

HAND SANITIZER- alcohol gel

Cosquim 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.

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. Sterile distilled water or boiled cold water.
- c. Glycerin
- d. Carbomer
- e. Fragrance
- f. Triethanolamine

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

Purified water USP, glycerin, carbomer, fragrance, triethalonamine.

Package Label - Principal Display Panel

□1000 mL NDC: 80215-001-01

FRENTE

WITH MOISTURIZERS
CON HUMECTANTES

70% Alcohol


**HAND
SANITIZER
GEL**

**GEL
ANTIBACTERIAL**



PASSINI
Net Cont. 33.8 fl oz
Cont. Neto 1 L

REVERSO

DRUG FACTS

ACTIVE INGREDIENT / INGREDIENTE ACTIVO: Ethyl Alcohol / Alcohol Etilico 70%	PURPOSE / USO: Antiseptic / Antiséptico
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Uses / Usos:

- To help decrease bacteria on the skin / Ayuda a disminuir las bacterias en la piel.
- Recommended for repeated use / Recomendado para uso repetido.

Warnings / Advertencias:

- For external use only / Exclusivo para uso externo.
- Flammable. Keep away from fire or flame / Flammable. Manténgase alejado del fuego.
- Avoid eye contact. In case of eye contact, rinse thoroughly with plenty water, seek for medical attention immediately / Evite contacto con los ojos. En caso de contacto con los ojos, enjuague con abundante agua, busque atención médica inmediatamente.
- Do not use on irritated skin / No se utilice en piel irritada.
- Stop use and ask a doctor if redness or irritation develops and persists for more than 72 hrs / Detenga el uso y pregunte a su médico si se desarrolla irritación por más de 72 hrs.
- Keep away from children. If swallowed, seek for medical attention immediately. Children must only use this products under adult supervision. / Mantenga alejado de los niños. En caso de consumo, busque atención médica inmediatamente. Niños deben usar el producto solo bajo supervisión adulta.

Directions / Instrucciones:

- Apply the gel directly on the palm. Spread the gel by rubbing your hands and fingers until dry / Aplique el gel directamente sobre las manos, distribuya uniformemente y frote las manos y dedos hasta que seque.

Other information / Información Adicional:

- Store below 105°F / Conserve debajo de 40°C.
- Avoid sunlight exposure / Evite exponer a la luz solar.

Inactive Ingredients: Benzyl Salicylate, Carbomer, Citronellol, Fragrance, Glycerin, Hexyl Cinnamal, Limonene, Linalool, Triethanolamine, Water. **Ingredientes Inactivos:** Salicilato de Bencilo, Carbomero, Citronelol, Fragancia, Glicerina, Hexil Cinnamal, Limoneno, Linalool, Trietanolamina, Agua.

NDC: 80215-001-001

**Cleans and disinfects your skin without using water.
Limpia y desinfecta tu piel sin necesidad de usar agua.
Contains moisturizers / Contiene Humectantes**

COSQUIM S.A. DE C.V. IS NOT RESPONSIBLE FOR THE MISUSE OF THIS PRODUCT. READ THE INSTRUCTIONS BEFORE USE. / COSQUIM S.A. DE C.V. NO ES RESPONSABLE POR EL MAL USO DE ESTE PRODUCTO. LEER LAS INSTRUCCIONES DE USO ANTES DE APLICARLO.


Lot No and best before. See container.
Número de lote y fecha preferencia de uso. Ver el envase.




7 501633 721728

**Made in Mexico
Hecho en México**
Manufactured by
Elaborado por:
Cosquim S.A. de C.V.
Eta 406 Fraccionamiento
Industrial Delta C.P. 37545
León, Gto., México
México 01 (477) 101 6400
USA 1 855 2057 225
correo@passini.com.mx
www.passini.com.mx
1HG527-D

Cleans and disinfects your skin without using water.

Limpia y desinfecta tu piel sin necesidad de usar agua.

Tip: Carry it with you and make sure your hands are clean everywhere.

Tip: Llévalo contigo y asegurate de mantener limpias las manos en todo lugar.

**Contains moisturizers
Contiene Humectantes**

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**WITH MOISTURIZERS
CON HUMECTANTES**

70% Alcohol



**HAND
SANITIZER
GEL**

**GEL
ANTIBACTERIAL**



PASSINI.
Net. Cont. 8.4 fl oz
Cont. Neto 250 ml

DRUG FACTS

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INGREDIENTE ACTIVO:** Ethyl Alcohol / Alcohol Etílico 70%.....**Antiseptic / Antiséptico**

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NDC: 80215-001-000

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80215-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TRIETHANOLAMINE TRIS(DIHYDRO GEN PHOSPHATE) (UNII: 36 YHT392ID)	
GLYCERIN (UNII: PDC6 A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0KO0R)	
BENZYL SALICYLATE (UNII: WAO5MNK9TU)	
ETHYL LINALOOL (UNII: SF2JS9GF5T)	
CYCLOHEXYL CINNAMATE (UNII: 2955WP594O)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
.BETA.-CITRONELLOL, (+/-)- (UNII: 565OK72VNF)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80215-001-01	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:80215-001-02	250 mL in 1 BOTTLE, PLASTIC; 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 - Cosquim S.A. de C.V. (813821477)

Establishment

Name	Address	ID/FEI	Business Operations
Cosquim S.A. de C.V.		813821477	manufacture(80215-001)

Revised: 9/2020

Cosquim S.A. de C.V.