

**HAND SANITIZER- alcohol 70% gel**  
**Neogenium Labs 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.*

-----

**Hand Sanitizer**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Alcohol 70% 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.

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.

**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**





Aqu



**Drug Facts**

**Active Ingredient**                      **Purpose**

Ethyl alcohol 70% w/v.....Antiseptic

**Uses** • To decrease bacteria on the skin that could cause diseases • Recommended for repeated use.

**Inactive ingredients** demineralized water, glycerin, carbomer, aloe vera extract, triethanolamine, disodium EDTA. **Directions:** Put enough product on hands to cover all surfaces. Rub hands together, until hands feel dry for 20 seconds. Do not rinse or wipe off. Children 6 year old and under should use only under adult supervision. **Warning**

Flammable product. Keep away from fire and flames. Keep out of reach of children. Keep container closed and upright. For external use only. Store in a cool, dry place at a temperature of 32°F to 95°F. Do not inhale or ingest, and avoid eye contact. Proceed to rinse thoroughly with water should any of these circumstances occur. Stop using this product and contact physician if irritation or redness develops for more than 72 hours.

**HAND SANITIZER GEL**

ALCOHOL  
ANTISEPTIC  
SURGICAL  
SOLUTION **70%**  
**alcohol**

127.81 FL OZ / 3,780 ML

Aloe Barbadosis Leaf Extract, Triethanolamine, EDTA Disodium Salt

a, Glycerin,

**Package Label - Principal Display Panel**

3,780 mL NDC: 75810-103-05







**Drug Facts**

<b>Active Ingredient</b>	<b>Purpose</b>
--------------------------	----------------

Ethyl alcohol 70%v/v.....	Antiseptic
---------------------------	------------

**Uses** • To decrease bacteria on the skin that could cause diseases • Recommended for repeated use.

**Inactive ingredients** demineralized water, glycerin, carbomer, aloe vera extract, triethanolamine, disodium EDTA.

**Directions:** Put enough product on hands to cover all surfaces. Rub hands together, until hands feel dry for 20 seconds. Do not rinse or wipe off. Children 6 year old and under should use only under adult supervision.

**Warning** Flammable product. Keep away from fire and flames. Keep out of reach of children. Keep container closed and upright. For external use only. Store in a cool, dry place at a temperature of 32°F to 95°F. Do not inhale or ingest, and avoid eye contact. Proceed to rinse thoroughly with water should any of these circumstances occur. Stop using this product and contact physician if irritation or redness develops for more than 72 hours.

**HAND SANITIZER**

alcohol 70% gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:758 10-103
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL
--	---------	-----------------

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.46 g in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.23 g in 100 mL
WATER (UNII: 059QF0K00R)	25.94 g in 100 mL
EDETIC ACID (UNII: 9G34HU7RV0)	0.09 g in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.46 g in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.046 g in 100 mL

### Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75810-103-05	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

### Marketing Information

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

**Labeler** - Neingenium Labs SA de CV (951576661)

**Registrant** - Neingenium Labs SA de CV (951276661)

### Establishment

Name	Address	ID/FEI	Business Operations
Neingenium Labs SA de CV		951576661	manufacture(75810-103)

Revised: 8/2020

Neingenium Labs SA de CV