

HANDZITIZER- alcohol gel
SYNBIONIC EVOLUTION, 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.

Hanzitizer

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

HANDZITIZER



Antiseptic Hand Gel

Kills harmful bacteria and germs

ACTIVE INGREDIENT: Alcohol, USP grade. 80% V/V.

PURPOSE: Antiseptic, Hand Sanitizer

USE: To help reduce bacteria that potentially can cause disease. For when soap and water are not available.

WARNING: For external use only. Flammable. Keep away from heat or flame.

DO NOT USE: In children less than 2 months of age, or 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 15-30°C (59-86°F). Avoid freezing and excessive heat above 40°C (104°F).

NON MEDICINAL INGREDIENTS: Purified Water USP, Glycerin, Acrylic Acid Copolymer

NDC: 79536-001-01

Manufactured by:

SynBionic Évolution Inc. Lot#

Exp:

255 Ave. Labrosse, Pointe-Claire, Québec, Canada H9R 1A3

4L



HANDZITIZER

alcohol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:79536-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79536-001-01	4 L in 1 JUG; Type 0: Not a Combination Product	10/08/2020	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/08/2020	

Labeler - SYNBIOTIC EVOLUTION, INC. (205437896)

Registrant - SYNBIOTIC EVOLUTION, INC. (205437896)

Establishment

Name	Address	ID/FEI	Business Operations
SYNBIONIC EVOLUTION, INC.		205437896	manufacture(79536-001) , label(79536-001) , pack(79536-001)

Revised: 10/2020

SYNBIONIC EVOLUTION, INC.