

**SHEA BUTTER SCENTED HAND SANITIZER- alcohol liquid
FOURSTAR GROUP 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.

SHEA BUTTER SCENTED HAND SANITIZER

Drug Facts

Active ingredient

Ethyl Alcohol, 70% v/v

Purpose

Antimicrobial

Uses

hand sanitizer to help reduce bacteria on skin

Warnings

For external use only.

Flammable, keep away from fire or flame.

Do not use

in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if

irritation, excessive redness or rash develops.

Keep out of reach of children.

If swallowed, get medical help contact a Poison Control Center right away.

Directions

Put a dime sized drop onto hands and rub together briskly until dry.

Other information

Store below 110°F (43°C)

Inactive ingredients

water, glycerin, propylene glycol, acrylates/c10-30 alkyl acrylate crosspolymer, fragrance, aminomethyl propanol

Package Labeling:



Front

Back



Drug Facts	
Active ingredient	Purpose
Ethyl Alcohol, 70% v/v.....	Antimicrobial
Uses hand sanitizer to help reduce bacteria on skin	
Warnings For external use only.	
Flammable, keep away from fire or flame.	
Do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation, excessive redness or rash develops.	
Keep out of reach of children. If swallowed, get medical help contact a Poison Control Center right away.	
Directions Put a dime sized drop onto hands and rub together briskly until dry.	
Other information Store below 110°F (43°C)	
Inactive ingredients water, glycerin, propylene glycol, acrylates/c10-30 alkyl acrylate crosspolymer, fragrance, aminomethyl propanol	
MANUFACTURED FOR: FOURSTAR GROUP USA, INC. 925 GRANT ST., AKRON, OH 44311 USA MADE IN CHINA LOT: EXP:	

SHEA BUTTER SCENTED HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80684-122
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80684-122-00	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/15/2023	

Labeler - FOURSTAR GROUP USA, INC. (140099503)

Revised: 8/2023

FOURSTAR GROUP USA, INC.