

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

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)

Uses

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

Hand Sanitizer

19,1mm

120mm

KILLS 99.99% OF GERMS



TAKE CARE OF YOUR HANDS AND YOUR HEALTH

Hand Sanitizer

Anti-Bacterial Gel

Net. Wt. 16.90 fl.oz (500 ml)

With Microbeads of Vitamin E to protect and soften your hands.



By SAMARA COSMETICS

Hand Sanitizer Mawie
It is a product that cleans and disinfects your hands when you don't have water, soap and towels close to you. It is ideal as a complement for your hand's hygiene for its content of linseed oil and vitamin E. Moisture and nourish your hands.

Manufactured By:
Samara Cosmetics S.A.S
(Itagüí, Antioquia, Colombia)
Phone: (574) 444 84 38
NSOC80510-17CO



Batch:



Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 65%	Antiseptic
Uses Hand sanitizer helps eliminate bacteria on hands. This product is not a substitute of soap hand washing. Avoid contact with broken or damaged skin.	
Warnings For external use only. When using this product avoid contact with eyes. In case of contact with eyes, flush with water for several minutes. Keep out of reach of children , except under adult supervision. If swallowed, get medical help, or contact a Poison Control Center right away. Flammable: Keep away from heat and flame. Highly flammable liquid and vapor. Stop use and ask a doctor: If skin irritation develops. Children under 6 years of age should be supervised when using this product. Do Not Swallow.	
Purpose Anti-septic Hand Sanitizer	
Directions Place enough product in your palm to thoroughly cover your hands • Rub hands together briskly until dry.	
Inactive Ingredients Aloe Barbadensis Extract, Camellia Sinensis Leaf Extract, Carbomer, Chamomilla Recutita Flower/Leaf Extract, Ethyl Lauroyl Arginate HCl (and) Propylene glycol, Fragrance, Glycerin, Linum Usitatissimum Seed Oil, Olea Europaea Fruit Oil, Panthenol, Phenoxyethanol (and) Ethylhexylglycerin, Rosmarinus Officinalis Leaf Extract, Tocopheryl acetate (Vitamina E) (and) Hydroxypropyl Methylcellulose, Triethanolamine, Thymus Vulgaris Leaf Oil, Water.	
KEEP OUT OF REACH OF CHILDREN	
Question or Comments? (574) 4448438 Ext. 108 (Monday to Friday from 6:30 am to 4:30 pm (UTC/GMT -5 hours))	

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79894-006
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:79894-006-01	500 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
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Revised: 8/2020

SAMARA COSMETICS S.A.S.