

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.

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 of 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

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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?

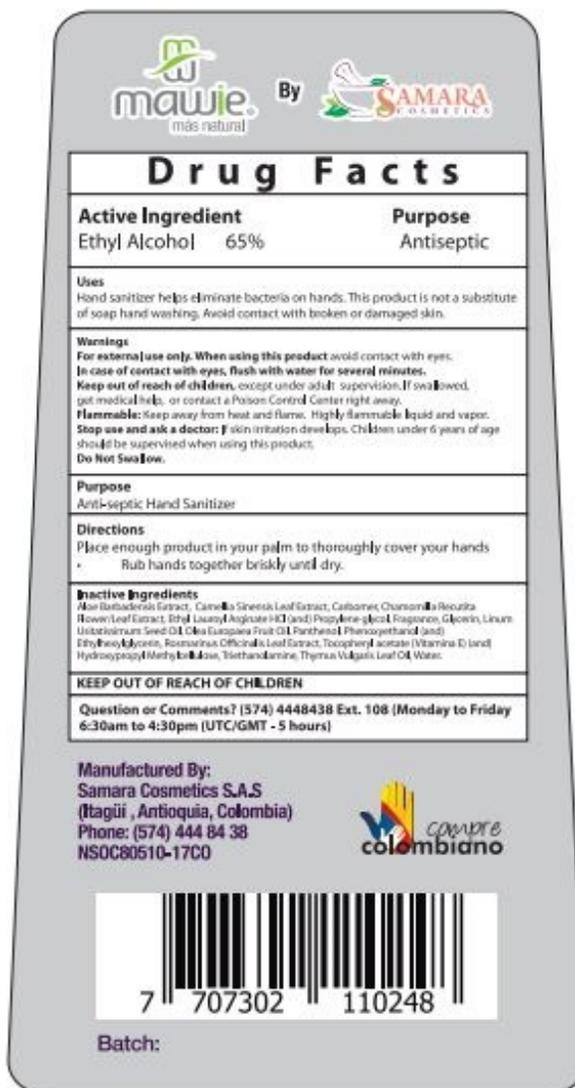
QUESTIONS OR COMMENTS: (574) 4448438 Ext 108 (Monday to Friday) 6:30 am to 4:30 pm (UTC/GMT 5 hours)

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alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79894-004
Route of Administration	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: 059QF0KO0R)	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:79894-004-01	30 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	

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

Establishment

Name	Address	ID/FEI	Business Operations
SAMARA COSMETICS S.A.S.		881793172	manufacture(79894-004)

Revised: 8/2020

SAMARA COSMETICS S.A.S.