

HAND CLEANER GEL- alcohol gel
Calvary Industries 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.

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.

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.

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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

15142ml NDC: 76796-083-04

HAND CLEANER GEL

80% Alcohol Gel

HEALTH & SAFETY INFORMATION

DANGER!

Flammable liquid and vapor. May be fatal if swallowed and enters airways. Causes eye irritation. May cause respiratory irritation. May cause dizziness or drowsiness.

Keep away from heat/sparks/open flames/hot surfaces – No smoking. Keep container tightly closed. Keep Cool. Take precautionary measures against static discharge. Do not get in eyes. Do not eat, drink or smoke when using this product.

HANDLING AND STORAGE

Avoid contact with eyes. Keep away from fire. Store in a cool area.

FIRST AID

EYES: Flush thoroughly with water for 15 minutes, lifting upper and lower lids. Seek medical attention immediately.

INGESTION: DO NOT induce vomiting. If conscious, give large amounts of water. Never give anything by mouth to an unconscious person. Seek medical attention immediately.

Consumer Commodity

ORM-D



| | |
|---------------------|---|
| HEALTH | 2 |
| FLAMMABILITY | 3 |
| PHYSICAL HAZARD | 0 |
| PERSONAL PROTECTION | A |

Calvary Industries, Inc.

9233 Seward Road • Fairfield, OH 45014 • (513) 874-1113 • Fax: (513) 860-6184

BEFORE USE, REVIEW MATERIAL SAFETY DATA SHEET FOR FURTHER INFORMATION, INCLUDING CHRONIC HEALTH EFFECTS.

LOT #: N/A

CONTENTS: 4x gallons

HAND CLEANER GEL

80% Alcohol Gel

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UN1987

ALCOHOLS, N.O.S., (ETHYL ALCOHOL), 3, PGII

BEFORE USE, REVIEW MATERIAL SAFETY DATA SHEET FOR FURTHER INFORMATION, INCLUDING CHRONIC HEALTH EFFECTS.

LOT #: 2003250

CONTENTS: 275 GALLONS

| | |
|---------------------|---|
| HEALTH | 2 |
| FLAMMABILITY | 3 |
| PHYSICAL HAZARD | 0 |
| PERSONAL PROTECTION | A |

HAND CLEANER GEL

80% Alcohol Gel

HEALTH & SAFETY INFORMATION

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LOT #: 2003250

CONTENTS: 55 GALLONS

| | |
|---------------------|---|
| HEALTH | 2 |
| FLAMMABILITY | 3 |
| PHYSICAL HAZARD | 0 |
| PERSONAL PROTECTION | A |

HAND CLEANER GEL

80% Alcohol Gel

HEALTH & SAFETY INFORMATION

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UN1987

ALCOHOLS, N.O.S., (ETHYL ALCOHOL), 3, PGII

BEFORE USE, REVIEW MATERIAL SAFETY DATA SHEET FOR FURTHER INFORMATION, INCLUDING CHRONIC HEALTH EFFECTS.

LOT #: 2003250

CONTENTS: 5 GALLONS

Calvary Industries, Inc.

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HAND CLEANER GEL

alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76796-083 |
| 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: 059QF0K00R) | |
| HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K) | 1.2 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|---|------------------|---|------------|--|
| 1 | NDC:76796-083-04 | 15142 mL in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:76796-083-05 | 18927 mL in 1 PAIL; Type 0: Not a Combination Product | 03/30/2020 | |
| 3 | NDC:76796-083-55 | 208198 mL in 1 DRUM; Type 0: Not a Combination Product | 03/30/2020 | |
| 4 | NDC:76796-083-27 | 1040875 mL in 1 TANK; 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 - Calvary Industries Inc (139637599)

Registrant - Calvary Industries Inc (139637599)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|------------------------|
| CALVARY INDUSTRIES INC | | 139637599 | manufacture(76796-083) |

Revised: 10/2020

Calvary Industries Inc