

## **NATOUCH- miconazole soap**

### **Natouch LLC**

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### **Natouch Tea Tree Soap**

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)**

Alcohol 70% 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**

- in 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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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, lavender oil, carbomer, purified water USP

### **Package Label - Principal Display Panel**



NDC: Natouch Antifungal Wipes Plus 79073-004-80

## NATOUCH

miconazole soap

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79073-008
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MICONAZOLE</b> (UNII: 7NNO0D7S5M) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE	1.2 g in 120 g

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	1.8 g in 120 g
<b>SODIUM PALMATE</b> (UNII: S0A6004K3Z)	112.92 g in 120 g
<b>WATER</b> (UNII: 059QF0KO0R)	1.8 g in 120 g

<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	0.48 g in 120 g
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	1.8 g in 120 g
<b>INDIGOTINDISULFONATE SODIUM</b> (UNII: D3741U8K7L)	0.06 g in 120 g
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	0.06 g in 120 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79073-008-04	120 g in 1 BOX; Type 0: Not a Combination Product	08/01/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	02/01/2020	

**Labeler** - Natouch LLC (117545701)

**Registrant** - Natouch LLC (117545701)

### Establishment

Name	Address	ID/FEI	Business Operations
Shaoxing Elite Bio-tech Co., LTD		546459425	manufacture(79073-008)

Revised: 2/2026

Natouch LLC