

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.

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) (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, Surface Sanitizer

Use

Hand and 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 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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

ALTAIO Sanitizing Wipes 700CT NDC: 78571-003-01



SANITIZING WIPES

ALCOHOL FORMULA

KILL 99.99% OF GERMS*

Ethanol 80%

700CT PRE-SOAKED



700 SHEETS

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

NDC 78571-003-01

*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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Warnings	
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ALTAIO SANITIZING WIPES are pre-soaked with 50.72 fl oz (1500 mL) of antiseptic liquid in total.

Expiration date: 12 months
Production date / lot number: 05.2020 / SWS-2020

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			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78571-003
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

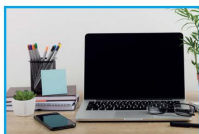
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78571-003-01	1500 mL in 1 PAIL; Type 0: Not a Combination Product	07/01/2020	



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OF
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part333A	07/01/2020	
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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(78571-003)

Revised: 6/2020

BIONATEO SP Z O O