HAND SANITIZER- alcohol solution LiDestri Beverages, 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.



DRUG FACTS

ACTIVE INGREDIENT (S) Alcohol 70% v/v Antiseptic

PURPOSE

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. 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 fragrance, glycerin, hydrogen peroxide, water



Manufactured by LiDestri Spirits, A Family Company Recipe 21° • Rochester, NY 14606 • (866) 377-6701

1 GAL (3.78 L)

NOT FOR CONSUMPTION.

alcohol solution

Product Information

HAND SANITIZER

HUMAN OTC DRUG NDC:75539-003 Product Type Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
LINALOOL, (+/-)- (UNII: D81QY6I88E)	$0.007\ mL$ in $100\ mL$		
BENZYL BENZOATE (UNII: N863NB338G)	0.008 mL in 100 mL		
METHYL DIHYDRO JASMO NATE (SYNTHETIC) (UNII: 3GW44CIE3Y)	0.008 mL in 100 mL		
LIMO NENE, (+)- (UNII: GFD7C86Q1W)	0.036 mL in 100 mL		
ETHYL MALTOL (UNII: L6Q8K29L05)	0.004 mL in 100 mL		
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)	$0.004\ mL$ in $100\ mL$		
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		
HYDROGEN PERO XIDE (UNII: BBX060AN9V)	$0.125\ mL$ in $100\ mL$		
.ALPHAMETHYLBENZYL ACETATE (UNII: FYS3E9NBA3)	$0.003\;mL$ in $100\;mL$		
.GAMMAUNDECALACTO NE (UNII: QB1T0 AG2YL)	$0.003\;mL$ in $100\;mL$		

l	P	ackaging			
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:75539-003-03	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2020	

Marketing Infor	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/18/2020		

Labeler - LiDestri Beverages, LLC (151558413)

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