### ALTAIO HAND SANITIZER- alcohol spray BIONATEO SP Z O O

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 ALTAIO 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):

- 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. Glycerin (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)

Ethyl 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

- on 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

• Spray 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**

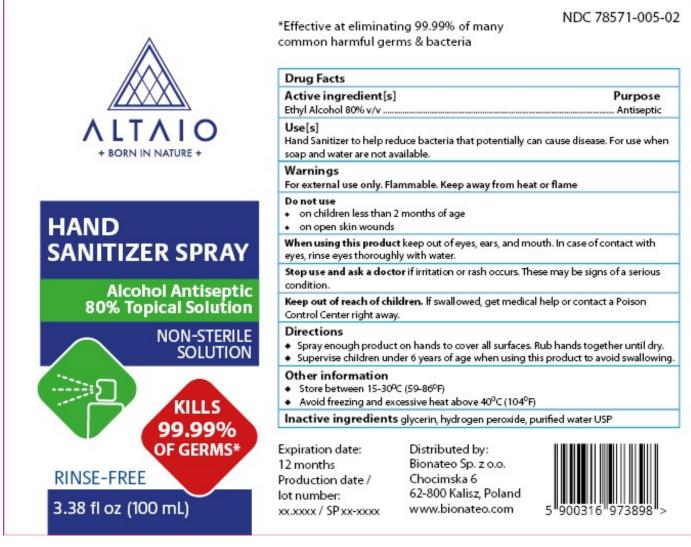
glycerin, hydrogen peroxide, purified water USP

#### Package Label - Principal Display Panel

50 mL NDC: 78571-005-01



100 mL NDC: 78571-005-02



1000 mL NDC: 78571-005-03



# ALTAIO HAND SANITIZER

alcohol spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Sou	rce)	NDC:78571-005
Route of Administration	TOPICAL			
A .1 T 31 ./A .1 3.F	• .			
Active Ingredient/Active Mo	iety			
Ingre	dient Name	Ba	sis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (AL	ALCOHOL		80 mL in 100 mL	
Inactive Ingredients				
Ŭ	ıgredient Name		5	Strength
Ŭ	ıgredient Name		5 1.45 mL in 100	•
I				mL

Packaging								
#	Item Code		Package Description	Marketing Start Date	Marketing End Date			
1	NDC:78571-005- 01	50 m Produ	L in 1 BOTTLE, SPRAY; Type 0: Not a Combination lct	06/25/2020				
2	NDC:78571-005- 02	100 m Produ	nL in 1 BOTTLE, SPRAY; Type 0: Not a Combination act	06/25/2020				
3	NDC:78571-005- 03	1000 Produ	mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination act	06/25/2020				
Marketing Information								
Marketing Category			Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final		final	part333A	06/25/2020				

Labeler - BIONATEO SP Z O O (438233495)

# **Registrant** - BIONATEO SP Z O O (438233495)

# Establishment

Name	Address	ID/FEI	Business Operations
BIONATEO SP Z O O		438233495	manufacture(78571-005)

Revised: 6/2020

BIONATEO SP Z O O