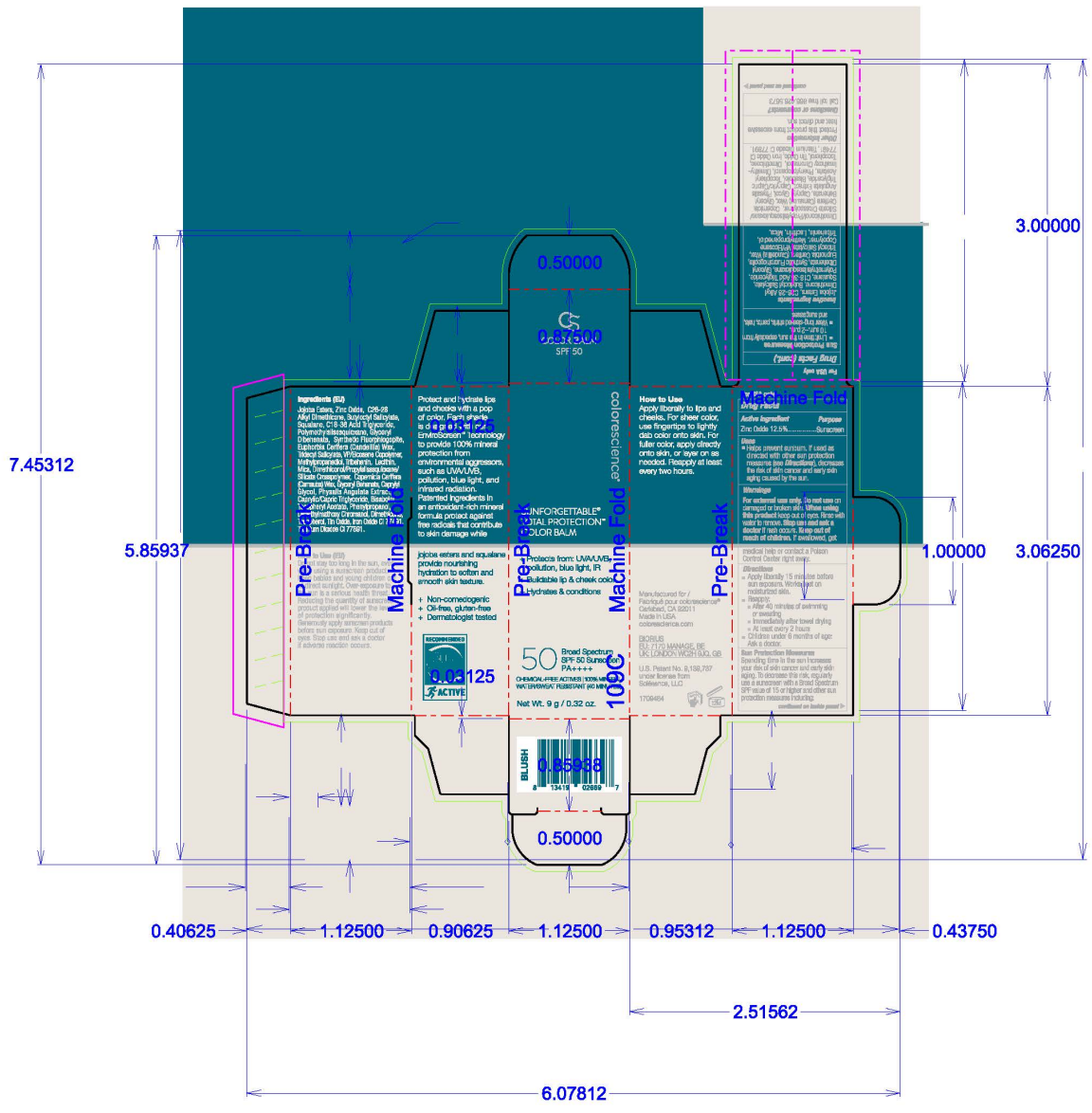


**SUNFORGETTABLE TOTAL PROTECTION COLOR BALM (BLUSH)- zinc
oxide stick
Colorescience**

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 Color Balm (Blush)

Sunforgettable Total Protection Color Balm (Blush)



SUNFORGETTABLE TOTAL PROTECTION COLOR BALM (BLUSH)

zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68078-034
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	125 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQ158VC)	
MICA (UNII: V8A1AW0880)	
TOCOPHEROL (UNII: R0ZB2556P8)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV951C3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (450000000 MW) (UNII: 9KB5R958PB)	
DIMETHYLMETHOXY CHROMANOL (UNII: XBH432G01F)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SQUALANE (UNII: GW89575KF9)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
C18-36 ACID TRIGLYCERIDE (UNII: ZRA72DR3R7)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68078-034-02	1 in 1 CARTON	02/01/2020	
1	NDC:68078-034-01	9 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph not final	part352	02/01/2020	

Labeler - Colorescience (128731929)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(68078-034)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(68078-034) , manufacture(68078-034)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	manufacture(68078-034) , pack(68078-034)

Revised: 3/2023

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