**HAND SANITIZER- alcohol liquid**
**MB Diversity 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.*

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**Hand Sanitizer**

**Do not use**

- in children less than 2 months of age
- on open skin wounds

**Active Ingredient(s)**

Alcohol 80% v/v. Purpose: Antiseptic

**Use**

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

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. 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.

**Purpose**

Antiseptic, Hand Sanitizer

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

**Warnings**

For external use only. Flammable. Keep away from heat or flame

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.

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**

118mL NDC: 78833-001-04

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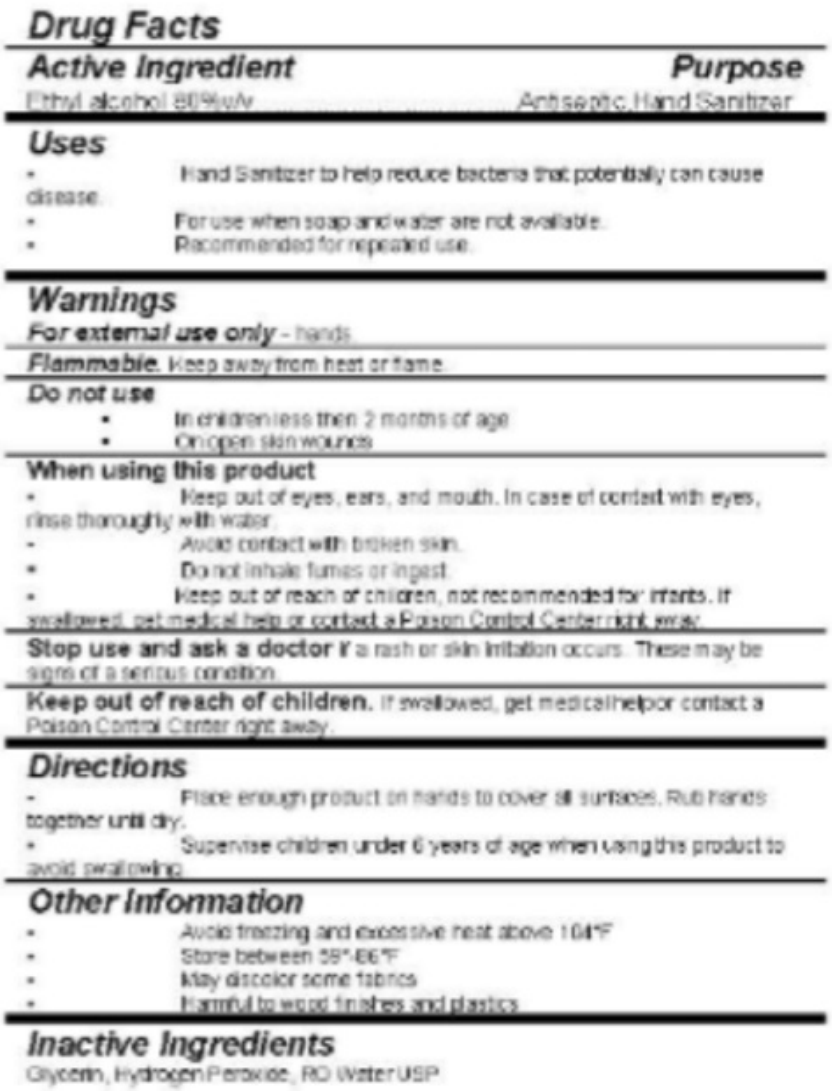

**Drug Facts**

**Active Ingredient** — **Purpose**

Ethyl alcohol 80%v/v — Antiseptic, Hand Sanitizer

**Uses**

- Hand Sanitizer to help reduce bacteria that potentially can cause disease.
- For use when soap and water are not available.
- Recommended for repeated use.

**Warnings**

**For external use only** - hands

**Flammable.** Keep away from heat or flame.

**Do not use**

- In children less then 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 thoroughly with water.
- Avoid contact with broken skin.
- Do not inhale fumes or ingest.
- Keep out of reach of children, not recommended for infants. If swallowed, get medical help or contact a Poison Control Center right away.

