

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.

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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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

50 mL NDC: 78571-001-01

NDC 78571-001-01

*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) 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.	
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Inactive Ingredients glycerin, hydrogen peroxide, purified water USP	

Expiration date: 12 months
Production date / lot number: xxxxxxxx / HSxxxxxxx

Distributed by:
Bionateo Sp. z o.o.
Chocimska 6
62-800 Kalisz, Poland
www.bionateo.com

5 900316 973768 >

100 mL NDC: 78571-001-02

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



HAND SANITIZER

**Alcohol Antiseptic
80% Topical Solution**

NON-STERILE SOLUTION

KILLS 99.99% OF GERMS*

RINSE-FREE

3.38 fl oz (100 mL)

5000 mL NDC: 78571-001-03

Drug Facts	
Active ingredient[s]	Purpose
Ethyl Alcohol 80% v/v	Antiseptic
Use[s] 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 <ul style="list-style-type: none"> 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.	
Directions <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Store between 15-30°C (59-86°F) Avoid freezing and excessive heat above 40°C (104°F) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

Expiration date:
12 months
Production date /
lot number:
xx.xxxx / HSxx-xxxx

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**HAND
SANITIZER**

**Alcohol Antiseptic
80% Topical Solution**

**NON-STERILE
SOLUTION**

**KILLS
99.99%
OF GERMS***

RINSE-FREE

1.32 gal (5 L)

20000 mL NDC: 78571-001-04

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]	
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	
<ul style="list-style-type: none"> ◆ 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.	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

Expiration date:
12 months
Production date /
lot number:
xx.xxxx / HSxx-xxxx

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**HAND
SANITIZER**

**Alcohol Antiseptic
80% Topical Solution**

**NON-STERILE
SOLUTION**



**KILLS
99.99%
OF GERMS***

RINSE-FREE

5.28 gal (20 L)

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

NDC 78571-001-04

Drug Facts	
Active ingredient[s]	Purpose
Ethyl Alcohol 80% v/v	Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

Expiration date:
12 months
Production date /
lot number:
xx.xxxx / HSxx-xxxx

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200000 mL NDC: 78571-001-05



**HAND
SANITIZER**

**Alcohol Antiseptic
80% Topical Solution**

**NON-STERILE
SOLUTION**



**KILLS
99.99%
OF GERMS***

RINSE-FREE

52.83 gal (200 L)

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

NDC 78571-001-05

Drug Facts	
Active ingredient[s]	Purpose
Ethyl Alcohol 80% v/v	Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

Expiration date:
12 months
Production date /
lot number:
xx.xxxx / HSxx-xxxx

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1000000 mL NDC: 78571-001-06



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

NDC 78571-001-06

HAND SANITIZER

**Alcohol Antiseptic
80% Topical Solution**

NON-STERILE SOLUTION

KILLS 99.99% OF GERMS*

RINSE-FREE

264.17 gal (1000 L)

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic
Use[s]	
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	
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Inactive ingredients	
glycerin, hydrogen peroxide, purified water USP	

Expiration date:
12 months
Production date /
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xx.xxxx / SWxx-xxxx

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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: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0K00R)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	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 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(78571-001)

Revised: 6/2020

BIONATEO SP Z O O