

ADVANCED HAND SANITIZER- alcohol liquid

Sanare Bioscience

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.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

For hand washing to decrease bacteria on the skin - recommended for repeated use.

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

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 occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help immediately or contact a Poison Control Center immediately

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

Wet hands thoroughly with product, and allow to dry without wiping. For children under six, use only under adult supervision

Other information

- Store between 15-30C. Avoid freezing and excessive heat above 40C (104F). May discolor some fabrics. Harmful to wood finishes and plastics

Inactive ingredients

glycerin, hydrogen peroxide, Lemon Grass Fragrance, purified water USP

Package Label - Principal Display Panel

SANARE BIOSCIENCE
 INNOVATES TO HEAL, TO BALANCE, TO CORRECT
ADVANCED Hand Sanitizer
 8 FL OZ (236 mL)
 Lemon Grass Fragrance

2X MORE STRENGTH Kills 99.99% of most illness causing germs*
 10% more alcohol than leading brands

Drug Facts
Active Ingredients Purpose Ethyl Alcohol 60%..... Antiseptic, Hand Sanitizer
Directions - For hand washing to decrease bacterial on the skin - recommended for repeated use
Warnings - For external use only. If accessible, keep away from face and eyes
Precautions - Children less than 2 months of age - Do not use on the face
When using this product - Keep out of eyes, ears, and mouth. In case of contact with eyes, do away as thoroughly with water. Stop use and get a doctor's attention as soon as there may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help, show label or contact a poison control center immediately
Directions - Wet hands thoroughly with product, and allow to dry without wiping. For children under six, use only under adult supervision
Inactive Ingredients - Purified water, hydrogen peroxide, and glycerin, Lemon Grass Fragrance
Other Information - Store between 15-30°C. Avoid excessive heat above 40°C (104°F). May discolor some fabrics. Harmful to wood finishes and plastics

Manufactured at 3301 Eastern Avenue • Fall River, MA 01924 • 401.735.6290
 *Based on alcohol content of leading brands for antiseptic and ethyl alcohol only. See NDC 78515-001-04 for more information. ©2019 Sanare Bioscience, Inc. All rights reserved. NDC: 78515-001-02

NDC: 78515-001-02

or

4 oz (118 mL) NDC: 78515-001-04

or

8 oz (236 mL) NDC: 78515-001-08

or

128 oz (3785 mL) NDC: 78515-001-28

ADVANCED HAND SANITIZER			
alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78515-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78515-001-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78515-001-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78515-001-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78515-001-28	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Sanare Bioscience (117382399)

Registrant - Sanare Bioscience (117382399)

Establishment

Name	Address	ID/FEI	Business Operations
Sonare Bioscience		117382399	manufacture(78515-001)