PRE FENSE UNSCENTED- 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.

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.12%

Hand and Skin Sanitizer

Keep out of reach of children.

Hand sanitizer to help reduce germs that potentially cause disease.

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

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

3-Chloropropyltrimethoxysilane, Acetic Acid, Anhydrous Citric Acid, Cocomidoprophyl betaine, Octadecyldimethyl (3-trimethoxysilylpropyl)ammonium chloride, Isotonic Sodium Chloride Solution, Water

pre•fense

HAND SANITIZER

Alcohol free
Unscented

protects

kills up to 99.99% of germs on contact

Moisturizes

silica based, alcohol-free

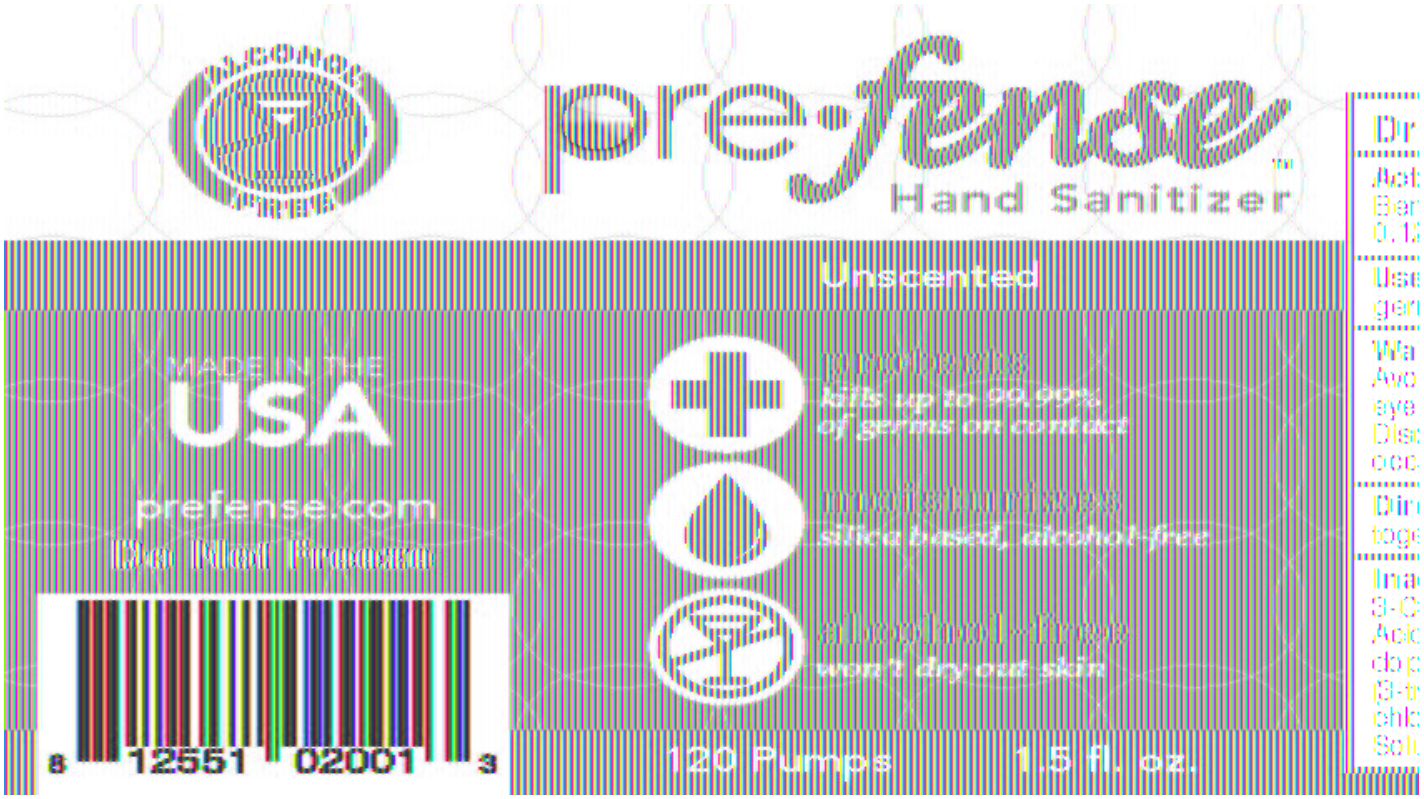
won't dry out skin

Made in USA

DO NOT FREEZE

US Patent # 6613755

www.prefense.com



PRE FENSE UNSCENTED

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:48404-050
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**
ACETIC ACID (UNII: Q40Q9N063P)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
WATER (UNII: 059QF0KO0R)	
(3-CHLOROPROPYL)TRIMETHOXYSILANE (UNII: T21BNL1S7F)	
ISOTONIC SODIUM CHLORIDE SOLUTION (UNII: VR5Y7PDT5W)	
METHYL ALCOHOL (UNII: Y4S76JWI15)	
DIMETHYLOCTADECYL(3-(TRIMETHOXYSILYL)PROPYL)AMMONIUM CHLORIDE (UNII: IQ36O85WQ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48404-050-01	44.4 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
2	NDC:48404-050-02	236.6 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
3	NDC:48404-050-03	502.8 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/15/2020	

Labeler - Prefense LLC (832498625)

Registrant - Prefense LLC (832498625)

Establishment

Name	Address	ID/FEI	Business Operations
Reynolds Engineering		807186333	manufacture(48404-050) , label(48404-050) , pack(48404-050)

Revised: 5/2020 Prefense LLC