

## **ALTAIO HAND SANITIZING GEL- 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.*

-----

The ALTAIO Hand Sanitizing Gel is manufactured using 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.

### **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.

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

50 mL NDC: 78571-002-01

**ALTAIO**  
+ BORN IN NATURE +

**HAND SANITIZING GEL**

Alcohol Antiseptic  
80% Topical Solution  
NON-STERILE SOLUTION

RINSE-FREE  
1.69 fl oz (50 mL)

**KILLS 99.99% OF GERMS\***

NDC 78571-002-01

\*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.	
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.	
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)	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

Expiration date:  
12 months

Production date /  
lot number:  
xxxxxxx / HGI001-xxxx

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

5 900316 973511 >

100 mL NDC: 78571-002-02



# HAND SANITIZING GEL

Alcohol Antiseptic  
80% Topical Solution

NON-STERILE  
SOLUTION



**KILLS  
99.99%  
OF GERMS\***

RINSE-FREE

3.38 fl oz (100 mL)

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

NDC 78571-002-02

Drug Facts	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Ethyl Alcohol 80% v/v .....	Antiseptic
<b>Use[s]</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>◆ on children less than 2 months of age</li> <li>◆ on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>◆ Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>◆ Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>◆ Store between 15-30°C (59-86°F)</li> <li>◆ Avoid freezing and excessive heat above 40°C (104°F)</li> </ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

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

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



500 mL NDC: 78571-002-03



# HAND SANITIZING GEL

Alcohol Antiseptic  
80% Topical Solution

NON-STERILE  
SOLUTION



**KILLS  
99.99%  
OF GERMS\***

RINSE-FREE

16.9 fl oz (500 mL)

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

NDC 78571-002-03

Drug Facts	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Ethyl Alcohol 80% v/v .....	Antiseptic
<b>Use[s]</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>◆ on children less than 2 months of age</li> <li>◆ on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>◆ Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>◆ Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>◆ Store between 15-30°C (59-86°F)</li> <li>◆ Avoid freezing and excessive heat above 40°C (104°F)</li> </ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

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

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



1000 mL NDC: 78571-002-04



# HAND SANITIZING GEL

Alcohol Antiseptic  
80% Topical Solution

NON-STERILE  
SOLUTION



**KILLS  
99.99%  
OF GERMS\***

RINSE-FREE

33.81 fl oz (1 L)

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

NDC 78571-002-04

Drug Facts	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Ethyl Alcohol 80% v/v .....	Antiseptic
<b>Use[s]</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>◆ on children less than 2 months of age</li> <li>◆ on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>◆ Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>◆ Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>◆ Store between 15-30°C (59-86°F)</li> <li>◆ Avoid freezing and excessive heat above 40°C (104°F)</li> </ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

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

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



5000 mL NDC: 78571-002-05



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

NDC 78571-002-05

**HAND SANITIZING GEL**

Alcohol Antiseptic  
80% Topical Solution

NON-STERILE SOLUTION

**KILLS 99.99% OF GERMS\***

RINSE-FREE

1.32 gal (5 L)

Drug Facts	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Ethyl Alcohol 80% v/v .....	Antiseptic
<b>Use[s]</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>on children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store between 15-30°C (59-86°F)</li> <li>Avoid freezing and excessive heat above 40°C (104°F)</li> </ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

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

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



## ALTAIO HAND SANITIZING GEL

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78571-002
<b>Route of Administration</b>	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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78571-002-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/26/2020	
2	NDC:78571-002-02	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/26/2020	
3	NDC:78571-002-03	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/26/2020	
4	NDC:78571-002-04	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/26/2020	
5	NDC:78571-002-05	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/26/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/26/2020	

**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(78571-002)

Revised: 6/2020

BIONATEO SP Z O O