

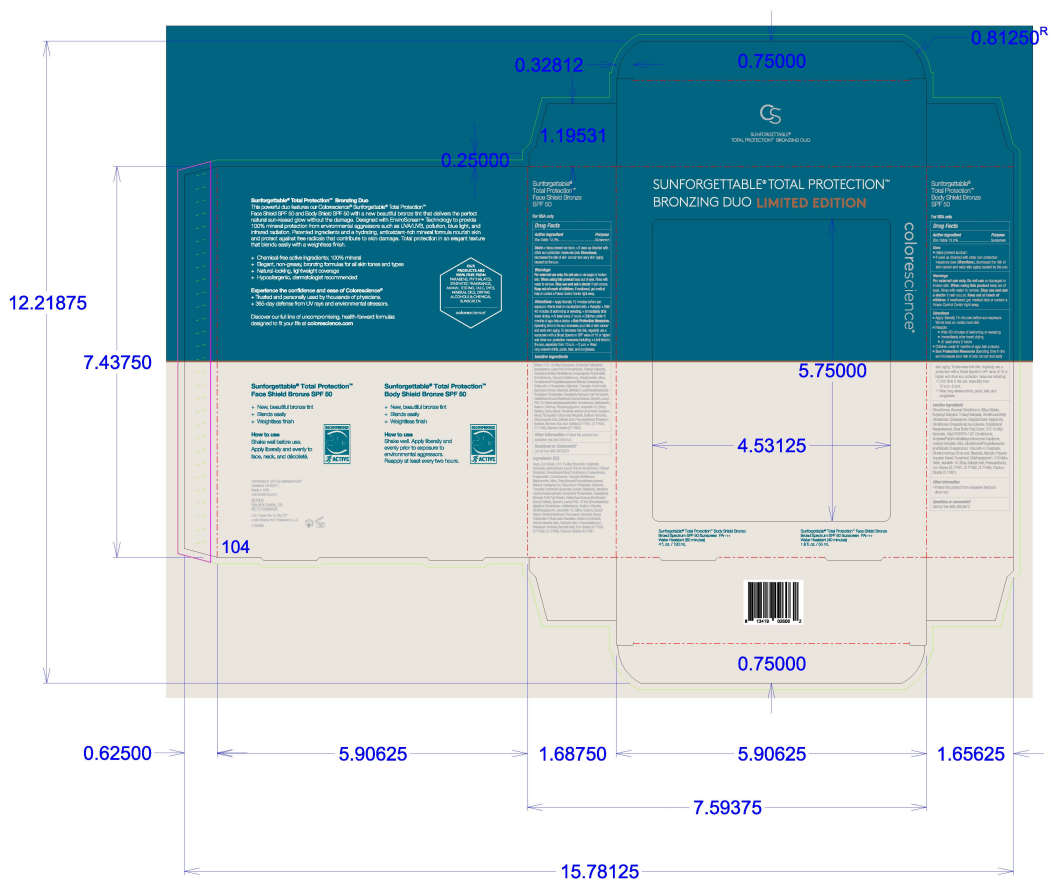
SUNFORGETTABLE TOTAL PROTECTION BODY SHIELD- zinc oxide lotion

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 Body Shield

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SUNFORGETTABLE TOTAL PROTECTION BODY SHIELD

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68078-031
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	129.6 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ISODECYL SALICYLATE (UNII: S7097PP4C)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PHYSALIS ANGULATA (UNII: W4TKW9D5GG)	
ISO CETETH-10 (UNII: 1K92T9919H)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
DIMETHYLMETHOXY CHROMANOL (UNII: XBH432G01F)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ISODODECANE (UNII: A8289P68Y2)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
DIMETHICONOL/PROPYLSILSESQUOXANE/SILICATE CROSSPOLYMER (45000000 MW) (UNII: 9KB5R958PB)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MICA (UNII: V8A1AW0880)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
ALLANTOIN (UNII: 344S277G0Z)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68078-031-01	120 mL in 1 TUBE; Type 0: Not a Combination Product	03/26/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/26/2019	

Labeler - Colorescience (128731929)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(68078-031)

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Nanophase Technologies Corporation		623502044	api manufacture(68078-031) , manufacture(68078-031) , pack(68078-031)

Revised: 3/2019

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