

**SILKEN HAND SANITIZER- ethyl alcohol gel**  
**COSMOBEAUTI LABORATORIES & MANUFACTURING, INC.**

*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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**ROSE PETALS SILKEN HAND SANITIZER WITH ALOE VERA**

**ACTIVE INGREDIENTS**

ETHYL ALCOHOL 70%

**PURPOSE**

ANTISEPTIC

**DIRECTIONS**

WET HANDS THOROUGHLY WITH PRODUCT AND ALLOW TO DRY WITHOOUT WIPING.

**USES**

FOR HANDWASHING TO DECREASE BACTERIA ON THE SKIN.

**WARNINGS**

- For external use only-hands.
- Flammable. Keep away from heat and flame. Do not store above 105°F.
- Keep out of eyes.
- Avoid contact with broken skin.
- Do not ingest or inhale.
  
- Keep out of reach of children. For children under 6, use only under adult supervision.
- In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

**INACTIVE INGREDIENTS**

ALOE BARBADENSIS (ALOE VERA) LEAF JUICE, AMINOMETHYL PROPANOL, CARBOMER, DISODIUM EDTA, GLYCERIN, ISOPROPYL MYRISTATE, PROPELENE GLYCOL, WATER (AQUA)

ROSE PETALS™

Silken®

HAND SANITIZER

with Aloe Vera

Unscented

8 Fl. Oz. / 237mL

8  
35138 00162  
5

**DRUG FACTS**

<b>Active Ingredients</b>	Purpose
Ethyl Alcohol 70% v/v.....	Antiseptic

**Uses:** For handwashing to decrease bacteria on the skin

**Directions:** Wet hands thoroughly with product and allow to dry without wiping.

**Warning:** ■ For external use only-hands.  
■ Flammable. Keep away from heat and flame. Do not store above 105°F. ■ Keep out of eyes. ■ Avoid contact with broken skin. ■ Do not ingest or inhale. ■ Keep out of reach of children. For children under 6, use only under adult supervision. ■ In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

**Inactive Ingredients:** Aloe Barbadensis (Aloe Vera) Leaf Juice, Aminomethyl Propanol, Carbomer, Disodium EDTA, Glycerin, Isopropyl Myristate, Propylene Glycol, Water (Aqua)

Item #RPHS138

Instantly kills 99.99% of most common germs without the need of soap, water and towels. Leaves hands feeling soft, smooth and moisturized with Aloe Vera and Vitamin E. Dries quickly without stickiness and residue.

**Silken**  
ROSE PETALS™

**SILKEN HAND SANITIZER**

ethyl alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69077-103
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69077-103-18	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:69077-103-11	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:69077-103-12	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:69077-103-14	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:69077-103-16	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:69077-103-21	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:69077-103-22	3785 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	

**Marketing Information**

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

**Labeler** - COSMOBEAUTILABORATORIES & MANUFACTURING, INC. (021687376)

Revised: 5/2020

COSMOBEAUTILABORATORIES &amp; MANUFACTURING, INC.