

**SUNFORGETTABLE TOTAL PROTECTION BODY 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 Body Shield Bronze

Sunforgettable Total Protection Body Shield Bronze



SUNFORGETTABLE®
TOTAL PROTECTION™
BODY SHIELD BRONZE
SPF 50

colorscience

SUNFORGETTABLE®
TOTAL PROTECTION™
BODY SHIELD BRONZE

<p>Enjoy a perfect, natural sun-kissed tone all year long without the damage! This powerful protector, infused with powerful copper ions with our exclusive IronOxide™ Technology to provide all-around protection from environmental aggressors such as UVA/UVB, pollution, blue light, and infrared radiation. Patented ingredients and a hydrating, antioxidant-rich formula fortify skin and protect against free radicals that contribute to premature aging and skin damage. New formulation offers improved skin adherence and minimal color transfer. This protection is so elegant, you're the only one who's really seeing it.</p> <ul style="list-style-type: none"> • Hydrates, soothes, and conditions • Apple Butyrate, niacinamide, and niacinamide • Non-comedogenic, dermatologist tested 	<p>For USA only</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Active Ingredient</th> <th style="text-align: left;">Purpose</th> </tr> </thead> <tbody> <tr> <td>Iron Oxide (CI 77491)</td> <td>Colorant</td> </tr> </tbody> </table> <p>Other Ingredients</p> <ul style="list-style-type: none"> • Water • Zinc Oxide • Titanium Dioxide • Iron Oxide (CI 77491) • Iron Oxide (CI 77492) • Iron Oxide (CI 77493) • Iron Oxide (CI 77494) • Iron Oxide (CI 77495) • Iron Oxide (CI 77496) • Iron Oxide (CI 77497) • Iron Oxide (CI 77498) • Iron Oxide (CI 77499) • Iron Oxide (CI 77500) • Iron Oxide (CI 77501) • Iron Oxide (CI 77502) • Iron Oxide (CI 77503) • Iron Oxide (CI 77504) • Iron Oxide (CI 77505) • 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Active Ingredient	Purpose					
Iron Oxide (CI 77491)	Colorant					
<p>How to Use</p> <p>Apply liberally and evenly for sun and environmental protection, hydration, and a hint of bronze. Allow to set for 1-2 minutes to minimize color transfer. Reapply at least every two hours for continued protection. Take care when in contact with delicate or light fabrics. Wash with warm water and gentle detergent if color has transferred.</p>	<p>with a broad spectrum SPF value of 15 or higher and when sun protection measures include:</p> <ul style="list-style-type: none"> • Limit time in the sun, especially from 10:00 a.m. to 4:00 p.m. • Wear long-sleeved shirts, pants, hats, and sunglasses. <p>Active Ingredients</p> <p>Water, Zinc Oxide, Copper Methacrylate, Titanium Dioxide, Iron Oxide (CI 77491), Iron Oxide (CI 77492), Iron Oxide (CI 77493), Iron Oxide (CI 77494), Iron Oxide (CI 77495), Iron Oxide (CI 77496), Iron Oxide (CI 77497), Iron Oxide (CI 77498), Iron Oxide (CI 77499), Iron Oxide (CI 77500), Iron Oxide (CI 77501), Iron Oxide (CI 77502), Iron Oxide (CI 77503), Iron Oxide (CI 77504), Iron Oxide (CI 77505), Iron Oxide (CI 77506), Iron Oxide (CI 77507), Iron Oxide (CI 77508), Iron Oxide (CI 77509), Iron Oxide (CI 77510), Iron Oxide (CI 77511), Iron Oxide (CI 77512), Iron Oxide (CI 77513), Iron Oxide (CI 77514), Iron Oxide (CI 77515), Iron Oxide (CI 77516), Iron Oxide (CI 77517), Iron Oxide (CI 77518), Iron Oxide (CI 77519), Iron Oxide (CI 77520), Iron Oxide (CI 77521), Iron Oxide (CI 77522), Iron Oxide (CI 77523), Iron Oxide (CI 77524), Iron Oxide (CI 77525), Iron Oxide (CI 77526), Iron Oxide (CI 77527), Iron Oxide (CI 77528), Iron Oxide (CI 77529), Iron Oxide (CI 77530), Iron Oxide (CI 77531), Iron Oxide (CI 77532), Iron Oxide (CI 77533), Iron Oxide (CI 77534), Iron Oxide (CI 77535), Iron Oxide (CI 77536), Iron Oxide (CI 77537), Iron Oxide (CI 77538), Iron Oxide (CI 77539), Iron Oxide (CI 77540), Iron Oxide (CI 77541), Iron Oxide (CI 77542), Iron Oxide (CI 77543), Iron Oxide (CI 77544), Iron Oxide (CI 77545), Iron Oxide (CI 77546), Iron Oxide (CI 77547), Iron Oxide (CI 77548), Iron Oxide (CI 77549), Iron Oxide (CI 77550), Iron Oxide (CI 77551), Iron Oxide (CI 77552), Iron Oxide (CI 77553), Iron Oxide (CI 77554), Iron Oxide (CI 77555), Iron Oxide (CI 77556), Iron Oxide (CI 77557), Iron Oxide (CI 77558), Iron Oxide (CI 77559), Iron Oxide (CI 77560), Iron Oxide (CI 77561), Iron Oxide (CI 77562), Iron Oxide (CI 