

HAND SANITIZER- ethanol liquid

Saraya Healthcare

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.

SARAYA HAND SANITIZER FOAM

Drug Facts

Active Ingredient

Ethanol 62%

Purpose

Hand Sanitizer

Uses

- Sanitizes hands to help reduce bacteria that potentially can cause diseases
- Helps to prevent cross-contamination
- Helps to prevent drying of the skin
- Recommended for repeated use

Warnings

- **For external use only**
- **Flammable, keep away from fire or flame**

When using this product

- Do not use in or near eyes
- Use in a well-ventilated area
- Discontinue use if irritation and redness develop

Keep out of reach of children

In case of accidental ingestion, seek medical attention or contact a poison control center immediately

Directions

- Receive a small amount of foam into palm of hand
- Rub thoroughly over all surfaces of both hands, especially fingernails and cuticles
- Rub hands together until dry

Other information

- Store in a cool, dry place below 104°F

Inactive ingredients

Water, DEA-C8-18 perfluoroalkylethyl phosphate, glycereth-2 cocoate, denatonium benzoate, tert-butyl alcohol

Questions?

Contact **Saraya Healthcare USA** Mon - Fri

9am - 4pm PST at 866.822.1801

Distributed by:

Saraya Healthcare USA

P.O. Box 1360

Penn Valley, CA 95946

866.822.1801

sarayahealthcareusa.com

SARAYA Healthcare USA

- Kills 99.999% of 26 tested pathogens in 15 seconds

- Formulated with emollients to help keep hands soft

- 62% Ethanol formula

Hand Sanitizer Foam

Net Contents: 1250mL (42 fl oz)

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SDS-18-15002

REORDER: SHC1002

105-171-00.00



HAND SANITIZER

ethanol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69674-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DIETHANOLAMINE BIS(C8-C18 PERFLUOROALKYLETHYL)PHOSPHATE (UNII: 4J55VM509S)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
WATER (UNII: 059QF0K00R)	
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69674-100-01	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/14/2016	
2	NDC:69674-100-04	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/14/2016	
3	NDC:69674-100-07	45 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/14/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/14/2016	

Labeler - Saraya Healthcare (079729980)**Establishment**

Name	Address	ID/FEI	Business Operations
Best Sanitizers		627278224	manufacture(69674-100)

Revised: 1/2019

Saraya Healthcare