

BOOSIETIZER PEACH SCENT- hand sanitizer gel

AWSM Marcin Szakoła

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.

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 6 years old
- 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

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 12 years of age when using this product to avoid swallowing.

Other information

- Store between 10-26C (50-79F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Alcohol, Aqua, Acrylates Copolymer, Perfum, Glycerin, Panthenol, Aloe Barbadensis Leaf Extract, Triethanolamine, Sodium Benzoate, Potassium Sorb

Package Label - Principal Display Panel

500 mL NDC: 79887-112-53

The image shows the front of a 500 ml bottle of Boosietizer Hand Sanitizer Gel. The background is orange with a repeating pattern of small, stylized peach icons. At the top center is a large, ornate gold letter 'B' with a crown on top. Below it, the brand name 'Boosietizer' is written in a white, cursive, dripping font. Underneath that, 'HAND SANITIZER GEL' is printed in bold, blue, block letters with a dripping effect. At the bottom of the label, there is a green horizontal bar with the words 'PEACH SCENT' in white. To the left of this bar are three small peach illustrations. Below the bar, three white droplet icons are arranged horizontally, each with text underneath: 'ALCOHOL ANTISEPTIC 70%', 'TOPICAL SOLUTION', and 'NON-STERILE SOLUTION'. On the left side of the label, there is a barcode with the number '00850020525010' below it, and '500 ml' printed in large white font. On the right side of the label, there is a full-body illustration of a Black man wearing a white t-shirt, blue jeans, and a thick silver chain necklace. He is holding a small bottle of the sanitizer in his right hand. To the right of the bottle, there is a column of text containing product information: 'Active ingredient: Alcohol 70% v/v', 'Use: Hand sanitizer to help reduce bacteria that potentially can be disease. For use when soap and water are not available.', 'Warning: For external use only. Flammable. Keep away from heat and flame.', 'Do not use: In children less than 6 years old on open skin wound. 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.', 'Directions for use: Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under twelve years of age when using this product to avoid swallowing.', 'Other information: Store between 10 and 26C. Avoid freezing and excessive heat above 40C.', 'Inactive ingredients: Alcohol Denat., Aqua, Acrylates Copolymer, Parfum, Glycerin, Panthenol, Aloe Barbadensis Leaf Extract, Triethanolamine, Sodium Benzoate, Potassium Sorb. SN/ Expiration Date: On bottle.', and 'Manufactured for: Wisconsin Wine and Spirits INC.'

200 mL NDC: 79887-112-23

The image shows the front of a 200 ml bottle of Boosietizer Hand Sanitizer Gel. The design is identical to the 500 ml version, featuring the same orange background with peach icons, the 'Boosietizer' brand name, 'HAND SANITIZER GEL' text, 'PEACH SCENT' label, and the man illustration. The main differences are the barcode number '00850020525003' and the volume '200 ml' printed in large white font on the left side. The product information text on the right side is also identical to the 500 ml version.

BOOSIETIZER PEACH SCENT

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79887-112
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

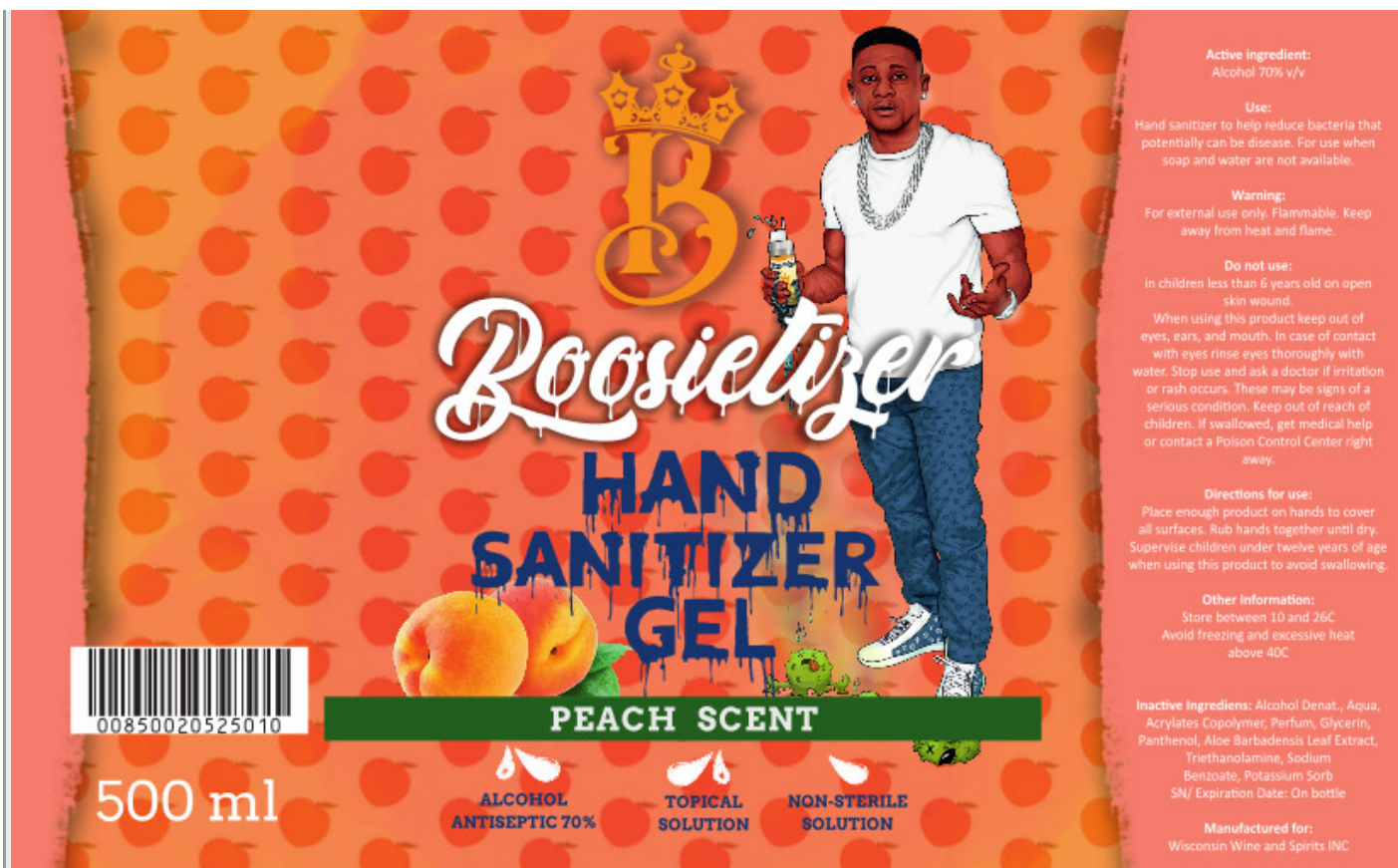
Ingredient Name	Strength
PANTHENOL (UNII: WW9CM0O67Z)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
ALOE (UNII: V5VD430YW9)	1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	PEACH	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79887-112-53	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:79887-112-23	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/03/2020	

Labeler - AWSM Marcin Szakoła (422446268)

Establishment

Name	Address	ID/FEI	Business Operations
AWSM Marcin Szakoła		422446268	manufacture(79887-112)

Revised: 4/2021

AWSM Marcin Szakoła