

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.

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

DEIONIZED WATER, TROLAMINE, CARBORMER HOMOPOLYMER

Package Label - Principal Display Panel



75% ALCOHOL CONTENT

CleanCare
nogerM

ADVANCED HAND SANITIZER
KILLS 99.9% OF GERMS

0.415 FL OZ (120 ML)

Drug Facts:

Active ingredients: Purpose: Ethyl Alcohol 75%.....Antimicrobial

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

WARNING:
Flammable. Keep away from fire or flame. For external use only. Non 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 until until product is completely absorbed and hands are dry.

Inactive ingredients: Distilled Water, Carbomer, Thaumococcus

Denaturing compound: Denatonium Benzoate

Ethanol 75% as determined by title degree

Distributed By:
ESPACEX, LLC
www.nogerM.com

Made in Mexico

DUNS number: 019190006
Manufacturer ID: 00000

Professionally:
PROFESSIONAL PHARMACEUTICALS
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250 mL NDC: 77492-008-50

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77492-008
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 POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77492-008-50	250 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 INTEGRALSA DE CV		816135065	manufacture(77492-008)

Revised: 5/2020

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