

HANDZITIZER- gel hand sanitizer 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.

Handzitizer

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.

Warning

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

Non medicinal ingredients

Purified water USP, Glycerin, Acrylic Acid Copolymer

Use

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

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.

Purpose

Antiseptic, Hand Sanitizer

Active Ingredient:

Alcohol, USP grade. 70% V/V

Handzitizer

HANDZITIZER



Antiseptic Hand Gel

Kills harmful bacteria and germs

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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.

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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: 79536-002-01

Manufactured by:

SynBionic Évolution Inc. Lot#

Exp:

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

4L



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

NDC: 79536-002-02

Manufactured by:

SynBionic Évolution Inc. Lot#

Exp:

255 Ave. Labrosse, Pointe-Claire, Québec, Canada H9R 1A3 1000L



HANDZITIZER

gel hand sanitizer gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:79536-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 934 (UNII: Z135WT9208)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79536-002-01	4000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/09/2020	
2	NDC:79536-002-02	1000000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	11/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/09/2020	

Labeler - SYNBIOTIC EVOLUTION, INC. (205437896)

Registrant - SYNBIOTIC EVOLUTION, INC. (205437896)

Establishment

Name	Address	ID/FEI	Business Operations
SYNBIONIC EVOLUTION, INC.		205437896	manufacture(79536-002)

Revised: 11/2020

SYNBIONIC EVOLUTION, INC.