

BLUME SUNBURST SUNSCREEN- zinc oxide lotion
Blume

Blume Sunburst Sunscreen

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Directions

· Shake well before 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 of age: 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 your time in the sun, especially from 10 a.m. – 2 p.m. · wear long-sleeved shirts, pants, hats, and sunglasses

Inactive Ingredients

Allantoin, Bisabolol, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Caprylyl Glycol, Centella Asiatica Leaf Extract, Citrus Aurantium Dulcis (Orange) Peel Extract, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Nobilis (Mandarin Orange) Peel Oil, Coco-Caprylate, Cocos Nucifera (Coconut) Fruit Extract, Hedychium Spicatum Extract, Helianthus Annuus (Sunflower) Extract, Hydrogenated Lecithin, Iron Oxides, Jojoba Esters, Lecithin, Methylpropanediol, Niacinamide, Nylon-12, Oryza Sativa (Rice) Bran Extract, Phenylpropanol, Polyglyceryl-2, Dipolyhydroxystearate, Polyglyceryl-3 Diisostearate, Polyglyceryl-3 Polycinoleate, Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate, Propanediol, Rosmarinus Officinalis (Rosemary) Leaf Extract, Rutin, Silica, Sodium Chloride, Sodium Hydroxide, Stearalkonium Hectorite, Tetrasodium Glutamate Diacetate, Tocopherol, Tridecyl Salicylate, Vanilla Planifolia Fruit Extract, Water

Uses

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

Blume Sunburst Sunscreen

Drug Facts

Active ingredient	Purpose
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Zinc Oxide 12%	Sunscreen
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Blume Sunburst Sunscreen

Warnings

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

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Other information

· Protect the product in this container from excessive heat and direct sun.

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BLUME SUNBURST SUNSCREEN

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83656-2106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	132 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)	
FERROUS OXIDE (UNII: G7036X8B5H)	
CENTELLA ASIATICA LEAF (UNII: 6810070TYD)	
JOJOBA OIL (UNII: 724GKU717M)	
ORYZA SATIVA WHOLE (UNII: 84IVV0906Z)	
TRIDECYL SALICYLATE (UNII: AZ Q08K38Z1)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TOCOPHEROL (UNII: R0Z B2556P8)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
NYLON-12 (UNII: 446U8J075B)	
PHENYLPROPANOL (UNII: 0F8970304M)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
ALLANTOIN (UNII: 344S277G0Z)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ROSMARINUS OFFICINALIS FLOWER (UNII: NR1A27F29O)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PROPANEDIOL (UNII: 5965N8W85T)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
RUTIN (UNII: 5G06TVY3R7)	

Product Characteristics

Color	brown	Score	
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Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83656-2106-2	1 in 1 CARTON	03/01/2024	
1	NDC:83656-2106-1	50 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/01/2024	

Labeler - Blume (242110723)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(83656-2106)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	manufacture(83656-2106) , pack(83656-2106)

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Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(83656-2106) , manufacture(83656-2106)

Revised: 9/2024

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