

BAIN DETE GALLON HAND SANITIZER- hand sanitizer gel
Eurocorp Caribbean LLC

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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% 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

BAIN D'ÉTÉ

EN

DRUG FACTS

Active ingredient

Ethyl alcohol 70% v/v

Purpose

Antiseptic

Uses: to decrease bacteria on the skin that could cause diseases.

Warnings:

For external use only. Flammable product. Keep out of reach of children. Keep at a temperature not higher than 105°F. May discolor some fabrics, harmful to wood finishes.

When using this product: Keep out of eyes. In case of contact, flush thoroughly with water. Do not inhale or ingest.

Stop using and ask a doctor: if irritation and redness develop and persists for more than 24 hours.

Keep out of reach of children: if swallowed, get medical help or contact a Poison Control Center right away.

Directions: apply a small amount in your hands and rub until it dries, for children under 6, use only under adult supervision.

Inactive ingredients: Aqua/Water, Acrylates/C 10-30 Alkyl Acrylate Crosspolymer, Carbomer, Aminomethyl Propanol.

ES

Modo de uso: aplique en sus manos y frote hasta que seque.

Advertencias: solo para uso externo. Producto inflamable. Evitar el contacto con los ojos, en caso de contacto enjuague con abundante agua. En niños menores de 6 años usar bajo la supervisión de un adulto. Conservar a temperaturas menores a 40°C.

Made in El Salvador for Distribuidora Cuscatlán S.A de C.V.

Hecho en El Salvador para Distribuidora Cuscatlán S.A. de C.V.

BAIN D'ÉTE

ALCOHOL GEL

ANTIBACTERIAL

KILLS GERMS AND BACTERIA

BAIN D'ÉTE



HAND
SANITIZER

DESINFECTANTE DE MANOS
ELIMINA GÉRMENES

70% VOL.

EN DRUG FACTS

Active ingredient	Purpose
Ethyl Alcohol (Alcohol Denat.) 70% v/v - - - - -	Antiseptic

Uses: to decrease bacteria on the skin that could cause diseases.

Warnings:

For external use only. Flammable product. Keep out of reach of children. Keep at a temperature not higher than 105°F. May discolor some fabrics, harmful to wood finishes. When using this product: Keep out of eyes. In case of contact, flush thoroughly with water. Do not inhale or ingest. Stop using and ask a doctor: if irritation and redness develop and persists for more than 24 hours. Keep out of reach of children: if swallowed, get medical help or contact a Poison Control Center right away.

Directions: apply a small amount in your hands and rub until it dries, for children under 6, use only under adult supervision.

Inactive ingredients: Aqua/Water, Acrylates/C 10-30 Alkyl Acrylate Crosspolymer, Carbomer, Aminomethyl Propanol.

ES

Modo de uso: aplique en sus manos y frote hasta que seque.
Advertencias: solo para uso externo. Producto inflamable. Evitar el contacto con los ojos, en caso de contacto enjuague con abundante agua. En niños menores de 6 años usar bajo la supervisión de un adulto. Conservar a temperaturas menores a 40°C.

Made in El Salvador for Distribuidora Cuscatlán S.A de C.V. | Hecho en El Salvador para Distribuidora Cuscatlán S.A. de C.V.

3,780 ml
127.8 Fl. Oz



En El Salvador Reg. San.: 1UC17320713
No. Lote y Fecha de vencimiento: Ver envase

000 ml NDC: 00000-000-00

BAIN DETE GALLON HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:758 18-087
---------------------	----------------	---------------------------	----------------

Route of Administration	TOPICAL
--------------------------------	---------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 70 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75818-087-72	3780 mL in 1 JUG; 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 - Eurocorp Caribbean LLC (087768954)

Establishment

Name	Address	ID/FEI	Business Operations
Eurocorp Caribbean LLC		087768954	label(75818-087)

Establishment

Name	Address	ID/FEI	Business Operations
Distribuidora Cuscatlan		851247924	manufacture(75818-087)