

HAND SANITIZER- ethanol liquid
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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% 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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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

HAND SANITIZER GEL 70%

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.

70% Alcohol Gel



UN1987

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

HEALTH	2
FLAMMABILITY	3
PHYSICAL HAZARD	0
PERSONAL PROTECTION	A

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

LOT #:

CONTENTS: 4x1 GALLON

Calvary Industries, Inc.

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

HAND SANITIZER GEL 70%

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ALCOHOL), 3, PGII

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FLAMMABILITY	3
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ALCOHOL), 3, PGII

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HAND SANITIZER GEL 70%

HEALTH & SAFETY INFORMATION

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LOT #:

CONTENTS: 275 GALLON

Calvary Industries, Inc.

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

Various ml NDC: 76796-089

HAND SANITIZER

ethanol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76796-089
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)	1.3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

Marketing Start Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76796-089-05	18927 mL in 1 PAIL; Type 0: Not a Combination Product	06/24/2020	
2	NDC:76796-089-04	15142 mL in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	06/25/2020	
3	NDC:76796-089-55	208198 mL in 1 DRUM; Type 0: Not a Combination Product	06/25/2020	
4	NDC:76796-089-27	1040875 mL in 1 TANK; Type 0: Not a Combination Product	06/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/24/2020	

Labeler - Calvary Industries Inc (139637599)

Registrant - Calvary Industries Inc (139637599)

Establishment

Name	Address	ID/FEI	Business Operations
CALVARY INDUSTRIES INC		139637599	manufacture(76796-089)

Revised: 10/2020

Calvary Industries Inc