HAND SANITIZER- alcohol liquid 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 and parts of the body that needs to be cleaned. This product is not a substitute of soap hand washing. Avoid contact with broken or damaged skin

Active Ingredient

Active Ingredient Purpose

• Ethyl Alcohol 68%......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 swalow** 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 swalow
- 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 inmediately.

Directions

Directions:

- Place enough product in your palm to throughly cover your hands.
- Rub hands together briskly until dry
- Apply it on the parts of the body that needs to be cleaned and rub it briskly until dry

Inactive Ingredients

Water, citric acid, glycerine, propylene glycol

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 Sanitize





HAND SANITIZER alcohol liquid **Product Information** HUMAN OTC DRUG NDC:79894-002 Product Type Item Code (Source) **Route of Administration** TOPICAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M) ALCOHOL 68 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)				
WATER (UNII: 059QF0KO0R)				
PROPANEDIOL (UNII: 5965N8W85T)				
GLYCERIN (UNII: PDC6A3C0OX)				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:79894-002- 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			
SAMARA COSMETICS S.A.S.		881793172	manufacture(79894-002)			

Revised: 7/2020 SAMARA COSMETICS S.A.S.