

COLLOID 5010 S- alcohol liquid
COLLOIDS DE MEXICO, 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.

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 Pharmacopeia (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 JFood 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 water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Alcohol 80% v/v. Purpose: Antiseptic.

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria tht potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from 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 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 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.

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.

Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C (104F)

Glycerin, Hydrogen Peroxide, purified Water USP

DRUG FACTS:
ACTIVE INGREDIENTS: Alcohol 80% V/V. Purpose: Antiseptic
PURPOSE: Antiseptic, Hand Sanitizer
USE: Hand Sanitizer to reduce bacteria and viruses that potentially can cause disease.
WARNINGS: For external use only. Flammable. Keep away from heat and flame.
DO NOT USE: In children less than two months of age. On open wounds.
WHEN USING: 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 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 Poison Control Center right away.
STOP USE: Stop use and ask doctor if irritation or rash occurs. These may be signs of a serious conditions.
KEEP OUT OF REACH OF CHILDREN: 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.
STORAGE AND HANDLING: Store between 15 - 30 C (59 - 86 F) Avoid freezing and excessive heat above 40 C (104 F)
INACTIVE INGREDIENTS: Glycerin, hydrogen peroxide, purified water USP
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COLLOIDS DE MEXICO S.A. DE C.V.

**COLLOID 5010 S
HAND SANITIZER**

Alcohol Antiseptic 80%
Topical Solution

Antiseptic Hand Rub
Non-Sterile Solution

Manufactured by Colloids de Mexico, S.A. de C.V.
Pirineos 227, Col. Santa Cruz Atoyac, CDMX

MADE IN MEXICO CONTENT 1,000 mL NCD: 79306-010-11

COLLOID 5010 S

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79306-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79306-010-11	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/05/2020	

Marketing Information

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

Labeler - COLLOIDS DE MEXICO, S.A. DE C.V. (811156074)

Revised: 7/2020

COLLOIDS DE MEXICO, S.A. DE C.V.