LUCAS HAND SANITIZER- alcohol liquid LUCAS OIL PRODUCTS, INC.

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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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



1893 mL NDC: 75182-100-64



59 mL NDC: 75182-100-02 1893 mL NDC: 75182-100-03

Alcohoi Antiseptic	Manufactured for and packaged by
LUCAS	Drug Facts Purpose Active ingredient(s) Purpose Alcohol 80% v/v Antiseptic
HAND SANITIZER	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
Alcohol Antiseptic 80% Topical Solution Hand Sanitizer	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. Dther information • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)
Non-Sterile Solution MADE IN USA 2 QT (64 FL OZ) 1.89 L	Inactive ingredients glycerin, hydrogen peroxide, purified water USP Lucas Oil Products, Inc. 302 N. Sheridan St. Corona, CA 92880 US/CAN/MEX (800) 342-2512 LucasOil.com 0 4 9 8 0 7 1 1 1 7 5 5

59 mL NDC: 75182-100-04



LUCAS HAND SANITIZER

alcohol liquid

Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:75182-100(NDC:74481-001)	
Route of Administration	TOPICAL				
Active Ingredient/Active I	Mojoty				
0	0		ъ ·		
Ingredient Name				s of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)					
ALCOHOL (UNII: 3K9958V90M)	(ALCOHOL - UNII:3K9958V9	00 M)	ALCOH	OL	80 mL in 100 mL
	(ALCOHOL - UNII:3K9958V9	00 M)	ALCOH	OL	80 mL in 100 mL
	(ALCOHOL - UNII:3K9958V9 Ingredient Name	00 M)	ALCOH		80 mL in 100 mL t rength
Inactive Ingredients	Ingredient Name	90 M)	ALCOH		•
Inactive Ingredients GLYCERIN (UNII: PDC6A3C0OX)	Ingredient Name	00 M)	ALCOH	SI	t rength nL
ALCOHOL (UNII: 3K9958V90M) Inactive Ingredients GLYCERIN (UNII: PDC6A3C0OX) HYDROGEN PEROXIDE (UNII: BH WATER (UNII: 059QF0K00R)	Ingredient Name	00 M)	ALCOH	St 1.45 mL in 100 r	t rength nL

Packaging						
# Item Code	Package Description	Marketing Star Date	t Marketing End Date			
1 NDC:75182-100- 03	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combina Product	tio n 04/16/2020				
2 NDC:75182-100- 04	DC:75182-100- 59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product					
Marketing Ir	formation					
Marketing Ir		n Marketing Start Date	Marketing End Date			

Labeler - LUCAS OIL PRODUCTS, INC. (622731073)

Establishment					
Name	Address	ID/FEI	Business Operations		
Lucas Oil Racing, Inc.		141034798	repack(75182-100), label(75182-100)		

Revised: 4/2020

LUCAS OIL PRODUCTS, INC.