#### BIOM SANITIZING ALCOHOL WIPES - TEA TREE BLISS- alcohol swab Biom Innovations Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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# [biom17] Sanitizing Alcohol Wipes - Tea Tree Bliss (10 wipe)

This is a hand sanitizer manufactured in compliance with (the now withdrawn) Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.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:

- Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (65%(w/w) or 70%(v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.

# Active Ingredient(s)

Alcohol 65% w/w. Purpose: Antiseptic

# Purpose

Reducing bacteria on skin.

#### Directions

Wipe hands thoroughly. Discard after use.

# Warnings

Flammable. Keep away from Fire and Flame. External Use Only. Do not use in eyes. If contact occurs, flush thoroughly with water. Stop use and ask doctor if redness or irritation develops and continues for more than 72 hours. Keep out of reach of children. If swallowed, get medical help or contact the poison control center immediately.

# Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact the poison control center immediately.

Stop use and ask a doctor if redness or irritation develops and continues for more than 72 hours.

#### Other information

Store below  $104^{\circ}$  F ( $40^{\circ}$  C). Each wipe is  $15 \times 20$  cm. May discolor certain fabrics. Do not use as a baby wipe, on the face, or in the genital area.

#### Inactive ingredients

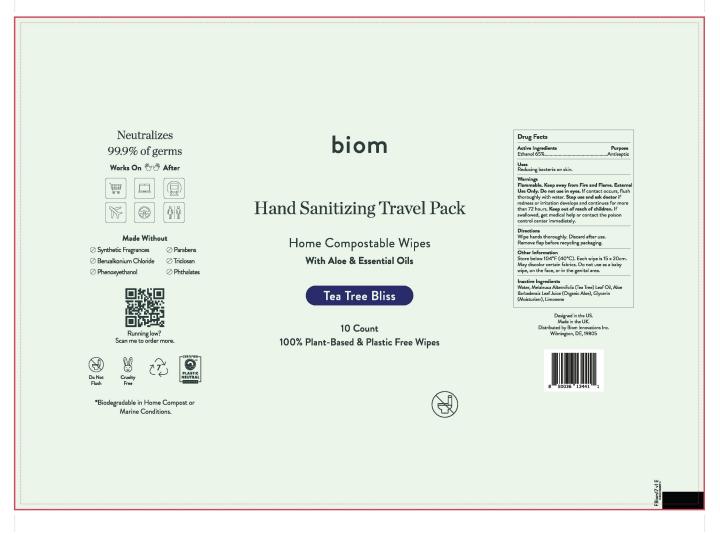
Water, Tea Tree Oil, Aloe Barbadensis Leaf Juice (Organic Aloe), Glycerin (Moisturizer)

#### **Dosage and Administration**

Ethanol 65%w/w. Wipe hands thoroughly. Discard after use.

#### Package Label - Principal Display Panel

10 wipes; NDC: 82311-0118-2, Hand Sanitizing Tea Tree Bliss



# **BIOM SANITIZING ALCOHOL WIPES - TEA TREE BLISS**

alcohol swab						
Product Info	rmation					
Product Type	HUMAN OTC DRUG		ltem Co	<b>ode (Source)</b> NDC:82311-0118		
Route of Admir	nistration	TOPICAL				
Active Ingred	lient/Active	Moiety				
	Ingredient	t Name	Ba	asis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALC	OHOL	42.854 mL in 61.22 mL	
Inactive Ingr	edients					
Ingredient Name			Strength			
TEA TREE OIL (UNII: VIF565UC2G)			0.03061 mL in 61.22 mL			
GLYCERIN (UNII: PDC6A3C0OX)			6.122 mL in 61.22 mL			
WATER (UNII: 059QF0KO0R)			11.5891845 mL in 61.22 mL			
ALOE VERA LEAF (UNII: ZY81Z83H0X)				0.6242055 mL in 61.22 mL		
Packaging						
# Item Code	Pa	Package Description		Marketing Star Date	rt Marketing End Date	
<b>1</b> NDC:82311- 0118-2	1- 61.22 mL in 1 PACKAGE; Type 0: Not a Combination Product			10/18/2023		
Marketing	Informat	ion				
Marketing Information Marketing Application Number or Monog				Marketing Star	t Marketing End	
Category	Арриса	Citation	Jiapii	Date	Date	
unapproved drug other				10/18/2023		

# Labeler - Biom Innovations Inc (118335373)

Revised: 10/2023

**Biom Innovations Inc**