BROMPTON AND LANGLEY HAND SANITIZER- alcohol gel Xiamen Afgamarine Biotechnology Co., Ltd.

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

Alcohol 70% w/w

Purpose

Antiseptic

Use

Antiseptic Cleanser, helps decrease bacteria on skin.

Warnings

For external use only. Flammable. Keep product away from fire or flame.

When using this product

Avoid contact with the eyes; in case of contct, flush eyes with water.

Stop use and ask a doctor if

Irritation or redness develops and persists.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on your palm to thoroughly cover your hands.
- Rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product.

Other information

• Store below 110°F (43°C). May discolor certain fabrics or surfaces.

Inactive ingredients

Questions?

1-800-548-4097

Label copy









BROMPTON AND LANGLEY HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77607-005	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	700 mg in 1 mL		

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
CARBOMER 934 (UNII: Z135WT9208)				
TROLAMINE (UNII: 903K93S3TK)				

P	ackaging			
#	# Item Code Package Description		Marketing Start Marketing End Date Date	
1	NDC:77607-	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a	10/06/2021	

1	005-01	Combination Product	10/00/2021	
2	NDC:77607- 005-02	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/06/2021	
3	NDC:77607- 005-03	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/06/2021	
4	NDC:77607- 005-04	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/06/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/06/2021	
	part333E	10/06/2021	

Labeler - Xiamen Afgamarine Biotechnology Co., Ltd. (420485152)

Registrant - Xiamen Afgamarine Biotechnology Co., Ltd. (420485152)

Establishment					
Name	Address	ID/FEI	Business Operations		
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(77607-005)		

Revised: 10/2021 Xiamen Afgamarine Biotechnology Co., Ltd.