

SUNSOLVE MD CALM AND REVITALIZE- zinc oxide lotion

Sunsolve MD Inc

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DocuSigned by:
Portia Anteria Alzais
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2/13/2024 | 11:01 AM CST

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DocuSigned by:
 Portia Antonia Mezis
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SUNSOLVE MD CALM AND REVITALIZE

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84878-654
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	132 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
LECITHIN, SOYBEAN (UNII: 1D156QDM62)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ISOAMYL LAURATE (UNII: M1SLX00M3M)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CETETH-20 (UNII: I835H2IHHX)	
PULLULAN (UNII: 8ZQ0AYU1TT)	
SQUALANE (UNII: GW89575KF9)	
STEARETH-20 (UNII: L0Q8IK9E08)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALLANTOIN (UNII: 344S277G0Z)	
PEG-75 STEARATE (UNII: OT38R0N74H)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	
SCLEROTIUM GUM (UNII: 2X51AD1X3T)	
AVENA SATIVA (OAT) KERNEL EXTRACT (UNII: Z6J799EAJK)	
ALOE BARBADENSIS LEAF JUICE POWDER (UNII: ZY81Z83H0X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PYRUS MALUS (APPLE) FRUIT (UNII: B423VGH5S9)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84878-654-02	1 in 1 CARTON	11/08/2024	
1	NDC:84878-654-01	48 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/08/2024	

Labeler - Sunsolve MD Inc (119376976)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	manufacture(84878-654) , pack(84878-654)

Revised: 11/2024

Sunsolve MD Inc