# ALTAIO HAND SANITIZER- alcohol liquid 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 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)**

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**

- 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

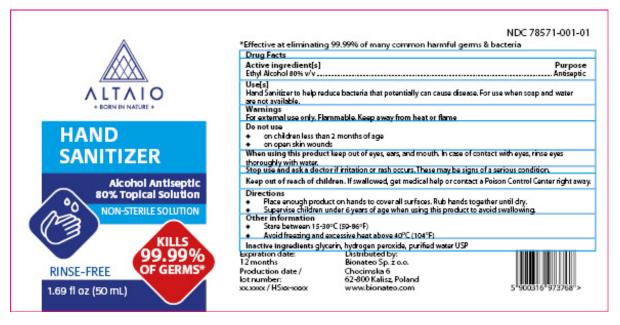
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

50 mL NDC: 78571-001-01



100 mL NDC: 78571-001-02





5000 mL NDC: 78571-001-03

\*Effective at eliminating 99.99% of many common harmful germs & bacteria

## **Drug Facts**

### Active ingredient[s]

Purpose

Ethyl Alcohol 80% v/v ....

Antiseptic

## Use[s]

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**Inactive ingredients** glycerin, hydrogen peroxide, purified water USP

Expiration date: 12 months Production date / lot number: xx.xxxx / HSxx-xxxx Distributed by: Bionateo Sp. z o.o. Chocimska 6 62-800 Kalisz, Poland www.bionateo.com







20000 mL NDC: 78571-001-04

\*Effective at eliminating 99.99% of many common harmful germs & bacteria

## **Drug Facts**

### Active ingredient[s]

Ethyl Alcohol 80% v/v ......

## Purpose

Antiseptic

#### Use[s]

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## **Drug Facts**

### Active ingredient[s]

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Purpose

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200000 mL NDC: 78571-001-05

5.28 gal (20 L)



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## **Drug Facts**

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1000000 mL NDC: 78571-001-06

52.83 gal (200 L)





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## **Drug Facts**

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## ALTAIO HAND SANITIZER

alcohol liquid

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:78571-001

Route of Administration **TOPICAL** 

## **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII: 3K9958 V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients				
Strength				
1.45 mL in 100 mL				
0.125 mL in 100 mL				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:78571-001- 01	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/25/2020		
2	NDC:78571-001- 02	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/25/2020		
3	NDC:78571-001- 03	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/25/2020		
4	NDC:78571-001- 04	20000 mL in 1 CONTAINER; Type 0: Not a Combination Product	06/25/2020		
5	NDC:78571-001- 05	200000 mL in 1 DRUM; Type 0: Not a Combination Product	06/25/2020		
6	NDC:78571-001- 06	1000000 mL in 1 TANK; Type 0: Not a Combination Product	06/25/2020		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	06/25/2020				

# Labeler - BIONATEO SPZOO (438233495)

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

Establishment					
Name	Address	ID/FEI	Business Operations		
BIONATEO SP Z O O		438233495	manufacture (78571-001)		

Revised: 6/2020 BIONATEO SP Z O O