

PRIMA FLEUR HAND SANITIZER BERGAMOTI NEROLI- ethyl alcohol gel
Prima Fleur Botanicals, Inc.

Prima Fleur Hand Sanitizer Bergamot Neroli

Directions for Use

Drug Facts	
Active Ingredient: Ethyl Alcohol 70% v/v.....	Purpose Antimicrobial
Use: hand sanitizer to help reduce bacteria on the skin	
Warnings: Flammable. Keep away from fire or flame. For external use only. Do not get into eyes. In case of contact, rinse eyes thoroughly with water. Stop use if irritation or rash develops. Consult physician if rash continues. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately. Children under 6 should be supervised by an adult while using.	
Other information: Store below 110°F (43°C)	
Directions for use: Wet hands thoroughly with product and rub together vigorously, covering all areas of hands. Do not wipe. Allow to dry.	
Inactive ingredients: Aloe barbadensis (aloe vera) leaf juice, glycerin, hydroxypropyl guar, Citrus aurantium bergamia (bergamot) peel oil, Citrus aurantium amara (neroli) flower/leaf oil, citric acid	
Ingredients in bold are Certified Organic WWW.PRIMAFLEUR.COM	Distributed by: PRIMA FLEUR, INC.
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Prima Fleur Hand Sanitizer Bergamot Neroli gallon front label

PRIMA

FLEUR®

Bergamot & Neroli



HAND SANITIZER



No. 1180

128 FL OZ / 3785 mL

Prima Fleur Hand Sanitizer Bergamot Neroli 16oz front label

PRIMA

FLEUR®

Bergamot & Neroli



HAND SANITIZER



No. 1180

16 FL OZ. / 473 mL

Prima Fleur Hand Sanitizer Bergamot Neroli 8oz front label

PRIMA

FLEUR®

Bergamot & Neroli



HAND SANITIZER

No. 1180

8 FL OZ (237mL)

Prima Fleur Hand Sanitizer Bergamot Neroli 2oz front label

PRIMA

FLEUR®

Bergamot & Neroli



HAND SANITIZER

No. 1180

2 FL OZ (59 mL)

PRIMA FLEUR HAND SANITIZER BERGAMOTI NEROLI

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71824-1800
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	2649.787 mL in 3785.41 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
HYDROXYPROPYL GUAR (2500-4500 MPA.S AT 1%) (UNII: 3A1I7376TC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE91OXH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71824-1800-1	1 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	08/14/2020	

PRIMA FLEUR HAND SANITIZER BERGAMOTI NEROLI

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71824-1816
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	331.2232 mL in 473.176 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
HYDROXYPROPYL GUAR (2500-4500 MPA.S AT 1%) (UNII: 3A1I7376TC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE91OXH)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71824-1816-1	1 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	08/14/2020	

PRIMA FLEUR HAND SANITIZER BERGAMOTI NEROLI

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71824-1802
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	41.40297 mL in 59.51 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
HYDROXYPROPYL GUAR (2500-4500 MPA.S AT 1%) (UNII: 3A1I7376TC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE91OXH)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71824-1802-1	1 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	08/14/2020	

PRIMA FLEUR HAND SANITIZER BERGAMOTI NEROLI

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71824-1808
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	165.6116 mL in 236.588 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
HYDROXYPROPYL GUAR (2500-4500 MPA.S AT 1%) (UNII: 3A1I7376TC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE91OXH)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71824-1808-1	1 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	08/14/2020	

Labeler - Prima Fleur Botanicals, Inc. (825058308)

Registrant - Prima Fleur Botanicals, Inc. (825058308)

Establishment

Name	Address	ID/FEI	Business Operations
Prima Fleur Botanicals, Inc.		825058308	manufacture(71824-1800, 71824-1816, 71824-1808, 71824-1802)

