

COMFORT MINERAL MOUSSE SUNSCREEN- titanium dioxide, zinc oxide aerosol, foam
BIOHEALTH PLUS LLC

DRUG FACTS

ACTIVE INGREDIENT: Titanium Dioxide 3%
 Zinc Oxide 10%

PURPOSE: Sunscreen
 Sunscreen

USES:
 Helps prevent sunburn. If used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early aging caused by the sun.

WARNINGS:
 For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

- Shake well before using.
- Press nozzle carefully during first use
- Apply liberally 15 minutes before sun exposure.
- Reapply:
 - After 40 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours
- Children under 6 months: Ask a doctor
- Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 am- 2 pm
 - Wear long-sleeved shirts, pants, hats, and sunglasses

INACTIVE INGREDIENTS:
 Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cellulose Gum, Cetareth-20, Cetearyl Alcohol, Citric Acid, Disodium EDTA, Glycereth-26, Glycerin, Glyceryl Stearate, Isododecane, Isohexadecane, Methyl Methacrylate Crosspolymer, Microcrystalline Cellulose, Octyldodecyl Erucate, Octyldodecyl Neopentanoate, Polymethyl Methacrylate, Polysorbate 80, Trans-1,3,3,3-Tetrafluoropropene, Tricontanyl PVP, Triethoxycaprylsilane, Water

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun
- Store between 68° to 104° F (20° to 40° C).
- Do not store at temperatures above 120° F.

MANUFACTURED FOR:
 Bio Health Plus | Weston, FL 33326
 (754) 213-9789




Bio H+
 ACTIVE PROTECTION SUNSCREEN



Comfort Mineral Mousse Sunscreen

Non-Tinted

Broad Spectrum SPF 30
 Water Resistant (40 minutes)

Mineral Sunscreen with
 Ceramides & Antioxidants C + E
 Moisturizing

Net Wt. 3.5 oz / 100 g

COMFORT MINERAL MOUSSE SUNSCREEN

titanium dioxide, zinc oxide aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85403-211(NDC:58892-211)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	100 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	
ISODODECANE (UNII: A8289P68Y2)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S) (UNII: 8Z5ZAL5H3V)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CELLULOSE GUM (UNII: K679OBS311)	
CITRIC ACID (UNII: 2968PHW8QP)	
GLYCERETH-26 (UNII: NNE56F2N14)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
OCTYLDODECYL ERUCATE (UNII: D4N66T98C2)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
1,3,3,3-TETRAFLUOROPROPENE, (1E)- (UNII: 5I2481U008)	
TRIACONTANYL PVP (UNII: N0SS3Q238D)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETEARETH-20 (UNII: YRC528SWJY)	
ISOHEXADECANE (UNII: 918X1OUF1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85403-211-04	100 g in 1 CYLINDER; Type 0: Not a Combination Product	03/21/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/21/2023	

Labeler - BIOHEALTH PLUS LLC (869441449)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85403-211)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85403-211)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85403-211)

Revised: 12/2025

BIOHEALTH PLUS LLC