

CIELE TINT AND PROTECT- zinc oxide lotion

Ciele

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.

Ciele Tint and Protect

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CIELE TINT AND PROTECT

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83103-1819
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
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
LAURYL PEG-8 DIMETHICONE (300 CPS) (UNII: ELL2U7K8T8)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
WATER (UNII: 059QF0KOOR)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PROPANEDIOL (UNII: 5965N8W85T)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ALLANTOIN (UNII: 344S277G0Z)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
ISODODECANE (UNII: A8289P68Y2)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (450000000 MW) (UNII: 9KB5R958PB)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

		Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83103-1819-2	1 in 1 CARTON	06/02/2023	
1	NDC:83103-1819-1	38 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 not final	part352	06/02/2023	

Labeler - Ciele (105041170)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(83103-1819)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	manufacture(83103-1819) , pack(83103-1819)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(83103-1819) , manufacture(83103-1819)

Revised: 7/2023

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