

CIELE BRONZE AND PROTECT- zinc oxide lotion
Ciele LLC

Ciele Bronze and Protect

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Directions

- Shake well • apply liberally 15 minutes before sun exposure
- Reapply • use a water-resistant sunscreen if swimming or sweating • 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

Water, C12-15 Alkyl Benzoate, **Zinc Oxide**, Butyloctyl Salicylate, Lauryl PEG-8 Dimethicone, Isododecane, Propanediol, Iron Oxides CI77491, Synthetic Fluorphlogopite, Dimethicone, Niacinamide, Polymethylsilsesquioxane, Isohexadecane, Trilaureth-4 Phosphate, Dimethiconol/Propylsilsesquioxane/Silicate Crosspolymer, Mica, Caprylyl Methicone, Dicyclopentyl Neopentanoate, Lauryl PEG-10 Tri(trimethylsilyloxy)silyethyl Dimethicone, Iron Oxides CI77492, Sodium Chloride, Phenoxethanol, Bisabolol, Disteardimonium Hectorite, Iron Oxides CI77499, Caprylyl Glycol, Allantoin, Titanium Dioxide, Ethylhexylglycerin, Hexylene Glycol, Propylene Carbonate, Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate, PEG-10, Tetrasodium Glutamate Diacetate, Hydrogenated Lecithin, Tin Oxide, Sodium Hydroxide.

Uses

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

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<i>Drug Facts</i>	
<i>Active ingredient</i>	<i>Purpose</i>
Zinc Oxide 12%.....	Sunscreen

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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.
- 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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Uses <ul style="list-style-type: none">• Helps prevent sunburn.  used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.	
Warnings <ul style="list-style-type: none">• 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 • 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.	
Directions <ul style="list-style-type: none">• Shake well • apply liberally 15 minutes before sun exposure• Reapply • use a water-resistant sunscreen if swimming or sweating • at least  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.	
Other information <ul style="list-style-type: none">• Protect the product in this container from excessive heat and direct sun.	
Inactive Ingredients  Water, C12-15 Alkyl Benzoate, Zinc Oxide , Butylcetyl Salicylate, Lauryl PEG-8 Dimethicone, Isododecane, Propanediol, Iron Oxides CI77491, Synthetic Fluorophlogopite, Dimethicone, Niacinamide, Polymethylsilsesquioxane, Isohexadecane, Trilaureth-4 Phosphate, Dimethiconol/Propylsilsesquioxane/Silicate Crosspolymer, Mica, Caprylyl Methicone, Octyldodecyl Neopentanoate, Lauryl PEG-10 Tri[Trimethylsilyloxy]silyethyl Dimethicone, Iron Oxides CI77492, Sodium Chloride, Phenoxethanol, Bisabolol, Distearidimonium Hectorite, Iron Oxides CI77499, Caprylyl Glycol, Allantoin, Titanium Dioxide, Ethylhexylglycerin, Hexylene Glycol, Propylene Carbonate, Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate, PEG-10, Tetrasodium Glutamate Diacetate, Hydrogenated Lecithin, Tin Oxide, Sodium Hydroxide.	
Questions? 1-866-860-0811	

CIELE BRONZE AND PROTECT

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83103-2255
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
MICA (UNII: V8A1AW0880)	
LAURYL PEG-8 DIMETHICONE (300 CPS) (UNII: ELL2U7K8T8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0KO0R)	
NIACINAMIDE (UNII: 25X51I8RD4)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)	
DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (45000000 MW) (UNII: 9KB5R958PB)	
PROPANEDIOL (UNII: 5965N8W85T)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
ISODODECANE (UNII: A8289P68Y2)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
ALLANTOIN (UNII: 344S277G0Z)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83103-2255-2	1 in 1 CARTON	05/02/2024	
1	NDC:83103-2255-1	30 mL in 1 BOTTLE, DROPPER; 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	05/02/2024	

Labeler - Ciele LLC (105041170)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(83103-2255)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	manufacture(83103-2255) , pack(83103-2255)

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Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	manufacture(83103-2255) , api manufacture(83103-2255)

Revised: 9/2024

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