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 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

Keep out of reach of children. Keep at temperature not higher than 105f may discolor some fabrics, harmful to wood finishes.

when using this product: keep out of eyes. in case of contact, flush throuughly with water. Do not inhale or ingest.

stop using 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

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

Acrylates/c10-30 purified water USP Carbomer,Amino propanol Acrylate crosspolymer

Label

BAIN D'ÉTÉ

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DRUG FACTS

Active ingredient	Purpose
Ethyl alcohol 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.

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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'ÉTÉ

ALCOHOL GEL

ANTIBACTERIAL

KILLS GERMS AND BACTERIA

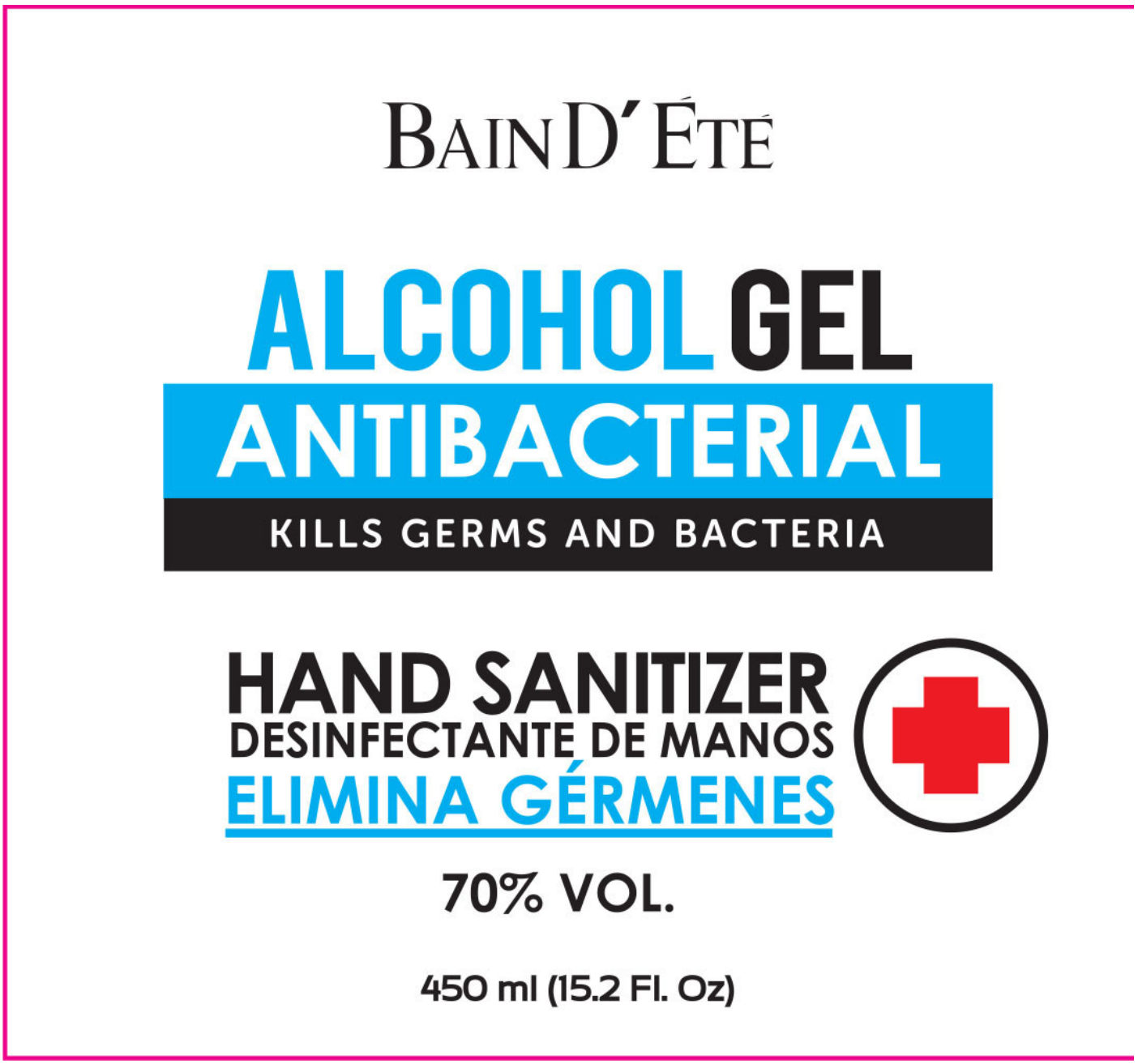
HAND SANITIZER

DESINFECTANTE DE MANOS

ELIMINA GÉRMENES

70% VOL.

450 ml (15.2 Fl. Oz)



HAND SANITIZER

hand sanitizer gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75818-450
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 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:75818-450-17	450 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	manufacture(75818-450)

Revised: 4/2020 EUROCORP CARIBBEAN LLC