

MELAN RX- zinc oxide lotion

Melan RX

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.

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Even Tone Daily Protecting Mineral Sunscreen

**BROAD SPECTRUM
SPF 50+**

**Tinted Lightweight Fluid
Water/Sweat Resistant
(80 Minutes)**

45ml | 1.5 fl. oz

Drug Facts

Active ingredient	Purpose
Zinc Oxide 12% w/w	Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

- **For external use only.**
- **Do not use** on damaged or broken skin.
- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and ask a doctor** if skin rash occurs.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **apply liberally 15 minutes before sun exposure**
- **reapply**
- **after 80 minutes of swimming or sweating**
- **immediately after towel drying**
- **at least every 2 hours.**
- **Sun Protection Measures** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
- **limit your time in the sun, especially from 10 a.m. - 2 p.m.**
- **wear long-sleeved shirts, pants, hats, and sunglasses**
- **Children under 6 months of age: ask a doctor.**

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

- Water/Aqua, C12-15 Alkyl Benzoate, Butylacetyl Salicylate, Isododecane, Lauryl PEG-8 Dimethicone, Polymethylsiloxesquioxane, Iron Oxides, Octyldodecyl Neopentanoate, Propanediol, Caprylyl Methicone, Niacinamide, Trilaureth-4 Phosphate, Dimethicone, Dimethiconol/Propylsilsesquioxane/Silicate Crosspolymer, Lauryl PEG-10 Tris (Trimethylsilylsilyl)ethyl Dimethicone, Sodium Chloride, Phenylethanol, Bisabolol, Caprylyl Glycol, Allantoin, Ethylhexylglycerin, Hexylene Glycol, PEG-10, Tetrasodium Glutamate Diacetate, Sodium Hydroxide.

**Question or Comments? Call Toll free US 4056511445 or
Email info@melanrx.com**

**Distributed by: Dayspring Cosmeceuticals, Katy TX 77494
Made in USA**

www.melanrx.com

zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82635-403
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
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
ALLANTOIN (UNII: 344S277G0Z)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
NIACINAMIDE (UNII: 25X51I8RD4)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (450000000 MW) (UNII: 9KB5R958PB)	
PROPANEDIOL (UNII: 5965N8W85T)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-TOCOPHEROL (UNII: 9U6A490501)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
ISODODECANE (UNII: A8289P68Y2)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
LAURYL PEG-8 DIMETHICONE (300 CPS) (UNII: ELL2U7K8T8)	

Product Characteristics			
Color	pink	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82635-403-01	45 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/23/2022	

Labeler - Melan RX (038285055)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(82635-403)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(82635-403) , manufacture(82635-403)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	manufacture(82635-403) , pack(82635-403)

Revised: 3/2023

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