EDEN HAND SANITIZER- alchohol gel
Rx SAN LLC

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

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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

EDEN

ALL THINGS NATURAL

HAND SANITIZER

KILLS 99.9% OF GERMS*

CONTAINS ALOE & VITAMIN E

16 Fluid Oz (473 mL)

Drug Facts

Active ingredient	***Purpose***
70% Ethyl Alcohol	Antimicrobial

Warnings

For external use only-hands

Flammable. Keep away from heat and flame

When using this product ■ Keep out of eyes, in case of contact with eyes, flush thoroughly with water. ■ Avoid contact with broken skin ■ Do not inhale or ingest.

Stop use and ask a doctor if skin irritation develops.

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 6, use only under adult supervision ■ Not recommended for infants

Other information ■ Store below 43°C (110°F)

Inactive ingredients: Water, Glycerin, Acrylate Copolymer, Triethanolamine, Aloe Vera Juice, Tocopheryl Acetate, Fragrance

*Effective at eliminating more than 99.9% of many common harmful germs and bacteria in as little as 15 seconds.

Enriched with Vitamin E and Aloe Vera extract.

NDC: 78662-702-16
Manufactured by: Rx San, LLC
1877 E 17th Ave. Columbus, OH 43219

EDEN

ALL THINGS NATURAL

HAND SANITIZER

KILLS 99.9% OF GERMS*

CONTAINS ALOE & VITAMIN E

1 Gallon (3.785 L)

Drug Facts

Active ingredient	***Purpose***
70% Ethyl Alcohol	Antimicrobial

Warnings

For external use only-hands

Flammable. Keep away from heat and flame

When using this product ■ Keep out of eyes, in case of contact with eyes, flush thoroughly with water. ■ Avoid contact with broken skin ■ Do not inhale or ingest.

Stop use and ask a doctor if skin irritation develops.

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 6, use only under adult supervision ■ Not recommended for infants

Other information ■ Store below 43°C (110°F)

Inactive ingredients: Water, Glycerin, Acrylate Copolymer, Triethanolamine, Aloe Vera Juice, Tocopheryl Acetate, Fragrance

*Effective at eliminating more than 99.9% of many common harmful germs and bacteria in as little as 15 seconds.

Enriched with Vitamin E and Aloe Vera extract.

NDC: 78662-702-01
Manufactured by: Rx San, LLC
1877 E 17th Ave. Columbus, OH 43219

EDEN

ALL THINGS NATURAL

HAND SANITIZER

KILLS 99.9% OF GERMS*

CONTAINS ALOE & VITAMIN E

8 Fluid Oz (237 mL)

Drug Facts

Active ingredient	***Purpose***
70% Ethyl Alcohol	Antimicrobial

Warnings

For external use only-hands

Flammable. Keep away from heat and flame

When using this product ■ Keep out of eyes, in case of contact with eyes, flush thoroughly with water. ■ Avoid contact with broken skin ■ Do not inhale or ingest.

Stop use and ask a doctor if skin irritation develops.

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 6, use only under adult supervision ■ Not recommended for infants

Other information ■ Store below 43°C (110°F)

Inactive ingredients: Water, Glycerin, Acrylate Copolymer, Triethanolamine, Aloe Vera Juice, Tocopheryl Acetate, Fragrance

*Effective at eliminating more than 99.9% of many common harmful germs and bacteria in as little as 15 seconds.

Enriched with Vitamin E and Aloe Vera extract.

NDC: 78662-702-08
Manufactured by: Rx San, LLC
1877 E 17th Ave. Columbus, OH 43219

EDEN
ALL THINGS NATURAL

HAND SANITIZER

KILLS 99.9% OF GERMS*

CONTAINS ALOE & VITAMIN E

4 Fluid Oz (118 mL)

Drug Facts

Active ingredient	Purpose
70% Ethyl Alcohol	Antimicrobial

Warnings

For external use only-hands

Flammable. Keep away from heat and flame

When using this product ■ Keep out of eyes, in case of contact with eyes, flush thoroughly with water. ■ Avoid contact with broken skin ■ Do not inhale or ingest.

Stop use and ask a doctor if skin irritation develops.

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 6, use only under adult supervision ■ Not recommended for infants

Other information ■ Store below 43°C (110°F)

Inactive ingredients: Water, Glycerin, Acrylate Copolymer, Triethanolamine, Aloe Vera Juice, Tocopheryl Acetate, Fragrance

*Effective at eliminating more than 99.9% of many common harmful germs and bacteria in as little as 15 seconds.

Enriched with Vitamin E and Aloe Vera extract.

NDC: 78662-702-04
Manufactured by: Rx San, LLC
1877 E 17th Ave Columbus, Oh 43201

EDEN HAND SANITIZER

alchohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78662-702
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	73.7 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
ECAMSULE DITRIETHANOLAMINE (UNII: 078Q44I6CD)	0.24 mL in 100 mL
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	1.8 mL in 100 mL
.ALPHA.-CITRONELLAL (UNII: A02IC9965Z)	0.3 mL in 100 mL
ALOE (UNII: V5VD430YW9)	0.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78662-702-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
2	NDC:78662-702-16	473 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/2021	
3	NDC:78662-702-12	355 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/2021	
4	NDC:78662-702-04	118 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/2021	
5	NDC:78662-702-75	1041000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	01/01/2021	
6	NDC:78662-702-50	18927 mL in 1 CONTAINER; Type 0: Not a Combination Product	01/01/2021	
7	NDC:78662-702-02	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/01/2021	

Labeler - Rx SAN LLC (117536764)

Registrant - Rx SAN LLC (117536764)

Establishment

Name	Address	ID/FEI	Business Operations
Rx SAN		117536764	manufacture(78662-702)

Establishment

Name	Address	ID/FEI	Business Operations
Vitalpure Labs LLC		117797259	manufacture(78662-702)