

**SUNFORGETTABLE TOTAL PROTECTION FACE SHIELD, GLOW- 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, Glow

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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68078-032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	134.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TREMELLA FUCIFORMIS FRUITING BODY (UNII: GG8N28393G)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
GLYCERIN (UNII: PDC6A3C0OX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES (UNII: 0K5Y9U1P6M)	
DIMETHYLMETHOXY CHROMANOL (UNII: XBH432G01F)	
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)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	
NIACINAMIDE (UNII: 25X51I8RD4)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (45000000 MW) (UNII: 9KB5R958PB)	
PROPANEDIOL (UNII: 5965N8W85T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MICA (UNII: V8A1AW0880)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:68078-032-02	1 in 1 CARTON	01/01/2019	
1	NDC:68078-032-01	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		01/01/2019	

Labeler - Colorescience (128731929)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment			
Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(68078-032)

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Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(68078-032) , manufacture(68078-032) , pack(68078-032)

Revised: 2/2020

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