

PRE FENSE- benzalkonium chloride liquid

Prefense 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.

Active Ingredient

Drug Facts

Active Ingredient

Benzalkonium Chloride0.12%

Purpose

Hand and Skin Sanitizer

Keep out of reach of children

Keep out of reach of children.

Uses:

Hand sanitizer to help reduce germs that potentially cause disease.

Warning:

For external use only. Avoid contact with eyes. In case of eye contact, flush with water. Discontinue use if irritation or redness occurs.

Directions:

Apply to dry hands, rub together, and let dry.

Inactive Ingredients:

3-Chloropropyltrimethoxysilane, Acetic Acid, Anhydrous Citric Acid, Cocamidoprophyl betaine, Octadecyldimethyl (3-trimethoxysilylpropyl)ammonium chloride, East Indian Lemongrass Oil, Isotonic Sodium Chloride Solution, Orange Oil, Water

pre•fense Product Label

pre•fense

HAND SANITIZER

Alcohol free

Original lemongrass scent

protects

kills up to 99.99% of germs on contact

Moisturizes

silica based, alcohol-free

won't dry out skin

Made in USA

DO NOT FREEZE

US Patent # 6613755

www.prefense.com



pre:fense™

Hand Sanitizer

Original Lemongrass Scent



protects
*kills up to 99.99%
of germs on contact*



moisturizes

Drug Facts	
Active Ingredient	Purpose
Benzalkonium Chloride	
0.12%	Sanitizer

Uses: Hand sanitizer to help reduce germs that potentially cause disease.

Warning: For external use only. Avoid contact with eyes. In case of eye contact, flush with water. Discontinue use if irritation or redness occurs. **Keep out of reach of children.**

Directions: Apply to dry hands, rub together, and let dry.

Inactive Ingredients: 3-Chloropropyltrimethoxysilane, Acetic Acid, Anhydrous Citric Acid, Cocamidopropyl betaine, Octadecyltrimethyl (3-trimethoxysilylpropyl)ammonium chloride, East Indian Lemongrass Oil, Isotonic Sodium Chloride Solution, Orange Oil, Water



Do Not Freeze



prefense.com MADE IN THE **USA** 33.82 fl. oz. / 1 Liter

PRE FENSE			
benzalkonium chloride liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48404-051
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	120 mg in 100 mL
Inactive Ingredients			
	Ingredient Name		Strength
	ISO TONIC SODIUM CHLORIDE SOLUTION (UNII: VR5Y7PDT5W)		
	DIMETHYLOCTADECYL(3-(TRIMETHOXYSYLYL)PROPYL)AMMONIUM CHLORIDE (UNII: IQ36O85WQ4)		

METHYL ALCOHOL (UNII: Y4S76JWI15)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
EAST INDIAN LEMONGRASS OIL (UNII: UP0M8M3VZW)	
ORANGE OIL (UNII: AKN3KSD11B)	
(3-CHLOROPROPYL)TRIMETHOXYSILANE (UNII: T21BNL1S7F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48404-051-01	44.4 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
2	NDC:48404-051-02	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
3	NDC:48404-051-03	1000 mL in 1 POUCH; Type 0: Not a Combination Product	05/11/2020	
4	NDC:48404-051-04	1893 mL in 1 JUG; Type 0: Not a Combination Product	05/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/11/2020	

Labeler - Prefense LLC (832498625)

Registrant - Prefense LLC (832498625)

Establishment

Name	Address	ID/FEI	Business Operations
Reynolds Engineering and Equipment, Inc.		807186333	manufacture(48404-051)

Revised: 5/2020

Prefense LLC