

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.

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



**HAND
SANITIZER SPRAY**

**Alcohol Antiseptic
80% Topical Solution**

NON-STERILE SOLUTION



**KILLS
99.99%
OF GERMS***

RINSE-FREE

1.69 fl oz (50 mL)

NDC 78571-005-01


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

Drug Facts	
Purpose	
Active ingredient(s) 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 • 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 • 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 15-30°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 / SPxx-xxxx

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



100 mL NDC: 78571-005-02



HAND SANITIZER SPRAY

**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 78571-005-02

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.

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Directions

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- ♦ Store between 15-30°C (59-86°F)
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Expiration date:

12 months

Production date /

lot number:

xx.xxxx / SP xx-xxxx

Distributed by:

Bionateo Sp. z o.o.

Chocimska 6

62-800 Kalisz, Poland

www.bionateo.com



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1000 mL NDC: 78571-005-03



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

NDC 78571-005-03

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 ageon 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">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	<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 / SP xx-xxxx

Distributed by:
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Chocimska 6
62-800 Kalisz, Poland
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ALTAIO HAND SANITIZER

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78571-005
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
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:78571-005-01	50 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/25/2020	
2	NDC:78571-005-02	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/25/2020	
3	NDC:78571-005-03	1000 mL in 1 BOTTLE, SPRAY; 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(78571-005)