

HAND SANITIZING RUB- alcohol 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. 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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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

1041L NDC: 76796-085-27

HAND SANITIZER RUB

80% Ethyl Alcohol

HEALTH & SAFETY INFORMATION

DANGER!

Flammable liquid and vapor. May be fatal if swallowed and enters airways. Causes eye irritation. May be harmful if inhaled. 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. Ground/bond container and receiving equipment. Use only non-sparking tools. 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.

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED:

Confine spill and pump liquid to storage tank. Mop up or collect with wet vacuum and neutralize. Take up remainder with absorbent material and dispose of in accordance with local, state and federal regulations.

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.



UN1987

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

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

LOT #: 2003334

CONTENTS: 275 GALLONS

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

HAND SANITIZER RUB

80% Ethyl Alcohol

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LOT #: 2003334

CONTENTS: 55 GALLONS

HEALTH	2
FLAMMABILITY	3
PHYSICAL HAZARD	0
PERSONAL PROTECTION	A

5

HAND SANITIZER RUB

80% Ethyl Alcohol

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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 #: 2003334

CONTENTS: 5 GALLONS

HEALTH	2
FLAMMABILITY	3
PHYSICAL HAZARD	0
PERSONAL PROTECTION	A

HAND SANITIZER RUB

HEALTH & SAFETY INFORMATION

! DANGER !

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80% ETHANOL RUB

Drug Facts	
Active ingredient(s)	Purpose
Alcohol 80% v/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	
• 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. There 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 20-30C (59-86F)	
• Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	



HEALTH	2
FLAMMABILITY	3
PHYSICAL HAZARD	0
PERSONAL PROTECTION	A



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

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

LOT #: 2002762

CONTENTS: 4X1 GALLONS

HAND SANITIZING RUB

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76796-085
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:76796			

1	NDC:76796-085-05	18927 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76796-085-55	208198 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76796-085-27	1040875 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
4	NDC:76796-085-04	15142 mL in 1 PACKAGE, COMBINATION; 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(76796-085)

Revised: 4/2020

CALVARY INDUSTRIES INC