

# **SILKEN HAND SANITIZER- ISOPROPYL ALCOHOL GEL**

COSMOBEAUTY 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**

ISOPROPYL ALCOHOL 70%

## **PURPOSE**

ANTISEPTIC

## **DIRECTIONS**

WET HANDS THOROUGHLY WITH PRODUCT AND ALLOW TO DRY WITHOUT 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, PROPYLENE GLYCOL, WATER (AQUA)

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69077-103
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
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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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

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

Labeler - COSMOBEAUTI LABORATORIES & MANUFACTURING, INC. (021687376)

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