

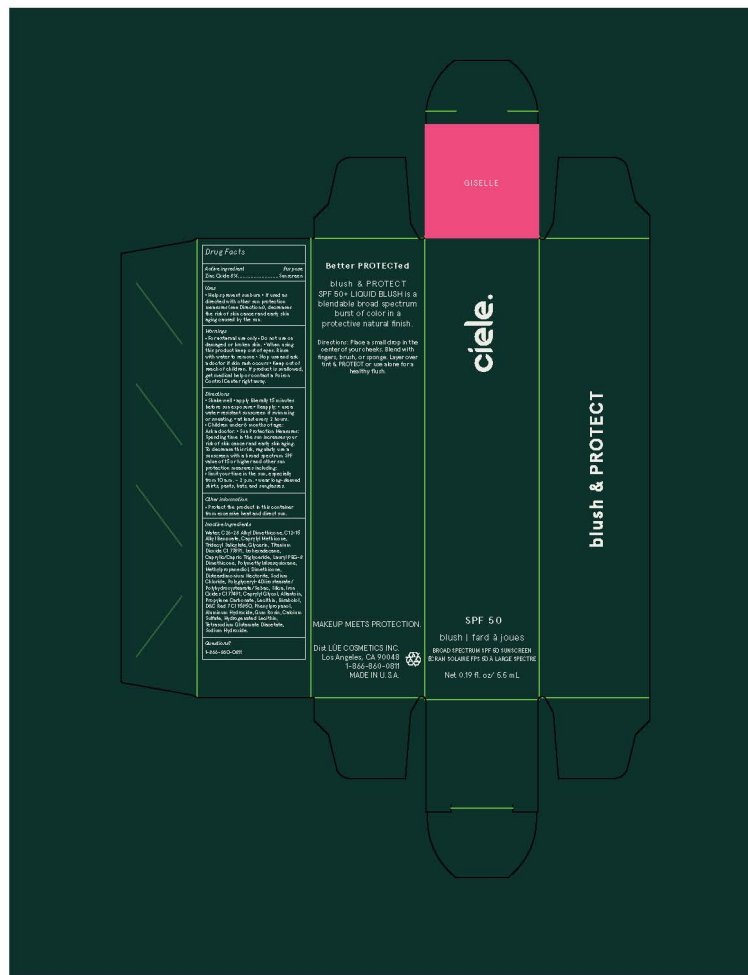
CIELE BLUSH AND PROTECT- zinc oxide lotion

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 Blush and Protect

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CIELE BLUSH AND PROTECT

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83103-1513
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	73.6 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
ALLANTOIN (UNII: 344S277G0Z)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
LAURYL PEG-8 DIMETHICONE (300 CPS) (UNII: ELL2U7K8T8)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83103-1513-2	1 in 1 CARTON	06/23/2023	
1	NDC:83103-1513-1	5.5 mL in 1 BOTTLE, WTH APPLICATOR; 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	06/23/2023	

Labeler - Ciele (105041170)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(83103-1513)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	manufacture(83103-1513) , pack(83103-1513)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(83103-1513) , manufacture(83103-1513)

Revised: 7/2023

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