

LEWCIZER 4- 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.

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, GLYCERIN, STERILE WATER

Package Label - Principal Display Panel

500 mL NDC: 74829-361-08

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

500 mL



A.P. Nonweiler Co., Inc.

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

3785.41 mL NDC: 74829-361-01

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

1 U.S. gallon



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18927.06 mL NDC: 74829-361-05

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

5 U.S. gallons



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189270.59 mL NDC: 74829-361-50

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

50 U.S. gallons



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946352.95 mL NDC: 74829-361-25

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

250 U.S. gallons



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3321 County Road A
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946.35 mL NDC: 74829-361-04

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer
Non-sterile Solution

1 U.S. quart



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LEWCIZER 4

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74829-361
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80.8 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	4.2 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	1.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74829-361-01	3785.41 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/22/2020	

2	NDC:74829-361-05	18927.06 mL in 1 PAIL; Type 0: Not a Combination Product	04/22/2020	
3	NDC:74829-361-50	208197.65 mL in 1 DRUM; Type 0: Not a Combination Product	04/22/2020	
4	NDC:74829-361-25	1040988.24 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	04/22/2020	
5	NDC:74829-361-04	946.35 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/22/2020	
6	NDC:74829-361-08	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/22/2020	

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

Establishment

Name	Address	ID/FEI	Business Operations
A.P. Nonweiler Co., Inc.		006069298	manufacture(74829-361)

Revised: 10/2020

A.P. Nonweiler Co., Inc.