

ORGANYS DERMA MADE- zinc oxide lotion
Organys Beauty

Organys Derma Made

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DRUG FACTS	
<i>Active Ingredients</i>	<i>Purpose</i>
Zinc Oxide 12%.....	Sunscreen

Inactive Ingredients

Water, C12-15 Alkyl Benzoate, Butyloctyl Salicylate, Isododecane, Lauryl PEG-8 Dimethicone, Polymethylsilsesquioxane, Octyldodecyl Neopentanoate, Propanediol, Caprylyl Methicone, Dimethicone, Niacinamide, Dimethiconol/Propylsilsesquioxane/Silicate Crosspolymer, Trilaureth-4Phosphate, Lauryl PEG-10 Tris(trimethylsiloxy)silylethyl Dimethicone, Sodium Chloride, Phenoxyethanol, Bisabolol, Caprylyl Glycol, Allantoin, Ethylhexylglycerin, Hexylene Glycol, PEG-10, Tetrasodium Glutamate Diacetate, Sodium Hydroxide, Tocopherol.

cancer and early skin aging caused by the sun.

Warning

- **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.

Organys Derma made

Directions

- shake well before each use
- 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.

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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.

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Zinc Oxide 12%.....	Sunscreen

DERMA MADE

Dermatologist Developed *Unscented*

SPF 50+ Moisturizer Sheer Mineral

Broad spectrum SPF 50+
sunscreen

Infrared & blue light
protection

Water resistant
(80 minutes)

100% mineral

1.5 fl oz (45 ml)

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Other Information

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

Question or Comments?

Call (312) 620-9240, or

Email: support@dermamade.com

Distributed by: Derma Made Arlington Heights, IL 60004

Made in USA



ORGANYS DERMA MADE

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83612-0282
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
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)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
NIACINAMIDE (UNII: 25X51I8RD4)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (450000000 MW) (UNII: 9KB5R958PB)	
PROPANEDIOL (UNII: 5965N8W85T)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
.BETA.-TOCOPHEROL (UNII: 9U6A490501)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83612-0282-1	45 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/24/2023	
2	NDC:83612-0282-2	5 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/21/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/24/2023	

Labeler - Organys Beauty (077820778)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(83612-0282)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	manufacture(83612-0282) , pack(83612-0282)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(83612-0282) , manufacture(83612-0282)

Revised: 1/2024

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