

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 LIQUID

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 68% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

* Helps eliminate bacteria 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

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

Do not use

Stop use and ask a doctor if

* Irritation develops

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product in your palm to thoroughly 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

Other information

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

Inactive ingredients

glycerin, water, citric acid, propanediol

Package Label - Principal Display Panel

Drug Facts	
Active Ingredient Ethyl Alcohol 68%	Purpose Antiseptic
Uses Glycerinated Ethyl Alcohol helps eliminate bacteria on hands 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.	
Warnings For external use only. When using this product. 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. Do not swallow. Children under 6 years of age should be supervised when using this product.	
Purpose Anti-septic Hand and body Sanitizer	
Directions Place enough product in your palm to thoroughly cover your hands <ul style="list-style-type: none"> • Rub hands together briskly until dry. • Apply it on the parts of the body that needs to be cleaned and rub it briskly until it dry. 	
Inactive Ingredients Citric acid, Glycerin, Propylene glycol, 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))	

Batch:



Manufactured by:
Samara Cosmetics S.A.S
(Itagüí, Antioquia, Colombia)
NS0C99679-20C0
Phone: (574) 444 84 38

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79894-008
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.05 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 100 mL
PROPANEDIOL (UNII: 5965N8W85T)	0.5 mL in 100 mL
WATER (UNII: 059QF0K00R)	29.45 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79894-008-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2020	

Marketing Information

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

Labeler - 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(79894-008)

Revised: 8/2020

SAMARA COSMETICS S.A.S.