

INSTA-SHIELD HAND SANITIZER GEL- alcohol gel

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.

Insta-Shield Hand Sanitizer Gel

Drug Facts

Active ingredient(s):

Alcohol (ethanol) 65%.

Purpose

Antiseptic

Use(s):

Helps reduce bacteria that can potentially become disease.

WARNING

For external use only. FLAMMABLE: Keep away from heat and flame.

Do NOT USE: On children less than 2 months of age.

Do NOT USE: On open skin wounds.

Keep out of eyes, ears, and mouth. Stop use if rash or irritation occurs. This could be a sign of a serious condition.

Keep out of reach of children. If swallowed contact doctor or poison control right away.

Directions:

Place enough product on hands to cover all surfaces, rub together until dry.

Supervise children under 6 years of age to prevent swallowing.

Other Information:

Store between 59-86°F. DO NOT store in heat above 105°F. May discolor some fabrics. Harmful to wood surfaces and plastics.

Inactive ingredient(s):

Glycerin, Aloe Barbadosensis Leaf Juice, Hydroxyethylcellulose, Purified Water, Essential Oils

One Drop GEL

Alcohol Antiseptic 65%/Topical Solution


Produced & Bottled By Four Fathers Distillery
2917 Borden St., Jacksonville, FL 32209

MADE IN USA

FOUR FATHERS Distillery, Jacksonville, Florida

For questions, concerns or help please call the distillery at 904-710-615

Packaging




Hand Sanitizer


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FOUR FATHERS Distillery, Jacksonville, Florida
For questions, concerns or help please call the distillery at 904-710-6150






FOUR FATHERS
DISTILLERY




Insta-Shield

Hand Sanitizer


One Drop GEL



3785 ml / 1 gallon
Alcohol Antiseptic 65%/Topical Solution



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2917 Borden St., Jacksonville, FL 32209



INSTA-SHIELD HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78829-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
WATER (UNII: 059QF0KO0R)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78829-101-38	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(78829-101)

Revised: 10/2020

Four Fathers Distillery LLC