

SAFESURE HAND SANITIZER- benzalkonium chloride liquid
SAFE SURE USA, INC.

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.

Active Ingredient

Benzalkonium Chloride 1.3%

Use

Helps reduce bacteria on the skin. Recommended for repeated use.

Directions

Apply product to hands and rub until dry.

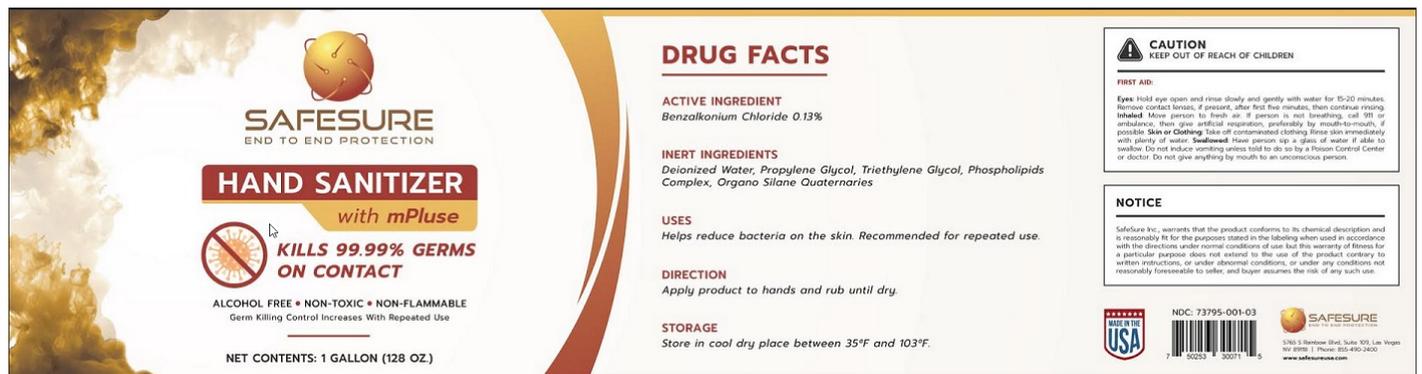
STORAGE

Store in cool dry place between 35°F and 103°F.

Inactive ingredients

Deionized Water, Propylene Glycol, Triethylene Glycol, Phospholipids Complex, Organo Silane Quaternaries

Package Label - Principal Display Panel



SAFESURE HAND SANITIZER			
benzalkonium chloride liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80852-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TRIETHYLENE GLYCOL (UNII: 3P5SU53360)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
DIMETHYLOCTADECYL(3-(TRIMETHOXYSYLYL)PROPYL)AMMONIUM CHLORIDE (UNII: IQ36O85WQ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80852-001-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/09/2020	
2	NDC:80852-001-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/09/2020	
3	NDC:80852-001-03	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/09/2020	
4	NDC:80852-001-04	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/09/2020	
5	NDC:80852-001-05	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/09/2020	

Labeler - SAFE SURE USA, INC. (117624760)

Revised: 10/2020

SAFE SURE USA, INC.