# LEWCIZER 3- alcohol liquid A.P. Nonweiler

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

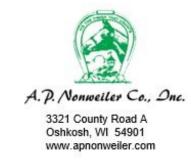
### Package Label - Principal Display Panel

946.35 mL NDC: 74829-359-04

# Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer
Non-sterile Solution

1 U.S. quart

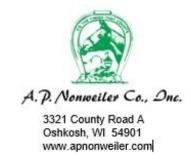


3785.41 mL NDC: 74829-359-01

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer
Non-sterile Solution

1 U.S. gallon

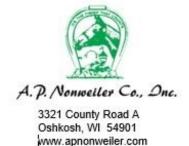


18927.06 mL NDC: 74829-359-05

# Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer
Non-sterile Solution

5 U.S. gallons



208197.65 mL NDC: 74829-359-50

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer
Non-sterile Solution

50 U.S. gallons

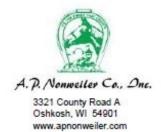


1040988.24 mL NDC: 74829-359-25

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-sterile Solution

250 U.S. gallons



### **LEWCIZER 3**

alcohol liquid

| n |    | A |     | Info             | rma   | tion |
|---|----|---|-----|------------------|-------|------|
| r | ΙU | u | uct | $\mathbf{IIII0}$ | Tilla | uon  |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:74829-359

Route of Administration TOPICAL

| Active Ingredient/Active Moiety                        |                   |                   |  |  |  |
|--|-------------------|-------------------|--|--|--|
| Ingredient Name  | Basis of Strength | Strength          |  |  |  |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 80.5 mL in 100 mL |  |  |  |

| Inactive Ingredients                   |                  |  |  |  |
|--|------------------|--|--|--|
| Ingredient Name                        | Strength         |  |  |  |
| HYDRO GEN PERO XIDE (UNII: BBX060AN9V) | 0.2 mL in 100 mL |  |  |  |
| WATER (UNII: 059QF0KO0R)               |                  |  |  |  |
| ISOPROPYL ALCOHOL (UNII: ND2M416302)   | 4.2 mL in 100 mL |  |  |  |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)      | 1.8 mL in 100 mL |  |  |  |

| Packaging |                      |   |                         |                       |  |  |
|-----------|----------------------|---|-------------------------|-----------------------|--|--|
| #         | Item Code            | Package Description                                       | Marketing<br>Start Date | Marketing<br>End Date |  |  |
| 1         | NDC:74829-<br>359-04 | 946.35 mL in 1 BOTTLE; Type 0: Not a Combination Product  | 04/22/2020              |                       |  |  |
| 2         | NDC:74829-<br>359-01 | 3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/16/2020              |                       |  |  |
| 3         | NDC:74829-<br>359-05 | 18927.06 mL in 1 PAIL; Type 0: Not a Combination Product  | 04/16/2020              |                       |  |  |

| N | Marketing  Marketing Ca |          |  | arketing S | tart Date Ma | rketing End Date |  |
|---|-------------------------|----------|--|------------|--------------|------------------|--|
| N | <b>Tarketing</b>        | Inform   | nation   |            |              |                  |  |
|   |                         |          |  |            |              |                  |  |
|   |                         |          |  |            |              |                  |  |
| 5 | NDC:74829-<br>359-25    |          | 40988.24 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: ot a Combination Product |            |              |                  |  |
| 4 | NDC:74829-<br>359-50    | 208197.6 | 5 mL in 1 DRUM; Type 0: Not a Combination Product  |            | 04/22/2020   |                  |  |

# **Labeler** - A.P. Nonweiler (006069298)

| Establishment  |         |           |                        |  |  |
|----------------|---------|-----------|------------------------|--|--|
| Name           | Address | ID/FEI    | Business Operations    |  |  |
| A.P. Nonweiler |         | 006069298 | manufacture(74829-359) |  |  |

Revised: 4/2020 A.P. Nonweiler