

EARTHS OWN HAND SANITIZER COOL CITRUS- 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 70% 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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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.

Inactive ingredients

glycerin, purified water USP, aloe vera, vitamin E, fragrance, hydroxypropyl methylcellulose

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Package Label - Principal Display Panel

1040875 mL NDC: 76796-091-27

EARTH'S OWN
CLEANING SOLUTIONS

HAND SANITIZER GEL
Cool Citrus

Made with Aloe Vera and Vitamin E

70% Ethyl Alcohol
Made from renewable ingredients

275 GALLON

Drug Facts

Active Ingredient(s)	Purpose
Ethyl Alcohol 70% w/v	Antiseptic

Use(s)
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

- on 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.

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, Aloe Vera, Vitamin E, Purified Water USP, Hydroxypropyl methylcellulose

Manufactured by:
Calvery Industries, Inc.
9233 Seward Road,
Fairfield, OH 46014
(513) 834-1113
Fax: (513) 880-8184

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208198 mL NDC: 76796-091-55



HAND SANITIZER GEL

Cool Citrus

Made with Aloe Vera and Vitamin E

70% Ethyl Alcohol
Made from renewable ingredients

55 GALLON

Drug Facts

Active Ingredient(s)	Purpose
Ethyl Alcohol 70% w/v	Antiseptic

Use(s)

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

- on 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 seek 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, Aloe Vera, Vitamin E, Purified Water USP, Hydroxyethyl methylcellulose

Manufactured by:
Calvary Industries, Inc.
9239 Beward Road,
Fairfield, OH 46014
(513) 874-1113
Fax: (513) 860-8164



18927 mL NDC: 76796-091-05



HAND SANITIZER GEL

Cool Citrus

Made with Aloe Vera and Vitamin E

70% Ethyl Alcohol
Made from renewable ingredients

5 GALLON

Drug Facts

Active Ingredient(s)	Purpose
Ethyl Alcohol 70% w/v	Antiseptic

Use(s)

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

- on children less than 2 months of age
- on open side 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 seek 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, Aloe Vera, Vitamin E, Purified Water USP, Hydroxypropyl methylcellulose

Manufactured by:
Calvary Industries, Inc.
9239 Beward Road,
Fairfield, OH 46014
(513) 874-1113
Fax: (513) 860-8164



15142 mL NDC: 76796-091-04



EARTHS OWN HAND SANITIZER COOL CITRUS

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76796-091
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
TOCOPHEROL (UNII: R0ZB2556P8)	0.05 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)	1.3 mL in 100 mL
WATER (UNII: 059QF0K00R)	
ALOE (UNII: V5VD430YW9)	0.0025 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76796-091-04	15142 mL in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	07/15/2020	
2	NDC:76796-091-05	18927 mL in 1 PAIL; Type 0: Not a Combination Product	07/15/2020	
3	NDC:76796-091-55	208198 mL in 1 DRUM; Type 0: Not a Combination Product	07/15/2020	
4	NDC:76796-091-27	1040875 mL in 1 TANK; Type 0: Not a Combination Product	07/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/15/2020	

Labeler - CALVARY INDUSTRIES INC (139637599)

Registrant - CALVARY INDUSTRIES INC (139637599)

Establishment

Name	Address	ID/FEI	Business Operations
CALVARY INDUSTRIES INC		139637599	manufacture(76796-091)

Revised: 10/2020

CALVARY INDUSTRIES INC