

**PRIME- 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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**Prime Hand Sanitizer**

**Active Ingredients**

Isopropyl alcohol 70% v/v

**Purpose**

Antiseptic

**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.

**Uses**

Hand sanitizer to help reduce bacteria that potentially can cause disease.

For use when soap and water are not available.

**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.

**Keep out of reach of children.**

If swallowed, get medical help or contact a poison control center right away.

**Other Information (if applicable)**

- Store between 15-30<sup>0</sup>C (59-86<sup>0</sup>F), Avoid freezing and excessive heat above 40<sup>0</sup>C (104<sup>0</sup>F)

**Inactive ingredients**

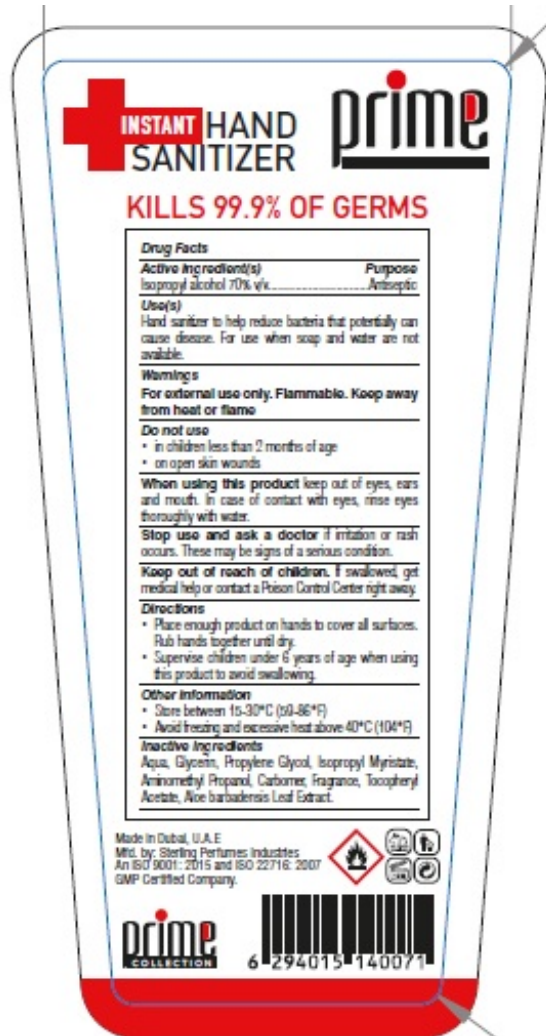
Aqua, Glycerin, Propylene Glycol, Isopropyl Myristate, Aminomethyl Propanol, Carbomer,

Fragrance, Tocopheryl Acetate, Aloe barbadensis Leaf Extract.

100mL



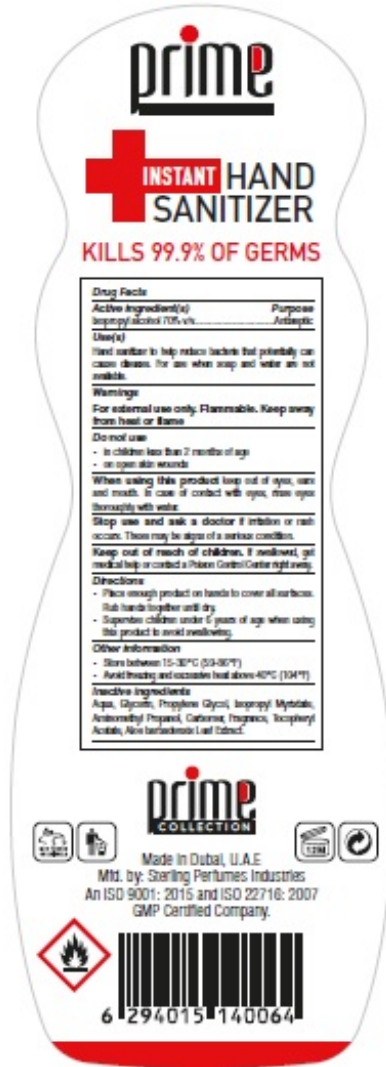
Front Opaque



Back Opaque



Front Opaque



Back Opaque

500mL



Front Opaque



Back Opaque

**PRIME**

isopropyl alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77716-011
<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	70 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Isopropyl Myristate (UNII: 0RE8K4LNJS)

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

ALOE VERA LEAF (UNII: ZY81Z83H0X)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77716-011-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
2	NDC:77716-011-02	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
3	NDC:77716-011-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/02/2020	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Sterling Perfumes Industries LLC		561432456	manufacture(77716-011)

Revised: 6/2020

Sterling Perfumes Industries LLC