

HAND SANITIZER- alcohol gel
Bio Systems de Mexico 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.

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 80% 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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

960 mL NDC: 75772-424-09

BIOVÈNE[®]
BARCELONA

#COWIN-20

ORIGINAL
70% ALCOHOL

**HAND
CLEANSING
GEL**

LIMITED EDITION



with Glycerin & Aloe

UNSCENTED

NO WATER REQUIRED

32.46 FL.OZ e (960 ML)

BIOVÈNE[®]
BARCELONA

ORIGINAL
70% ALCOHOL

EN Take care of your hands with Biovène Original 70% Alcohol, Hand Cleansing Gel. The advanced fast-drying formula is enriched with soothing Aloe Vera and moisturizing glycerin, leaving your hands feeling soft, fresh and clean.

ES Cuide sus manos con Biovène Original 70% Alcohol, el gel de limpieza para manos. La fórmula avanzada de secado rápido está enriquecida con las suaves propiedades del Aloe Vera y la hidratación de la glicerina, dejando sus manos suaves, frescas y limpias.

DRUG FACTS

Active ingredient	Purpose
Ethyl alcohol 70% v/v	Antimicrobial

Use: Hand sanitizer to help reduce bacteria on the skin.

Warnings: Flammable. Keep away from fire or flame. For external use only. Do not ingest, if swallowed seek medical help. Avoid contact with eyes. Keep out of reach of children. Children under 6 years old to use under adult supervision. In case of irritation, discontinue use and consult your doctor.

Directions: Apply the Gel on the hands and rub gently for 20 seconds until the product evaporates.

Other information: Store below 106°F (41°C). May discolor certain fabrics or surfaces.

Inactive ingredients: demineralized water, glycerin, carbomer, triethanolamine, dmdm hydantoin, aloe barbadensis extract, iodopropynyl butylcarbamate, butylene glycol.

32.46 FL OZ (960 ml)

/BiovèneBarcelona

@BIOVENEBCARCELONA
Make sure that you tag your photos with #biovene for a chance to receive a reward, and visit BiovèneBarcelona.com to learn more about our products.

WELCOME TO
BiovèneBarcelona.com

Biovène Cosmetics SL, Paseo de Gracia 95, 5-1 Barcelona, Spain. Developed in Barcelona. Manufactured in Mexico. REF 9Q20119MX. Distributed in USA by: IP Branding Group, LLC 2549 Waukegan Rd. Suite 24. Bannockburn IL, 60015, USA.
Biovène Barcelona © 2020 All rights reserved. The Biovène Barcelona logo, wordmark and packaging are intellectual properties of Biovène Cosmetics SL, Barcelona, Spain.



BEST BEFORE AND BATCH NO. /
FECHA DE CADUCIDAD Y NÚMERO DE LOTE

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75772-424
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75772-424-09	960 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 - Bio Systems de Mexico SA de CV (589751791)**Establishment**

Name	Address	ID/FEI	Business Operations
Bio Systems de Mexico SA de CV		589751791	manufacture(75772-424)

Revised: 5/2020

Bio Systems de Mexico SA de CV