## BIOLUXE INSTANT HAND SANITIZER- is opropyl alcohol spray 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.
$\qquad$
bioLuxe Ins tant Hand Sanitizer (Spray):
( 200 mL ) NDC: 77716-014-06
( 100 mL ) NDC: 77716-014-03

## 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 Barbadensis Leaf Extract, Fragrance, Glycerin, Isopropyl Myristate, Propylene Glycol, Tocopheryl Acetate, Water.

Package Label - Principal Display Panel
Manufactured by Sterling Perfumes Industries LLC
bioLuxe Instant Hand Sanitizer Spray (200 mL) NDC: 77716-014-06

bioLuxe Instant Hand Sanitizer Spray (100 mL) NDC: 77716-014-03


| BIOLUXE INSTANT HAND SANITIZER <br> isopropyl alcohol spray |  |  |  |
| :--- | :--- | :--- | :--- |
| Product Information |  |  |  |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77716-014 |
| Route of Administration | TOPICAL |  |  |

## Active Ingredient/Active Moiety

Ingredient Name
ISO PROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL -
UNII:ND2M416302)

Basis of Strength
ISOPROPYL $\quad 75 \mathrm{~mL}$
ALCOHOL
in 100 mL

## Inactive Ingredients

Ingredient Name
Strength
.ALPHA.-TO CO PHEROL ACETATE (UNII: 9 E8 X8 0D2L0)
ISO PROPYL MYRISTATE (UNII: 0 RE8K4LNJS)
PRO PYLENE GLYCOL (UNII: 6DC9Q167V3)
GLYCERIN (UNII: PDC6A3C0OX)
ALOE (UNII: V5VD430 YW9)
WATER (UNII: 059 QF0 KO0 R)

## Packaging

Date

Marketing End Date

| $\mathbf{1}$NDC:77716-014- <br> 06 | 200 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination <br> Product | $06 / 26 / 2020$ |
| :--- | :--- | :--- |
| NDC:77716-014- <br> 03 | 100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination <br> Product | $06 / 26 / 2020$ |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| :---: | :---: | :---: | :---: |
| OTC monograph not final | part333A | $06 / 26 / 2020$ |  |

Labeler - Sterling Perfumes Industries LLC (561432456)

