HAND SANITIZER- alcohol 70% gel
Neoingenium 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) (80%, 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% 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.

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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

Package Label - Principal Display Panel

Drug Facts

Active Ingredient **Purpose**
Ethyl alcohol 70%.....Antiseptic

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

Warnings
For External use only: hands.
Flammable. Keep away from fire or flame.
When using this product • Keep out of eyes. In case of contact with eyes flush thoroughly with water • Avoid contact with broken skin • Do not inhale or ingest.
Stop use and ask a doctor if • Irritation and redness develop • Condition persists for more than 72 hours.
Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions: Wet hands thoroughly with product and allow to dry without wiping • For children under 6, use only under adult supervision • Not recommended for infants.

Other information: Do not store above 105° F (40.5° C) • May discolor some fabrics • Harmful to wood finishes and plastics.

Inactive ingredient
Aqua, Glycerin, Carbomer, Aloe Barbadensis Leaf Extract, Triethanolamine, Propylen Glycol, EDTA Disodium Salt, D&C Violet 2.

Made in Mexico. / Hecho en México.
By / Por: **NEOINGENIUM LABS S.A. DE C.V.**
Manuel Gómez Morín No. 6370.
Zapopan, Jalisco, México.
NLA150112LM2

Lot and expiration date, printed on the packaging. /
Lote y fecha de caducidad, impresos en el envase.

000 mL

NDC: 75810-101-02

HAND SANITIZER
alcohol 70% gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75810-101

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**
EDETIC ACID (UNII: 9G34HU7RV0)	0.09 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.46 g in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.46 g in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.46 g in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.23 g in 100 mL
WATER (UNII: 059QF0KO0R)	25.94 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:75810-101-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/06/2020	

Labeler - Neoingenium Labs SA de CV (951576661)

Registrant - Neoingenium Labs SA de CV (951576661)

Establishment

Name	Address	ID/FEI	Business Operations
Neoingenium Labs SA de CV		951576661	manufacture(75810-101)

Revised: 5/2020 Neoingenium Labs SA de CV