

LEWCIZER 6- 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.

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, sterile water

Package Label - Principal Display Panel

250 mL NDC: 74829-365-08

**Alcohol Antiseptic 80%
Topical Solution**

**Hand Sanitizer
Non-sterile Solution**

250 mL

**Lemon Scent
Liquid Formula**

500 mL NDC: 74829-365-16



A.P. Nonweiler Co., Inc.

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

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

500 mL

Lemon Scent
Liquid Formula

3785 mL NDC: 74829-365-01

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

1 U.S. gallon

Lemon Scent
Liquid Formula

18927 mL NDC: 74829-365-05



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Topical Solution

Hand Sanitizer
Non-sterile Solution

5 U.S. gallons

Lemon Scent
Liquid Formula

208197 mL NDC: 74829-365-50



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Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

50 U.S. gallons

Lemon Scent
Liquid Formula

1040988 mL NDC: 74829-365-25



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Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-sterile Solution

250 U.S. gallons

Lemon Scent
Liquid Formula



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LEWCIZER 6

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74829-365
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	81.1 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.5 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.2 mL in 100 mL
WATER (UNII: 059QF0K00R)	13 mL in 100 mL
CITRAL (UNII: T7EU009VPP)	0.1 mL in 100 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302)	4.1 mL in 100 mL

Packaging

		Marketing	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74829-365-16	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/23/2020	
2	NDC:74829-365-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/23/2020	
3	NDC:74829-365-08	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/23/2020	
4	NDC:74829-365-05	18927 mL in 1 PAIL; Type 0: Not a Combination Product	07/23/2020	
5	NDC:74829-365-50	208197 mL in 1 DRUM; Type 0: Not a Combination Product	07/23/2020	
6	NDC:74829-365-25	1040988 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	07/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/22/2020	

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

Establishment

Name	Address	ID/FEI	Business Operations
A.P. Nonweiler Co., Inc.		006069298	manufacture(74829-365)

Revised: 10/2020

A.P. Nonweiler Co., Inc.