

HAND SANITIZER- alcohol gel
EUROFORTE 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.

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) (72%, 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
- c. Carbomer 940
- d. Glycerin
- e. 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 72% 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

1 Gallon NDC: 78473-001-01



72% Alcohol.

**Clinical aroma.
With moisturizers**



Drug Facts

ACTIVE INGREDIENTS:

Ethyl alcohol 72%

PURPOSE: Antiseptic

Uses:

- To help decrease bacteria on the skin
- Recommended for repeated use.

Warnings:

and emollients

warnings:

- For external use only.
- Flammable. Keep away from fire or flame.
- Keep out eyes. In case of eye contact, flush it thoroughly with water, seek medical attention immediately.
- Avoid contact with broken skin.
- Stop use and ask a doctor if redness or irritation develops and persists for more than 72 hrs.
- Keep away from children. If swallowed, seek medical attention immediately. Children must only use this product under adult supervision.

Direction:

- Place small amount of sanitizer in your palm. Thoroughly spread on both hands and rub together until dry.

Other information:

- Store below 105 °F
- May discolor some fabrics

Inactive Ingredients: Deionized water, carbomers, glycerin, triethanolamine

Cont. **1 Gal (3.785 L)**



Manufacture By:

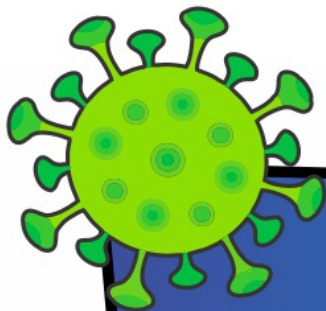
Euroforte, S.A. de C.V.

Gamma No. 103. Industrial Delta

León, Gto. CP 37545 Phone: +52 477 761 0375



33.8 fl oz NDC:78473-001-02



DEFFEND

HAND SANITIZER

72% Alcohol.

Clinical aroma.
With moisturizers
and emollients



Drug Facts

ACTIVE INGREDIENTS:

Ethyl alcohol 72%

PURPOSE: Antiseptic

Uses:

- To help decrease bacteria on the skin
- Recommended for repeated use.

Warnings:

- For external use only.
- Flammable. Keep away from fire or flame.
- Keep out eyes. In case of eye contact, flush it thoroughly with water, seek medical attention immediately.
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- Stop use and ask a doctor if redness or irritation develops and persists for more than 72 hrs.
- Keep away from children. If swallowed, seek medical attention immediately. Children must only use this product under adult supervision.

Direction:

- Place small amount of sanitizer in your palm. Thoroughly spread on both hands and rub together until dry.

Other information:

- Store below 105 °F
- May discolor some fabrics

Inactive Ingredients: Deionized water, carbomers, glycerin, triethanolamine

Cont. **33.8 fl oz. (1 L)**



Manufacture By:

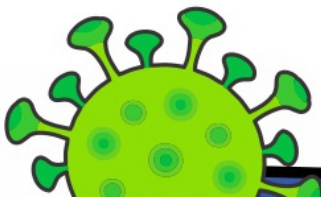
Euroforte, S.A. de C.V.

Gamma No. 103. Industrial Delta

León, Gto. CP 37545 Phone: +52 477 761 0375



68 fl oz NDC:78473-001-03





DEFFEND

HAND SANITIZER

72% Alcohol.

Clinical aroma.
With moisturizers
and emollients

Eliminate
99.9%
Of the most
common germs

Drug Facts

ACTIVE INGREDIENTS:

Ethyl alcohol 72%

PURPOSE: Antiseptic

Uses:

- To help decrease bacteria on the skin
- Recommended for repeated use.

Warnings:

- For external use only.
- Flammable. Keep away from fire or flame.
- Keep out eyes. In case of eye contact, flush it thoroughly with water, seek medical attention immediately.
- Avoid contact with broken skin.
- Stop use and ask a doctor if redness or irritation develops and persists for more than 72 hrs.
- Keep away from children. If swallowed, seek medical attention immediately. Children must only use this product under adult supervision.

Direction:

- Place small amount of sanitizer in your palm. Thoroughly spread on both hands and rub together until dry.

Other information:

- Store below 105 °F
- May discolor some fabrics

Inactive Ingredients: Deionized water, carbomers, glycerin, triethanolamine

Cont. **68 oz. (2 L)**
Net.

Manufacture By:
Euroforte, S.A. de C.V.



Gamma No. 103. Industrial Delta
León, Gto. CP 37545 Phone: +52 477 761 0375



16.9 fl oz NDC:78473-001-04



72% Alcohol.

Clinical aroma.
With moisturizers
and emollients

Eliminate
99.9%
Of the most
common germs

Drug Facts

ACTIVE INGREDIENTS: Ethyl alcohol 72%.....
PURPOSE: Antiseptic

Uses:
• To help decrease bacteria on the skin
• Recommended for repeated use.

Warnings:
• For external use only.
• Flammable. Keep away from fire or flame.
• Keep out eyes. In case of eye contact, flush it thoroughly with water, seek medical attention immediately.
• Avoid contact with broken skin.
• Stop use and ask a doctor if redness or irritation develops and persists for more than 72 hrs.
• Keep away from children. If swallowed, seek medical attention immediately. Children must only use this product under adult supervision.

Direction:

• Place small amount of sanitizer in your palm. Thoroughly spread on both hands and rub together until dry.

Other information:

- Store below 105 °F
- May discolor some fabrics

Inactive Ingredients: Deionized water, carbomers, glycerin, triethanolamine

Cont. Net. **16.9 fl oz. (500 ml)**

Manufacture By:
Euroforte, S.A. de C.V.
Gamma No. 103. Industrial Delta
León, Gto. CP 37545 Phone: +52 477 761 0375



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78473-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TRIETHANOLAMINE TRIS(DIHYDROGEN PHOSPHATE) (UNII: 36YHT392ID)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78473-002-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78473-002-02	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78473-002-03	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78473-002-04	500 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 - EUROFORTE SA DE CV (812835744)**Establishment**

Name	Address	ID/FEI	Business Operations
EUROFORTE SA DE CV		812835744	manufacture(78473-002)