

**HAND SANITIZER- alcohol gel**  
**SAMARA COSMETICS S.A.S.**

*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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**Hand Sanitizer**

**Uses**

Uses

\* Helps eliminate bacterias on the hand. This product is not a substitute of soap hand washing. Avoid contact with broken or damaged skin

**Active Ingredient**

Active Ingredient Purpose

- Ethyl Alcohol 65%.....Antiseptic

**Warnings**

- **For external use only-**
- **When using this product** keep out o f eyes. In case of contact, flush with water several minutes.
- **Keep out of reach of children except under adult supervision**
- **If swallow** get medical help or contact a Poison Control Center right away.
- **Flammable:** Keep away from heat and flame.
- **Stop use and ask Doctor:** if skin irritation develops.
- **Do not swallow**
- **Children under 6 years** old should be supervised when using this product

**Stop use and ask a doctor if**

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\* Irritation develops

**Keep out of reach of children**

**Keep out of reach of children.** In case of incidental ingestion, see professional advice or contact a Poison Control Center immediately.

**Directions**

**Directions:**

- Place enough product in your palm to thoroughly cover your hands.
- Rub hands together briskly until dry

**Inactive Ingredients**

Water Carbomer, Triethanolamine, Olea Europaea Fruit Oil, Panthenol, Glycerin, Aloe Barbadensis Extract, Camellia Sinensis Leaf Extract, Chamomilla Recutita Flower/Leaf Extract, Rosmarinus

Officinalis Leaf Extract, Thymus Vulgaris Leaf Oil, Linum Usitatissimum Seed Oil, Tocopheryl acetate (Vitamina E), Hydroxypropyl methylcellulose, Ethyl Lauroyl Arginate, Propylene Glycol, Fragrance, Phenoxyethanol, Ethylhexylglycerin, Citric Acid

## Questions?

**QUESTIONS OR COMMENTS:** (574) 4448438 Ext 108 (Monday to Friday) 6:30 am to 4:30 pm (UTC/GMT 5 hours)

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## Hand Sanitizer



## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79894-007
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	68 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	0.4 mL in 100 mL
OLEA EUROPAEA FRUIT VOLATILE OIL (UNII: 8E7358CX1J)	0.01 mL in 100 mL
PANTHENOL (UNII: WV9CM0O67Z)	0.3 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.5 mL in 100 mL
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	0.3 mL in 100 mL
THYMUS VULGARIS LEAF (UNII: GRX3499643)	0.1 mL in 100 mL
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.1 mL in 100 mL
HYPROMELLOSES (UNII: 3NXW29V3WO)	0.1 mL in 100 mL
PROPANEDIOL (UNII: 5965N8W85T)	0.2 mL in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.72 mL in 100 mL
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	0.3 mL in 100 mL
ROSMARINUS OFFICINALIS FLOWER (UNII: NR1A27F29O)	0.3 mL in 100 mL
LINUM USITATISSIMUM WHOLE (UNII: 310OJT00CG)	0.1 mL in 100 mL
ETHYL LAUROYL ARGINATE HYDROCHLORIDE (UNII: XPD6ZY79TB)	0.1 mL in 100 mL
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.07 mL in 100 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.1 mL in 100 mL
WATER (UNII: 059QF0K00R)	29.79 mL in 100 mL
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	0.1 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
CAMELLIA OIL (UNII: T1PE06G0VE)	0.3 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79894-007-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/29/2020	

**Labeler** - SAMARA COSMETICS S.A.S. (881793172)

**Registrant** - SAMARA COSMETICS S.A.S. (881793172)

### Establishment

Name	Address	ID/FEI	Business Operations
SAMARA COSMETICS S.A.S.		881793172	manufacture(79894-007)