

**HAND SANITIZER- isopropyl alcohol liquid**  
**Brazilian Hair LLC**

*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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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)**

Isopropyl Alcohol 75% 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 2 months of age
- 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 6 years of age when using this product to avoid swallowing.

## Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

140 ml NDC: 75753-140-01

125 mm



Drug Facts	
<b>Active ingredient</b>	<b>Purpose</b>
Ethyl Alcohol 70% v/v.....	Antiseptic
<b>Uses</b> ■ Decrease bacteria on the skin.	
<b>Warnings</b> For external use only <b>Flammable. Keep away from heat and flame.</b> <b>When using this product,</b> avoid contact with eyes. In case of contact, flush with water. <b>Stop use and ask a doctor</b> if irritation and redness develop and persist for more than 72 hours.	
<b>Keep out of reach of children</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> ■ Wet hands thoroughly with product and allow to dry. ■ Children under 6 years of age, use only under adult supervision.	
<b>Other Information</b> ■ Do not store above 105° F(43°C) ■ May discolor some fabrics and surfaces.	
<b>Inactive Ingredients</b> ALCOHOL, AQUA, PROPYLENE GLYCOL, GLYCERIN, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, PARFUM, AMINOMETHYL PROPANOL, CINNAMYL ALCOHOL, ALOE BARBADENSIS LEAF EXTRACT, SORBITOL, POTASSIUM SORBATE, SODIUM BENZOATE	
Manufactured by: PHITOTERAPHIA BIOFITOGENIA LABORATORIAL BIOTA LTDA Distributed by: Brazilian Hair LLC, 1275 Bloomfield Ave. Bldg 7 Unit 42 Fairfield, NJ 07004. www.novexhaircare.com	
7896013572091	

100 mm

175 mm

EMBELLEZE

BioSalut



Antiseptico para las manos

Disinfects while moisturizes, leaving hands feeling refreshed.  
Desinfecta mientras hidrata, dejando las manos sintiéndose renovado.

8 FL Oz e  
(236.5) mL



**Drug Facts**

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Ethyl Alcohol 70% v/v.....	Antiseptic

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Manufactured by: Chemco Corp  
Distributed by: Brazilian Hair LLC,  
1275 Bloomfield Ave. Bldg 7 Unit 42  
Fairfield, NJ 07004.  
www.novexhaircare.com

7896013572077

100 mm

90 mm

 **EMBELLEZE**

**BioSalut**



**Com Aloe Vera**

**Gel antisséptico perfumado para as mãos.**

*Hand Sanitizer with Scent  
Gel antiséptico perfumado para mãos*

**ANTES DE USAR LEIA AS INSTRUÇÕES DO RÓTULO.**

**2.0 fl Oz e 60 mL**

**Além de higienizar e proteger prevenindo contra as impurezas do dia a dia, proporciona suavidade e maciez para as mãos.** In addition to cleaning and protecting, preventing the impurities of everyday life, it provides softness and smoothness for your hands. Además de desinfectar y proteger, evitando las impurezas de la vida cotidiana, proporciona suavidad y sedosidad para las manos. **Modo de Uso: Aplicar sobre as mãos e friccionar levemente até total absorção do produto. Repetir quantas vezes forem necessárias ao longo do dia. Directions for Use:** Apply on your hands and rub lightly until the product is completely absorbed. Repeat as many times as necessary throughout the day. **Modo de uso:** aplicar sobre las manos y frotar ligeramente hasta que el producto se absorba por completo. Repita tantas veces como sea necesario durante todo el día. **Precauções:** Não utilizar em serviços de saúde. Antes de usar leia as instruções do rótulo. Não perfurar a tampa. Não derramar sobre o fogo. Em caso de queimadura, lavar a área com água corrente. Em caso de ingestão, não provocar vômito e consultar imediatamente o Centro de Intoxicações ou Serviço de Saúde mais próximo. **NÃO INGERIR - CONTEM DESNATURANTE.** O produto contém como desnatante o **GLICERINA.** Manter afastado do fogo e do calor.

