mL

l	Pacl	kaging			
l	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1 ND	C:78770-4000-7	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/17/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/17/2020	

# Labeler - GUT IERREZ RAZO Y ASOCIADOS, S.A. DE C.V. (951578901)

# **Registrant -** GUT IERREZ RAZO Y ASOCIADOS, S.A. DE C.V. (951578901)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
GUTIERREZ RAZO Y ASOCIADOS, S.A. DE C.V.		951578901	manufacture(78770-4000)	

Revised: 6/2020 GUTIERREZ RAZO Y ASOCIADOS, S.A. DE C.V.