

RESPONSIBLE HAND SANITIZER- alcohol liquid
SanitizeNow Inc.

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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The hand sanitizer is manufactured using only the following ingredients in the preparation of the product:

Alcohol (ethanol) (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.

Sterile distilled water or boiled cold water.

Hydrogen Peroxide

Glycerin

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

Water, Hydrogen Peroxide, Glycerin.

Package Label - Principal Display Panel

59 mL NDC: 74988-740-20



| Drug Facts | |
|---|--|
| Active Ingredient Ethyl Alcohol 80% | Purpose Antiseptic |
| 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 fire or flame. | |
| Do not use • on open skin wounds • on children under the age of 2 months | |
| 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. | |
| 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 59° - 86°F (15° - 30°C) • Avoid freezing and excessive heat above 104°F (40°C) | |
| Inactive Ingredients Water, Hydrogen Peroxide, Glycerin. | |
| PRO: 6/3/2020 EXP: 6/3/2022 | |
| Made in USA • 74988-740-20 Distributed by Clover Imaging Group Hoffman Estates, IL 60169 |  0 374988 740204 |

118 mL NDC: 74988-740-40

RESPONSIBLE™

HAND SANITIZER

Advanced Moisturizing Formula With Vitamin E

Kills 99.99% of Germs

80% Alcohol

118 mL (4 oz)

| Drug Facts | |
|---|------------------------------|
| Active Ingredient Ethyl Alcohol 80% | Purpose Antiseptic |
| 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 fire or flame. | |
| Do not use • on open skin wounds • on children under the age of 2 months | |
| 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. | |
| 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 59° - 86°F (15° - 30°C) • Avoid freezing and excessive heat above 104°F (40°C) | |
| Inactive Ingredients Water, Hydrogen Peroxide, Glycerin. | |

Made in USA • 74988-740-40
Distributed by Clover Imaging Group
Hoffman Estates, IL 60169

236 mL NDC: 74988-740-80

RESPONSIBLE™

HAND SANITIZER

Advanced Moisturizing Formula With Vitamin E

Kills 99.99% of Germs

80% Alcohol

8 fl oz 236mL

| Drug Facts | |
|---|------------------------------|
| Active Ingredient Ethyl Alcohol 80% | Purpose Antiseptic |
| 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 fire or flame. | |
| Do not use • on open skin wounds • on children under the age of 2 months | |
| 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. | |
| 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 59° - 86°F (15° - 30°C) • Avoid freezing and excessive heat above 104°F (40°C) | |
| Inactive Ingredients Water, Hydrogen Peroxide, Glycerin. | |

Made in USA • 74988-740-80
Distributed by Clover Imaging Group
Hoffman Estates, IL 60169

473 mL NDC: 74988-740-16

RESPONSIBLE.
HAND SANITIZER

Advanced Moisturizing Formula
With Vitamin E

Kills 99.99% of Germs

80% Alcohol

16 fl oz 473mL

Made in USA
74988-740-16
Distributed by Clover Imaging Group
Hoffman Estates, IL 60169

0 374988 740167

| Drug Facts | |
|---|------------------------------|
| Active Ingredient Ethyl Alcohol 80% | Purpose Antiseptic |
| 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 fire or flame. | |
| Do not use • on open skin wounds • on children under the age of 2 months | |
| 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. | |
| 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 59° - 86°F (15° - 30°C) • Avoid freezing and excessive heat above 104°F (40°C) | |
| Inactive Ingredients Water, Hydrogen Peroxide, Glycerin. | |

3.78 L NDC: 74988-740-37

RESPONSIBLE.
HAND SANITIZER

Advanced Moisturizing Formula
With Vitamin E

Kills 99.99% of Germs

80% Alcohol

1 GAL (128 fl oz) 3.78L

Made in USA • 74988-740-37
Distributed by Clover Imaging Group
Hoffman Estates, IL 60169

0 374988 740372

| Drug Facts | |
|---|------------------------------|
| Active Ingredient Ethyl Alcohol 80% | Purpose Antiseptic |
| 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 fire or flame. | |
| Do not use • on open skin wounds • on children under the age of 2 months | |
| 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. | |
| 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 59° - 86°F (15° - 30°C) • Avoid freezing and excessive heat above 104°F (40°C) | |
| Inactive Ingredients Water, Hydrogen Peroxide, Glycerin. | |

RESPONSIBLE HAND SANITIZER

alcohol liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74988-740 |
| 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) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:74988-740-20 | 59 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/05/2020 | |
| 2 | NDC:74988-740-40 | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/05/2020 | |
| 3 | NDC:74988-740-80 | 236 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/05/2020 | |
| 4 | NDC:74988-740-16 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/05/2020 | |
| 5 | NDC:74988-740-37 | 3780 mL in 1 JUG; Type 0: Not a Combination Product | 06/05/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 06/05/2020 | |

Labeler - SanitizeNow Inc. (117475870)

Registrant - SanitizeNow Inc. (117475870)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|------------------------|
| SanitizeNow Inc. | | 117475870 | manufacture(74988-740) |