

**SHIELDFORCE AFS GEL- hand sanitizer gel**  
**Force Fluids LLC**

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This is a hand 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. Benzalkonium Chloride (.11% v/v)
- b. Glycerin (.64% v/v).
- c. Lactic Acid (3% v/v)
- d. Sterile distilled water or boiled cold water.
- e. Carbopol (.2% v/v)
- f. Fragrance (.75% v/v)

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)**

Benzalkonium Chloride .11% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**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.

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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. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

## Other information

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

## Inactive ingredients

glycerin, carbopol, lactic acid, fragrance, purified water USP

## Package Label - Principal Display Panel



**Alcohol Free  
Hand Sanitizer Gel**

Fresh Clean Fragrance  
Skin Conditioners  
Natural Ingredients  
Non Toxic Non Flammable

NET WT 2 Fl oz/60 mL

Manufactured by:  
Force Fluids 5431 Hwy 90 E Broussard, LA 70518  
337-354-2350

**Shield Force AFS  
Alcohol-Free Hand Sanitizer**

Drug Facts	
<b>Active ingredient:</b> Benzalkonium chloride 0.13% w/v	<b>Purpose:</b> Antimicrobial
<b>Use:</b> Hand sanitizer to help reduce bacteria on the skin.	
<b>Warnings:</b> For external use only. Do not use in eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if skin irritation develops.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions:</b> Apply to hands thoroughly. Gently massage into skin until absorbed. Supervise children in the use of this product.	
<b>Other Information:</b> Avoid extreme temperatures.	
<b>Inactive ingredients:</b> Water, carbomer, glycerin, lactic acid, fragrance	
<b>Questions? Call toll free 337-354-2350</b>	

FDA 199203



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AFS Gel 2oz NDC: 80743-120-02

AFS Gel 4oz NDC: 80743-120-04



**Alcohol Free  
Hand Sanitizer Gel**

Fresh Clean Fragrance  
Skin Conditioners  
Natural Ingredients  
Non Toxic Non Flammable

NET WT 4 Fl oz/118 mL

Manufactured by:  
Force Fluids 5431 Hwy 90 E Broussard, LA 70518  
337-354-2350

**Shield Force AFS  
Alcohol-Free Hand Sanitizer**

Drug Facts	
<b>Active ingredient:</b> Benzalkonium chloride 0.13% w/v	<b>Purpose:</b> Antimicrobial
<b>Use:</b> Hand sanitizer to help reduce bacteria on the skin.	
<b>Warnings:</b> For external use only. Do not use in eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if skin irritation develops.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions:</b> Apply to hands thoroughly. Gently massage into skin until absorbed. Supervise children in the use of this product.	
<b>Other Information:</b> Avoid extreme temperatures.	
<b>Inactive ingredients:</b> Water, carbomer, glycerin, lactic acid, fragrance	
<b>Questions? Call toll free 337-354-2350</b>	

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AFS Gel 8oz NDC: 80743-120-08



# Alcohol Free Hand Sanitizer Gel

Fresh Clean Fragrance  
Skin Conditioners  
Natural Ingredients  
Non Toxic Non Flammable

NET WT 8 Fl oz/237 mL

Manufactured by:  
Force Fluids 5431 Hwy 90 E Broussard, LA 70518  
337-354-2350

**Shield Force AFS**  
Alcohol-Free Hand Sanitizer

Drug Facts	
<b>Active Ingredient</b> Benzalkonium chloride 0.13% w/v	<b>Purpose</b> Antimicrobial
<b>Use</b> Hand sanitizer to help reduce bacteria on the skin.	
<b>Warnings</b> For external use only. Do not use in eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if skin irritation develops.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> Apply to hands thoroughly. Gently massage into skin until absorbed. Supervise children in the use of this product.	
<b>Other Information</b> Avoid extreme temperatures.	
<b>Inactive Ingredients</b> Water, carbomer, glycerin, lactic acid, fragrance	
Questions? Call toll free 337-354-2350	

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AFS Gel 1gal NDC: 80743-120-17



# Alcohol Free Hand Sanitizer Gel

Fresh Clean Fragrance  
Skin Conditioners  
Natural Ingredients  
Non Toxic Non Flammable

NET WT 1gal/128oz

Manufactured by:  
Force Fluids 5431 Hwy 90 E Broussard, LA 70518  
337-354-2350

**Shield Force AFS**  
Alcohol-Free Hand Sanitizer

Drug Facts	
<b>Active Ingredient</b> Benzalkonium chloride 0.13% w/v	<b>Purpose</b> Antimicrobial
<b>Use</b> Hand sanitizer to help reduce bacteria on the skin.	
<b>Warnings</b> For external use only. Do not use in eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if skin irritation develops.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> Apply to hands thoroughly. Gently massage into skin until absorbed. Supervise children in the use of this product.	
<b>Other Information</b> Avoid extreme temperatures.	
<b>Inactive Ingredients</b> Water, carbomer, glycerin, lactic acid, fragrance	
Questions? Call toll free 337-354-2350	

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## SHIELDFORCE AFS GEL

hand sanitizer gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80743-120
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM (UNII: 7N6JUD5X6Y) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM	1 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0K00R)	
LACTIC ACID (UNII: 33X04XA5AT)	
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	

FRAGRANCE ORANGE ORC2000765 (UNII: GX5JI7UXQ7)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80743-120-02	60 mL in 1 BOTTLE, PLASTIC; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	03/30/2020	
2	NDC:80743-120-04	118 mL in 1 BOTTLE, PLASTIC; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	03/30/2020	
3	NDC:80743-120-08	237 mL in 1 BOTTLE, PLASTIC; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	03/30/2020	
4	NDC:80743-120-17	3785.41 mL in 1 BOTTLE, PLASTIC; 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(80743-120)

Revised: 11/2020

Force Fluids LLC