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.

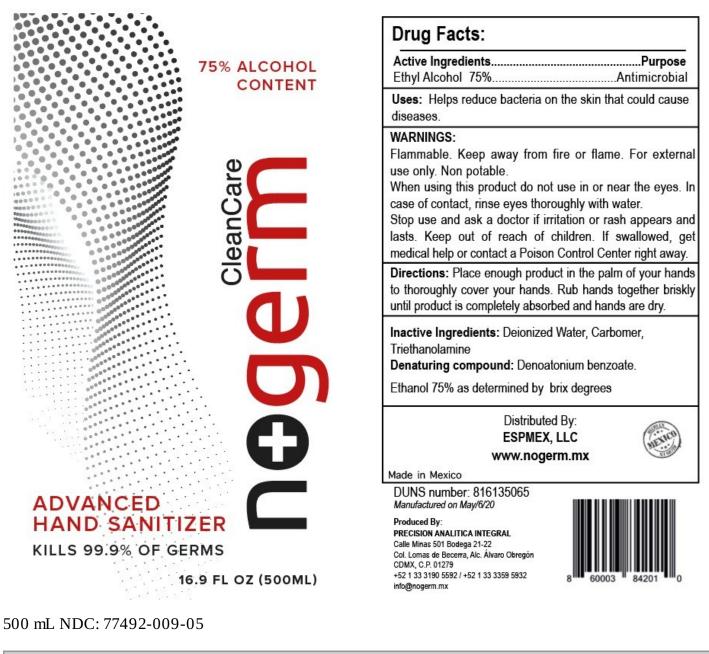
Other information

- 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



HAND SANITIZER							
alcohol gel							
Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:77492-009			
Route of Administration	TOPICAL						
-							
Active Ingredient/Active Moiety							
Ingredient Name			Basis of Strength		Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	75 n	nL in 100 mL		

Inactive Ingredients							
Ingredient Name							
TROLAMINE (UNII: 90	D3K93S3TK)						
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)							
WATER (UNII: 059QF0KO0R)							
Packaging							
# Item Code	Package Description	Marketing Start Date	Marketing End Date				
1 NDC:77492-009-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020					
Marketing Information							
Marketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not fin	nal 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
Enter Establishment Name		8 16 1350 6 5	manufacture(77492-009)

Revised: 5/2020

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