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.

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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

fragrance, glycerin, hydrogen peroxide, sterile water

Package Label - Principal Display Panel

250 mL NDC: 74829-365-08

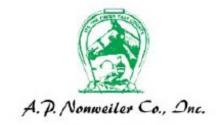
Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer
Non-sterile Solution

250 mL

Lemon Scent Liquid Formula

500 mL NDC: 74829-365-16



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



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18927 mL NDC: 74829-365-05

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer
Non-sterile Solution

5 U.S. gallons

Lemon Scent Liquid Formula

208197 mL NDC: 74829-365-50

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer
Non-sterile Solution

50 U.S. gallons

Lemon Scent Liquid Formula



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1040988 mL NDC: 74829-365-25

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

Proc	luct	Infor	mation

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 PERO XIDE (UNII: BBX060AN9V)	0.2 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	13 mL in 100 mL		
CITRAL (UNII: T7EU0O9VPP)	0.1 mL in 100 mL		
ISOPROPYL ALCOHOL (UNII: ND2M416302)	4.1 mL in 100 mL		

Packaging				
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#	Item Code	Package Description	Start Date	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.