77563), Iron Oxide (CI 77564), Iron Oxide (CI 77565), Iron Oxide (CI 77566), Iron Oxide (CI 77567), Iron Oxide (CI 77568), Iron Oxide (CI 77569), Iron Oxide (CI 77570), Iron Oxide (CI 77571), Iron Oxide (CI 77572), Iron Oxide (CI 77573), Iron Oxide (CI 77574), Iron Oxide (CI 77575), Iron Oxide (CI 77576), Iron Oxide (CI 77577), Iron Oxide (CI 77578), Iron Oxide (CI 77579), Iron Oxide (CI 77580), Iron Oxide (CI 77581), Iron Oxide (CI 77582), Iron Oxide (CI 77583), Iron Oxide (CI 77584), Iron Oxide (CI 77585), Iron Oxide (CI 77586), Iron Oxide (CI 77587), Iron Oxide (CI 77588), Iron Oxide (CI 77589), Iron Oxide (CI 77590), Iron Oxide (CI 77591), Iron Oxide (CI 77592), Iron Oxide (CI 77593), Iron Oxide (CI 77594), Iron Oxide (CI 77595), Iron Oxide (CI 77596), Iron Oxide (CI 77597), Iron Oxide (CI 77598), Iron Oxide (CI 77599), Iron Oxide (CI 77600).</p>	<ul style="list-style-type: none"> • Protects from UVA/UVB, pollution, blue light, infrared radiation • Natural-looking tint • Hydrating, antioxidant-rich 	<p>How to Use (EU)</p> <p>Apply liberally and evenly for sun and environmental protection, hydration, and a hint of bronze. Allow to set for 1-2 minutes to minimize color transfer. Reapply at least every two hours for continued protection. Take care when in contact with delicate or light fabrics. Wash with warm water and gentle detergent if color has transferred.</p>			
<p>Manufactured by TheraSkin ColorScience® 10000 W. 10th St. Minnetonka, MN 55341 www.sunforgettable.com</p> <p>©2024 SUNFORGETTABLE, INC. LONDON, MICHIGAN, USA</p> <p>U.S. Patent No. 8,520,277 U.S. Patent No. 8,520,278 U.S. Patent No. 8,520,279</p>	<p>with a broad spectrum SPF value of 15 or higher and when sun protection measures include:</p> <ul style="list-style-type: none"> • Limit time in the sun, especially from 10:00 a.m. to 4:00 p.m. • Wear long-sleeved shirts, pants, hats, and sunglasses. <p>Active Ingredients</p> <p>Water, Zinc Oxide, Copper Methacrylate, Titanium Dioxide, Iron Oxide (CI 77491), Iron Oxide (CI 77492), Iron Oxide (CI 77493), Iron Oxide (CI 77494), Iron Oxide (CI 77495), Iron Oxide (CI 77496), Iron Oxide (CI 77497), Iron Oxide (CI 77498), Iron Oxide (CI 77499), Iron Oxide (CI 77500), Iron Oxide (CI 77501), Iron Oxide (CI 77502), Iron Oxide (CI 77503), Iron Oxide (CI 77504), Iron Oxide (CI 77505), Iron Oxide (CI 77506), Iron Oxide (CI 77507), Iron Oxide (CI 77508), Iron Oxide (CI 77509), Iron Oxide (CI 77510), Iron Oxide (CI 77511), Iron Oxide (CI 77512), Iron Oxide (CI 77513), Iron Oxide (CI 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/ 120 mL</p>	<p>How to Use (EU)</p> <p>Apply liberally and evenly for sun and environmental protection, hydration, and a hint of bronze. 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SUNFORGETTABLE TOTAL PROTECTION BODY SHIELD BRONZE

zinc oxide lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68078-044

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
ISOHEXADECANE (UNII: 918X1OUF1E)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
DIMETHYLMETHOXY CHROMANOL (UNII: XBH432G01F)	
ALLANTOIN (UNII: 344S277G0Z)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)	
ISODODECANE (UNII: A8289P68Y2)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (45000000 MW) (UNII: 9KB5R958PB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TREMELLA FUCIFORMIS FRUITING BODY (UNII: GG8N28393G)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES (UNII: 0K5Y9U1P6M)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
PHYSALIS ANGULATA (UNII: W4TKW9D5GG)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ISOCETETH-10 (UNII: 1K92T9919H)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICA (UNII: V8A1AW0880)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68078-044-02	1 in 1 CARTON	06/02/2021	
1	NDC:68078-044-01	120 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	06/02/2021	

Labeler - Colorescience (128731929)**Registrant** - Nanophase Technologies Corporation (623502044)**Establishment**

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(68078-044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(68078-044) , manufacture(68078-044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	manufacture(68078-044) , pack(68078-044)

Revised: 3/2023

Colorescience