**ATENÇÃO:** Manter fora do alcance de crianças e animais domésticos.

**PERIGO:** produto inflamável.



INFLAMÁVEL

**Warnings:** For external use only. Flammable, keep away from heat and flame. Do not use in the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours. Keep out of reach children. If swallowed, get medical help or contact a Poison Control Center right away.

**Precauciones:** Evitar el contacto con los ojos y boca. Interrumpa el uso en caso de sensibilización. En caso que esto ocurra lave con agua en abundancia. Mantenga en un lugar fresco y seco. Mantener fuera del alcance de los niños. Inflamable. **INGREDIENTES / INGREDIENTS:** ALCOHOL, AQUA, PROPYLENE GLYCOL, GLYCERIN, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, PARFUM, AMINOMETHYL PROPANOL, CINNAMYL ALCOHOL, HEXYL CINNAMAL, D-LIMONENE, COUMARIN, BENZYL SALICYLATE, GERANIOL, ALOE BARBADENSIS LEAF EXTRACT, SORBITOL, POTASSIUM SORBATE, SODIUM BENZOATE. AFE/PROC: 2.02.100-5/



**Fabricado por / Manufactured by / Fabrique par:** Phitoterapia Biofitogenia Laboratorial Biota Ltda Rua Maria de Andrade 79A, CEP 26261 – 200 Nova Iguaçu/ RJ. CNPJ: 00.104.603/0001-33. Indústria Brasileira • Tec. Resp: Eni Figueiredo CRO III 03212976 • Imported and distributed in USA by: Brazilian Hair LLC, 1275 Bloomfield Ave, Bldg. 7 Unit 42 Fairfield, NJ 07004, Ph: +1 800 519 2946 –info@embellezeusa.com – www.novexhaircare.com; • Importado para a Comunidade Europeia por Brazilian Secrets Cosmética lda - Avenida da República nº101 – 3A - 1050-190 Lisboa - Portugal / www.embelleze.eu – tel: +351 216 096 050 **Origem/Origin: Brazil**

7896013572060

70 mm

125 mm



# BioSalut



Álcool em Gel  
higienizante

Sanitizer Gel

70°<sup>GL</sup>  
ou  
68.6%  
INPM

Com Aloe Vera

Gel antisséptico  
perfumado para as mãos.

*Hand Sanitizer with Scent*  
*Gel antiséptico perfumado para manos*

ANTES DE USAR LEIA AS INSTRUÇÕES DO RÓTULO.

140 mL

4.7 fl Oz e

**Além de higienizar e proteger prevenindo contra as impurezas do dia a dia, proporciona suavidade e maciez para as mãos.** In addition to cleaning and protecting, preventing the impurities of everyday life, it provides softness and smoothness for your hands. Además de desinfectar y proteger, evitando las impurezas de la vida cotidiana, proporciona suavidad y sedosidad para las manos.

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**ATENÇÃO:** Manter fora do alcance de crianças e animais domésticos.



**PERIGO:** produto inflamável.



INFLAMÁVEL

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LOT: FAB: VAL:

7896013572091

100 mm

**HAND SANITIZER**

isopropyl alcohol liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75753-140
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL



HYDROGEN PEROXIDE (UNII: BBX060AN9V)

0.125 mL in 100 mL

WATER (UNII: 059QF0K00R)

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75753-140-09	140 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75753-140-07	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75753-140-06	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75753-140-01	140 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

125 mm



**EMBELLEZE**

**BioSalut**

**Álcool em Gel higienizante Sanitizer Gel**

**70° GL ou 68.6% INPM**

**Com Aloe Vera**

**Gel antisséptico perfumado para as mãos.**

*Hand Sanitizer with Scent*  
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**ANTES DE USAR LEIA AS INSTRUÇÕES DO RÓTULO.**

**140 mL 4.7 fl Oz e**

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**ATENÇÃO: Manter fora do alcance de crianças e animais domésticos.** **PERIGO: produto inflamável.**

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LOT: VAL: FAB: VAL:

7896013572091

100 mm

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Brazilian Hair LLC (009780655)

## Establishment

Name	Address	ID/FEI	Business Operations
PHITOTERAPHIA BIOFITOGENIA LABORATORIAL BIOTA LTDA		678448921	manufacture(75753-140)

Revised: 4/2020

Brazilian Hair LLC