

BIOSALUT HAND SANITIZER ADVANCED- alcohol gel
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.

EMBELLEZE BioSalut Hand Sanitizer ADVANCED

Drug Facts

Active ingredient

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Uses • Decrease bacteria on the skin.

Warnings

For external use only

Flammable. Keep away from heat and flame.

When using this product, avoid contact with eye. In case of contact, flush with water.

Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.

Keep out of reach of children If swallowed, get medical help or contact a Poison Control Centre right away.

Directions• Wet hands thoroughly with product and allow to dry. • Children under 6 years of age, use only under adult supervision.

Other Information • Do not store above 105°F (43°C) • May discolor some fabrics and surfaces.

Inactive Ingredients 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: 2.02.100-5

KILLS 99.9% OF GERMS

Disinfects while moisturizes, leaving hands feeling refreshed.

Manufactured by : Phitoteraphia Biofitogenia Laboratorial Biota

Ltda Rua Maria de Andrade 79A . CEP 26261 - 200 Nova Iguaçu/RJ. CNPJ:

00.104.603/0001-33. Brazilian Industry • Téc. Resp:

Eni Figueiredo CRQ III 03212976 • Imported and distributed in USA by: Brazilian Hair LLC. 1275 Bloomfield Ave. Bldg. 7 Unit 48 Fairfield, NJ 07004.

Ph: +1 800 519 2946 -info@embellezeusa.com - www.novexhaircare.com **Origem/Origin: Brazil**

Packaging



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.

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.
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 - CONTÉM DESNATURANTE.** O produto contém como desnaturante 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: Phitoteraphia Biofitogenia Laboratorial Biota Ltda Rua Maria de Andrade 79A . CEP 26261 – 200 Nova Iguaçu/ RJ. CNPJ: 00.104.603/0001-33. Indústria Brasileira • Téc. Resp: Eni Figueiredo CRQ 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 Ida - Avenida da República nº101 – 3A - 1050-190 Lisboa - Portugal / www.embelleze.eu – tel: +351 216 096 050 **Origem/Origin: Brazil**



LOT: FAB: VAL:

7896013572091



Antiséptico para las manos

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

10.1 fl Oz e
(300) mL



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	876120004712

BIOSALUT HAND SANITIZER ADVANCED

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75753-300
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
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CINNAMYL ALCOHOL (UNII: SS8YOP444F)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
COUMARIN (UNII: A4VZ22K1WT)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
GERANIOL (UNII: L837108USY)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)

SORBITOL (UNII: 506T60A25R)

POTASSIUM SORBATE (UNII: 1VPU26JZZ4)

SODIUM BENZOATE (UNII: OJ245FE5EU)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75753-300-09	140 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/10/2020	
2	NDC:75753-300-01	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/10/2020	

Labeler - Brazilian Hair Llc (009780655)

Establishment

Name	Address	ID/FEI	Business Operations
PHITOTERAPHIA BIOFITOGENIA LABORATORIAL BIOTA LTDA		678448921	manufacture(75753-300)

Revised: 9/2020

Brazilian Hair Llc