HAND SANITIZER- hand sanitizer liquid Kolts Fine Spirits

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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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

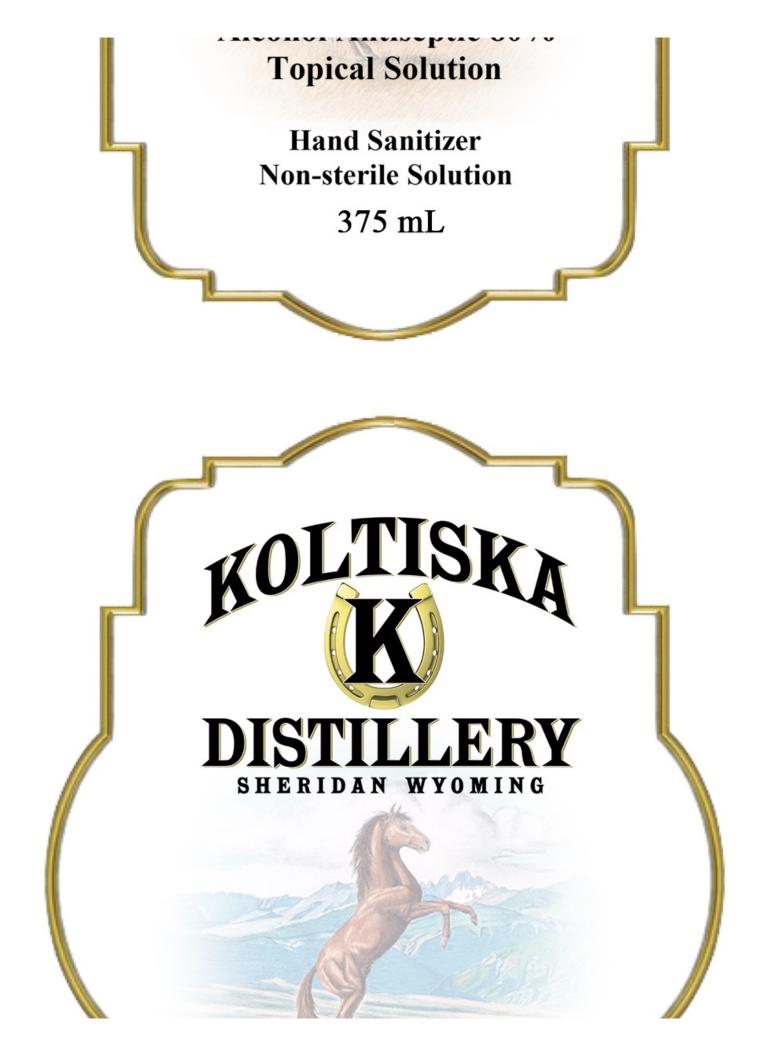
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel







Hand Sanitizer **Non-sterile Solution**

3785.41mL (1Gallon)

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Use[s]
Alcohol 80% v/v
Active ingredient[s]
Drug Facts

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Purpose

NDC: 74244-0375-01

3785.41mL NDC: 74244-0001-01

HAND SANITIZER							
hand sanitizer liquid							
Product Information							
Product T ype	HUMAN OTC DRUG	Item Code (Source) NDC:74244-0375			375		
Route of Administration	TOPICAL						
Active Ingredient/Active Moi	ety						
Ingred		Basis of Strength		Strength			
ALCOHOL (UNII: 3K9958V90M) (ALC		ALCOHOL		$300\ mL$ in $375\ mL$			
Inactive Ingredients							
Ing		Strength					
HYDROGEN PEROXIDE (UNII: BBX060AN9V)					0.468 mL in 375 mL		
WATER (UNII: 059QF0KO0R)					69.1 mL in 375 mL		
GLYCEROL FORMAL (UNII: 3L7GR2604E)					5.43 mL in 375 mL		
GLYCEROL FORMAL (UNII: 3L7GR26	504E)			5.43 mL in 37	75 mL		

