

DEAD LIGHTNING - HAND SANITIZER- dead lightning - hand sanitizer liquid

Dead Lightning 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.

Active Ingredients & Back Label

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that potentially 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. (Approx. 1/2 oz.) 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	
Date of Production _____	Batch Number _____

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Alcohol 80% v/vAntiseptic

Purpose Section

Use[s]
Hand Sanitizer to help reduce bacteria that potentially cause disease. For use when soap and water are not available.

Indications and usage section

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When using section

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Keep out of reach of children section

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Directions section

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Dosage and Administration

Place enough product on hands to cover all surfaces. (Approx. 1/2 oz.) Rub hands together until dry.

Other safety information

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Inactive ingredients section

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Date of Production & Batch Number

Date of Production

Batch Number



HAND SANITIZER
Alcohol Antiseptic 80%
Topical Solution

WHO Recommended Hand Rub
Formulation #1

FOR EXTERNAL USE ONLY
NOT SAFE FOR CONSUMPTION
NON-STERILE SOLUTION

NET WT.: 5 Gallons (18,926.06 ML)

Dead Lightning Distillery, LLC
233 Plum Street, Lemoyne, PA 17043
Made in USA

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75451-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	141.6 mL in 177 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.23 mL in 177 mL
WATER (UNII: 059QF0K00R)	32.6 mL in 177 mL
GLYCEROL FORMAL (UNII: 3L7GR2604E)	2.57 mL in 177 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75451-001-01	18927.06 mL in 1 PAIL; Type 0: Not a Combination Product	03/25/2020	
2	NDC:75451-001-02	7570.82 mL in 1 PAIL; Type 0: Not a Combination Product	03/25/2020	
3	NDC:75451-001-03	7570.82 mL in 1 JUG; Type 0: Not a Combination Product	03/25/2020	
4	NDC:75451-001-04	709.76 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/25/2020	
5	NDC:75451-001-05	739.34 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/25/2020	
6	NDC:75451-001-06	177.44 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/25/2020	
7	NDC:75451-001-07	236.59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/25/2020	

Labeler - Dead Lightning Distillery, llc (928310072)

Registrant - Dead Lightning Distillery, llc (928310072)

Establishment

Name	Address	ID/FEI	Business Operations
Dead Lightning Distillery, LLC		928310072	manufacture(75451-001)

Revised: 4/2020

Dead Lightning Distillery, llc