#### HAND SANITIZER- alcohol gel Nanoolflon de México, 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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# Active Ingredient(s)

Alcohol 80% 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**

GLYCERIN, HYDROXYETHYL CELLULOSE, N-ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE (C12-C18), BENZYLDIDECYLMETHYLAMMONIUM CHLORIDE, PURIFIED WATER USP.

# Package Label - Principal Display Panel

#### 236 mL NDC: 78262-001-01

14.5 x 7.5cm

CMYK + White on Clear BOPP with Gloss Laminate

(Impresión cian, magenta, amarillo, negro y tinta blanco. Etiqueta transparente. Laminado brillo)



500 mL NDC: 78262-001-02



HAND SANITIZER alcohol gel				
Product Information				
Product T ype	HUMAN OTC DRUG	Item Code	e (Source)	NDC:78262-001
Route of Administration	TOPICAL			
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Active Ingredient/Active I			Dacia of Strong	th Strongth
ALCOHOL (UNII: 3K9958V90M)	g <b>redient Name</b> (ALCOHOL - UNII:3K9958V90M)		Basis of Streng	th Strength 80 mL in 100 mL
Inactive Ingredients				
	Strength			
BENZYLDIDECYLMETHYLAMM	0.0025 mL in 100 mL			
N-ALKYL DIMETHYL BENZYL A	0.0025 mL in 100 mL			

HY	DROXYETHYL CE	0.005 mL in 100 mL					
WA	ATER (UNII: 059QF0	KO0R)					
Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:78262-001-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020				
2	NDC:78262-001-02	78262-001-02 500 mL in 1 BOTTLE; Type 0: Not a Combination Product					
Marketing Information							
N	Marketing Catego	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
		al part333A	03/30/2020				

Labeler - Nanoolflon de México, S.A. de C.V. (951577403)

Registrant - Nanoolflon de México, S.A. de C.V. (951577403)

# Establishment

Name	Address	ID/FEI	Business Operations
Nanoolflon de México, S.A. de C.V.		951577403	manufacture(78262-001), label(78262-001)

Revised: 5/2020

Nanoolflon de México, S.A. de C.V.