

**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.*

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**Desinfectante de manos**

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. 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.

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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)

**Aqua, glycein, carbomer, aloe barbadensis leaf extract, thrietanolamine, propylen glycol, EDTA Disodium Salt**

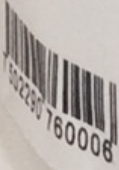
Aqua, glycerin, carbomer, aloe barbadensis leaf extract, thrietanolamine, EDTA Disodium Salt





Manufactured by:  
 Proprietary Labs S.A. de C.V.,  
 Avenida Gomez Morin No. 6370,  
 Toluca, Jalisco, Mexico  
 Tel: +52-55-150112-LM2

Made in Mexico for:  
 Comercializadora Internacional  
 S.A. de C.V. Blvd.  
 Independencia Las Torres 1154 Int.3  
 Toluca, Jalisco, Mexico  
 Ampliacion Lazaro  
 Cardenas, CP 50180 Toluca,  
 Jalisco, Mexico  
 Tel: +52-55-150609-341.  
 www.safemedix.com  
 Lot: [blank] EXP: DATE  
 [blank]



**HAND SANITIZER GEL**

ALCOHOL  
 ANTISEPTIC  
 TOPICAL  
 SOLUTION **70% alcohol**

**135.25 FL OZ / 4,000 ML**

**Drug Facts**

**Active Ingredient** Ethyl alcohol 70% (v/v)  
**Uses** - To decrease bacteria on the skin that could cause disease.  
**Recommended for repeated use**  
**Inactive ingredients** denatured water, glycerin, carbonyl diurea extract, triethanolamine, disodium EDTA.  
**Directions** Put a small amount of product on hands to cover all surfaces. Rub hands together until hands feel dry for 20 seconds. Do not rinse or wipe off. Children 2 and older and under should use only with adult supervision.  
**Warnings** 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 86°F. Do not inhale or ingest, and avoid eye contact. Proceed to rinse thoroughly with water should any of these circumstances occur. See using this product and contact physician if irritation or redness develops in more than 72 hours.





**Drug Facts**

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



**Package Label - Principal Display Panel**

4000 mL NDC: 75810-103-04





Manufactured by:  
 Argemum Labs S.A. de C.V.,  
 Carretera Gomez Morin No. 6370,  
 Toluca, Jalisco, Mexico  
 REG. NLA-150112-LM2

Sold in Mexico for:  
 Comercializadora Internacional  
 S.A. de C.V. Blvd.  
 Independencia las Torres 1154 Int.3  
 Toluca, Jalisco, CP 50180 Toluca,  
 Mexico  
 Tel: 01-52-55-130809-341.  
 www.argemum.com  
 www.safemedix.com

EXP. DATE  
 LOT



**HAND SANITIZER GEL**

ALCOHOL  
 ANTISEPTIC  
 TOPICAL  
 SOLUTION **70%**  
**alcohol**

**135.25 FL OZ / 4,000 ML**

**Drug Facts**

**Active Ingredient** Ethyl alcohol 70% v/v

**Uses** - To decrease bacteria on the skin that could cause disease.

**Recommended for repeated use**

**Inactive ingredients** demineralized water, glycerin, carbomer, zinc oxide extract, triethanolamine, disodium EDTA.

**Directions** Put a group of product on hands to cover all surfaces. Rub hands together until hands feel dry for 20 seconds. Do not rinse or wipe off. Children 12 and old and under should use only with adult supervision.

**Warnings**  
 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 85°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 in more than 72 hours.



**Drug Facts**

**Active Ingredient**

Ethyl alcohol 70% v/v

**Purpose**

Antiseptic



## HAND SANITIZER

alcohol 70% gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:758 10-103
Route of Administration	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
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<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	0.46 g in 100 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	0.46 g in 100 mL
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	0.23 g in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	25.94 g in 100 mL
<b>EDETIC ACID</b> (UNII: 9G34HU7RV0)	0.09 g in 100 mL
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	0.46 g in 100 mL

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75810-103-04	4000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/28/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/27/2020	

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

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

### Establishment

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

Revised: 7/2020

Neingenium Labs SA de CV