BIOM SANITIZING ALCOHOL WIPES - BERGAMOT BLOOM- 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.

[biom02] Sanitizing Alcohol Wipes - Bergamot Bloom (50 wipe)

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:

- Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (65%, volume/volume (w/w)) 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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Other information

Store below 104° F (40° C). Each wipe is 15 x 20 cm. May discolor certain fabrics. Do not use as a baby wipe, on the face, or in the genital area.

Inactive ingredients

Water, Citrus Bergamia Peel Oil (Bergamot Essential Oil), Aloe Barbadensis Leaf Juice (Organic Aloe), Glycerin (Moisturizer)

Keep out of reach of children

If swallowed, get medical help or contact the poison control center immediately.

Dosage and Administration

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

Package Label - Principal Display Panel

50 wipes; NDC: 82311-0102-1



BIOM SANITIZING ALCOHOL WIPES - BERGAMOT BLOOM

alcohol swab

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82311-0102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	184.1 mL in 263 mL

Inactive Ingredients	
Ingredient Name	Strength
CITRUS AURANTIUM FRUIT RIND (UNII: 055456JHI7)	0.1315 mL in 263 mL

ALOE VERA LEAF (UNII: ZY81Z83H0X)	2.63 mL in 263 mL
GLYCERIN (UNII: PDC6A3C0OX)	2.64315 mL in 263 mL
WATER (UNII: 059QF0KO0R)	73.49535 mL in 263 mL

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:82311- 0102-1	263 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/31/2021	

lication Number or Monograph Citation	Marketing Start Date	Marketing End Date
	10/04/2021	
		Citation Date

Labeler - Biom Innovations Inc (118335373)

Revised: 10/2023 Biom Innovations Inc