**Stop use and ask a doctor if** a rash or skin 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.

**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**

- Avoid freezing and excessive heat above 104°F
- Store between 59°-86°F
- May discolor some fabrics
- Harmful to wood finishes and plastics

**Inactive Ingredients**

Glycerin, Hydrogen Peroxide, RO Water USP

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) recommen

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.
Glycerol (1.45% v/v).
Hydrogen peroxide (0.125% v/v).
Sterile Reverse Osmosis water
MB Diversity does not add other active or inactive ingredients.
Different or additional ingredients may impact the quality and potency of the product.

## [Package Label - Principal Display Panel's]

118 mL
NDC: 78833-001-04

MB DIVERSITY
EMBRACE CHANGE

HAND SANITIZER

kills 99.99% of common germs in 15 seconds

4 oz (118 mL)

237mL NDC: 78833-001-02

**Drug Facts**

| **Active Ingredient** | **Purpose** |
|---|---|
| Ethyl alcohol 80 % v/v | Antiseptic, Hand Sanitizer |

**Uses**

- Hand Sanitizer to help reduce bacteria that potentially can cause disease.
- For use when soap and water are not available.
- Recommended for repeated use.

## Warnings

*For external use only* - hands.

*Flammable.* Keep away from heat or flame.

*Do not use*

- In children less then 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 thoroughly with water.
- Avoid contact with broken skin.
- Do not inhale fumes or ingest.
- Keep out of reach of children, not recommended for infants. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if a rash or skin 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.

## 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

- Avoid freezing and excessive heat above 104°F
- Store between 59°-86°F
- May discolor some fabrics
- Harmful to wood finishes and plastics

## Inactive Ingredients

Glycerin, Hydrogen Peroxide, RO Water USP

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:

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.
Glycerol (1.45% v/v).
Hydrogen peroxide (0.125% v/v).
Sterile Reverse Osmosis water
MB Diversity does not add other active or inactive ingredients.
Different or additional ingredients may impact the quality and potency of the product.

[Package Label - Principal Display Panel's]

473 mL

NDC: 78833-003-16


473mL NDC: 78833-001-03

## Drug Facts

**Active Ingredient** — **Purpose**

Ethyl alcohol 80%v/v ..... Antiseptic, Hand Sanitizer

### Uses

- Hand Sanitizer to help reduce bacteria that potentially can cause disease.
- For use when soap and water are not available.
- Recommended for repeated use.

### Warnings

***For external use only*** - hands.

***Flammable.*** Keep away from heat or flame.

***Do not use***

- In children less then 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 thoroughly with water.
- Avoid contact with broken skin.
- Do not inhale fumes or ingest.
- Keep out of reach of children, not recommended for infants. If swallowed, get medical help or contact a Poison Control Center right away.

**Stop use and ask a doctor** if a rash or skin 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.

### 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

- Avoid freezing and excessive heat above 104°F
- Store between 59°-86°F
- May discolor some fabrics
- Harmful to wood finishes and plastics

### Inactive Ingredients

Glycerin, Hydrogen Peroxide, RO Water USP

236.5 mL
NDC: 78833-002-08

MB DIVERSITY
EMBRACE CHANGE

HAND SANITIZER

kills 99.99% of common germs in 15 seconds

8 oz (236.5 mL)

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:

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.
Glycerol (1.45% v/v).
Hydrogen peroxide (0.125% v/v).
Sterile Reverse Osmosis water
MB Diversity does not add other active or inactive ingredients.
Different or additional ingredients may impact the quality and potency of the product.

[Package Label - Principal Display Panel's]

# HAND SANITIZER

alcohol liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:78833-001 |
| **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** |
| **GLYCERIN** (UNII: PDC6A3C0OX) | 1.45 mL in 100 mL |
| **HYDROGEN PEROXIDE** (UNII: BBX060AN9V) | 0.125 mL in 100 mL |
| **WATER** (UNII: 059QF0KO0R) | 18.425 mL in 100 mL |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:78833-001-04 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/08/2020 | |
| **2** | NDC:78833-001-02 | 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/08/2020 | |
| **3** | NDC:78833-001-03 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/08/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333A | 06/08/2020 | |

## Labeler - MB Diversity LLC (079725725)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| MB Diversity | | 079725725 | relabel(78833-001) |

Revised: 7/2020 MB Diversity LLC