## LEWCIZER 3- alcohol liquid A.P. Nonweiler Co., 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.

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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.

#### 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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#### 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**

hydrogen peroxide, aloe vera gel, sterile water

Package Label - Principal Display Panel500 mL NDC: 74829-359-08



946.35 mL NDC: 74829-359-04

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-sterile Solution

1 U.S. quart



A.P. Nonweiler Co., Dnc.

3321 County Road A Oshkosh, WI 54901 www.apnonweiler.com

3785.41 mL NDC: 74829-359-01

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-sterile Solution

1 U.S. gallon



A.P. Nonweiler Co., Dnc.

3321 County Road A Oshkosh, WI 54901 www.apnonweiler.com

18927.06 mL NDC: 74829-359-05

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-sterile Solution

5 U.S. gallons



A.P. Nonweiler Co., Dnc.

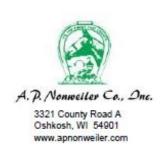
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208197.65 mL NDC: 74829-359-50

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-sterile Solution

50 U.S. gallons

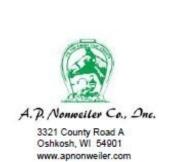


1040988.24 mL NDC: 74829-359-25

Alcohol Antiseptic 80% **Topical Solution** 

Hand Sanitizer Non-sterile Solution

250 U.S. gallons



3785.41 mL NDC: 74829-359-01IS2



Shake Well

1 U.S. gallon (3.79 L) Made in the USA

Distributed by IS2 LLC Oshkosh, WI 302-379-1265 www.is2sanitizer.com

LEWCIZER 3					
alcohol liquid					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74829-359		
Route of Administration	TOPICAL				

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80.5 mL in 100 mL
nactive Ingredients		
Ingredient Name		Strength
IYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.2 mL in	100 mL
VATER (UNII: 059QF0KO0R)		
SOPROPYL ALCOHOL (UNII: ND2M416302)	4.2 mL in	100 mL
		100 mL

Packaging
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#	Item Code	Package Description		Marketi Start Da	0	Marketing End Date	
1	NDC:74829- 359-04	946.35 mL in 1 BOTTLE; Type 0: Not a Combination Product		04/22/2020			
2	NDC:74829- 359-01	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product			04/16/2020		
3	NDC:74829- 359-05	18927.06 mL in 1 PAIL; Type 0: Not a Combination Product			04/16/2020		
4	NDC:74829- 359-50	208197.65 mL in 1 DRUM; Type 0: Not a Combination Product			04/22/2020		
5	NDC:74829- 359-25	1040988.24 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0 Not a Combination Product			04/22/2020		
6	NDC:74829- 359-08	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		uct	05/14/2020		
Marketing Information							
	Marketing Ca	tegory	Application Number or Monograph Citation	Marketing	Start Date	Mark	eting End Date
0	OTC monograph not final part333A 04/16/2020		part333A	04/16/2020			

# Labeler - A.P. Nonweiler Co., Inc. (006069298)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
A.P. Nonweiler Co., Inc.		006069298	manufacture(74829-359)		

Revised: 10/2020

A.P. Nonweiler Co., Inc.