

FOUR FATHERS DISTILLERY ALCOHOL ANTISEPTIC 80% - alcohol solution

Four Fathers Distillery LLC

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.

Four Fathers Distillery Alcohol Antiseptic 80%

Drug Facts

Active Ingredient(s)

Alcohol 80% v/v

☐ Purpose

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 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 serious condition.

Keep out of reach of children.

☐ If swallowed, get medical help or contact 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 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

Alcohol Antiseptic 80%/ Topical Solution

Hand Sanitizer/ Non-Sterile Solution

904-710-6150

Packaging

Four Fathers Distillery

Alcohol Antiseptic 80% / Topical Solution
Hand Sanitizer / Non-Sterile Solution

3785 ml / 1 gallon

904-710-6150



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alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78829-100
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)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78829-100-38	3785 mL in 1 JUG; Type 0: Not a Combination Product	06/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/10/2020	

Labeler - Four Fathers Distillery LLC (085564625)

Establishment

Name	Address	ID/FEI	Business Operations
Four Fathers Distillery LLC		085564625	manufacture(78829-100)

Revised: 10/2020

Four Fathers Distillery LLC