

**SUNFORGETTABLE TOTAL PROTECTION FACE SHIELD BRONZE- zinc
oxide lotion
Colorescience**

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.

Sunforgettable Total Protection Face Shield Bronze

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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68078-043
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	135.6 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CAESALPINIA SPINOSA FRUIT POD (UNII: EXY4496LWD)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
MICA (UNII: V8A1AW0880)	
NIACINAMIDE (UNII: 25X51I8RD4)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (450000000 MW) (UNII: 9KB5R958PB)	
PROPANEDIOL (UNII: 5965N8W85T)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES (UNII: 0K5Y9U1P6M)	
DIMETHYLMETHOXY CHROMANOL (UNII: XBH432G01F)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ALLANTOIN (UNII: 344S277G0Z)	
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ISODODECANE (UNII: A8289P68Y2)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HELIANTHUS ANNUUS SPROUT (UNII: 4P26HG1S5W)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68078-043-02	1 in 1 CARTON	05/24/2021	
1	NDC:68078-043-01	55 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	05/24/2021	

Labeler - Colorescience (128731929)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(68078-043)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(68078-043) , manufacture(68078-043)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	manufacture(68078-043) , pack(68078-043)

Revised: 3/2023

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