

## **BIINI HAND SANITIZER- isopropyl alcohol gel** **Biini, Inc.**

*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.*

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Isopropyl Alcohol 75% v/v Purpose Antiseptic

Antiseptic

Hand sanitizer to help reduce bacteria that potentially can cause diseases

For external use only. Not intended for ingestion. Flammable. Keep away from fire or flame.

- on open skin wounds
- in children less than 2 months of age

Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

glycerin, lemon fragrance, PEG-6 AMP-acrylates/ vinyl isodecanoate crosspolymer, purified water USP

- store between 15-30C (59-86F)
- avoid freezing and excessive heat above 40C (104F)
- place enough product on hands to cover all surfaces and rub together until dry
- supervise children under 6 years of age when using product to avoid swallowing

If swallowed, get medical help or contact a Poison Control Center right away.

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

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:

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.

Glycerol (1.45% v/v).

Hydrogen peroxide (0.125% v/v).

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.



<b>Drug Facts</b>	
<b>Active ingredients</b> .....	<b>Purpose</b>
Isopropyl Alcohol 75% v/v.....	Antiseptic
<b>Uses</b>	
Hand Sanitizer Gel topical solution hand rub used to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b>	
<b>For external use only. Not intended for ingestion. Flammable. Keep away from heat or flame.</b>	
<b>Do not use</b>	
- in children less than 2 months of age	
- on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
- 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.	
<b>Other information</b>	
- Store between 15-30C (59-86F)	
- Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> glycerol, hydrogen peroxide, hypromellose, lemon fragrance, purified water USP	



Manufactured by  
Biini, Inc.  
1201 TODD DUCHAME DR  
BELCOURT ND 58316  
1-800-998-3215

## BIINI HAND SANITIZER

isopropyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83156-562
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.07 mL in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>LEMN</b> (UNII: 24RS0A9880)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%)</b> (UNII:	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83156-562-08	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/16/2022	
2	NDC:83156-562-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/16/2022	
3	NDC:83156-562-02	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	12/16/2022	
4	NDC:83156-562-04	118 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	12/16/2022	



<b>Drug Facts</b>
<b>Active ingredients.....Purpose</b> Isopropyl Alcohol 75% v/v.....Antiseptic
<b>Uses</b> Hand Sanitizer Gel topical solution hand rub used to help reduce bacteria that potentially can cause disease.
<b>Warnings</b> <b>For external use only. Not intended for ingestion. Flammable. Keep away from heat or flame.</b> <b>Do not use</b> - in children less than 2 months of age - on open skin wounds <b>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</b>
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.
<b>Directions</b> - 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.
<b>Other information</b> - Store between 15-30C (59-86F) - Avoid freezing and excessive heat above 40C (104F)
<b>Inactive Ingredients</b> glycerol, hydrogen peroxide, hypromellose, lemon fragrance, purified water USP

This Product Meets the Food Code Criteria of Section 2-301.16  
Hand Antiseptics Published by the FDA.



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**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	12/16/2022	

**Labeler** - Biini, Inc. (118757471)

**Registrant** - Biini, Inc. (118757471)

### Establishment

Name	Address	ID/FEI	Business Operations
Biini, Inc.		118757471	manufacture(83156-562) , label(83156-562) , pack(83156-562)

Revised: 12/2022

Biini, Inc.