

**HAND SANITIZER- alcohol gel**  
**PRECISION ANALITICA INTEGRAL SA DE CV**

*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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**Active Ingredient(s)**

Alcohol 75% 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**

TROLAMINE, CARBOMER HOMOPOLUMER, DEIONIZED WATER

Package Label - Principal Display Panel



**75% ALCOHOL CONTENT**

CleanCare  
**no+germ**

**ADVANCED HAND SANITIZER**  
KILLS 99.9% OF GERMS

**33.8 FL OZ (1L)**

**Drug Facts:**

**Active Ingredients:**.....**Purpose:**  
Ethyl Alcohol 75%.....**Antimicrobial**

**Uses:** Helps reduce bacteria on the skin that could cause disease.

**WARNINGS:**  
Flammable. Keep away from fire or flame. For external use only. Not potable.  
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 the palm of your hands to thoroughly cover your hands. Rub hands together briefly until product is completely absorbed and hands are dry.


**Inactive Ingredients:** Deionized Water, Carbomer, Triethanolamine  
Desaturating compound: Dioctylsodium succinate  
Ethanol 75% as determined by titer degree

Distributed By:  
**EBPMED, LLC**  
www.no+germ.com

Made in Mexico

DUNS number: 818136086  
Manufactured on May 19/10

Produced by:  
FABRICA NACIONAL ATENCIONAL  
De la Industria del Alcohol S de RL  
Caj. Lomas de Berrón, Av. Puerto Olimpia  
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1000 mL NDC: 77492-007-

01

HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77492-007
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	75 mL in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
TROLAMINE (UNII: 9O3K93S3TK)			
CARBOMER HO MO POL YMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			
WATER (UNII: 059QF0K00R)			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77492-007-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - PRECISION ANALITICA INTEGRAL SA DE CV (816135065)

**Registrant** - PRECISION ANALITICA INTEGRAL SA DE CV (816135065)

**Establishment**

Name	Address	ID/FEI	Business Operations
PRECISION ANALITICA INTEGRAL SA DE CV		816135065	manufacture(77492-007)

Revised: 5/2020

PRECISION ANALITICA INTEGRAL SA DE CV