

**GFS BIOPROTECT HAND SANITIZER ALOE VERA- benzalkonium chloride aerosol, foam
GFS US LLC**

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.

DRUG FACTS

BioProtect Hand Sanitizer contains 0.13% antiseptic agent Benzalkonium Chloride formulated with Water, 1-Octadecanaminium, N-N-dimethyl-N-[3-(trimethoxysilyl)propyl]-, chloride, C12-C15 Pareth-3, Polyaminopropyl biguanide, Caprylyl glucoside, Citronellol, Sorbic Acid, Glycerin, Aloe Barbadensis (Aloe) Leaf Extract, and D and C Green No.5. It is alcohol-free, non-toxic and kills 99.99% of germs.

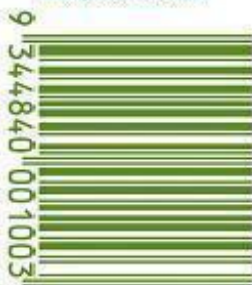
Benzalkonium Chloride 0.13%.....Antiseptic

- Antispetic
- Hand sanitizer to help decrease bacteria on skin
- Recommended for repeated use
- For external use only
- Do not use in ears or mouth
- Keep out of reach on children
- Children must be supervised in use of this product
- Apply a small amount into your palm and thoroughly spread on both hands
- Rub into skin until dry
- Review MSDS before handling the product
- When using this product do not use in ears or mouth
- Avoid contact with eyes
- In case of eye contact, rinse eyes thoroughly with water
- Stop use and ask a doctor if skin irritation or redness develops and persists for more than 72 hours
- Water, 1-Octadecanaminium, N-N-dimethyl-N-[3-(trimethoxysilyl)propyl]-, chloride, C12-C15 Pareth-3, Polyaminopropyl biguanide, Caprylyl glucoside, Citronellol, Sorbic Acid, Glycerin, Aloe Barbadensis (Aloe) Leaf Extract, and D and C Green No.5

Distributed By:
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www.gfsbioprotect.com



building a sustainable future



Drug Facts	
Active Ingredient:	Benzalkonium Chloride 0.13%
Purpose: Antiseptic Hand Sanitizer	
Uses: Hand sanitizer to help decrease bacteria on the skin. Recommended for repeated use.	
Warnings: For external use only. Do not use in ears or mouth. • When using this product, avoid contact with the eyes. • In case of contact, flush eyes with water. • Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours. • Keep out of reach of children. • Children must be supervised in use of this product.	
Directions: • Apply a small amount into your palm and thoroughly spread on both hands. Rub into skin until dry.	
Inactive Ingredients: Aqua, 1-Octadecanoin, N,N-dimethyl-N-(3-trimethoxysilylpropyl)diisole, C12-15 Pareth-3, Polyan (sopropyl biguanide), Ca pyrlyl Glucoside, Citronellol, Sorbic acid, Glycerin, Aloe Barbadensis (Aloe Leaf Extract), Green SCL 61570.	
Humanized System Code 2928	

GFS BIOPROTECT HAND SANITIZER ALOE VERA

benzalkonium chloride aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76426-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzalkonium Chloride (UNII: F5UM2KM3W7) (Benzalkonium - UNII:7N6JUD5X6Y)	Benzalkonium Chloride	0.0013 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
DIMETHYLOCTADECYL(3-(TRIMETHOXYSYLYL)PROPYL)AMMONIUM CHLORIDE (UNII: IQ36O85WQ4)	
C12-15 PARETH-12 (UNII: 131316X18L)	
POLYAMINOPROPYL BIGUANIDE (UNII: 322U039GMF)	
CAPRYLYL GLUCOSIDE (UNII: V109WUT6RL)	
.BETA.-CITRONELLOL, (+/-)- (UNII: 565OK72VNF)	
SORBIC ACID (UNII: X045WJ989B)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
D&C Green No. 5 (UNII: 8J6RDU8L9X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76426-010-01	28 g in 1 BOTTLE, PUMP		
2	NDC:76426-010-02	55 g in 1 BOTTLE, PUMP		
3	NDC:76426-010-03	110 g in 1 BOTTLE, PUMP		
4	NDC:76426-010-04	225 g in 1 BOTTLE, PUMP		
5	NDC:76426-010-05	1000 g in 1 BOTTLE		
6	NDC:76426-010-06	3790 g in 1 BOTTLE		
7	NDC:76426-010-07	204300 g in 1 DRUM		
8	NDC:76426-010-08	2204600 g in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK		
9	NDC:76426-010-09	800 g in 1 BAG		
10	NDC:76426-010-10	1200 g in 1 BAG		
11	NDC:76426-010-11	1800 g in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/20/2011	

Labeler - GFS US LLC (967789228)