SHIELDFORCE ESS- antimicrobial liquid
Force Fluids LLC

This is a 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. .13% Benzalklonium Chloride
b. 1.75% citric acid
c. <1% lemongrass
d. <1% eucalyptus
e. <1% lavender

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)

Benzalklonium Chloride, citric acid

Antiseptic, Antimiicrobial

Use

Sanitizer to help reduce bacteria that potentially can cause disease.

Warnings

For external use only. Non flammable.

Do not use

- in children less than 2 months of age
- on open skin wounds

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 on hands to cover all surfaces. Let dry.

Other information

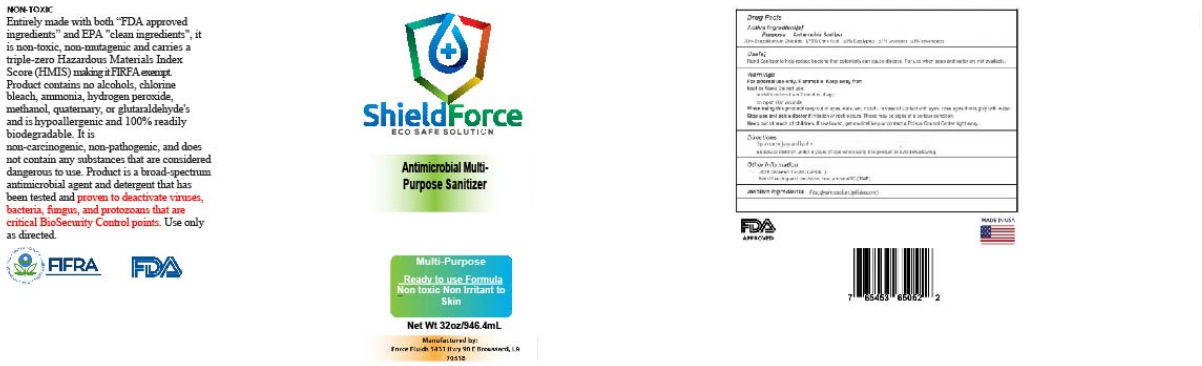
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

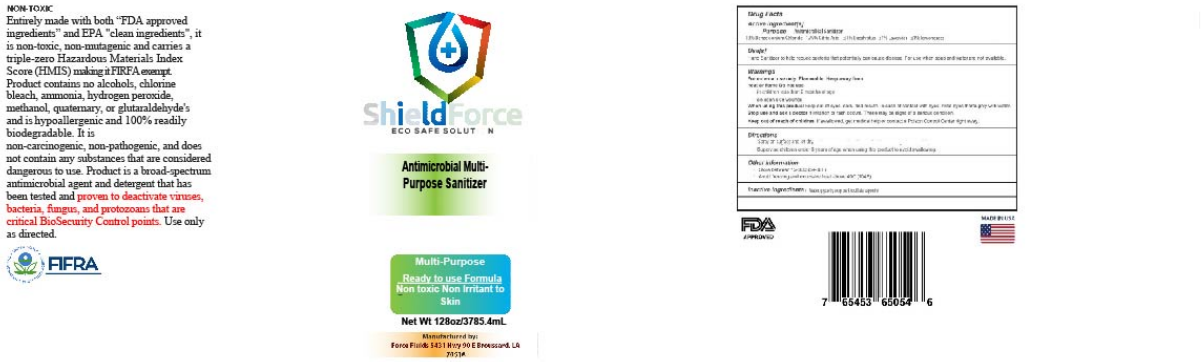
glycerin, soap bark extract, purified water USP

Package Label - Principal Display Panel

NDC Code: 80743-151-32



NDC Code: 80743-151-17



SHIELDFORCE ESS

antimicrobial liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80743-151
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M) (LAVANDULA ANGUSTIFOLIA FLOWER - UNII:19AH1RAF4M)	LAVANDULA ANGUSTIFOLIA FLOWER	0.0002 g in 100 mL
BENZALKONIUM (UNII: 7N6JUD5X6Y) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM	0.13 g in 100 mL
CYMBOPOGON CITRATUS LEAF (UNII: 06JMS448M5) (CYMBOPOGON CITRATUS LEAF - UNII:06JMS448M5)	CYMBOPOGON CITRATUS LEAF	0.0002 g in 100 mL
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	0.0002 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
QUILLAJA SAPONARIA BARK (UNII: 8N0K3807ZW)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80743-151-32	946.3 mL in 1 BOTTLE, SPRAY; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	03/30/2020	
2	NDC:80743-151-17	3785.41 mL in 1 BOTTLE, SPRAY; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Multi-Market Approved Product		03/30/2020	

Labeler - Force Fluids LLC (099027352)

Establishment

Name	Address	ID/FEI	Business Operations
Force Fluids LLC		099027352	manufacture(80743-151)

Revised: 11/2020 Force Fluids LLC