

HAND SANITIZER- alcohol gel
Kapril Industrial Laboratorio SRL

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
Alcohol 70%

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% 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, Triethanolamine, Carbomer, purified water USP

Package Label - Principal Display Panel

473.6 mL NDC: 78846-100-16

Desinfectante de manos para ayudar a reducir las bacterias que potencialmente pueden causar enfermedades. Para usar cuando no hay agua y jabón disponible.

Modo de Uso: Coloque suficiente producto en las manos para cubrir todas las superficies. Frotar las manos juntas hasta que se sequen. Supervise a los niños menores de 6 años cuando use este producto para evitar que se lo traguen.

Advertencias: Sólo para uso externo. Inflamable. Mantener alejado del calor o las llamas.

No utilice

- En niños menores de 2 meses de edad.
- En heridas abiertas de la piel.

Cuando use este producto, manténgalo fuera de los ojos, oídos y boca. En caso de contacto con los ojos, enjuague bien los ojos con agua.

Suspenda su uso y consulte a un médico si se produce irritación o sarpullido. Estos pueden ser signos de una afección grave. Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato.

Información Adicional

Almacenar entre 15-30C (59-86F)
Evite la congelación y el calor excesivo por encima de 40C (104F)

For suggest and comments:

Tels: 809-530-9984

Email: info@kaprilindustrial.com

Manufactured by:

KAPRIL INDUSTRIAL LABORATORIO S.R.L.

Santo Domingo, Dominican Republic

www.kaprilindustrial.com

Reg. Ind.: 164725



Fenoxclean

HAND SANITIZER

GEL SANITIZANTE

ALCOHOL 70%

16 Oz. Fl

Drug Facts

Active Ingredient	Purpose
Alcohol 70% v/v.....	Antiseptic

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Other Information: Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients: Purified Water, Glycerin, Triethanolamine, Carbomer.

Questions: 809-530-9984



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78846-100
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
CARBOMER 940 (UNII: 4Q93RCW27E)	0.3 mL in 100 mL
TRIETHANOLAMINE TRIS(DIHYDROGEN PHOSPHATE) (UNII: 36YHT392ID)	0.063 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78846-100-02	59.2 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2020	
2	NDC:78846-100-04	118.4 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2020	
3	NDC:78846-100-08	236.8 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2020	
4	NDC:78846-100-16	473.6 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2020	
5	NDC:78846-100-01	3789 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/30/2020	

Labeler - Kapril Industrial Laboratorio SRL (815941214)

Registrant - Kapril Industrial Laboratorio SRL (815941214)

Establishment

Name	Address	ID/FEI	Business Operations
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Kapril Industrial Laboratorio SRL		8 159 412 14	manufacture(78846-100)
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Revised: 6/2020

Kapril Industrial Laboratorio SRL