

AME HAND SANITIZER- hand sanitizer liquid
DR.AMERICO GROUP JOINT STOCK COMPANY

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. 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, purified water USP



DRUG FACT

| Active ingredient(s) | Purpose |
|----------------------|------------|
| ALCOHOL 80% | Antiseptic |

Use(s)

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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 at 1-800-222-1222.

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

PURIFIED WATER USP, GLYCERIN

MFG: 11/2020 – EXP: 11/2023 – LOT: AHSS1gal.23111

PRODUCT OF DR. AMERICO GROUP JOINT STOCK COMPANY

Head office: 50 Tran Khac Chan st., Tan Dinh ward, dist. 1, Ho Chi Minh city, Vietnam.

Tel: +84.907.336.043 - Web: www.drmericofactory.com

A BRAND OF DR. AMERICO GROUP LLC.





AME HAND SANITIZER SOLUTION

**HAND
SANITIZER**
80% TOPICAL SOLUTION



Alcohol Antiseptic
Non-sterile Solution

250 ml/8.4 oz

DRUG FACT

| Active ingredient(s) | Purpose |
|----------------------|------------|
| ALCOHOL 80% | Antiseptic |

Use(s)
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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 at 1-800-222-1222.

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
PURIFIED WATER USP, GLYCERIN

MFG: 11/2020 - **EXP:** 11/2023 - **LOT:** AHSS250.23111

PRODUCT OF DR. AMERICO GROUP JOINT STOCK COMPANY
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AME HAND SANITIZER SOLUTION

**HAND
SANITIZER**
80% TOPICAL SOLUTION



Alcohol Antiseptic
Non-sterile Solution

100ml/3.4oz

DRUG FACT

| Active ingredient(s) | Purpose |
|----------------------|------------|
| ALCOHOL 80% | Antiseptic |

Use(s)
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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 at 1-800-222-1222.

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
PURIFIED WATER USP, GLYCERIN

MFG: 11/2020 – **EXP:** 11/2023 – **LOT:** AHSS100.23111

PRODUCT OF DR. AMERICO GROUP JOINT STOCK COMPANY

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AME HAND SANITIZER SOLUTION



Alcohol Antiseptic
Non-sterile Solution

5,000 ml/168 oz

DRUG FACT

| Active ingredient(s) | Purpose |
|----------------------|------------|
| ALCOHOL 80% | Antiseptic |

Use(s)
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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 at 1-800-222-1222.

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
PURIFIED WATER USP, GLYCERIN

MFG: 11/2020 - **EXP:** 11/2023 - **LOT:** AHSS5000.23111

PRODUCT OF DR. AMERICO GROUP JOINT STOCK COMPANY

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AME HAND SANITIZER SOLUTION

**HAND
SANITIZER**

80% TOPICAL SOLUTION



Alcohol Antiseptic
Non-sterile Solution

1000 ml/ 34 oz

DRUG FACT

| Active ingredient(s) | Purpose |
|----------------------|------------|
| ALCOHOL 80% | Antiseptic |

Use(s)
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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 at 1-800-222-1222.

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
PURIFIED WATER USP, GLYCERIN

MFG: 11/2020 - **EXP:** 11/2023 - **LOT:** AHSS1000.23111

PRODUCT OF DR. AMERICO GROUP JOINT STOCK COMPANY
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AME HAND SANITIZER SOLUTION

HAND SANITIZER

80% TOPICAL SOLUTION



Alcohol Antiseptic
Non-sterile Solution

500 ml/17 oz

DRUG FACT

| Active ingredient(s) | Purpose |
|----------------------|------------|
| ALCOHOL 80% | Antiseptic |

Use(s)
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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.
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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
PURIFIED WATER USP, GLYCERIN

MFG: 11/2020 - EXP: 11/2023 - LOT: AHSS500.23111

PRODUCT OF DR. AMERICO GROUP JOINT STOCK COMPANY
Head office: 50 Tran Khac Chan st., Tan Dinh ward, dist. 1, Ho Chi Minh city, Vietnam.
Tel: +84.907.336.043 - Web: www.dr Americofactory.com
A BRAND OF DR. AMERICO GROUP LLC.




0 784099 831959

AME HAND SANITIZER

hand sanitizer liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:80870-801 |
| Route of Administration | CUTANEOUS | | |

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 |
|-----------------|----------|
|-----------------|----------|

| GLYCERIN (UNII: PDC6A3C0OX) | | 1.45 mL in 100 mL | | |
|------------------------------|--|--|----------------------|--------------------|
| WATER (UNII: 059QF0K00R) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:80870-801-01 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/26/2020 | |
| 2 | NDC:80870-801-03 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/22/2020 | |
| 3 | NDC:80870-801-05 | 3785.4 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/22/2020 | |
| 4 | NDC:80870-801-04 | 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/22/2020 | |
| 5 | NDC:80870-801-06 | 5000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/22/2020 | |
| 6 | NDC:80870-801-02 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/22/2020 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333A | 10/22/2020 | | |

Labeler - DR.AMERICO GROUP JOINT STOCK COMPANY (555835686)

| Establishment | | | |
|--------------------------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| DR.AMERICO GROUP JOINT STOCK COMPANY | | 555835686 | relabel(80870-801) |

Revised: 12/2020

DR.AMERICO GROUP JOINT STOCK COMPANY