

## **ALTAIO SANITIZING WIPES- alcohol cloth 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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The ALTAIO Sanitizing Wipes is a product manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (w/w)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerin (3% w/w).
- c. 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 70% w/w. Purpose: Antimicrobial

### **Purpose**

Antimicrobial, Hand Sanitizer, Hard Surface Sanitizer

### **Use**

Hand and hard surface sanitizer to help reduce bacteria that potentially can cause disease.

### **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**

- Wet hands or hard surface thoroughly with product and allow to dry. Discard after single use.
- 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)
- Best used within 30 days of opening

### Inactive ingredients

glycerin, purified water USP

### Package Label - Principal Display Panel

ALTAIO Sanitizing Wipes 700CT NDC: 78571-004-01



The image shows the principal display panel of the ALTAIO Sanitizing Wipes 700CT package. It features a blue and white color scheme with a central logo and several key messages. On the left, there are four small images showing the product being used in various settings: a casino, a laptop, a surgical tray, and a car. The central text reads 'ALTAIO + BORN IN NATURE + SANITIZING WIPES ALCOHOL FORMULA'. Below this, two red diamond-shaped callouts state 'KILL 99.99% OF GERMS\*' and 'Ethanol 70%'. At the bottom, it says '700CT PRE-SOAKED'. On the right side, there is a roll of wipes icon with '700 SHEETS' and 'Size of 1 wipe: 7.87 in. x 6.89 in. (20 cm x 17.5 cm)'. Below this is a table with drug facts, warnings, directions, and other information. At the bottom right, there is a barcode and a warning symbol.

NDC 78571-004-01

**700 SHEETS**

**Size of 1 wipe:**  
7.87 in. x 6.89 in.  
(20 cm x 17.5 cm)

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

Drug Facts	Purpose
<b>Active ingredient[s]</b> Ethyl Alcohol 70% w/w	Antimicrobial
<b>Use[s]</b> Hand and hard surface sanitizer to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b> • on children less than 2 months of age • on open skin wounds	
<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> • Wet hands or surface thoroughly with product and allow to dry. Discard after single use. • Supervise children under 6 years of age when using this product to avoid swallowing.	
<b>Other information</b> • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F) • Best used within 30 days of opening	
<b>Inactive ingredients</b> glycerin, purified water USP	

ALTAIO SANITIZING WIPES are pre-soaked with 2.86 lbs (1300 g) of antiseptic liquid in total.

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

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

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## ALTAIO SANITIZING WIPES

alcohol cloth

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78571-004
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 g in 100 g
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### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	3 g in 100 g
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78571-004-01	1300 g in 1 PAIL; Type 0: Not a Combination Product	06/24/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/24/2020	

**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(78571-004)

Revised: 6/2020

BIONATEO SP Z O O