BOOSIETIZER- 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. Isopropyl Alcohol (75%, 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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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

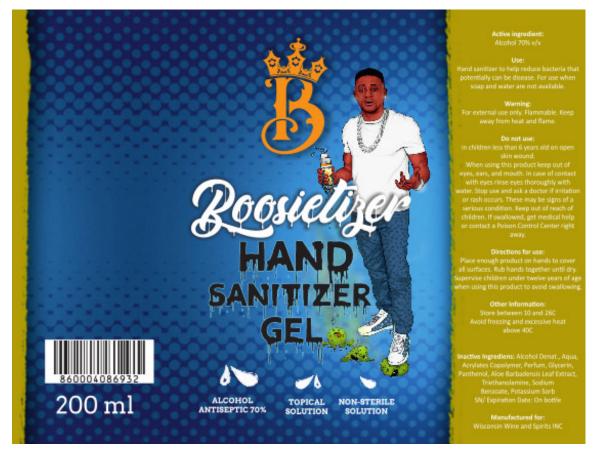
- Store between 10-26C (50-79F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

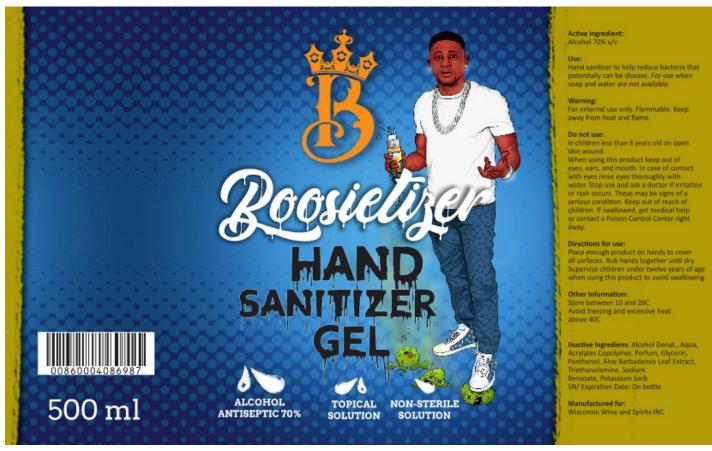
glycerin, acrylates copolymer, perfum, panthenol, aloe barbadensis leaf extract, triethanolamine, sodium benzoate, potassium sorb, purified water USP

Package Label - Principal Display Panel

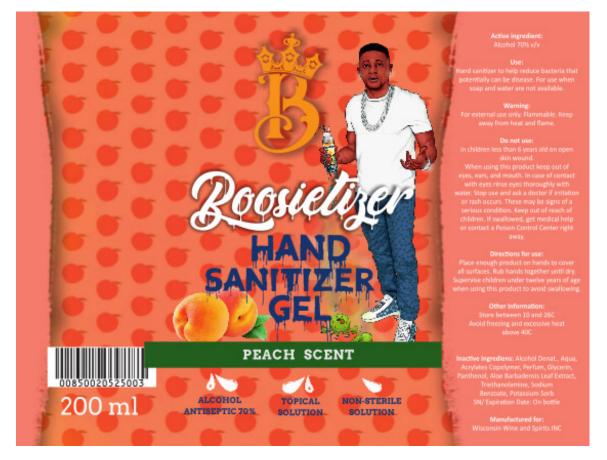
200 ml NDC: 79887-111-21



500 ml NDC: 79887-111-51



200 ml NDC: 79887-112-21



500 ml NDC: 79887-112-51



200 ml NDC: 79887-113-21



Active ingredient: Alcohol 70% v/v

Use: Pland sanifizer 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 since wound.

When using this product keep out of eyes, ears, and resuft, in case of contact with eyes rises eyes throughly with water. Step use and ask a doctor if irradion or rash occurs. These may be rispro of a serious condition. Keep out of reach of children. It wan allowed, get modical help or contact a Poison Control Center right always.

Directions for use:
Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under twike years of age when using this product to avoid swellowing.

Other Information: Store between 10 and 26C Avoid freezing and excessive heat above 40C

Inactive Ingrediens: Alcohol Denat., Aqua, Annylates Capolymer, Perfum, Glycerin, Panthenel, Alice Barbadenis Leaf Extract, Triethanelamine, Sodium Benzoste, Potassium Sorti SW Espiration Date: On bottle



500 ml NDC: 79887-113-51



200 ml NDC: 79887-114-21

Active ingredient: Alcohol 70% v/v

Hand sanitizer to help reduce bacteria that potentially can be disease. For use when soap and water are not available.

For external use only. Flammable. Keep away from heat and flame.

in children less than 6 years old on open skin wound.

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

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

Inactive Ingrediens: Alcohol Denat., Agua, Acrylates Copolymer, Perfum, Glycerin, Panthenol, Aloe Barbadensis Leaf Extract, Triethanolamine, Sodium Benzoate, Potassium Sorb SN/ Expiration Date: On bottle

Manufactured for:



HAND SANITIZER GEL



200ml

500 ml NDC: 79887-114-51



HAND SANITIZER GEL



500ml

Active ingredient

Alcohol 70% v/v

Used

Hand sanitizer to help reduce bacteria that potentially can be disease. For use when soap and water are not available.

Warnin

For external use only. Flammable. Keep away from heat and flame.

Do not use:

- · in children less than 6 months of age.
- 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 and ask a doctor if imitation or rash o cours. 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, Perfum, Glycerin, Parthenol, Aloe Burbadensis Leaf Extract, Titethanolamine, Sodium Benzoate, Potassium Sorb Best before/SN/Expiration Date: On bottle

Manufactured for Wisconsin Wine and Spirits INC



Active ingredient:

Alcohol 70%

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 months of age.
- 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 and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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Other Information:

Store between 10 and 26C

Avoid freezing and excessive heat above 4OC

Inactive Ingredients: Alcohol Denat., Aqua, Acrylates Copolymer, Perfum, Glycerin, Panthenol, Aloe Barbadensis Leaf Extract, Triethanolamine, Sodium Benzoate, Potassium Sorb

Best before/ SN/ Expiration Date: On bottle

Manufactured for:

Wisconsin Wine and Spirits INC



hand sanitizer gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:79887-111

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M) ALCOHOL 70 mL in 100 mL

Inactive Ingredients

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

Product Characteristics

1 Todact characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

Packaging

NDC:79887-111- 500 mL in 1 BOTTLE; Type 0: Not a Combination 08/01/2020	# Item Code	Package Description	Marketing Start Date	Marketing End Date
51 Product	1 NDC:79887-111- 51	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2020	



Labeler - AWSM Marcin Szakoła (422446268)

part333A

OTC monograph not

final

Establishment			
Name	Address	ID/FEI	Business Operations
AWSM Marcin Szakoła		422446268	manufacture(79887-111)

08/01/2020

Revised: 4/2021 AWSM Marcin Szakoła