

**BIOLUXE INSTANT HAND SANITIZER- isopropyl alcohol gel**  
**Sterling Perfumes Industries 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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**BioLuxe Instant Hand Sanitizer (gel)**

**200 mL NDC: 77716-013-06**

**500 mL NDC: 77716-013-16**

**Active Ingredient(s)**

Isopropyl Alcohol 75% v/v.

**Purpose**

Antiseptic

**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.

**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**

Aloe Barbadosis Leaf Extract, Aminomethyl Propanol, Carbomer, Fragrance, Glycerin, Isopropyl Myristate, Propylene Glycol, Tocopheryl Acetate, Water

**Package Label - Principal Display Panel**

**Manufactured by Sterling Perfumes Industries LLC**

**bioLuxe Instant Hand Sanitizer (200 mL) NDC: 77716-013-06**



**bioLuxe Instant Hand Sanitizer (500 mL) NDC: 77716-013-16**



**BIOLUXE INSTANT HAND SANITIZER**  
isopropyl alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77716-013
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE (UNII: V5VD430YW9)	
WATER (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77716-013-06	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/24/2020	
2	NDC:77716-013-16	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/24/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/24/2020	

**Labeler** - Sterling Perfumes Industries LLC (561432456)

Revised: 11/2020

Sterling Perfumes Industries LLC