

**PFA STRONGHOLD SANITIZING HANDLOTION SHEA BUTTER- alcohol lotion
STRONGHOLD TRADING LLC**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

80969-007-01 PFA STRONGHOLD SANITIZING HAND LOTION_SHEA BUTTER

Active ingredient

Alcohol 62%

Purpose

Sanitizer

Use

Hand sanitizing to help reduce bacteria on the skin.

Warnings

For external use only.

Flammable. Keep away from fire or flame.

When using this product

avoid contact with the eyes.

In case of contact, flush eyes thoroughly with water.

Stop use and ask a doctor

if irritation and redness develops and persists.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- Put enough product in the palm to cover hands & rub together briskly the liquid is dry
- Children under 6 should be supervised when using Sanitizers.

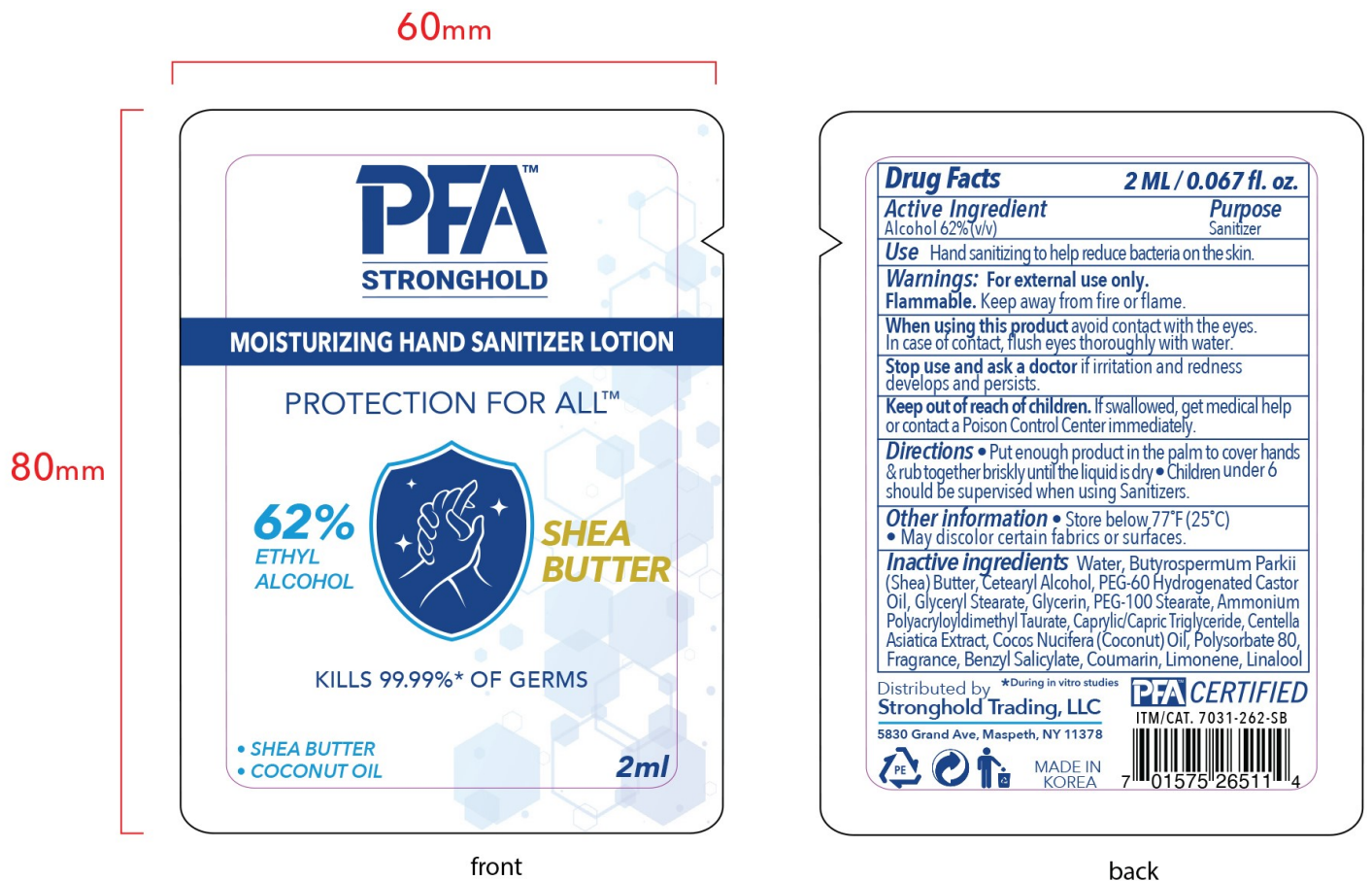
Other information

- Store below 77°F (25°C)
- May discolor certain fabrics or surfaces.

Inactive ingredients

Water, Butyrospermum Parkii (Shea) Butter, Cetearyl Alcohol, PEG-60 Hydrogenated Castor Oil, Glyceryl Stearate, Glycerin, PEG-100 Stearate, Ammonium Polyacryloyldimethyl Taurate, Caprylic/Capric Triglyceride, Centella Asiatica Extract, Cocos Nucifera (Coconut) Oil, Polysorbate 80, Fragrance, Benzyl Salicylate, Coumarin, Limonene, Linalool

Package Label



PFA STRONGHOLD SANITIZING HANDLOTION SHEA BUTTER

alcohol lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80969-007
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
COUMARIN (UNII: A4VZ22K1WT)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
BENZYL SALICYLATE (UNII: WAO5MNMK9TU)	
COCONUT OIL (UNII: Q9L0O73W7L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
AMMONIUM POLYACRYLOYLDIMETHYL TAURATE (55000 MPA.S) (UNII: F01RIY4371)	
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80969-007-01	2 mL in 1 POUCH; Type 0: Not a Combination Product	11/26/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/26/2021	

Labeler - STRONGHOLD TRADING LLC (117694134)

Registrant - S-ONE PHARMACEUTICAL INC (694626932)

Establishment

Name	Address	ID/FEI	Business Operations
S-ONE PHARMACEUTICAL INC		694626932	manufacture(80969-007)