375 mL

Packaging	3							
# Item C	Code		Mai	rketing Start Da	ate	Marketing End Date		
1 NDC:74244	4-0375-1	<u> </u>				0/2020		
Marketi	ng Inf	ormation						
	-		tion Number or Monograph C	itation	Ma	rketing Start Da	ite	Marketing End Date
-	Marketing CategoryApplication Number or Monograph CitationDTC monograph not finalpart333A							
HAND Sanand sanitize		IZER						
Product I	nforma	tion						
Product Ty	рe		HUMAN OTC DRUG	Ite m Co	ode (S	Source)	N	DC:74244-0001
Route of Ad		ation	TOPICAL			,		
Active Ing	radian	t/A atima Mai						
Active Ingredient/Active Moiety Ingredient Name Basis								
fictive ing	sreulen			В	Basis	of Strength		Strength
		Ingredie			Basis .coh	of Strength	028.	Strength 33 mL in 3785.41 mL
ALCOHOL (UNII: 3K9	Ingredie 9958V90M) (ALC	nt Name			•	028.	•
ALCOHOL (UNII: 3K9	Ingredie 9958V90M) (ALC ents	nt Name			DL 3		•
ALCOHOL (Inactive II	(UNII: 3K9 ng re die	Ingredie 9958V90M) (ALC ents	nt Name COHOL - UNII:3K9958V90M) edient Name			DL 3	Str	33 mL in 3785.41 mL ength
ALCOHOL (Inactive II HYDROGEN WATER (UNI	(UNII: 3K9 ng re die PERO XI II: 059 QF6	Ingredie 0958V90M) (ALC ents Ingre DE (UNII: BBX00 0KO0R)	nt Name COHOL - UNII:3K9958V90M) edient Name 60AN9V)			OL 31 4.73 mL in 3785.4 697.85 mL in 378	Str 41 ml 35.41	33 mL in 3785.41 mL ength L I mL
ALCOHOL (Inactive II HYDROGEN WATER (UNI	(UNII: 3K9 ng re die PERO XI II: 059 QF6	Ingredie 9958V90M) (ALC ents Ingre DE (UNII: BBX00	nt Name COHOL - UNII:3K9958V90M) edient Name 60AN9V)			OL 31	Str 41 ml 35.41	33 mL in 3785.41 mL ength L I mL
ALCOHOL (Inactive II HYDROGEN WATER (UNI GLYCEROL	UNII: 3K9 ng re die PERO XI II: 059 QF(FO RMA)	Ingredie 0958V90M) (ALC ents Ingre DE (UNII: BBX00 0KO0R)	nt Name COHOL - UNII:3K9958V90M) edient Name 60AN9V)			OL 31 4.73 mL in 3785.4 697.85 mL in 378	Str 41 ml 35.41	33 mL in 3785.41 mL ength L I mL
ALCOHOL (Inactive II HYDROGEN WATER (UNI GLYCEROL Packaging	UNII: 3K9 ng re die PERO XI II: 059 QF4 FORMAI	Ingredie 0958V90M) (ALC ents Ingre DE (UNII: BBX00 0KO0R)	nt Name COHOL - UNII:3K9958V90M) edient Name 60AN9V)		COH	OL 31 4.73 mL in 3785.4 697.85 mL in 378	Str (41 m] 35.41 41 m]	33 mL in 3785.41 mL ength L I mL
ALCOHOL (Inactive II HYDROGEN WATER (UNI GLYCEROL Packaging # Item C	UNII: 3K9 ng re die PERO XI II: 059 QF FO RMAI g Co de 4-000 1-	Ingredie 0958V90M) (ALC ents Ingre DE (UNII: BBX00 0KO0R) L (UNII: 3L7GR2	nt Name COHOL - UNII:3K9958V90M) edient Name 50AN9V) 604E)	AL	COH	DL 34 4.73 mL in 3785.4 697.85 mL in 378 54.5 mL in 3785.4 Marketing Star	Str (41 m] 35.41 41 m]	33 mL in 3785.41 mL ength L I mL L Marketing End
ALCOHOL (Inactive In Hydrogen WATER (UNI GLYCEROL Packaging # Item C 1 NDC:74244	UNII: 3K9 ng re die PERO XI II: 059 QF0 FORMAN G Co de 4-000 1-	Ingredie 9958 V90 M) (AL ents Ingre DE (UNII: BBX00 0K00 R) L (UNII: 3L7GR2 3785.41 mL in 1 h	nt Name COHOL - UNII:3K9958V90M) edient Name 50AN9V) 604E) Package Description	AL	COH	2) L 31 4.73 mL in 378 5.4 697.85 mL in 378 54.5 mL in 378 5.4 Marketing Star Date	Str (41 m] 35.41 41 m]	33 mL in 3785.41 mL ength L I mL L Marketing End
ALCOHOL (Inactive In Hydrogen WATER (UNI GLYCEROL Packaging # Item C 1 NDC:74244	UNII: 3K9 ng re die PERO XI II: 059 QF0 FORMAN 3 Code 4-0001-	Ingredie 9958 V90 M) (AL ents Ingre DE (UNII: BBX00 0 K00 R) L (UNII: 3L7GR2 3785.41 mL in 1 1 Product	nt Name COHOL - UNII:3K9958V90M) edient Name 50AN9V) 604E) Package Description	io n	03	2) L 31 4.73 mL in 378 5.4 697.85 mL in 378 54.5 mL in 378 5.4 Marketing Star Date	Str(41 ml 35.41 41 ml	33 mL in 3785.41 mL ength L I mL L Marketing End

Labeler - Kolts Fine Spirits (175799837)

Establishment

Name	Address	ID/FEI	Business Operations
Kolts Fine Spirits		175799837	manufacture(74244-0375, 74244-0001)

Revised: 3/2020

Kolts Fine Spirits